

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/03/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/12/2020	Condition category Cancer	<input type="checkbox"/> 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?

Tom Møller PhD MPH RN
tom@ucsf.dk

Contact information

Type(s)

Scientific

Contact name

Mr Tom Møller

Contact details

Copenhagen University Hospital Rigshospitalet Department 9701
Blegdamsvej 9
Copenhagen
Denmark
2100
+45 3545 7366
tom@ucsf.dk

Additional identifiers

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

Primary study design

Interventional

Study design

Two-armed randomized controlled trial

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

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

2100

Sponsor information

Organisation

Novo Nordic Foundation (Novo Nordisk Fonden) (Denmark)

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

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