TITLE PAGE (Consent Document):

PROTOCOL TITLE:

INTENSE: INvestigation of TENS Efficacy versus Posterior Tibial Nerve Stimulation for overactive bladder

NCT NUMBER: Not yet assigned

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The University of New Mexico Health Sciences Center
Consent and Authorization to Participate in a Research Study
HRRC ID 22-003

Key Information for INTENSE: INvestigation of TENS Efficacy versus Posterior Tibial Nerve Stimulation for overactive bladder

You are being invited to take part in a research study about comparing the efficacy of transcutaneous tibial nerve stimulation (TENS), a device used at home to stimulate nerves through the skin of the ankle, to percutaneous tibial nerve stimulation (PTNS), a device used in clinic to simulate nerves of the ankle with a small acupuncture-type needle, for the treatment of overactive bladder symptoms (OAB), a sense of urgent need to go to the bathroom with or without frequent voiding or leaking of urine with urinary urgency.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THE STUDY?
By doing this study, we hope to learn how TENS used at home compares to PTNS treatments in the office for treating OAB. Current OAB treatments can be expensive, time consuming and have significant side effects, which is why we are studying a treatment that can be done at home. Currently, we do not know if home TENS is similarly effective as PTNS for treating OAB. You will be assigned by chance to either a PTNS group that will receive weekly treatments or a TENS group that will give themselves daily treatments at home. The TENS device is off-label for its use in the treatment of OAB. Your participation in this research will last about 12 weeks. Up to 130 women at the University of New Mexico will take place in this study.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?
For women with OAB that has not improved with behavioral changes or medication, participation in this study may improve your condition. Your participation may provide information to help other women with OAB in the future. There is no guarantee that any individual will personally benefit by participating in this research study. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE THE KEY REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS STUDY?
Participation in this study may require you to purchase a TENS unit, if you are randomly assigned to that group. If funding becomes available, you will be compensated with a merchandise card. Otherwise, you will not receive any reimbursement and will be fully responsible for the cost of the TENS 7000 device, which can be between $25-$50 in cost. This will be your device to keep at the end of the study. Both PTNS and TENS are proven safe and effective treatments for OAB with no known serious risks. For a complete description of the risks, refer to the Detailed Consent/Appendix.

Alternative treatments for refractory OAB include lifestyle and behavioral interventions, medications and surgical treatment. For a complete description of alternate treatment/procedures, refer to the Detailed Consent/Appendix.

DO YOU HAVE TO TAKE PART IN THE STUDY?
If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?
The person in charge of this study is Dr. Kate Meriwether of the University of New Mexico Health Sciences Center, Department of Obstetrics & Gynecology, Urogynecology Division. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, her contact information is (505) 967-8428.
If you have any questions or concerns about your rights as a volunteer in this research, contact staff in the University of New Mexico Health Sciences (UNMHSC) Human Research Review Committee (HRRC) between the business hours of 8AM and 5PM, Mountain Standard Time (MST), Monday-Friday at 505-272-1129.

DETAILED CONSENT
HRRC ID 22-003
Version 01/09/2022

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

The following are reasons you would not qualify for this study:

- Age < 18 years
- Male genital anatomy
- Recurrent or current urinary tract infections (5 or more infections in the last 12 months)
- Presence of urinary fistula
- Bladder stones
- Bladder cancer or suspected bladder cancer
- Bloody urine
- Pregnancy or planning to become pregnant during the study (3 months)
- Neurologic disorders such as Multiple Sclerosis, Parkinson's disease, spina bifida, or other spinal cord lesion
- Metal implants such as pacemaker, implantable defibrillator, or metal implants where PTNS or TENS device needs to be placed (ankle/leg)
- Uncontrolled diabetes
- Diabetes with numbness of fingers/toes/arms/legs
- Current use of blood thinners
- Current use of anticholinergics or use within the last 4 weeks
- Current use of botox bladder injections or bladder botox injection within the last year
- Current use of sacral neuromodulation therapy or currently implanted sacral neuromodulation device or leads
- Difficulties with urinating on your own
- Painful Bladder Syndrome/Interstitial Cystitis
- Unable to be contacted for follow up by telephone
- Inability to speak/read/understand English or Spanish

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted at University of New Mexico (UNM) Eubank Women's Primary Care Clinic, Sandoval Regional Medical Center (SRMC) Urogynecology Clinic or at your home. You will need to come at least 1 time during the study, but up to 12 times if you are randomly assigned to the PTNS group. Each of those visits will take about 30 minutes. The total amount of time you will be asked to volunteer for this study is 20 minutes every day in the TENS group or once a week in the PTNS group over the next 3 months. At your first visit, 6 weeks and 12 weeks you will be asked to fill out some questionnaires which will take a total of 20 minutes during the study.

WHAT WILL YOU BE ASKED TO DO?

Each participant will be assigned to either the PTNS or TENS group randomly (by chance) by a computer. If you are in the PTNS group, you will come to the UNM Eubank Clinic once a week to receive a 30-minute PTNS treatment for 3 months. PTNS is similar to acupuncture, using a very small needle to electrically stimulate a nerve that is involved with your bladder function. This will not be any different from the standard of care for OAB treatment using PTNS. At 6 weeks and 12 weeks treatment sessions, you will be asked to complete a voiding diary that tracks your urination habits as well as two questionnaires about your OAB symptoms and satisfaction with treatment. This information will be used to compare the effectiveness of this therapy to the TENS group.

If you are in the TENS group, you will be asked to purchase a TENS 7000 device and to give yourself treatment at home.

Treatment of OAB is an off-label use of TENS device. If funding becomes available, you will be reimbursed with a merchandise card. Before you begin treatment, you will be asked to come to the UNM Eubank Clinic to make sure you have the correct device and to educate you on how to properly use the device and correctly place the electrode pads on your leg. You will be given an information handout with the proper device settings, electrode placement and treatment schedule. At home, you will be asked to complete 20-minute treatment sessions once a day for 3 months. After 6 weeks and 12 weeks, you will be contacted by phone to complete a voiding diary that tracks your urination habits, as well as two questionnaires about your OAB symptoms and satisfaction with treatment. These forms may also be completed online through a secure link that will be emailed to you. This information will be used to compare the effectiveness of this therapy to the PTNS group.

If there is concern you are pregnant during the study, a pregnancy test will be performed. If you are pregnant, you will no longer be able to participate in the study. However, this will not affect your ability to receive the standard of care treatments for OAB.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

There is always a chance that any medical treatment can harm you. The research treatments/procedures in this study are no different. The risks of this study are very low as both PTNS and TENS have been proven to be safe and effective treatments for OAB and there are no known serious risks to either. With PTNS, you may experience skin irritation, pain, bruising, tingling or bleeding at the insertion site and leg cramping or temporary numbness, though these are rare. With TENS, you may experience skin irritation and leg cramping or temporary numbness, though these are rare. With either PTNS or TENS use, women can experience a sense of a "shocking" sensation or temporary pain with stimulation, although this is unusual. There are no reports of permanent or irreversible nerve damage or permanent or long-term loss of muscle function with either PTNS or TENS unit use.

If you experience any of the side effects, these will be recorded. You may choose to withdraw from the study at any time for any reason. You can also continue to participate in the study because of the very low risk of the known side effects. Pregnant women will not be included in this study. However, PTNS and TENS may involve risks to the embryo or fetus which are currently unforeseeable if you are pregnant or become pregnant during the study. The risk of fetal harm of either PTNS or TENS is unknown.

Participation in this study also involves the risk of loss of confidentiality. We will take every measure to try to ensure your privacy and the security of the information you provide for the study. Further details to protect your information is listed in the section "Who Will See the Information You Give?" below.

Because you will be randomly assigned to a study group, there is the risk that you may be assigned to a group that does better or worse than the other group.

There is also a risk of emotional discomfort of responding to research questions, especially those that may be of a sensitive nature, such as answering questions about your bladder or how your bladder interferes with your life.

In addition to risks described in this consent, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

We do not know if you will get any benefit from participating in this study. However, many people have experienced improvement in OAB symptoms and quality of life when receiving PTNS or TENS for the treatment of OAB. If you take part in this study, information learned may help others with your condition. If you are randomly assigned to the TENS group, you will have a personal TENS device that you will keep at the end of the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

You may have to pay for the cost of getting to the clinic and data charges for mobile devices for phone calls or Zoom visits.

You and/or your insurance company, Medicare, or Medicaid will be responsible for the costs of all care and treatment that you would normally receive for any conditions you may have. These are costs that are considered medically necessary and will be part of the care you receive even if you do not take part in this study.

The University of New Mexico may not be allowed to bill your insurance company, Medicare, or Medicaid for the medical procedures done strictly for research. Therefore, these costs will be your responsibility. This includes the possible cost of the TENS device and replacement adhesive pads if you are randomly assigned to the TENS group, which can be between $25-$50. Your insurer, Medicare, or Medicaid, may agree to pay for the costs. If you are required to expend a co-payment or deductible, the amount of this co-payment or deductible may be costly.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave information, or what the information is. All communication with you for the study will be conducted in a private location, complying with HIPAA guidelines. All information collected from you will be kept in locked cabinets in a UNM OBGYN research office. Any identifying information will be removed from your file and you will be assigned as study number. The link identifying patients and their study numbers will be stored on a password protected computer on a secure UNM OBGYN department server.

You should know there are some circumstances in which we may have to show your information to other people because of legal purposes. For example, the law may require us to share your information with the following agencies and for the following reasons:

- The law requires us to share your information with authorities if you report information about a child being abused
- If you pose a danger to yourself or someone else.
- A court or agencies, if you have a reportable disease or condition.
- Authorities, if you report information about a child being abused, if you pose a danger to yourself or someone else.

REDCap is a secure, web-based program to capture and store data at the University of New Mexico. Please be aware, while we make every effort to safeguard your data once received on servers via REDCap, given the nature of online surveys, as with anything involving the internet, we can never guarantee the confidentiality of the data while still in route to the server.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. The study intervention and/or PTNS device will no longer be provided to you and may not be available for purchase. This may occur for a number of reasons.

You may be removed from the study if:

- You are not able to follow the directions.
- The researchers find that your participation in the study is more risk than benefit to you.
- The researchers choose to stop the study early for a number of scientific reasons.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEACH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may take part in this study if you are currently involved in another research study. It is important to let the investigator and your doctor know if you are in another research study. You should discuss this with the investigator and your doctor before you agree to participate in another research study while you are in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Dr. Kate Meriwether at (505) 967-8428 immediately.

Dr. Meriwether will determine what type of treatment, if any, is best for you at that time.

It is important for you to understand that the University of New Mexico does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of New Mexico will not pay for any wages you may lose if you are harmed by this study.

Medical costs related to your care and treatment because of study-related harm will be your and/or your insurance company, Medicaid or Medicare's responsibility. You will be responsible for any associated co-payments or deductibles required by the insurance.

WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

You will not receive any rewards or payment for taking part in the study. If funding becomes available, you may receive $50 compensation in the form of a merchandise card for taking part in this study.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

You will be informed if the investigators learn new information that could change your mind about staying in the study. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESARCH TESTS?

Generally, tests/surveys done for research purposes are not meant to provide clinical information information/diagnoses and cannot be used to make decisions about standard medical care

A description of this clinical trial will be available on 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 website at any time.

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of about 130 people to do so.

FUTURE USE OF YOUR PROTECTED HEALTH INFORMATION

Your information collected for this study will NOT be used or shared for future research studies, even if we remove the identifiable information like your name, medical record number or date of birth.

HIPAA AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATIN (PHI).

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

Protected Health Information (PHI)

By signing this Consent Document, as described in this consent form, you are allowing the investigators and other authorized personnel to use your protected health information for the purposes of this study. This information includes your name, date of birth, phone number, email, medical record number and medical history.

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 health oversight activities and public health measures, safety, monitors, other sites in the study, companies that sponsor this study, government agencies such as Food and Drug Administration (FDA).

Right to Withdraw Your Authorization

Your authorization for the use and disclosure of your health information for this study shall not expire unless you cancel this authorization. This is because the information used and created during the study may be analyzed for many years and it is not possible to know when this will be complete. Your health information will be used or disclosed 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:

Kate Meriwether, MD
Department of OB/GYN
MSC10 5580, 1 University of New Mexico
Albuquerque New Mexico 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 the date that your withdrawal is received.

You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form it will not affect your:

- Current or future healthcare at the University of New Mexico;
- Current or future payments to the University of New Mexico;
- Ability to enroll in any health plans (if applicable); or
- Eligibility for benefits (if applicable).

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:

- You will send a written letter to Dr. Kate Meriwether at the address listed above to inform her of your decision.
- Researchers may use and release your health information already collected for his research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).

The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of New Mexico Health Sciences Privacy Officer between the business hours of 8am and 5pm Mountain Pacific Time, Monday-Friday at (505) 272-1493.

Appendix: Alternative Treatments/Options

IF YOU DON'T' WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

You always have the option of choosing to treat your OAB with a TENS unit or with PTNS, and not be in the study that could assign you to either. If you are not in the study, you and your provider will decide if PTNS or TENS unit use is right for you.

Treatment options for OAB that don't involve either PTNS or TENS unit use include:

- Medical Treatment: OAB medications help your bladder hold more urine for longer periods of time and reduce urine leakage.
- Surgical Treatment
    - Sacral Nerve Stimulation: a device is surgically implanted near the spine. It acts like a pacemaker for the bladder.
    - Botulinum Toxin (Botox): Botox relaxes the bladder muscle, which allows more urine to be held in your bladder before you have to go to the bathroom. Under local anesthetic or sedation, your doctor will use a small camera and needle to inject Botox into the bladder wall.
- Lifestyle Intervention
    - Changing your diet: certain drinks with caffeine, artificial sweeteners, fruit juices and alcohol can provoke bladder spasms.
- Behavioral Intervention
    - Bladder training: with OAB, going to the bathroom often can make symptoms worse. Your bladder learns to hold less urine, leading to even more frequent bathroom trips. Bladder re-training involves your pelvic floor muscles and "mind over bladder" techniques to gradually increase time between bathroom visits. The more you do this, your bladder muscles readjust to allow you to make fewer bathroom trips.
    - Pelvic Floor Physical Therapy: Working with a specialized physical therapist to learn pelvic floor muscles exercises and other techniques to improve OAB symptoms.

INFORMED CONSENT SIGNATURE PAGE

You are participating or are authorized to act on behalf of the participant. This consent includes the following:

- Key Information Page
- Detailed Consent
- Appendix: Alternative Treatments/Options

You will receive a copy of this consent form after it has been signed.

_____ _____

Signature of research subject, *or if applicable, *research subject's legal representative* **Date**

_____

Printed name of research subject