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The impact of physical activity on breast cancer survivors

Submission date
28/11/2021

Recruitment status
No longer recruiting

Registration date
04/01/2022

Overall study status
Completed

Last Edited
05/01/2022

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Due to the variety of disorders that are a consequence of breast cancer treatment, the rehabilitation of patients is complicated. Its aim is to minimize complications and side effects during treatment. Following breast cancer surgery, multifactorial physiotherapy, including exercises with increasing intensity, is an effective way to increase exercise tolerance and improve mobility and functional abilities. It is also an important element of psychotherapy because it gives patients the opportunity to be in a group of other women with similar problems and support each other in the disease. Taking the above into consideration, training programs should be created to provide patients with the appropriate type and level of physical activity to reduce the risk factors and disease progression. The aim of this study is to assess the impact of different types of physical activity on breast cancer survivors.

Who can participate?
Women aged 30 - 70 years treated for breast cancer

What does the study involve?
The patients will be divided into three groups – two experimental groups and one control group. Patients in the first experimental group will receive general fitness exercises (two times a week for 45 minutes), virtual reality based exercises (once a week for 45 minutes). All patients will also take part in a series of educational meetings twice a week for 45 minutes. Patients in the second experimental group will receive general fitness exercises (two times a week for 45 minutes), water aerobics exercises (once a week for 45 minutes). All patients will also take part in a series of educational meetings twice a week for 45 minutes. The third group (control) will consist of 60 patients who do not exercise for 6 weeks, but only obtain information in a series of educational meetings on the importance of physical activity in the treatment and prevention of cancer. After 6 weeks, patients from the control group have the opportunity to take part in exercises conducted in experimental groups if they are willing to do so.

What are the possible benefits and risks of participating?
Participants' exercise tolerance, locomotor function and postural stability may increase and their quality of life may improve. The study provides patients with the appropriate level of physical activity to reduce risk factors and disease progression. Physical training ordered by an oncologist

and conducted under the supervision of physiotherapists should not cause adverse effects harmful to the patients although dizziness may rarely occur during virtual reality based exercise. Participants in the control group do not start exercise until 6 weeks have passed.

Where is the study run from?
1. Academy of Physical Education in Katowice (Poland)
2. Oncology Centre in Katowice (Poland)

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

Who is funding the study?
Academy of Physical Education in Katowice (Poland)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
3/2018

Study information

Scientific Title
The impact of physical activity on the quality of life, fatigue, locomotor function and postural stability in women treated for breast cancer

Study objectives
1. Does virtual reality based exercise reduce fatigue in women treated for breast cancer?
2. Does virtual reality based exercise influence posture stability in women treated for breast cancer?
3. Does virtual reality based exercise affect locomotor function in women treated for breast cancer?
4. Does virtual reality based exercise improve quality of life in women treated for breast cancer?
5. Does aerobic exercise reduce fatigue in women treated for breast cancer?
6. Does aerobic exercise influence posture stability in women treated for breast cancer?
7. Does aerobic exercise affect locomotor function in women treated for breast cancer?
8. Does aerobic exercise improve quality of life in women treated for breast cancer?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/11/2018, Bioethics Commission for Scientific Research at The Jerzy Kukuczka Academy of Physical Education in Katowice (Mikołowska 72a Street, 40-065 Katowice, Poland; +48 (0)322075152; komisjabioetyczna@awf.katowice.pl), ref: 3/2018

Study design
Single-centre interventional single-blind randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
The impact of physical activity on health in breast cancer survivors

Interventions
The study will include women treated for non-disseminated breast cancer in Oncology Centre in Katowice.

The intervention will consist of two stages. In the first stage, after the medical examination and meeting the inclusion criteria, patients will be randomly assigned by the attending physician to participate in the study to one of the three groups.

1. In the first experimental group 60 patients will receive general fitness exercises (two times a week for 45 minutes), virtual reality based exercises (once a week for 45 minutes). All patients will also take part in a series of educational meetings twice a week for 45 minutes.
2. In the second experimental group 60 patients will receive general fitness exercises (two times a week for 45 minutes), water aerobics exercises (once a week for 45 minutes). All patients will also take part in a series of educational meetings twice a week for 45 minutes.

3. The third group (control) will consist of 60 patients who do not exercise for 6 weeks, but only obtain information in a series of educational meetings on the importance of physical activity in the treatment and prevention of cancer. But after 6 weeks, patients from the control group have the opportunity to take part in exercises conducted in experimental groups if they are willing to do so.
In all experimental groups, physical exercises will be conducted 3 times a week for 6 weeks.

During a series of meetings, information will be provided on the prevention of breast cancer, nutrition in oncological disease, lymphoedema prevention, risk factors for cancer, the importance of physical activity in the prevention and treatment of cancer and side effects resulting from oncological treatment.

General fitness exercises in both experimental groups will be conducted in the gym, twice a week, for 50 minutes, and will be the same in both experimental groups. Exercises will be performed at a pace adapted to the patients' capacity. They will include a set of exercises in which large muscle groups will be involved, as well as stretching, relaxing, balance and dexterity exercises. Training load will be determined at 40 to 70% of patients' maximum exercise heart rate.

In the first experimental group the virtual reality based exercises will be aimed at improving motor coordination and body balance. Exercises on stabilometric platforms and exercises of motor coordination of lower limbs with elastic resistance were will be used in the study. These devices will be equipped with software enabling feedback based on virtual reality. Exercises on the platforms will be conducted in a standing position and during the exercises monitors will display tasks that require the patient to perform specific tasks in the virtual world. Exercises will be focused on improving the distribution of body weight on the lower limbs and on improving the control of the body’s center of gravity during body swings in different directions.

In the second experimental group, classes will be held in the form of water aerobics exercises and will be conducted once a week, using elements of aerobic and resistance training (using water resistance to strengthen muscles).

The attending physician who qualifies for the examination will be blinded. Researchers assessing the effects of therapy, researchers preparing a database for statistical analysis, and researchers conducting statistical analysis of the results will also be blinded. The main investigator responsible for the organization of training and educational activities and the study director will not be blinded.

Intervention Type
Behavioural

Primary outcome(s)
1. Quality of life assessed with the EORTC QLQ – C30 - Quality of Life Questionnaire of Cancer Patients at baseline, after finishing 6-week physical training and 6 weeks after treatment
2. Quality of life assessed with the EORTC QLQ – BR 23 - Quality of Life Questionnaire for Breast Cancers at baseline, after finishing 6-week physical training and 6 weeks after treatment
3. Postural stability assessed by AMTI's AccuGait Optimized™ multi-axis force platform tests at baseline, after finishing 6-week physical training and 6 weeks after treatment
4. Postural stability assessed by Timed Up and Go test (TUG) at baseline, after finishing 6-week physical training and 6 weeks after treatment

Key secondary outcome(s))

1. Physical activity level assessed by Physical Activity Questionnaire (IPAQ) questionnaire at baseline, after finishing 6-week physical training and 6 weeks after treatment
2. Fatigue level assessed by Brief Fatigue Inventory (BFI) at baseline, after finishing 6-week physical training and 6 weeks after treatment
3. Locomotor function assessed by 4-Meter Gait Speed test (4MGS) at baseline, after finishing 6-week physical training and 6 weeks after treatment
4. Pain is measured using a visual analogue scale (VAS) at baseline, after finishing 6-week physical training and 6 weeks after treatment
5. Fall risk is measured using the Falls Efficacy Scale-International (FES-I) at baseline, after finishing 6-week physical training and 6 weeks after treatment

Completion date
30/09/2022

Eligibility

Key inclusion criteria
1. Patient's written consent to participate in the study
2. Age 30 - 70 years
3. First treatment of non-disseminated breast cancer
4. 0 - III degree of cancer
5. Overweight and obesity (BMI >25 kg/m^2)
4. Treatment of breast cancer (mastectomy and minimally invasive surgery)
5. Adjuvant treatment (chemotherapy, immunotherapy, hormone therapy, radiotherapy) based on the medical indications
6. Completed radiotherapy and chemotherapy from 4 weeks to 6 months before the study start
7. No physical training for more than 60 minutes a week before the start of the study
8. Hormone therapy and/or immunotherapy,
9. Minimum of 5 years from the end of treatment for another malignant tumor

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Contraindications to physical training at the intensity specified in the study
2. Refusal to participate in the study
3. Co-morbidities disrupting the body’s balance including diseases of the nervous system, balance organ, eyes, muscles and joints (amputations, unequal limb length >2 cm, joint stiffness and limited range of movement in lower extremities above 15 degrees)

Date of first enrolment

10/01/2022

Date of final enrolment
30/06/2022

Locations

Countries of recruitment
Poland

Study participating centre
The Jerzy Kukuczka Academy of Physical Education in Katowice
72a Mikołowska Street
Katowice
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Study participating centre
Oncology Centre in Katowice
Raciborska 26 Street
Katowice
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40-074

Sponsor information

Organisation
Akademii Wychowania Fizycznego im. Jerzego Kukuczki w Katowicach

ROR
https://ror.org/05wtrdx73

Funder(s)

Funder type
University/education

Funder Name
Akademia Wychowania Fizycznego im. Jerzego Kukuczki w Katowicach

Alternative Name(s)
The Jerzy Kukuczka Academy of Physical Education in Katowice, AWF Katowice

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Poland

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date