Official Title: Feasibility of Pelvic Physical Therapy for Sexual Dysfunction in Gynecologic Oncology Survivors
NCT05242770
IRB-Approved Date: 3/6/23

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Division of Gynecologic Oncology

# FEASIBILITY OF PELVIC PHYSICAL THERAPY FOR SEXUAL DYSFUNCTION IN GYNECOLOGIC ONCOLOGY SURVIVORS

Informed Consent Form to Participate in Research
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## SUMMARY

You are invited to participate in a research study. The purpose of this research is to evaluate the feasibility of a long term pelvic physical therapy regimen for gynecologic oncology survivors with sexual dysfunction. You are invited to be in this study because you have reported symptoms of sexual dysfunction on our screening questionnaire. Your participation in this research will involve potentially 10 physical therapy visits that last about 30-45 minutes or receiving education about these symptoms in the form of pamphlets.

Participation in this study will involve filling out three sets of questionnaires that will ask about your symptoms. This study involves very minimal risk, though all research studies involve some risks. A risk to this study that you should be aware of is tissue irritation and risk of triggering an emotional reaction or PTSD if you have a history of sexual trauma or abuse. You may or may not benefit from participation in this study. There is no cost associated with participation in the study. Grant funding will cover all physical therapy visit costs.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices may include learning more about sexual dysfunction independently, discussing your symptoms further with your provider, or attending pelvic physical therapy outside of this study. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Anya Menzies, MD. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: [redacted] (email) and [redacted] (phone).

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

## INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have reported symptoms of sexual dysfunction. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

## WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to investigate the use of pelvic physical therapy for gynecologic cancer survivors who report sexual dysfunction. Survivors may have short and long term effects from their cancer therapies, whether they underwent surgery, chemotherapy, radiation, or a combination. Sexual health is an important aspect of your comprehensive care and survivorship. There are various causes and therapies for sexual dysfunction. Pelvic physical therapy has been shown to be helpful for a variety of pelvic problems including incontinence and pelvic organ prolapse. Not many studies have looked at the effect of pelvic physical therapy on sexual function, though it is widely believed to have beneficial effects. Physical therapy experts believe that a full 10 week regimen is necessary for true improvement of symptoms. We aim to see if this tense regimen is feasible for survivors. We also aim to see if patients have an improvement in their sexual function and quality of life.

## HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Approximately twenty people at one research site will take part in this study.

## WHAT IS INVOLVED IN THE STUDY?

At today's visit, you were given a questionnaire to assess if you have symptoms of sexual dysfunction. Based on your answers, you could be enrolled in this study. If you agree to participate you fill out two additional questionnaires that tell us more about your sexual function and quality of life. You will fill out these same two questionnaires again in about 3 and 6 months.

You will be randomized into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have an equal chance of being placed in any group.

If you are randomized to group 1, you will receive educational reading materials about sexual dysfunction. You will not participate in physical therapy at this time. We will contact you in 3 and 6 months to fill out the two questionnaires about sexual function and quality of life. After 6 months, if you desire a referral to physical therapy, we can provide that for you. If you do not wish to participate in this study but would like a referral to physical therapy we can also give you a referral. After 6 months you will be asked to complete a short exit interview so that we may learn more about your experience.

If you are randomized to group 2, you will be provided a referral to begin a pelvic physical therapy regimen. As a participant in the study, you will be prioritized for scheduling. There is no cost to you for the physical therapy visits.

The following procedures will be done as part of the group two regimen:

Physical therapy:

• Manual Therapy: Soft tissue massage, deep tissue massage, myofascial release (massaging the membranes that surround your muscles), scar tissue mobilization

• Down training nervous system response:
  - education on your nervous system (sympathetic versus parasympathetic, or your involuntary response to stressful situations versus your body relaxing when the stressful situation is over)
  - how to respond to expected pain
  - strategies to improve tensing up and pain response with pelvic floor exercises
  - pain science education

• Diaphragmatic breathing: used to help your body relax and manage the pressure within your abdomen to improve movement of muscles and scar tissue

• Coordination training: managing pressure within the abdomen, pairing breathing with activity, how to correctly contract and bulge pelvic floor

• Strength training

• Education (i.e. sexual function, positions, lubrication options, timing of HEP, bowel and bladder)

• Dilator training: option for self-manual therapy and scar tissue management to help your treatment in clinic

• Pelvic wand training: option for self-manual therapy and scar tissue management to help your treatment in clinic

• Range of motion for hips and lumbar spine

• sEMG biofeedback training: surface electromyography, or measuring your muscle activity, means that we use surface electrodes (a patch that carries an electrical signal from your muscles to a recording device) to look at your pelvic floor. This will help you see what your muscles are doing and may help you improve strength, coordination, and improve your awareness of increased tone/guarding.

During an evaluation, the PT (physical therapist) will assess your breathing pattern, lumbar (lower back) range of motion, hip range of motion, core strength, hip strength, flexibility, and movement. After identifying any potential problem areas, the PT will use manual therapy, self-care home training/education, and therapeutic exercises.

Pelvic floor physical therapy often uses intravaginal (within your vagina) treatment options to help make your pelvic muscles less sensitive. This may include manual stretching, release, and massage or tolerance to touch/penetration so you may not feel pain during intercourse or future disease assessments. Pelvic floor physical therapists may also help you through exercises that make your pelvic floor strength/coordination better as well as teaching self-desensitization and release with tools such as pelvic wands or vaginal dilators to help you with your pelvic muscles.

We will contact you to complete the sexual function and quality of life questionnaires after completing the physical therapy regimen and again 3 months after that. You will have a brief exit interview.

## How Long Will I Be in the Study?

You will be in the study for about 6 months.

You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

## What Are the Risks of the Study?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff.

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff.

The quite rare risks involved in participating in the study are limited to the group which will be receiving pelvic physical therapy. The risks involved include possible tissue irritation, possible trigger of PTSD or emotional reaction in patients with a history of sexual trauma or abuse, possible heat irritation or burn from the use of a warm heating pad.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other risks that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

Taking part in this research study may involve providing information that you consider

confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

A Data Safety and Monitoring Committee, an independent group of experts, will be reviewing the data from this research throughout the study.

## ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be improvement of sexual dysfunction symptoms, improvement of pelvic pain, and improvement in general quality of life.

Based on experience with pelvic physical therapy in patients with incontinence and pelvic organ prolapse, we believe this therapy may improve the symptoms you have reported. Because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case.

## WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. Instead of being in this study, you have these options:

- Discuss your symptoms further with your provider to identify any alternative approaches to address those symptoms
- Read more about sexual dysfunction
- Referral for pelvic physical therapy outside of this study
- Observation

## WHAT ARE THE COSTS?

Grant funding will cover the cost of the physical therapy visits. There is no cost to you for the physical therapy visits. All costs for your regular medical care will be the responsibility of you or your insurance company.

## WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

## WILL YOU BE PAID FOR PARTICIPATING?

You will be paid $50 by gift card if you complete all the scheduled study visits and questionnaires.

## WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Atrium Health Wake Forest Baptist Comprehensive Cancer Center. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

## WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes information about your visits with physical therapy, your oncologic history, treatment history, and questionnaire responses.

This research study involves the diagnosis or treatment of a medical condition. Protected Health Information collected from you during this study may be placed in your medical record and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any



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publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records until results have been distributed.

You can tell Anya Menzies that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Anya Menzies, MD
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

Laboratory test results and other clinically relevant medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.



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A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

## WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest, your condition worsened, new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

## WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Anya Menzies at [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will be given a copy of this signed consent form.

## SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____



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Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent: Date:_____ Time:_____ am pm

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm



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