Project Title: A randomized controlled trial investigating the efficacy of percutaneous tibial nerve stimulation (PTNS) in the treatment of female sexual dysfunction (FSD)

Principal Investigator: Jason Kim
Co-Investigator: Xiaohui Liang, Kuemin Hwang, Rosen Jeong, Edwin Lee, Heng Ruan, Jonathan Aronov, and Sina Mehraban Far

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RESEARCH CONSENT FORM

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Key Information

(1) The information in this form is being used to seek your consent for a research study. Being in the study is voluntary; it is up to you.
(2) This research is being done to find out the efficacy of Percutaneous Tibial Nerve Stimulation (PTNS) in treatment of Female Sexual Dysfunction (FSD). Participation will last up to 12 weeks. Study procedures for this research are:
    - You will be placed into either active or inactive treatment group at the beginning of the study.
    - Both active and inactive treatment groups receive baseline physical evaluation from Dr. Jason Kim prior to starting the study.
    - Both active and inactive treatment groups complete four (4) Female Sexual Function questionnaires to monitor improvements in symptoms at three different times in the study.
    - Both active and inactive treatment groups have a small needle placed near one of your ankles with three (3) electrode pads placed onto the same foot and receive electrical stimulation
    - If placed into the active treatment group, you will receive electrical stimulation through the acupuncture needle.
    - If placed into the inactive treatment group, you will receive electrical stimulation through the adhesive pads that reproduce similar electrical sensation without direct stimulation to through the acupuncture needle.
    - Sessions for either active and inactive treatment group will lasts for 30-minutes once a week for twelve (12) consecutive weeks.
    - On Week 13 you will have a follow up physical evaluation with Dr. Jason Kim.
    - Co-investigators and clinicians will obtain and document medical record related to your condition and the treatment you received.

(3) The most likely risks to you of the research are:
- Mild pain or discomfort
- Tingling sensation
- Skin inflammation
- Bleeding or bruising near the site of needle insertion
- Slight risk of infection at the site of needle insertion

Please see the RISKS AND DISCOMFORTS section for a complete list of expected side effects

(4) The most likely but not guaranteed benefits to you of the research are:
- Improvement in pain during sexual intercourse
- Improve ability to achieve orgasm
- Increase in sexual desire

(5) If you decide to not be in the research, your choices (if any) are:
- Hormonal therapy
- Pelvic floor muscle exercises

You are being asked to be a volunteer in a research study. You are encouraged to take your time in making your decision. You may want to discuss this study with your friends and family.

PURPOSE

You are being asked to be a volunteer in a research study. You are eligible to participate in this study because you are a patient with female sexual dysfunction (FSD) syndrome who is interested in receiving percutaneous tibial nerve stimulation (PTNS) treatment, which is an FDA-approved therapy for Overactive Bladder (OAB) that has also shown improvements in FSD symptoms in other preliminary studies. FSD is a medical condition characterized by pain or discomfort with intercourse, decreased sexual desire and impaired arousal.

This is an experimental study being done to understand the efficacy of PTNS on the treatment of female sexual dysfunction syndrome.

A total of 66 subjects will be enrolled in this study at Stony Brook University. Half the subjects, 33, will be receiving 1 PTNS treatment per week. The other half, 33, will receive one inactive treatment per week. If you enroll in this study, you would be randomly assigned to one of the two groups.

PROCEDURES

If you decide to be in this study, your part will involve:

- Initial visit to assess your eligibility to participate in the study where one of the study co-investigators will discuss the study procedures in great detail. This visit will be approximately 30 minutes to 1 hour long.

- Although there are no known risks related to PTNS on pregnant women or a fetus, you will not be eligible to participate in this study if you are pregnant or planning to become pregnant during the course of this study. A negative pregnancy test is mandated for women of childbearing age at the point of enrolment. If you have been post-menopausal for at least one year, you will not be required to undergo a urine pregnancy test.

- If you are eligible to participate you will need baseline evaluation of your female sexual dysfunction symptoms. Female Pelvic Medicine urologist, Dr. Jason Kim will take a full history and conduct a physical exam including pelvic examination. You will also be filling out questionnaires during this visit to help us understand the severity of your symptoms. This visit will be 2 hours long.

After the baseline assessments:

- You are expected to come to the clinic for one 30-minute sessions every week. Depending on your random group assignment, you might receive either 1 PTNS treatment per week or 1 inactive treatment per week.

- The PTNS treatment works by delivering very mild electrical stimulations to a specific nerve (tibial nerve) in your leg through a small needle inserted near your ankle. The inactive treatment is meant to mimic the sensory effects of the PTNS treatment but does not stimulate your tibial nerve like the PTNS treatment and will not penetrate the skin. A small needle will similarly be placed near your ankle in the inactive treatment but this one will **not** pierce the skin. Both the active and inactive treatments will involve placing 2 surface electrode stickers on the top of the foot and underneath the big toe and another smaller surface electrode sticker at the base of your foot.

- During your first visit, you will be given multiple sexual dysfunction questionnaires including a Female Sexual Function Index (FSFI) questionnaire. It is a 19-item questionnaire that is used to assess female sexual function.

- During your visit on week 6 and 12, you will be given multiple sexual dysfunctional questionnaires.

- On week 13, you are expected to come to the clinic for a safety follow up visit, so we can assess whether you are experiencing any side effects. This visit should take about 30 minutes.

RISKS / DISCOMFORTS

The following risks/discomforts may occur as a result of you being in this study:

There are very minimal foreseeable risks if any with participating in the study. Both PTNS and our placebo are non-significant risk devices that do not involve any implantable components. They have shown no side effects in most patients; a few patients experience mild pain, skin inflammation, tingling, minimal bleeding or bruising near the site of the electrode placement. Insertion of a needle has minimal risk of infection at the site of insertion.

Pelvic exam is often a routine physical exam done to evaluate your reproductive organs such as the vagina, cervix, ovaries, and uterus. It is done to assess your gynecological health. There is minimal risk involved in a pelvic exam, but there is a still chance of infection, pain, and discomfort on examination.

BENEFITS

The following benefits may occur as a result of being in this study:

By participating in the study, you may see improvements in your symptoms related to female sexual dysfunction, but this cannot be guaranteed.

PAYMENT TO YOU

If you complete all 12 visits, you will receive $200. In the event you do not complete all study visits, payment will be prorated to reflect the number of sessions completed.

You and your insurance(s) will not be charged for the study. All visits and study-related interactions will be free of charge.

__ I am a U.S. Citizen or Resident Alien. If paid $600 or more a year as a research subject, your social security number and amount paid will be reported to those in charge of taxes (IRS) by the Research Foundation and you may have to pay taxes on this money.

__ I am a Nonresident Alien. For tax purposes, all payments made to you must be done through the Research Foundation and are subject to a 30% tax withholding. All withholdings and payments will be reported to those in charge of taxes (IRS) by the Research Foundation.

PAYMENT TO THE INSTITUTION

This project is funded, in part, by a grant or contract from the Society of Urodynamics, Female Pelvic, and Urogenital Reconstruction to the Research Foundation of Stony Brook University, in support of the Investigators' work on this study. Amount of payment from this sponsor is fixed and does not depend on any external factors.

CONFIDENTIALITY

We will take steps to help make sure that all the information we get about you is kept confidential. Your name will not be used wherever possible. We will use a code instead. All the study data that we get from you will be kept locked up. The code will be locked up too. If any papers and talks are given about this research, your name will not be used.

We want to make sure that this study is being done correctly and that your rights and welfare are being protected. For this reason, we will share the data we get from you in this study with the research team, Stony Brook University's Committee on Research Involving Human Subjects, applicable Institutional officials and certain federal offices, including the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA). However, if you tell us you are going to hurt yourself, hurt someone else, or if we believe the safety of a child is at risk, we will have to report this.

In a lawsuit, a judge can make us give him the information we collected about you.

While you are in this study we will get data about your health from your medical record. We will also get health data from the results of the tests and questionnaires you will have done in this study. You have a right to privacy but the data we get about your health in this study can be shared with the people referenced above (the study team, Stony Brook University's Committee on Research Involving Human Subjects, applicable institutional officials, and federal offices such as OHRP, FDA) as well as:

- your medical doctor

Your health data are shared to make sure the study is being done correctly, costs are charged correctly, and to make sure your rights and safety are protected. Not all of these people are required by law to protect your health data. They might share it with others without your permission. For example, OHRP does not have to make the same promise under the law to protect your health data, however they are bound by other ethical regulations.

You have the right to stop allowing us to use or give out your health data. You can do this at any time by writing to Dr. Jason Kim at:

Jason.kim@stonybrookmedicine.edu

-or-

Jason Kim, M.D.
Stony Brook University Medical Center
Department of Urology
Health Sciences Center T-9 Room 40
Stony Brook NY 11794-8093

If you do this, we will stop collecting any new health data from you. We will use any data we collected before you wrote your letter. When you sign the consent form at the end, it means:

- That you have read this section.
- That you will allow the use and reporting of your health data as described above.

COSTS TO YOU

We do not anticipate any costs to you as a result of participation in this study.

ALTERNATIVES

You will be properly consulted about current, alternative options for FSD, which include hormonal therapy, benzodiazepines, hypnotherapy, botulinum toxin type A injections and pelvic floor muscle exercises. If you are on any alternative treatments, you will not be eligible for this study. You should at no point feel it is necessary to enroll in this study to receive the standard of care treatment. Your decision to participate or not will not affect your medical care.

IN CASE OF INJURY

If you are injured as a result of being in this study, please contact Dr. Jason Kim at telephone (631) 444-1910. The services of Stony Brook University Hospital will be open to you in case of such injury. However, you and/or your insurance company will be responsible for payment of any resulting treatment and/or hospital stay.

CONSEQUENCES OF WITHDRAWING

You may withdraw from the study for any reason simply by explaining this to the Principal investigator or the co-investigator. If you decide not to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future care.

REMOVAL FROM STUDY

You may be removed from this study due to non-compliance.

YOUR RIGHTS AS A RESEARCH SUBJECT

- Your participation in this study is voluntary. You do not have to be in this study if you don't want to be.
- You have the right to change your mind and leave the study at any time without giving any reason, and without penalty.
- Any new information that may make you change your mind about being in this study will be given to you.
- You will get a copy of this consent form to keep.
- You do not lose any of your legal rights by signing this consent form.

QUESTIONS ABOUT THE STUDY OR YOUR RIGHTS AS A RESEARCH SUBJECT

- If you have any questions, concerns, or complaints about the study, you may contact Dr. Jason Kim at telephone (631) 444-1910.
- If you have any questions about your rights as a research subject or if you would like to obtain information or offer input, you may contact Ms. Lu-Ann Kozlowski, Committee on Research Involving Human Subjects by e-mail at: Lu-ann.kozlowski@stonybrook.edu
- Visit Stony Brook University's Community Outreach page, http://research.stonybrook.edu/orc/community.shtml#overview-of-volunteering-in-research for more information about participating in research, frequently asked questions, and an opportunity to provide feedback, comments, or ask questions related to your experience as a research subject.

If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a volunteer in this study.

_____	_____	_____
Subject Name (Printed)	Subject Signature	Date

_____	_____	
Name of Person Obtaining Consent (printed)	Signature of Person Obtaining Consent	Date