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Evaluation of the effectiveness of a combined protocol with pelvic floor muscle retraining, use of relaxation techniques, and vaginal dilators to improve health and quality of life in women with sexual dysfunction after treatment for breast cancer

Submission date
27/03/2022

Recruitment status
No longer recruiting

Registration date
15/06/2022

Overall study status
Ongoing

Last Edited
16/07/2024

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
The most common symptoms of the genitourinary syndrome of menopause (GSM) that lead women who have had breast cancer (BC) to seek treatment are vaginal dryness and dyspareunia (painful intercourse).
Pelvic floor physical therapy (PFMT) is recommended by the International Continence Society (ICS) as a first-line treatment for the management of GSM symptoms. However, despite its promising results, PFMT is not well known and widespread among patients or health professionals and as a result, it is not recommended and not widely used. The aim of this randomized clinical control study is to evaluate the effectiveness of combined physiotherapy intervention in female patients after treatment for breast cancer with GSM symptoms, such as vaginal dryness and dyspareunia. The main hypothesis of the study is that the combined implementation of a programme of physical therapy (PT) and use of vaginal dilators improves symptoms of sexual dysfunction as well as quality of life (QoL). In particular, vaginal dryness, dyspareunia and pelvic pain will be assessed and the effects on quality of life will be investigated.

Who can participate?
Eligible for the study will be BC survivors who will be in a sexually active relationship aged 35-65 with vaginal dryness and dyspareunia. In addition, amenorrheaic women for at least 6 months (if pre-menopausal at diagnosis) those taking aromatase inhibitors (AI), (if postmenopausal at diagnosis), or had undergone adjuvant chemotherapy and report symptoms of vaginal dryness and dyspareunia will be included in the study.

What does the study involve?
Participants will be randomly allocated to two groups. Group A (intervention group) will follow

the combined physiotherapy treatment protocol including retraining of the pelvic floor muscles, use of relaxation techniques and vaginal dilators. Group B (control group) will follow a "usual treatment" protocol with the application of specific lubricating and moisturizing applications and counseling. Thereafter, the progress of the two groups will be monitored and recorded. Then the results of the two groups will be recorded and correlated.

What are the possible benefits and risks of participating?
There are no risks at participating in the study protocol. Benefits of participating in the study is the alleviation of symptoms of GSM for women survivors from BC who undergo hormonal therapy, hence improving the health and quality of their life (HRQL).

Where is the study run from?
University of West Attica (Greece)

When is the study starting and how long is it expected to run for?
September 2021 to December 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Mimi Marcellou, mimimarcellou@gmail.com

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Exploring the level of efficacy of pelvic floor physiotherapy intervention for the treatment of Genitourinary Syndrome of Menopause (GSM) in women after the treatment of breast cancer

Study objectives
Pelvic floor physiotherapy may contribute effectively in the management of Genitourinary Syndrome of Menopause (GSM) and symptoms of sexual dysfunction, such as vaginal dryness and dyspareunia, therefore improving the quality of life of women breast cancer survivors.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/11/2021, Aretaiio Hospital (ΕΚΠΑ/Medical School) Research Ethics Committee (76 Vassilissis Sofias street, 11528 Athens, Greece; +30 210 728 6128; bxeir@aretaieio.uoa.gr), ref: #380

Study design
Single-centre randomized single-blind controlled cross-over study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
GP practice

Study type(s)
Treatment

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
Genitourinary Syndrome of Menopause and symptoms of vaginal dryness and sexual dysfunction in women survivors after breast cancer

Interventions
Initially, the intervention will include a thorough medical examination, all relevant laboratory and diagnostic tests will be recorded, as well as pathological psychosocial factors and disorders that require drug intervention to exclude any other cause of vaginal dryness and dyspareunia. For the purpose of the study, validated questionnaires will be administered in the Greek

language. The intervention will include, conducting a digital evaluation and recording of muscle tone of the pelvic floor (PF) at rest, by manometry. Then, a randomized separation of patients into two groups will be performed: In Group A (intervention group), the therapeutic protocol will be implemented with manual relaxation techniques, pelvic floor muscle retraining (PTMT) and use of vaginal dilators. The therapeutic intervention programme for Group A will be completed in 12 weeks with one session per week. In Group B (control group), standard treatment practice with vaginal lubrication and moisturizing products and counseling assistance will be implemented. Participants in Group B, will attend a next scheduled session at week 12 for necessary new measurement recordings and data updating.
After the completion of the therapeutic interventions, a final pelvic floor physical therapy re-evaluation will follow with measurement and recording of all parameters and variables (outcomes) under study, data will be collected and possible differences between the two groups will be investigated.

Intervention Type
Mixed

Primary outcome measure
Measured at the initial visit and at the end of the study protocol:
1. Sexual function will be measured using the Female Sexual Function Index (FSFI-Gr),
2. The effects of vaginal symptoms, associated sexual matters and impact on quality of life (QoL) will be measured with the subscale of the International Consultation on Incontinence Questionaire vaginal Symptoms Module in Greek (ICIQ-VS-GR)
3. Pain assessment will be recorded with the Visual Analog Pain Scale (VAS).
4. Baseline muscle tone at rest will be assessed with the method of manometry at initial visit and at the end of the study protocol.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
21/09/2021

Completion date
31/12/2025

Eligibility

Key inclusion criteria
Women aged 35-65 years with :
1. Pain during and/or after vaginal intercourse, greater than 7/10, based on the Visual Analogue Pain Scale (VAS).
2. Also, women who have undergone immunosuppressive chemotherapy, received or are receiving adjuvant hormone therapy with tamoxifen (TAM), or aromatase inhibitors (AIs) and report symptoms of vaginal dryness and dyspareunia will also be included.
3. Willing to be assigned to the study

Participant type(s)
Patient

Age group

Adult

Lower age limit
35 Years

Upper age limit
65 Years

Sex
Female

Target number of participants
Total target number: 60 participants. (Each of the two study groups will include 30 participants)

Key exclusion criteria
1. Metastatic breast cancer
2. Vaginal or intravaginal stenosis
3. Pelvic surgery
4. Allergy to lubricating oils and moisturizers
5. Women using hormone replacement therapy (HRT)
6. Women who are on long-term use of birth control pills
7. Women who are on some type of drug intervention for dyspareunia
8. Diabetes
9. Hypertension
10. Obesity
11. Hypothyroidism
12. Urogynaecological infections
13. Psychiatric conditions
14. Vascular conditions
15. In addition after enrollment, patients who present with difficulty understanding how to coordinate their pelvic floor muscles

Date of first enrolment
01/06/2022

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
Greece

Study participating centre
University of West Attica
Laboratory of Neuromuscular and Cardiovascular Study of Motion (LANECASM)
Physiotherapy Department
School of Health and Caring Sciences
28 Ag. Spyridonos Street

Egaleo – Attica
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Sponsor information

Organisation
University of West Attica

Sponsor details
Laboratory of Neuromuscular and Cardiovascular Study of Motion (LANECASM) Physiotherapy Department School of Health and Caring Sciences
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Sponsor type
University/education

Website
https://lanecasm.uniwa.gr

ROR
https://ror.org/00r2r5k05

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

21/09/2026

Individual participant data (IPD) sharing plan

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 aims in the approved proposal. Proposals should be directed to Ms. Mimi Marcellou (mimimarcellou@gmail.com). To gain access, data requestors will need to sign a data access agreement. After 36 months the data will not be applicable. During recruitment, patients are informed of the purposes of our study.
Upon acceptance, and prior to baseline measurements, participants give their written informed consent (document in Greek).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	Cross-sectional study poster		16/07/2024	No	No