

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	<input type="checkbox"/> Prospectively registered
Registration date 15/06/2022	Overall study status Ongoing	<input type="checkbox"/> Protocol
Last Edited 16/07/2024	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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, amenorrheic 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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Contact details

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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, Aretaio 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 Questionnaire 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
Greece
12243

Sponsor information

Organisation

University of West Attica

Sponsor details

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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