Official Title: Exploring the Role of Sarcopenia and Functional Impairment on the Non-Surgical Management of Urinary Incontinence in Older Women
NCT03057834
IRB-Approved Date: 9/18/2019

Wake Forest®
School of Medicine

Department of Obstetrics and Gynecology

URINARY INCONTINENCE TREATMENT STUDY (UNITS)

The Impact of Sarcopenia and Functional Impairment on the Non-Surgical Management of Urinary Incontinence in Older Women

Informed Consent to Participate in Research

Candace Parker-Autry, MD, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to see how a 12 week program that asks you to do pelvic floor muscle exercises (PFME or "Kegels") affects you and your urinary incontinence symptoms. You are invited to be in this study because you are a woman age 69 or older and have urinary incontinence. Your participation in this research will involve 4-5 visits and your participation will last about 12 weeks after it is determined you are eligible.

Participation in this study will involve performing the PFME or Kegels multiple times a day and coming into the clinic for before and after tests and measurements. All research studies involve some risks. A risk that you should be aware of is the chance of falling or injury due to the physical performance testing, a small amount of radiation from the DXA scan, and discomfort when performing the PFMEs. There is the possibility that you may benefit from participation in this study.

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 seeing your physician and about your incontinence and forming PFME exercises under their supervision. 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 Candace Parker-Autry, MD. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is [redacted], or [redacted] after hours.

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 urinary incontinence. 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 find out how a standard, 12 week prescription of pelvic floor muscle exercises (PFME or "Kegels") have on you and your urinary incontinence symptoms. There is increased evidence to show that urinary incontinence in aging adults can be related to physical disability or a condition known as sarcopenia (a loss of muscle tissue due to aging.) This study will examine this relationship further. We would like to see if the information collected from you can help us develop a better, non-surgical treatment for urinary incontinence in patients just like you.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

We aim to recruit 100 women at this research site for this study. In order to identify the 100 women needed, we may need to screen as many as 200 because some people will not qualify to be included in the study.

WHAT IS INVOLVED IN THE STUDY?

To determine if you are eligible, a research study coordinator will ask you questions about your urinary incontinence symptoms using a specific set of questions regarding your condition and diagnosis. If you are eligible for participation in this study via the phone questions, the study coordinator will schedule you for an in-person screening appointment, which will be located in the Wake Forest Baptist Hospital Geriatric Clinical Research Unit located in the Sticht Center. Your participation requires 4 visits.

Pre-screening Visit:

We may ask that you come to Wake Forest Baptist Medical Center for a non-fasting visit. You will learn all the details of the study and then be asked to sign this informed consent form. After signing the consent form, we will ask you to perform the following:

- A short series of balance tests
- A short-distance (4 meters or 13-feet) walking speed and narrow walk test
- A chair rise test (stand up from a seated position in a chair 5 times)

If you continue to qualify, you will be asked to return for the rest of the screening and baseline visit. This prescreen visit will take up to 30 minutes.

Visit 1: Screening/Baseline Visit (3 hours):

This visit will take place in the Sticht Center – 1st floor. Here, the study staff will collect the following information:

- Your age, medical history, emotional health, and overall health status
- History of your urinary incontinence (UI) and other pelvic floor symptoms, the impact they have on your daily life, and prior treatments you may have received
- Your weekly physical activity level, duration, and your feelings toward exercise
- Your mobile abilities which include watching short video clips on an iPad and about your level of disability when doing daily activities
- A series of questions to test your memory and thinking skills

Additionally, you will be asked to complete the following tests:

- A physical examination that includes a strength test of your pelvic floor muscles by the study Urogynecology physician (Dr. Parker-Autry) or by a women's health physical therapist (Lisa Colombo). Most times, this exam is performed through the vagina. Occasionally, it may be important to assess the pelvic floor muscles through the anal canal.
- A short series of balance tests – if not done at prescreening visit
- A short-distance (4 meters or 13-feet) walking speed and narrow walk test– if not done at prescreening visit
- A chair rise test (stand up from a seated position in a chair 5 times)– if not done at prescreening visit
- Measurements of your height, weight, waist circumference, and Body Mass Index
- A 400 meter walk (10 laps around an indoor track on even ground)
- Test the strength of your leg muscles
- A DEXA (Dual Energy X-ray Absorptiometry) scan, which is a painless whole body scan that determines the quality of your bones (see risk section for more information)
- A hand grip strength test

Before you leave this visit, you will be prescribed a home regimen of PFME (similar to Kegel) exercises that should be performed daily. Typically, the exercise regimen takes less than 1 minute to complete. Most women will perform them three times a day, so a total of 3 minutes will be necessary to complete the exercises daily. You will be asked to keep a diary (calendar) of how often you are doing your pelvic muscle exercises for 12 weeks and bring it with you at your follow-up visits. You will also be asked to complete a bladder diary for 3 days and bring it with you to your next visit.

Visit 2: Follow Up Week 2 (1 hour):

This visit will take place in the same facility as above. You will see Dr. Parker-Autry or Ms. Colombo who will perform a brief digital exam of your pelvic floor muscles to ensure that you are doing your exercises properly. She will also collect and review your bladder diary and review your diary to ensure you are logging the exercises correctly.

Between this visit and the next, a member of the study staff will stay in contact with you via telephone every 2 weeks. This will be to check on how you are doing, answer any questions you might have, and to make sure you are doing your PFME exercises as prescribed. You will be given another bladder diary to be completed 3 days before your next scheduled visit.

Visit 3: Follow Up Week 6 (2.5 hours):

After 6 weeks, you will be asked to return to the Sticht center for another follow-up visit. At this visit we will collect the following information:

- Your compliance with the pelvic floor muscle exercises assessed by your completion of the calendar
- Your weekly physical activity level, duration, feelings toward exercise, and mobile abilities which include watching short video clips on an iPad and about your level of disability when doing daily activities
- Current urinary incontinence symptoms. You will be asked to return with your bladder diary. We will ask questions regarding your urinary incontinence and other pelvic floor symptoms and how they may impact your daily life.
- Questions about your emotional health, and overall health status
- A series of questions to test your memory and thinking skills
- How much you feel that your UI symptoms and level of disability have improved

Additionally, you will be given the following tests:

- A physical examination that includes a vaginal strength test of your pelvic floor muscles
- A short series of balance tests
- A short-distance (4 meters or 13-feet) walking speed and narrow walk test
- A chair rise test (stand up from a seated position in a chair 5 times)
- A hand grip strength test

For the next 6 weeks of your participation in the study, we ask that you continue to record each time you do the pelvic floor muscle exercises on the calendars provided to you by the study coordinator.

Visit 4: Follow Up Week 12 (2 hours):

During week 12, your last 3-day bladder diary should be completed to assess how helpful the exercises are with urinary incontinence symptoms. Both the diary and the calendars to log your daily exercises for the past 6 weeks should be returned at this visit. We also plan to collect the following follow-up information:

- Your compliance with the pelvic floor muscle exercises assessed by your completion of the calendar
- Your weekly physical activity level, duration, feelings toward exercise, and mobile abilities which include watching short video clips on an iPad and about your level of disability when doing daily activities
- Current urinary incontinence symptoms. You will be asked to return with your bladder diary. We will ask questions regarding your urinary incontinence and other pelvic floor symptoms and how they may impact on your daily life.
- How much you feel that your UI symptoms and level of disability have improved

Additionally, you may be asked to complete the following tests at the study doctor's discretion:

- A physical examination that includes a vaginal strength test of your pelvic floor muscles
- A short series of balance tests
- A short-distance (4 meters or 13-feet) walking speed and narrow walk test

- A chair rise test (stand up from a seated position in a chair 5 times)
- A hand grip strength test

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about 12 weeks following your initial screening visit. 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. Risks and side effects related to some of the tests and exercises that are done as part of this study are:

1. Physical Function Tests:

Your ability to perform certain physical activities will be measured at two different time points during this study. There is a slight risk of falls while participating in the balance and walking tests. However, you will be positioned beside a step or wall that can be reached immediately if you feel that you are going to lose your balance. Additionally, the person conducting the test will stand next to you at all times. You may have slight hand or leg discomfort during the grip and leg strength tests, but this usually stops once the tests are over. There is a small possibility that you may stumble, fall or aggravate one of your joints/muscles during the walking test or knee strength test. You will not be asked to conduct these tests if you have a pre-existing knee or hip injury.

2. Questionnaires

During the clinic visits we will ask you a variety of questions that you may feel are boring or wonder why we need this information. Please know that we only collect information that we feel may be useful to know for this study. You may become tired during the questionnaires and if this occurs, we can take a break until you are ready to continue.

3. Pelvic Floor Muscle Exercises

If you feel pain in your abdomen or back after a PFME/Kegel exercise session, there is a chance that you may not be doing them correctly. If you continue to experience discomfort with these exercises, contact your study doctor or study staff as soon as possible for help.

4. Radiation from the DEXA

A dual energy X-ray absorptiometry machine (DXA) can measure the amount of your muscle, bone and fat. This machine uses photons (energy) which scan your body while you are lying quietly on a padded table. You will lay on a padded table with a machine moving around you for about 3 minutes or the duration of the scan. You will be lying down the whole time and will not be able to get up until the scan is complete.

This research study involves exposure to radiation from the DXA scan. The risk of this procedure is small and is similar to that received from clinical x-ray and nuclear medicine studies. The amount of radiation exposure that you will receive from this procedure is equivalent to a uniform whole body exposure of 1 millirem. This is equal to 0.33% of the amount of natural

background radiation that the average person in the United States receives each year (300millirem).

The risk of this procedure is small. Please be aware that this radiation exposure is necessary for this research study only and is not essential for your medical care. Wake Forest Baptist Health's Radiation Safety Committee, a group of experts on radiation matters, has reviewed the use of radiation in this research study and has approved this use as being necessary to obtain the research information desired. The potential long-term risk from these radiation doses is uncertain, but these doses have never been associated with any definite adverse effects. Thus, the risk to you, if any, is estimated to be slight.

5. Confidentiality

Taking part in this research study may involve providing information that you consider confidential or private. As such, there is always a slight risk of a breach of confidentiality. 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.

There may be other side effects 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.

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 a decrease in your urinary incontinence symptoms as a result of the pelvic floor exercises. In addition, you may benefit from knowledge regarding your overall physical function from the physical tests performed at your research visits.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment for your urinary incontinence symptoms. You should talk to your doctor about all the choices you have. Instead of being in this study, you have the option of receiving a pelvic floor muscle exercise regimen as part of your standard, routine medical care.

WHAT ARE THE COSTS?

There are no costs to you for taking part in this study. All study costs, including any study medications and procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOU BE PAID FOR PARTICIPATING?

You will be given a gift card $30 for the completion of study visits 1, 3, and 4. This means you may receive up to $90 in gift cards for the entire study. You may choose from a Target or WalMart gift card at each of these visits. If you withdraw for any reason from the study before completion, you will still receive a gift card for all the visits you complete.

To receive payment, you must provide your social security number, name, and address so that we

can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not let them know what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study but you will not be paid.

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.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the Claude D. Pepper Center (National Institute on Aging) and by the Clinical and Translational Science Institute (National Center for Advancing Translational Sciences). The sponsors are 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 HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional

information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted].

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Dr. Candace Parker-Autry at [redacted], or [redacted] after hours.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and/or 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**:** your contact information, basic demographics, medical diagnoses and history, urinary incontinence treatment history or procedures, vital signs, and medication prescriptions.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will 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), 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 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 will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified. This authorization does not expire and any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.
You can tell Dr. Parker-Autry 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:

Candace Parker-Autry, 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.

Test results and other 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.

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 to your treatment, you failed to follow instructions, or because the entire study has been stopped. 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, Candace Parker-Autry at [redacted], or [redacted] after hours.

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].

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):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

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