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Effects of a 12-week strength and aerobic exercise program on muscular strength and quality of life in breast cancer survivors

Submission date
22/07/2019

Recruitment status
No longer recruiting

Registration date
01/08/2019

Overall study status
Completed

Last Edited
22/06/2022

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
Breast cancer is the type of cancer with the highest incidence worldwide, however, it is well treated with the survival rate nearly 90% at 5-years. As a result, the number of people living with the consequences of the disease and its treatment (loss of muscle mass and strength, shoulder joint problems, lymphedema, cardiac toxicity and decreased quality of life) increases every year. All these disease-related consequences can be improved through physical exercise, especially when resistance and cardiovascular training are combined. In order to maximize the training benefits, individualization is essential. The aim of this study is to evaluate the effects of 12 weeks of supervised resistance training combined with home-based cardiovascular training on muscular strength in women survivor of breast cancer and to assess how this intervention affects cardiorespiratory fitness, fatigue and different aspects of disease-related quality of life.

Who can participate?
Survivors of breast cancer aged 18-65 who have completed central treatments of breast cancer within the past 5 years

What does the study involve?
60 women will be randomly assigned to either an exercise group (EG) or a control group (CG). The EG which will perform two resistance training sessions per week for 12 weeks (i.e. 2 weeks of one-to-one individual training and 10 weeks in groups of 4-5 participants) and will be required to perform ~10,000 steps per day as home-based aerobic training. The CG will also be required to undertake ~10,000 steps per day as home-based aerobic training but will not perform supervised resistance training. At baseline and at week 12 (i.e. after the intervention) all participants will be assessed for upper- and lower-body muscular strength, estimated maximum oxygen consumption, usual physical activity, range of motion (i.e. shoulder flexion), presence of lymphedema, health-related quality of life, fatigue, depression, and satisfaction with life. (updated 02/09/2019, previously: 60 women will be randomly assigned to either an exercise group (EG) or a control group (CG). The EG which will perform two resistance training sessions per week during 12 weeks (i.e. 2 weeks of one-to-one individual training and 10 weeks in groups of 4-5 participants) and will be required to meet the WHO physical activity guidelines of at least

10,000 steps per day as home-based aerobic training. The CG will be required to meet the WHO physical activity guidelines of at least 10,000 steps per day but will not undertake resistance training. At baseline and at week 12 (i.e. after the intervention) all participants will be assessed for upper- and lower-body muscular strength, estimated maximum oxygen consumption, usual physical activity, range of motion (i.e. shoulder flexion), presence of lymphedema, health-related quality of life, fatigue, depression, and satisfaction with life.)

What are the possible benefits and risks of participating?
Possible benefits include improvement of physical fitness and several aspects related to quality of life (see primary and secondary outcomes and hypotheses). Potential risks are those intrinsically associated with exercise, such as potential injuries. However, this is unlikely to occur as all sessions will be closely supervised by qualified professionals.

Where is the study run from?
1. Universidad de Almería, Spain
2. Patronato Municipal de Deportes. Ayuntamiento de Almería, Spain

When is the study starting and how long is it expected to run for?
August 2019 to December 2019

Who is funding the study?
1. Universidad de Almería, Spain
2. Patronato Municipal de Deportes. Ayuntamiento de Almería, Spain

Who is the main contact?
Dr Alberto Soriano-Maldonado
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
TRFE-SI-2019/004

Study information

Scientific Title
Effects of a 12-week exercise program combining strength and aerobic training on muscular strength and quality of life in breast cancer survivors

Acronym
EFICAN

Study objectives
1. Muscular strength will increase in the exercise group compared to the control group at week 12
2. Cardiorespiratory fitness will increase in the exercise group compared to the control group at week 12
3. Range of motion (i.e. shoulder flexion) will increase in the exercise group compared to the control group at week 12
4. Cancer-related fatigue and depression will decrease in the exercise group compared to the control group at week 12
5. Health-related quality of life will increase in the exercise group compared to the control group at week 12
6. Life satisfaction will increase in the exercise group compared to the control group at week 12

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/07/2019, Ethics Committee of the Torrecárdenas University Hospital (Calle Hermandad de Donantes de Sangre, 04009, Almería, Spain; +34 950 016 000; al42_cetico_cht.hto.sspa@juntadeandalucia.es), ref: Ejercicio-CáncerUAL(98/2019)

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions
Current interventions as of 02/09/2019:
The study is a randomized controlled trial. Patients will be randomly assigned to either an exercise group (combining supervised strength training and home-based aerobic training) or a control group. A simple randomization sequence will be generated by computer. Each participant will be randomized after meeting the inclusion criteria, signing the informed consent, and performing the baseline (pre-test) assessment. Baseline assessments (pre-test) will be carried out within 15 days before the start of the intervention, and follow-up assessment will be performed at the end of the intervention (week 12).
Due to the nature of the intervention (i.e. exercise), it will not be possible to mask allocation to the patients. Investigator will be blinded to the participants' allocation.

Exercise group: 12 weeks of exercise combining supervised strength training and home-based aerobic training. The sessions will begin with a warm-up including five minutes of cardiovascular work on a treadmill or cycle ergometer, and about 10 minutes including thoracic mobility, core stability, scapulohumeral joint stability, and dynamic stability exercises. Thereafter, a strength training block will be conducted including two sets of eight repetitions of seven exercises including squat, chest press, deadlift, seated row, leg press, triceps extensions and lat pulldown (specific adaptations will be carried out whenever necessary). The intensity will be set at six out of 10 in the OMNI perceived exertion scale for resistance exercise. The first two weeks will be aimed at familiarization with basic movement patterns and will be on a one-to-one basis. From week three to week 12, there will be group sessions (i.e. 4-5 participants per group). The home-based aerobic training will consist of performing ~10,000 steps per day.

Control group: usual care including healthy lifestyle recommendations. In addition, the control group will receive indications to perform ~10,000 steps per day to meet the physical activity guidelines.

Previous interventions:
The study is a randomized controlled trial. Patients will be randomly assigned to either an exercise group (combining supervised strength training and home-based aerobic training) or a control group. A simple randomization sequence will be generated by computer. Each participant will be randomized after meeting the inclusion criteria, signing the informed consent, and performing the baseline (pre-test) assessment. Baseline assessments (pre-test) will be carried out within 15 days before the start of the intervention, and follow-up assessment will be performed at the end of the intervention (week 12).
Due to the nature of the intervention (i.e. exercise), it will not be possible to mask allocation to the patients. Investigator will be blinded to the participants' allocation.

Exercise group: 12 weeks of exercise combining supervised strength training and home-based aerobic training. The sessions will begin with a warm-up including five minutes of cardiovascular work on a treadmill or cycle ergometer, and about 10 minutes including thoracic mobility, core stability, scapulohumeral joint stability, and dynamic stability exercises. Thereafter, a strength training block will be conducted including two sets of eight repetitions of seven exercises including squat, chest press, deadlift, seated row, leg press, triceps extensions and lat pulldown (specific adaptations will be carried out whenever necessary). The intensity will be set at six out of 10 in the OMNI perceived exertion scale for resistance exercise. The first two weeks will be aimed at familiarization with basic movement patterns and will be on a one-to-one basis. From week three to week 12, there will be group sessions (i.e. 4-5 participants per group). The home-based aerobic training will consist of performing a minimum of 10,000 steps per day to meet the WHO physical activity guidelines.

Control group: usual care including healthy lifestyle recommendations. In addition, the control group will receive indications to perform a minimum of 10,000 steps per day to meet the WHO physical activity guidelines.

Intervention Type
Behavioural

Primary outcome measure
Muscular strength assessed at baseline and week 12:
1. Upper-body muscular strength will be a standardized score computed as the average of the normalized score (z-score = [value-mean] / standard deviation) of 2 different exercise tests, including:
- Sum of right and left unilateral isometric seated bench press. Muscular strength will be measured in N with an electromechanical dynamometer (Dynasystem® Research, Symotech, Granada, Spain).
- Sum of right and left unilateral isometric seated row. Muscular strength will be measured in N with an electromechanical dynamometer (Dynasystem® Research, Symotech, Granada, Spain).
2. Lower-body muscular strength will be a standardized score computed as the average of the normalized score (z-score = [value-mean] / standard deviation) of 2 different exercise tests, including:
- Sum of right and left unilateral isometric knee extension in closed kinetic chain at 90° (average of the right and left knees). Muscular strength will be measured in N with an electromechanical dynamometer (Dynasystem® Research, Symotech, Granada, Spain).
- Mid-thigh isometric pull test. Bilateral muscular strength will be measured in N with an electromechanical dynamometer (Dynasystem® Research, Symotech, Granada, Spain).
3. Overall muscular strength will be a standardized score computed as the average of the normalized score (z-score = [value-mean] / standard deviation) of the above-mentioned upper- and lower-body exercise tests.

Secondary outcome measures
At baseline and week 12:
1. Other Muscular strength measures:
1.1. Bilateral isometric seated bench press measured in N with an electromechanical dynamometer (Dynasystem® Research, Symotech, Granada, Spain).
1.2. Isometric seated bench press bilateral deficit [bilateral deficit = (100 x bilateral / (right unilateral + left unilateral)) - 100].
1.3. Bilateral isometric seated row measured in N with an electromechanical dynamometer (Dynasystem® Research, Symotech, Granada, Spain).

1.4. Isometric seated row bilateral deficit [bilateral deficit = (100 x bilateral / (right unilateral + left unilateral)) - 100].
1.5. Handgrip strength (of the right and left sides) assessed with a digital dynamometer (Model T.K.K.540®; Takei Scientific Instruments Co., Ltd, Niigata, Japan).
1.6. The difference between right unilateral and left unilateral handgrip strength, assessed with a digital dynamometer (Model T.K.K.540®; Takei Scientific Instruments Co., Ltd, Niigata, Japan).
2. Cardiorespiratory fitness assessed through the Siconolfi Step Test.
3. Shoulder range of motion: flexion. Assessed through digital goniometer (HALO medical services).
4. Disabilities of the Arm, Shoulder, and Hand (DASH), assessed through the DASH Questionnaire.
5. Quality of life will be assessed with:
5.1 European Organization for Research and Treatment of Cancer Quality of Life Questionnaires-Core30, including the extension for breast cancer (EORTC QLQ-BR23).
5.2 Functional Assessment of Cancer Therapy-Breast (FACT-B).
6. Cancer-related fatigue, assessed with the functional assessment of cancer therapy-fatigue (FACT-F).
7. Depressive symptoms, assessed with the 20-item Center for Epidemiologic Studies-Depression Scale (CES-D).
8. Life satisfaction, assessed with the Satisfaction with life scale (SWLS).
9. Body composition:
9.1 Weight (in kg) and body composition (including body fat percentage, fat-free mass (kg), etc.) will be assessed with a bioelectrical impedance device (InBody 120, InBody Co. Ltd., Seoul, Korea).
9.2 Hip and waist circumference will be measured with an anthropometric tape (Harpenden, Holtain Ltd, Wales, United Kingdom). Waist-to-height ratio and waist-to-hip ratio will be calculated.
9.3 Body mass index will be calculated (kg/m^2).

Overall study start date
09/07/2019

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Women aged 18-65
2. Have undergone breast cancer surgery and have finished core treatment (i.e. chemotherapy and/or radiotherapy) in the past 5 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit

65 Years

Sex
Female

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
1. Metastatic breast cancer.
2. Not awaiting breast reconstruction in the following 6 months.
3. Any pathology that might prevent them from exercising:
3.1 Decompensated heart failure.
3.2 Unstable ischemic heart disease.
3.3 Severe untreated high blood pressure.
3.4 Moderate-severe valvulopathies.
3.5 Aortic aneurysm.
3.6 Moderate-severe COPD
3.7 Pulmonary hypertension.
3.8 Chronic respiratory insufficiency.
4. Patients who perform more than 300 minutes per week of structured exercise

Date of first enrolment
12/08/2019

Date of final enrolment
01/09/2019

Locations

Countries of recruitment
Spain

Study participating centre
Universidad de Almería
Ctra. Sacramento s/n.
Almería
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04120

Study participating centre
Patronato Municipal de Deportes - Ayuntamiento de Almería
Calle Alcalde Santiago Martínez Cabrejas, 5
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Sponsor information

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University/education

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Funder(s)

Funder type
University/education

Funder Name
Universidad de Almería

Funder Name
Patronato Municipal de Deportes. Ayuntamiento de Almería

Results and Publications

Publication and dissemination plan
The results will be presented at national and international conferences and will be published in peer reviewed international journals.

Intention to publish date
01/11/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will not be publicly available. Proposals should be directed to the principal investigator (PI) Dr Alberto Soriano-Maldonado (asoriano@ual.es). To gain access, data requestors will likely need to sign a data access agreement. The data will be shared with investigators whose proposed use of the data has been approved by an independent review committee identified for this purpose. Individual participant data underlie the results reported in the published article after deidentification (text, tables, figures and appendices) will be shared. The data will be available from 9 months to 36 months following article publication. The data will be shared to achieve aims in the approved proposal.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/11/2019		Yes	No
Results article		22/03/2022	21/06/2022	Yes	No