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Rhythmic therapeutic exercise program for breast cancer survivors

Submission date 06/01/2023	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 13/01/2023	**Overall study status** Ongoing	
Last Edited 03/03/2025	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Background and study aims
Worldwide, breast cancer is the most common type of cancer affecting women; however, nowadays, the survival rate is increasing. Cancer survivors commonly experience a range of medical and psychosocial consequences related to the disease and its treatment. Cancer-related fatigue (CRF) is recognized as one of the most common and distressing side effects, which has a negative impact on work performance, mood, and daily activities and causes significant impairment in overall quality of life.
Updated data on managing CRF's symptoms focus on exercise programs, physical activity, and psychosocial interventions. In recent years, rhythmic or music therapy methods are integrated into various physiotherapy interventions and studies are shown that patients have multiple therapeutic benefits. This study aims to develop a rhythmic therapeutic exercise program and evaluates its possible effects on cancer-related fatigue, physical activity, mental health, and quality of life of women with breast cancer.

Who can participate?
Women aged 45-60 years who are breast cancer survivors

What does the study involve?
This study involves:
1. The creation of an evidence-based intervention program of rhythmic therapeutic exercise (RhyKaTheA), suitable for breast cancer women survivors.
2. Personalized evaluation and intervention in matters of safe performance of the RhyKaTheA program
3. Checking the effectiveness of this novel program through this study

Participants will be randomly allocated to one of two groups; in the intervention group the RyKaTheA program will be implemented, while in the control group participants will be taught self-stretching of main muscle groups, which will be performed without supervision. They also will be encouraged to remain active but not to participate in any exercise program during the study's timeframe.

What are the possible benefits and risks of participating?
The primary expected outcome is reducing cancer-related fatigue and improving the functionality, mood, and quality of life of women with breast cancer. In addition, it is expected to determine the possible barriers and motivations for implementing the intervention and whether endogenous factors, such as dysthymia and other pathologies, impact the intervention's outcomes.
There are no notable risks to participating. Participation in the study is voluntary. Participants can refuse to participate or stop participating at any time. All information obtained for this study will be used for research purposes only and will be kept strictly confidential.

Where is the study run from?
1. University of West Attica (Greece)
2. Hellenic Cancer Society (Greece)

When is the study starting and how long is it expected to run for?
January 2023 to January 2028

Who is funding the study?
Hellenic Cancer Society (Greece)

Who is the main contact?
Dr Dafne Bakalidou, dbakalid@uniwa.gr

Study website
http://www.cancerhellas.org/

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
803/14-12-2022

Study information

Scientific Title
Effectiveness of a rhythmic therapeutic-exercise program on cancer-related fatigue and quality of life of breast cancer women

Acronym
RhyKaTheA

Study objectives
To investigate if a rhythmic therapeutic-exercise programme could increase functionality and reduce cancer-related fatigue.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/12/2022, Hellenic Cancer Society Board of Directors (Hellenic Cancer Society, An. Tsoha 18-20, 115-21 Athens, Greece; +30 (0)210 3826600; +30 (0)210 6456713; dioikisi@cancerhellas.org), ref: 803/14-12-2022

Study design
Multicenter randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Other therapist office, University/medical school/dental school

Study type(s)
Treatment

Participant information sheet
Not available in web format

Health condition(s) or problem(s) studied
Fatigue in breast cancer survivors

Interventions

After the baseline assessment, participants will be randomly assigned to one of two groups: group A (intervention) or group B (control). The sample allocation will be carried out using the block randomization method (block size of 4). In group A, the RyKaTheA program will be implemented. In contrast, the participants of group B (control) will be taught self-stretching of main muscle groups, which will be performed without supervision. They will also be encouraged to remain active but not to participate in any exercise program during the study's timeframe.

Participants will be assessed before the 8-week exercise program, immediately after, and 16 weeks after the program has finished.

Intervention Type
Behavioural

Primary outcome measure
1. Cancer-related fatigue will be evaluated using the Greek version of the Multidimensional Fatigue Inventory (MFI-Greek version) and the Greek version of the Modified Fatigue Impact Scale (MFIS) at baseline, 8, and 16 weeks
2. Functional mobility will be assessed using the Timed Up and Go Test at baseline, 8, and 16 weeks
3. Physical activity will be assessed using 6 minutes walking test (6MWS) at baseline, 8, and 16 weeks
4. Quality of life will be evaluated using the Greek version of the SF-36 Scale at baseline, 8, and 16 weeks

Secondary outcome measures
1. Grip strength will be assessed using a hand dynamometer at baseline, 8, and 16 weeks
2. Lower limbs' muscle strength will be assessed using the 30-sec sit-to-stand test at baseline, 8, and 16 weeks
3. Balance will be assessed using the Functional Reach Test at baseline, 8, and 16 weeks
4. Depression and anxiety will be assessed using the Greek version of the Depression, Anxiety and Stress Scale-21 (DASS-21) at baseline, 8, and 16 weeks

Overall study start date
06/01/2023

Completion date
01/01/2028

Eligibility

Key inclusion criteria
1. Breast cancer disease-free women aged 45-60 years (meaning that they completed their oncology treatment 2 to 6 months before enrollment in the study), except if they are receiving hormonotherapy
2. Willing to be assigned to any of the two study intervention groups

Participant type(s)
Patient

Age group

Adult

Sex
Female

Target number of participants
65

Key exclusion criteria
1. Cognitive impairments
2. Neurological disorders
3. Cardiovascular diseases or high blood pressure not controlled with medication
5. Surgery on lower limbs affecting gait within the previous 6 months
6. Medical or other musculoskeletal problems that could affect the ability to complete objective assessments or exercise with safety
7. Cancer recurrence

Date of first enrolment
01/03/2023

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
Greece

Study participating centre
University of West Attica
Ag. Spyridonos str, Egaleo
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Study participating centre
Hellenic Cancer Society
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Sponsor information

Organisation
Hellenic Cancer Society

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Sponsor type
Other

Website
http://www.cancerhellas.org/

ROR
https://ror.org/039p74p43

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/01/2028

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be stored in a non-publically available repository. Access is only available to the corresponding author (Prof. Dafne Bakalidou) and the four additional researchers (Dr Stasi S, Elpidoforou M, and Dr Fillopoulos E). During recruitment, participants will be informed of the purposes of the study. Participants will agree to participate and will sign an informed consent form. Names of participants on the datasets will be replaced with codes, ensuring anonymisation (not applicable via weblink). Individual participant data collected during the trial will be available after de-identification (text, tables, figures, and appendices), beginning 9 months and ending 36 months following article

publication. Access will be granted to researchers who provide a methodologically sound proposal in order for them to achieve the aims of the approved proposal. Proposals should be directed to dbakalidou@uniwa.gr. Data requestors need to sign a data access agreement to gain access. After 36 months, the data will not be available.

IPD sharing plan summary

Stored in non-publicly available repository, Available on request