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Effects of an exercise training program on cardiac health in women with breast cancer: the Mama Move Gaia on treatment trial

Submission date
30/09/2018

Recruitment status
No longer recruiting

Registration date
24/10/2018

Overall study status
Completed

Last Edited
03/03/2023

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Due to the improvement in survival time of breast cancer survivors, the long term effects of anti-cancer (antineoplastic) treatments are becoming increasingly apparent in this group. One of the most serious and significant effects of these treatments is cardiotoxicity (damage to the heart muscle), which can lead to cardiovascular health complications. Therefore, physical exercise is widely recommended as a supporting therapy for cancer and heart rehabilitation.
This study aims to look at the effects of supervised physical exercise on cardiotoxicity and cardiac health in women with breast cancer during antineoplastic treatment. It also aims to examine the effects of physical exercise on physical functionality, quality of life, fatigue and peripheral neuropathy (weakness, numbness and pain in the hands and feet as a result of nerve damage).

Who can participate?
Adult women with breast cancer (stage IA-IIIC) undergoing a neo/adjuvant anthracycline-containing chemotherapy.

What does the study involve?
Participants will be randomly allocated to either the intervention group or the control group. The intervention group will be asked to participate in a supervised physical exercise program for two months, which will involve aerobic exercise and resistance training, with a progressive increase in volume and intensity. The control group will not receive any exercise program. Before and after the exercise program, measurements will be taken, including blood pressure, heart rate and biomarkers, along with various questionnaires. After the final set of measurements are taken, participants in the control group will then be offered the exercise program received by the intervention group. Additionally, 24 hours before the end of each treatment cycle, blood samples will be taken from all participants.

What are the possible benefits and risks of participating?
Participants may feel the benefits derived from the supervised physical exercise such as prevention of cardiac dysfunction, improvement of cardiac health, improved physical fitness,

improved quality of life, and reduced fatigue, peripheral neuropathy and pain. The possible risksof participating in the study are fractures (from exercise), lymphedema (swelling in the arms and legs), hot flushes and extra fatigue.

Where is the study run from?
Centro Hospitalar Vila Nova de Gaia/Espinho (Portugal)

When is the study starting and how long is it expected to run for?
December 2018 to August 2022

Who is funding the study?
Centro Hospitalar de Vila Nova de Gaia/Espinho, Universidade da Beira Interior e Associação de Investigação de Cuidados de Suporte em Oncologia (Portugal)

Who is the main contact?
1. Mr. Pedro Antunes (pantunes_14@hotmail.com)
2. Dr. Ana Joaquim (anaisabeljoaquim@gmail.com)

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Not applicable

Study information

Scientific Title
Effects of supervised physical exercise on cardiotoxicity and cardiac health in women breast cancer survivors during anthracycline-containing chemotherapy: a randomised controlled trial

Study objectives
We anticipate that performing physical exercise during anthracycline-containing chemotherapy or trastuzumab will be associated with:
1. Attenuation of subclinical cardiotoxicity markers, such as systolic function (left ventricular ejection fraction), myocardial deformation (global longitudinal strain), and circulating cardiac biomarkers
2. Attenuation of cardiopulmonary capacity reduction
3. Control of cardiac health parameters, such as: blood pressure, resting heart, resting heart rate variability, and recovery heart rate

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval information as of 11/01/2019:
Ethics committee of the Centro Hospitalar de Vila Nova de Gaia/Espinho (CHVNG/E), 19/11 /2018, ref: 145/2018-1

Previous ethics approval information:
The present study was submitted to the ethics committee of the Centro Hospitalar de Vila Nova de Gaia/Espinho. We expect to obtain its ethical approval by the end of October.

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)

Prevention

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Breast cancer

Interventions
Patients will be randomised to either the intervention or the control group using a permutated block design with random four and six block sizes.
Patients in the intervention group will perform a supervised physical exercise program specifically developed for BC patients, based on the guidelines of the American College of Sports Medicine and a close cooperation between physical sports technicians and medical staff. The physical program comprises 3 weekly sessions, oriented in small groups (3-5 patients), supervised by the main author. Each session will involve an initial warm-up (5 min) followed by strength muscle and aerobic training (60 min) and ending with a cooldown phase (5 min).
During the intervention period, patients allocated to the control group will receive only the usual supportive care.
There will be a 3 month follow-up period.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measures as of 10/01/2019:
1. Cardiotoxicity markers:
1.1. Systolic function (left ventricular ejection fraction), assessed using standard transthoracic echocardiography at the baseline, at the end of treatment and 3 months afterwards
1.2. Myocardial deformation (global longitudinal strain), assessed using standard transthoracic echocardiography at the baseline, at the end of treatment and 3 months afterwards
1.3. Circulating cardiac biomarkers (amino-terminal pro-brain natriuretic peptide), assessed using blood samples at the baseline, 24 hours before the start of each treatment cycle, at the end of treatment and 3 months afterwards
2. Cardiac health outcomes will be assessed at the baseline, at the end of treatment and 3 months afterwards:
2.1. Resting blood pressure, measured in a seated comfortable position using a cardiac monitor
2.2. Resting heart rate, measured in a seated comfortable position using a cardiac monitor
2.3. Resting heart rate variability, measured in a seated comfortable position after at least 5 minutes of rest using a Polar V800 heart rate monitor with a Polar H7 Heart Rate Sensor chest strap. Analysis will be done using Kubios v2 Heart Rate Variability software.
2.4. Heart rate recovery (measured using a cardiac monitor after 30 seconds and 60 seconds after completion of a cardiopulmonary test), defined as the difference between peak heart rate achieved in the cardiopulmonary test and the heart rate at 30 seconds and 60 seconds following this.

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Secondary outcome measures
All secondary outcomes will be measured at the baseline, at the end of treatment and 3 months afterwards:
1. Functional outcomes:
1.1. Cardiopulmonary capacity (maximum oxygen consumption), evaluated using a Bruce treadmill test with an echocardiogram and continuous analysis of the O_2/CO_2 exchange
1.2. Upper limb strength (maximum voluntary handgrip strength), assessed using a handgrip dynamometer (6 trials per participant with 3 in each arm)
1.3. Lower limb functionality, assessed using the sit-stand test
2. Health-related quality of life and fatigue, assessed using the European Organization for Research and Treatment in Cancer Quality of Life C-30 (EORTC QLQ-C30) questionnaire
3. Neuropathy-related chemotherapy, assessed using The Functional Assessment of Cancer Therapy/Gynecologic Oncology Group -Neurotoxicity (FACT/GOG-Ntx) Scale)

Overall study start date
01/01/2018

Completion date
31/08/2022

Eligibility

Key inclusion criteria
Current inclusion criteria as of 10/01/2019:
1. Female
2. Aged 18 years or older
3. Histological confirmation of invasive breast cancer
4. Breast cancer stage IA-IIIC
5. Scheduled to receive neoadjuvant or adjuvant anthracycline-containing chemotherapy by decision of the Multidisciplinary Group Consultation of Centro Hospitalar de Vila Nova de Gaia /Espinho
6. Able to provide informed consent
7. Acceptance of randomization to intervention group or control group
8. Baseline assessments before anthracycline-containing chemotherapy begins.

Previous inclusion criteria:
1. Female
2. Aged 18 years or older
3. Histological confirmation of invasive breast cancer
4. Breast cancer stage IA-IIIC
5. Scheduled to receive neoadjuvant or adjuvant anthracycline-containing chemotherapy and/or trastuzumab by the Multidisciplinary Group Consultation of Centro Hospitalar de Vila Nova de Gaia/Espinho decision
6. Able to provide informed consent
7. Acceptance of randomization to intervention group or control group

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
86 participants

Total final enrolment
93

Key exclusion criteria
Current exclusion criteria as of 10/01/2019:
1. Contraindications to maximal exercise testing
2. Decompensated diabetes mellitus
3. Severe anaemia (<8 g/dl) uncorrectable with transfusion and/or iron and/or vitamin deficiency replacement
4. Significant heart disease (myocardial infarction, congestive heart failure, cardiomyopathy)
5. Usual medication containing beta-blockers
6. Contraindication to exercise

Previous exclusion criteria:
1. Heart failure class >1 of the New York Heart Association.
2. Osteoporosis (Tscore < 2.5)
3. Contraindications to maximal exercise testing
4. Usual medication containing beta-blockers
5. Severe anaemia (<8 g/dl) that cannot be corrected with transfusion and/or replacement of iron deficiency and/or vitamin deficiency

Date of first enrolment
01/11/2018

Date of final enrolment

31/01/2022

Locations

Countries of recruitment
Portugal

Study participating centre
Centro Hospitalar de Vila Nova de Gaia/Espinho
Rua Conceição Fernandes, s/n
Vila Nova de Gaia
Portugal
4434-502

Sponsor information

Organisation
Centro Hospitalar de Vila Nova de Gaia

Sponsor details
Rua da Conceição Fernandes s/n
Vila Nova de Gaia
Portugal
4434-502

Sponsor type
University/education

Website
http://www.chvng.pt/

ROR
https://ror.org/042jpy919

Organisation
Universidade da Beira Interior

Sponsor details
Convento de Sto. António
Covilhã
Portugal
6201-001

Sponsor type
University/education

Website
http://www.ubi.pt/

Organisation
Direção Geral de Saúde

Sponsor details
Alameda D. Afonso Henriques, 45,
Lisboa
Portugal
1049-005

Sponsor type
Government

Website
https://www.dgs.pt/

Funder(s)

Funder type
Not defined

Funder Name
Self funded

Results and Publications

Publication and dissemination plan
The findings will be:
1. Involved in a doctoral thesis
2. Submitted to a peer-reviewed journal for publication.
3. Presented at conferences and the whole community concerned

Intention to publish date
28/02/2023

Individual participant data (IPD) sharing plan

The data that will support the findings of this study will be available on request from the corresponding author Pedro Antunes (pantunes_14@hotmail.com). The request will be analysed by the research team and the ethics committee that ethically approved the study.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	15/07/2019	17/07/2019	Yes	No
Results article	primary outcome results	28/02/2023	03/03/2023	Yes	No