Title: Investigation of Potential Therapeutic Effects of Pulsed Electromagnetic Field for the Treatment of Symptoms Associated With Interstitial Cystitis/Bladder Pain Syndrome
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Wake Forest School of Medicine

Investigation of Potential Therapeutic Effects of Pulsed Electromagnetic Field for the Treatment of Symptoms Associated With Interstitial Cystitis/Bladder Pain Syndrome

Informed Consent to Participate in Research

Stephen J. Walker, PhD Principal Investigator
Robert J. Evans, MD Co-Principal Investigator

INTRODUCTION

You are invited to participate in a research study. Research studies are designed to gain scientific knowledge that may help you now or impact other people in the future. You are being asked to take part in this study because you have been diagnosed with Interstitial Cystitis/Bladder Pain Syndrome (IC/BPS).

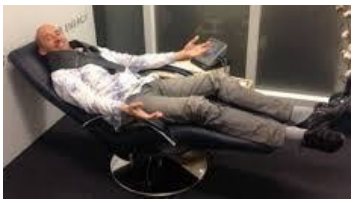
IC/BPS is a disease of the urinary bladder, causing generalized pelvic pain and urinary symptoms, such as urinary urgency and frequency. It is more common in females than in males. Late stages of this disease can cause severe symptoms and significantly decrease the bladder capacity. The cause of this disease is currently unknown, and there is very little understanding of how it progresses. As a result, the best standard of care is under investigation.

Your participation is voluntary. This study will last 12 weeks, so please take your time in making your decision to participate. The treatment and majority of the data collection will be done in the privacy of your home via phone and email surveys. Ask your 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 wish to discuss the study with your friends and family.

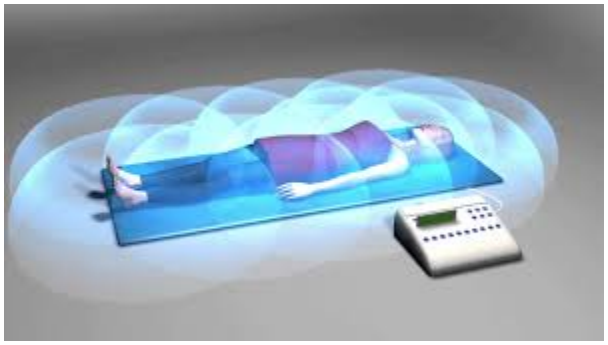
WHY IS THIS STUDY BEING DONE?

The purpose of this study is to gather information from the investigation of a non-pharmacological (non-drug) treatment known as low frequency pulsed electromagnetic field (PEMF). We will be using the PEMF therapy in female patients with IC/BPS to measure its ability to decrease bladder pain. We will compare the results *before*, and at 4 and 12 weeks *after*, initiating treatment.

Once you have consented to participate and are accepted into the study, Dr. Evans will examine you. Then, following a brief in-clinic training, you will be given the PEMF treatment device in the form of a whole body mat and a pad (that lies over the pelvic area) to take home and use (see pictures below).



Research administrators will provide the active PEMF treatment mat and pad. You can either lay the mat on your bed or in a reclining chair, whichever is more comfortable for you. You will be asked to lay on the mat, with the pad over your pelvic area, 2 times per day (morning and evening) for 8 minutes each time. Once on the mat, you will turn the PEMF devices on with a control box that starts the 8-minute treatment. The PEMF machine is easy to turn on and will automatically shut off after 8 minutes have elapsed. Even though very low-frequency PEMFs are moving through your body, most people do not feel anything. However, you may occasionally feel tingling in your fingers and toes.



The device must be returned to the Study Staff after the 4-week treatment. As this instrument is expensive, on loan from a company, and will be used by subsequent subjects in this clinical trial, the expectation of the study team is that all devices will be returned on time (directly after completing the 4-week treatment), in clean working order, and in the same condition that it was initially supplied.

It is important to be as accurate as possible when filling out the results of the surveys you will be given to report the results of this treatment.

You will be asked to report what (if any) pain medications you have taken in the 3 months prior to study enrollment, and what additional medications you will be using during the 12-week study period. We will also ask that you keep a 7-day voiding diary at three main time points throughout the study to evaluate if the PEMF treatment decreases the number of times you urinate per day and/or decreases the feeling of needing to urinate.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

We will be asking 10 patients to participate in this study. The Wake Forest Baptist Medical Center will be the only research site.

WHAT IS INVOLVED IN THE STUDY?

If you have already been diagnosed with interstitial cystitis/bladder pain syndrome (IC/BPS) you are eligible for this study. Your medical records will be reviewed to make sure that you meet all the study criteria. You will fill out a brief questionnaire so that we can assess your current urologic status. This should take approximately 20 minutes.

Your initial baseline pelvic exam will be performed by Dr. Robert Evans. Additionally, you will

be asked to fill out a quality of life (QoL) survey before you start your treatment, and then at your 4 and 12 weeks follow up.

Pregnant women will be excluded from participation in this study. Because some methods of birth control are not 100% reliable, as part of your normal pre-operative work up, a pregnancy test will be administered within 10 days from your last normal menstrual period if you are sexually active and of childbearing potential. If positive, you will not be included in this study, as you will likely NOT undergo the procedure. Due to unknown risks and potential harm to the unborn fetus, sexually active women of childbearing potential must use a reliable method of birth control while participating in this study. Reliable methods of birth control are: abstinence (not having sex), oral contraceptives, OrthoEvra patch, NuvaRing, intrauterine devices (IUD), Nexplanon implant, DepoProvera, tubal ligation, or vasectomy of the partner (with confirmed negative sperm counts) in a monogamous relationship (same partner). An acceptable, although less reliable, method involves the careful use of condoms and spermicidal foam or gel and/or a diaphragm with spermicide with Plan B used for any noticed condom or diaphragm failures. We encourage you to discuss this issue further with your physicians if you have any questions.

Patients with pacemakers, transplanted organs, immune suppressant drug prescriptions, or metal joint replacements will also not be included in the study. If you have any of these exclusion qualifiers, please notify study staff.

Identifiers (your name, address, date of birth, etc.) may be removed from the private information collected as part of this research. When the identifying information is removed, your private information may be used for future research studies or given to other research investigators without getting additional informed consent from you or your legally authorized representative.

HOW LONG WILL I BE IN THE STUDY?

You will be in this study for 12 weeks. You may be contacted for future follow up. You can stop participating at any time.

WHAT ARE THE RISKS OF THE STUDY?

The PEMF therapy presents no risk of harm or discomfort during and/or after treatment. Some patients may report a mild tingling in their fingers or toes. After each PEMF session, you may return to your normal daily activities. If you have any concerns, you should discuss the risk of being in this study with our study staff.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts including 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.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

Potential benefits of this study include a decreased need for opioids (painkillers) due to IC/BPS pain, bladder pain, urgency, or frequency of urination. Secondary benefits might include better

sleep, less mood swings, more energy, and better quality of life.

WHAT OTHER CHOICES ARE THERE?

IC/BPS is a disease without a clinical or biological marker. Most patients receive several different, non-invasive interventions along with medications including anti-depressants, painkillers, anti-inflammatories, anti-histamines, lidocaine and heparin bladder instillations, etc. To date, PEMF has never been formally tested in IC/BPS patients and therefore, the benefits of PEMF in IC/BPS patients are not yet known. Your alternative is to not participate in this study.

WHAT ABOUT MY HEALTH INFORMATION?

By taking part in this research study, your personal health information, as well as information that directly identifies you may be used and disclosed. Information that identifies you includes, but is not limited to, your name, address, telephone number, and date of birth.

Your personal health information includes all information about you, which is collected or created during the study for research purposes only. It also includes your personal health information that is related to this study and that is maintained in your medical record at this institution.

Your personal health information and information that identifies you 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.

If this research study involves the treatment or diagnosis of a medical condition, then information collected or created as part of this study may be placed in your medical record and discussed with individuals caring for you who are not part of the study. This will help in providing you with appropriate medical care. In addition, all or part of your research related health information may be used or disclosed for treatment, payment, or healthcare operations purposes related to providing you with medical care.

Laboratory test results and other medical reports from your participation in the research study may be entered into the electronic health record system of Wake Forest University Health Sciences

and the North Carolina Baptist Hospital (NCBH). These will be kept secure, with access to this information limited to individuals with proper authority, who may not be directly involved with this research study.

When you sign this consent and authorization form you authorize or give permission for the use of your health information as described in this consent form. This authorization does not have an expiration date. You can revoke or take away your authorization to use and disclose your health information at any time. You do this by sending a written notice to the investigator in charge of the study at the following address:

Stephen Walker, PhD

[redacted]

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 anyways to ensure that this 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.

If you withdraw your authorization, you will not be able to be in this study and no new health information that identifies you will be gathered after your withdrawal date. Your health information that has already been gathered may still be used and disclosed to others. This would be done if it were necessary for the research to be reliable. You will not have access to your health information that is included in the research study records until the end of the study including medical records, along with any routine medical test results that were obtained at NCBH.

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.

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 I BE PAID FOR PARTICIPATING?

There will be no monetary compensation for participating in this study. The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the Department of Urology. BEMER USA LLC (Carlsbad, CA) is providing complimentary use of 3 sets of mats and pads.

WHAT HAPPENS IF I 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, Inc. does 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].

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, Gopal Badlani, MD at [redacted] or your treating doctor, Robert Evans, MD at [redacted].

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose to not participate and, if you do choose to participate, 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 new information has become available, 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. Clinically relevant research results will not be disclosed to you.

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 co-PI Dr. Robert Evans, MD at [redacted] or the urology outpatient clinic 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, would like to discuss problems or concerns, have questions or want to offer input, or 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 and one will be made available to me. I have had a chance to ask questions about participating in this study and have had 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. Furthermore, I agree that I will return the PEMF devices at the conclusion of the 4-week treatment period.

_____

Subject Name (Printed)

AM/PM

_____ _____

Subject Signature Date/Time

_____

Person Obtaining Consent (Printed)

AM/PM

_____ _____

Person Obtaining Consent Date/Time