The University of New Mexico
Consent to Participate in Research

(SQEASI) Systematized Exercise Alternatives for Stress Incontinence: A Randomized Control Trial

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Purpose and General Information

You are being asked to participate in a research study that is being done by Dr. Gena Dunivan, who is the Principal Investigator, and Associates from the Department of Female Pelvic Medicine and Reconstructive Surgery. This research is studying treatment for stress urinary incontinence.

Urinary incontinence, or accidental loss of urine, is a common problem that affects many women. Prior studies have shown that pelvic floor physical therapy (PT) and biofeedback training are both excellent non-surgical options and are recommended as first-line therapy for stress urinary incontinence (leaking with laugh, cough, and sneeze) and mixed urinary incontinence (leaking from laugh, cough and sneeze AND urinary urgency or "gotta go" leakage). Though some studies have looked at PT plus biofeedback compared to PT alone, none have evaluated home biofeedback devices alone. With home biofeedback, patients who live far from the care can obtain treatment in the privacy of their homes. Our hypothesis is that home devices may offer the same improvements in quality of life and amount of urine leakage compared to physical therapy for women with SUI.

You are being asked to participate in this study because you have stress urinary incontinence, or mixed urinary incontinence with more leakage due to cough, laugh or sneeze than from urgency related leakage. Up to 75 people will take part in this study at the University of New Mexico (UNM).

This form will explain the research study, and will also explain the possible risks as well as the possible benefits to you. We encourage you to talk with your family and friends before you decide to take part in this research study. If you have any questions, please ask one of the study investigators.

What will happen if I decide to participate?
If you agree to participate, you will be assigned by chance (like a flip of a coin) to receive either:

1. An FDA approved PeriCoach© biofeedback device to perform Kegel exercises at home. This biofeedback device is made out of silicone and inserted into your vagina to perform the exercises at home. A smartphone application on your phone will Bluetooth connect to the device to show you how well you are doing in real time. We will give you an information sheet today that demonstrates how to use the device.

Or

2. Pelvic floor physical therapy with a licensed physical therapist for 4 sessions over 3 months.

You will have an equal chance of being assigned to either arm of the study and you will be assigned prior to leaving clinic today after you consent. Either way you will receive treatment. Standard of care for your condition is to undergo pelvic floor physical therapy and return for a follow up appointment 3 months after treatment to follow up on your progress. You do not have to participate to receive this therapy.

If you agree to participate, you will also complete questionnaires that tell us how urine leakage is affecting your life when you enroll and after 3 months of treatment. You may refuse to answer any questions at any time. These questions will take about 20 minutes to complete. Additionally, we will ask that you undergo a brief pelvic examination and cough test at your 3-month visit to check your muscle strength and pelvic support.

You will be asked to keep track of how often you do Kegel exercises per week for the 3-month study period. At the end of 3 months, you will return to clinic for another visit to see how you are doing or receive a phone call to discuss how you are doing if you are unable to return to clinic.

We will collect demographic information from you when you are enrolled, and will review your medical record if we have missing data.

How long will I be in this study?

Participation in this study will take a total of 4 hours over a period of 3 months.

What are the risks or side effects of being in this study?

Randomization risks: You will be assigned to a study procedure by chance, and the procedure you receive may prove to be less effective or to have more side effects than the other study procedure(s) or other available treatments.

There are risks of stress, emotional distress, inconvenience and possible loss of privacy and confidentiality associated with participating in a research study. There is a risk of discomfort while completing the questionnaires provided.

Risks and side effects related to the biofeedback device "Pericoach" are listed below:

- Rare (Less than 2%) Side Effects Include: vaginal spotting or bleeding, sore muscles

For more information about risks and side effects, ask the investigator.

What are the benefits to being in this study?

There may or may not be benefit to you from participating in this study. Pelvic floor physical therapy and biofeedback are both used as first line treatment for your condition The results from this study can help other women in their treatment of urinary leakage.

What other choices do I have if I do not want to be in this study?

You do not have to participate in this study to receive treatment for your condition. Physical therapy and instruction on how to perform exercises are our typical first line options and you do not have to participate to receive them.

How will my information be kept confidential?

We will take measures to protect the security of all your personal information, but we cannot guarantee confidentiality of all study data.

Information contained in your study records is used by study staff and, in some cases it will be shared with the sponsor of the study. The University of New Mexico Institutional Review Board (IRB) that oversees human subject research and/or other entities may be permitted to access your records. There may be times when we are required by law to share your information. However, your name will not be used in any published reports about this study.

We will take measures to protect the security of all your personal information, but we cannot guarantee confidentiality of all study data.

Information collected as part of the study will be labeled with a study number; Information (without your name) will be entered into a computer database/locked file cabinet in the Urogynecology Research office. The PI and her associates will have access to your study information as well as research staff. Data will be stored for 5 years, and then will be destroyed.

Medical information created by this study may become part of your hospital medical record. Information that does not become part of your medical record will be stored in your study file.

What are the costs of taking part in this study?

The study will pay for only those services, supplies, procedures, and care associated with this research that would not normally be provided as part of your medical care, such as the biofeedback device. If you would like to review the specific details of what is paid for by the study, please let the investigator or the research staff know at the time of informed consent or at any time during the study. If you participate in this study, there may be additional

costs to you. Additional costs may include the personal time necessary to attend study visits, time missed from work, transportation fees, and any copayment required by your insurance for pelvic floor PT. If you are randomized to home biofeedback and perform the exercises while using cellphone data, the app will use a small amount of your data, which the study will not cover specifically.

Will I be paid for taking part in this study?

You will be paid to offset the cost to you for participating in this study. If you complete all the visits or phone calls, the payment total is $50 in merchandise cards. This will be provided as follows:

- $10 merchandise card today after enrolling
- $40 merchandise card at the 3 month follow up visit or phone call encounter

If you decide to stop being in the study before the 3 month follow-up, you will only be compensated for the encounter completed.

How will I know if you learn something new that may change my mind about participating?

You will be informed of any significant new findings that become available during the course of the study, such as changes in the risks or benefits resulting from participating in the research or new alternatives to participation that might change your mind about participating.

Can I stop being in the study once I begin?

Your participation in this study is completely voluntary. You have the right to choose not to participate or to withdraw your participation at any point in this study without affecting your future health care or other services to which you are entitled.

Your participation in this study is completely voluntary. You have the right to choose not to participate or to withdraw your participation at any point in this study without affecting your future health care or other services to which you are entitled.

If you have a negative reaction to using the biofeedback device, such as an allergic response or repeated vaginal infections, withdrawal from the study is permissible.

Whom can I call with questions or complaints about this study?

If you have any questions, concerns or complaints at any time about the research study, Gena Dunivan, or her associates will be glad to answer them at 505-967-8428 .

If you need to contact someone after business hours or on weekends, please call 505-272-2111 and ask for Urogynecology Fellow on Call.

If you would like to speak with someone other than the research team, you may call the UNMHSC HRPO at (505) 272-1129.

Whom can I call with questions about my rights as a research participant?

If you have questions regarding your rights as a research participant, you may call the UNMHSC Human Research Protections Office (HRPO) at (505) 272-1129. The HRPO is a group of people from UNM and the community who provide independent oversight of safety and ethical issues related to research involving human participants. For more information, you may also access the IRB website at http://hsc.unm.edu/som/research/hrrc/irbhome.shtml.

HIPAA Authorization for Use of Your Protected Health Information (HIPAA)

As part of this study, we will be collecting health information about you. This information is "protected" because it is identifiable or "linked" to you.

Protected Health Information (PHI)

By signing this Consent Document, you are allowing the investigators and other authorized personnel to use your protected health information for the purposes of this study. This information may include: results of physical exams, medical history, body mass index, number of pregnancies, and medical conditions.

In addition to researchers and staff at UNMHSC and other groups listed in this form, there is a chance that your health information may be shared (re-disclosed) outside of the research study and no longer be protected by federal privacy laws. Examples of this include disclosures for law enforcement, judicial proceeding, health oversight activities and public health measures.

Right to Withdraw Your Authorization

Your authorization for the use of your health information for this study shall not expire unless you cancel this authorization. Your health information will be used as long as it is needed for this study. However, you may withdraw your authorization at any time provided you notify the UNM investigators in writing. To do this, please send letter notifying them of your withdrawal to:

Dr. Gena Dunivan
Department of OB/GYN
MSC10 5580, 1 University of New Mexico
Albuquerque, NM 87131

Please be aware that the research team will not be required to destroy or retrieve any of your health information that has already been used or shared before your withdrawal is received.

Contact for Future Research

There may be studies in the future that may be of interest to you. If you are interested in hearing more about these research projects we can contact you in the future. The person contacting you would be your physician or a member of the UNM research team.

Please initial below to indicate permission regarding contact for future research.

_____ Yes, you may contact me in the future regarding research projects
(Initials)

_____ No, you may not contact me in the future regarding research projects
(Initials)

Participant: By signing below, you indicate that you have read the information written above and have indicated your choice for future contact regarding research projects.

_____ _____
Signature of Participant Date

Consent and Authorization

You are making a decision whether to participate in this study. Your signature below indicates that you read the information provided (or the information was read to you). By signing this Consent Form, you are not waiving any of your legal rights as a research participant.

I have had an opportunity to ask questions and all questions have been answered to my satisfaction. By signing this Consent Form, I agree to participate in this study and give permission for my health information to be used or disclosed as described in this Consent Form. A copy of this Consent Form will be provided to me.

_____ _____/_____
Name of Adult Participant (print) Signature of Adult Participant Date

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information in this consent form and freely consents to participate.

_____ _____/_____
Name of Research Team Member Signature of Research Team Member Date