ISRCTN24901641 https://doi.org/10.1186/ISRCTN24901641

At cancer diagnosis A window of opportunity for behavioural change towards physical activity for colon and breast cancer patients

Submission date
25/01/2012

Recruitment status
No longer recruiting

Registration date
04/04/2012

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Survival following colon or breast cancer is now possible for 50 to 80% of patients who receive chemotherapy. Studies have found that increased physical activity and regular exercise have favorable physical, functional and emotional effects during chemotherapy. Furthermore, sustained exercise of moderate to high intensity may improve long-term survival. The aim of this study is to investigate whether it is possible to support and motivate previously inactive patients to initiate and maintain physical activity during and after their chemotherapy treatment and to increase their physical fitness.

Who can participate?
Sedentary (inactive) patients with colon or breast cancer receiving chemotherapy.

What does the study involve?
This study tests the feasibility and effectiveness of two 12-week programs of varying intensity and exercise setting. All participants receive the oncologist's advice to meet national recommendations for physical activity. Participants are randomly assigned to one of three groups. The first group receives a supervised 12-week hospital-based moderate-to-high intensity physical training program. The second group receives a non-supervised 12-week home-based program with a view to increasing their physical activity to the minimum national recommendations of 150 minutes of moderate activity plus at least two times 20 minutes of strenuous activity per week. The third group are offered one of the two exercise programs after the 12-week period.

What are the possible benefits and risks of participating?
Not provided at time of registration.

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?
January 2012 to January 2013.

Who is funding the study?
Novo Nordic Foundation and the Danish Cancer Society.

Who is the main contact?
Tom Møller
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
At cancer diagnosis A window of opportunity for behavioural change towards physical activity for colon and breast cancer patients: a randomised feasibility study

Study objectives
The overall hypothesis is that intervention initiated early in the treatment of (pre-diagnostic) non-workout accustomed patients with breast and colon cancer will increase the aerobic capacity, physical activity, improve patients reaction control and functional, emotional and social capacity and reduce the risk of lifestyle comorbidity.

A supervised hospital-based multidimensional intervention compared with an unsupervised home pedometer-based intervention after 12 weeks will be more effective in relation to:
1. Increase the maximal oxygen uptake (VO2-peak) and muscle strength (1 RM)
2. To motivate patients to improve and maintain their physical activity level of 150 min /week and at least 20 minutes strenuous exercise twice weekly
3. To improve vitality, functional capacity, general well being, pain, sleep problems, fatigue and

depression
4. To promote health behaviour (smoking), social integration and return to work

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethical Committee of the Capital Region Copenhagen Denmark, 19/12/2011, ref: H-1-2011-131
2. The Danish Data Protection Agency, ref: J.nr. 2011-41-6349

Study design
Three-armed randomised feasibility study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Colon and breast cancers receiving adjuvant chemotherapy

Interventions
Two interventions are tested with a comparable control group. All study group participants receives the oncologists advice of meeting national recommendations for physical activity. The two intervention groups receives motivational and individual counseling to support behavioural change towards increased physical activity.

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

Intervention 2: A non-supervised 12-week progressive pedometer program with a view to increasing participants physical activity to the minimum national recommendations of 150 minutes of moderate activity plus two times 20 minutes of strenuous activity / week.

Control: Control group participants are offered one of the two intervention after 12 weeks.

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 / DXA scan (Baseline and 12 weeks)
2. Muscular strength (baseline and at 6, 12 and 39 weeks)
3. Blood cholesterols (baseline, 12 and 39 weeks)

4. Blood pressure, pulse (baseline and 6, 12 and 39 weeks)
5. Body Mass index (baseline and 6, 12 and 39 weeks)
6. Performance status (baseline and 6, 12 and 39 weeks)
7. Self-reported physical activity, Quality of Life (EORTC QLQ C-30) (baseline and at 6, 12 and 39 weeks)
8. General Wellbeing (SF 36) (baseline and at 6, 12 and 39 weeks)
9. Anxiety and Depression (HADs) (baseline and at 6, 12 and 39 weeks)
10. Motivational readiness (baseline and at 6, 12 and 39 weeks)
11. Decisional balance (baseline and at 6, 12 and 39 weeks)
12. Exercise self-efficacy (baseline and at 6, 12 and 39 weeks)
13. Social support, (baseline and at 6, 12 and 39 weeks)
14. Labor market affiliation - Questions on matters relating to work for people who have a cancer and consist of 13 items (baseline and at 12 and 39 weeks)
15. Cardiovascular comorbidity
16. Disease free survival and recurrence (mainly 1 and 2 year follow-up data in the following RCT)

Completion date
30/01/2013

Eligibility

Key inclusion criteria
1. Patients diagnosed with breast cancer (stage I - III) or colon cancer (stage II and 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
All

Total final enrolment
45

Key exclusion criteria
1. Patients with myocardial infarction within the past three months
2. Symptomatic heart failure

3. Angina pectoris
4. Abnormal pathological ECG

Date of first enrolment
30/01/2012

Date of final enrolment
30/01/2013

Locations

Countries of recruitment
Denmark

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

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

ROR
https://ror.org/04txyc737

Funder(s)

Funder type
Government

Funder Name
Novo Nordic Foundation (Denmark)

Funder Name
Danish Cancer Society (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	qualitative results	23/08/2017	17/12/2020	Yes	No
Results article	results	23/10/2015	17/12/2020	Yes	No
Protocol article	protocol	04/11/2013	17/12/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes