

INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH

Building Strength through Rehabilitation for Heart Failure Patients- BISTRO STUDY

Christine Haedtke, PhD, RN, PCCN

Assistant Professor, School of Nursing

National Institute of Research Nursing – IRB Protocol Number 1801643369

WHY IS THIS RESEARCH BEING DONE?

The purpose of this study is to learn more about the effects of electrical stimulation on muscle mass and strength, activity levels, heart failure symptoms, and quality of life in people with heart failure. Leg weakness and muscle deterioration is often found in those with heart failure. Due to profound weakness, patients are more likely to need to be in the hospital, have more falls, be unable to participate in daily activities, and have a poor quality of life. Actions that improve strength without causing additional fatigue are needed to improve the lives of people with heart failure. We will test the use of an electrical stimulation device to see if it is a treatment option for heart failure patients. The device will provide stimulation to your thighs. In order to determine if the stimulation does improve symptoms, activity levels, quality of life, or strength, people will be randomly assigned to one of two possible treatment groups, either the “intervention” group or the “sham” group. In this study, sham means you will do everything as the other group but the settings on the machine will be different. You will not know which group you are in.

The study is being conducted by Dr. Christine Haedtke, Indiana University School of Nursing and Dr. Jeffrey Kline, Indiana University School of Medicine. It is funded by National Heart Lung and Blood Institute/National Institute of Nursing Research – Emergency Care Award number 068853-00006B.

HOW MANY PEOPLE WILL TAKE PART?

If you agree to participate, you will be one of 60 participants taking part in this study.

WHAT WILL HAPPEN DURING THE STUDY?

If you agree to be in this study (the BISTRO study), you also will be required to participate in a second study, “Musculoskeletal Function, Imaging and Tissue” (the FIT study, IRB Protocol #1707550885), which is conducted by Dr. Stuart Warden and is similar to the BISTRO study. Because participation in the FIT Core study is required to participate in this study, you should review the consent for the FIT study before making a decision about whether to sign this consent.

The FIT study focuses on how people are affected by aging, injury, disease, and illness over time. The FIT study includes drawing blood and measuring how well you perform physical tests that will take about 30-45 minutes to complete including: hand grip strength, how fast you can walk, and how quickly you stand up and sit down. Data collected in the FIT study will be used in future studies by other researchers to understand the causes and consequences of different physical function and activity

levels across a large population. The main risks of participation in the FIT study are the risk of blood draw (pain, infection, bruising) and fatigue and falls from the testing. More information about the FIT study is in the separate Informed Consent you will receive.

For the BISTRO study you will be asked to fill out survey questions (9 forms) 4 times, participate in physical tests, have a DXA (Dual-energy x-ray absorptiometry) scan, wear an activity monitor (ActivPal) 3 times, and use the study device for electrical stimulation of your thighs for 6 weeks. To assure your safety and satisfaction, we will call you once a week to check on you while you are using the BISTRO study device.

The time frame for the BISTRO study is 6 months, although the bulk of the study is done in 10 weeks. Details are included in the FIT study informed consent statement and brief description is provided below. Your participation in the FIT study may last longer than the BISTRO study, if you choose.

Study Timeline

Visits	Visit 1 Week 1	Visit 2 Week 2	Week 3-8	Visit 3 Week 9-10	Week 10-20	Visit 4 Week 21-26
Informed consent	X					
Survey Questions	X	X		X		X
Physical Tests		X		X		X
DXA Scan		X		X		X
Biodex		X		X		X
Wear activity monitor	X			X		X
Use device		X	X			
Weekly phone calls			X			
Participate in formal exercise program					X	

Study Visit 1 is expected to take 1 hour

- You will review and sign consent statements for the BISTRO and FIT studies.

You will be asked to answer survey questions regarding heart failure symptoms,



fatigue, pain, depression, social support, and self-efficacy. We will collect demographic and health status information using a standard questionnaire.

Lastly, we will show you an activity monitor, (ActivPal) explain how you use it, and place it on your leg. You are asked to wear the activity monitor on your thigh for 1 week. See picture on the left.

Study Visit 2: is about one week later and is expected to take 2-4 hours. You will be asked to

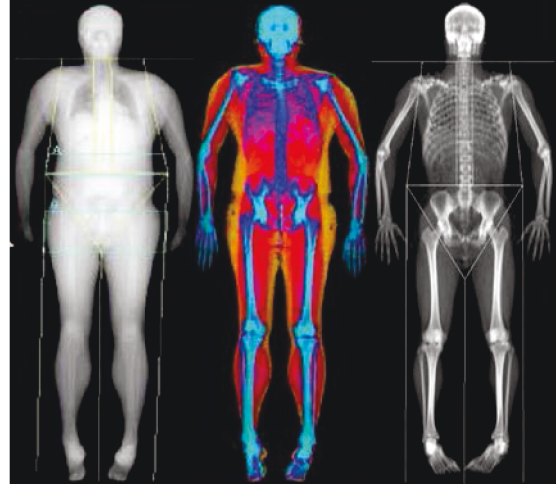
go to the Indiana Center for Musculoskeletal Health to have the physical tests for both studies completed. As we don't want you to feel rushed, the time planned for the physical tests will allow for adequate breaks to rest and drink water. We are allowing a large amount of time to perform the physical tests because the amount of time needed to perform the tests and have adequate rest breaks may be very different from person to person.

One of the physical tests includes having your leg strength measured on a machine called a Biodex. For the test, you will be seated in the padded chair of the testing device and have padded straps placed across your chest and thigh to stop them moving during the test. When instructed, you will kick (tighten your thigh muscle and try to straighten your knee as hard as you can against the testing machine). This will be performed 5 times on your dominate leg with a 120 second rest period between each set of 3 attempts. The second part of the test includes kicking 50 times in a row. Following the 50 kicks you will be given 30 seconds to rest, then asked to repeat 3 kicks for a series of 5 times.



The leg strength test will take approximately 40 minutes to complete.

A DXA scan will also be done at this time. See picture below. You will need to remove any metal from your body and/or clothes (belts, keys, etc.) before the scan. This scan will tell us about your muscles and bones and you will be given a copy of the results at that time.



After the tests and surveys are completed, a second person from the BISTRO research



study will teach you how to use the electrical stimulation device including how to place the patches. You will take the device with you to perform the treatment in your own home, 15 minutes a day, 5 days a week, for 6 weeks. The person helping you with the physical tests, questionnaires, and scans will not know which group you are in. All the tests, use of the study device, placement of patches, and interactions with study staff, is the same for both groups.

During the 6 weeks of electrical stimulation, you will receive a weekly phone call to check in with you and see how everything is going. This is the time to report any skin issues, muscle soreness, questions, problems, or supply needs you may have.

Study Visit 3: 6-8 weeks after receiving the electrical stimulation device

- Following the 6 weeks of electrical stimulation, you will return and perform the same physical function tests, answer surveys, and get a DXA scan that is not part of the FIT Core study.
- You will be given an activity monitor to wear on your thigh for 1 week.
- You will be encouraged to begin participation in a formalized exercise program of your choosing. Depending on the program you chose, your physician may need to evaluate your health to determine if it is safe for you to participate in your chosen program.

Study Visit 4: 12-18 weeks after returning the electrical stimulation device

- Lastly, you will return one more time and perform physical function tests, answer survey questions, and get a DXA scan.
- You will wear an activity monitor on your thigh for 1 week.
- We will ask you about any exercise program you may have been participating in.

How long will each of the visits take?

- The in-person visits are expected to take between 2-4 hours each. The time will vary based on how quickly you are able to perform the physical tests. We do not want you to feel rushed and risk injuring yourself, so up to 4 hours will be allotted for completion.
- The phone visits are expected to 5-15 minutes of your time each week while you are using the electrical stimulation device.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?

There is a potential risk of loss of confidentiality. You may feel uncomfortable completing the questionnaires. You do not have to answer any questions you don't want to. The risks for the physical tests include muscle soreness, falls, and feeling tired. The risk of wearing the activity monitor is possible skin irritation. The risk of using the electrical stimulation device is possible skin irritation and sore muscles. The risk of the scans is a slight exposure to additional radiation equal to living in Indianapolis for less than a week. There is no evidence that such low levels of radiation expose humans to any risk. The estimated radiation dose resulting from your participation in this study is available upon request.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?

You may benefit from participating in this research study, however there is no guarantee that it will help you. The information gathered from this study may help researchers better understand musculoskeletal health in the future. You will be given the results from your DXA scan.

WILL I RECEIVE MY RESULTS?

We may learn things about you from the study activities, which could be important to your health or well-being. For example, some of the questions asked in the surveys may indicate further follow-up with your provider is prudent. If that is the case, we will let you know in person during the visit or call you and let you know that you need to contact your provider for further evaluation. This study will not cover the costs of any follow-up consultations or actions your provider recommends.

HOW WILL MY INFORMATION BE PROTECTED?

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. No information which could identify you will be shared in publications about this study or databases in which results may be stored.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP) and the National Institutes of Health (NIH), the Food and Drug Administration (FDA), etc., who may need to access the research records.

A description of this clinical trial is 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.

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

1. If there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
2. if you consent to the disclosure, including for your medical treatment;
3. if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects
4. for the purpose of auditing or program evaluation by the government or funding agency
5. if required by the federal Food and Drug Administration (FDA)

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

Information collected for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information or specimens are shared. Since identifying information will be removed, we will not ask for your additional consent.

WILL I BE PAID TO PARTICIPATE?

You will receive payment for taking part in this study in the form of voucher checks that are mailed to you from Indiana University.

- Payment 1: \$50 will be paid when you return for the first physical testing visit and bring the activity monitor (ActivPal) with you.
- Payment 2: \$10 will be paid after you complete each of the 6 weekly phone calls. Payment will be sent for processing and mailed or direct deposited in the day or two following the phone call.

- Payment 3: \$50 will be paid when you return the activity monitor by mail (we will pay for the shipping costs). The payment will be sent for processing and mailed or direct deposited in the day or two after we receive the ActivPal.
- Payment 4: \$50 will be paid upon return of the ActivPal, after the third physical testing visit. The payment will be sent for processing and mailed or direct deposited in the day or two after we receive the ActivPal. *If you fail to return the equipment, you will not receive the payment scheduled for that visit.

Also, vouchers for the Parking Garage will be available to you for study visits. If you withdraw or are removed from the study, you will be paid only for the parts of the study you have completed. Payments will be mailed after study equipment is received by study personnel.

WILL IT COST ME ANYTHING TO PARTICIPATE?

Taking part in this study may lead to added costs to you or your insurance company where applicable. You or your insurance company will be responsible for the following costs: health care visits with your provider.

You will not be responsible for these study-specific costs: DXA, physical function tests, surveys, use of the study equipment including the electrical stimulation, or parking in the Riley parking garage during study visits at IU Health.

WHO WILL PAY FOR MY TREATMENT IF I AM INJURED?

In the event of physical injury resulting from your participation in this research, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, contact the researcher, Dr. Christine Haedtke, at 317-274-5358. If you cannot reach the researcher during regular business hours (i.e., 8 a.m. to 5 p.m.), please contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, to obtain information or to offer input, please contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu.

WILL I BE CONTACTED ABOUT RESEARCH IN THE FUTURE?

If you agree, we may contact you after your participation is over to request additional information or ask if you might be interested in another study. Please initial one of the following options:

_____ Yes, I agree to be contacted for the purpose of collecting additional health information and/or possibly participating in future studies.

_____ I do NOT agree to be contacted for the purpose of collecting additional health information and/or possibly participating in future studies.

Can I withdraw from the study?

If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this study will not affect your current or future relations with your physician or health care team. The study team will help you withdraw of the study safely and assist you in returning study equipment. You may withdraw by telling the study team you are no longer interested in participating in the study by calling Dr. Christine Haedtke at 317-274-5358, emailing the BISTRO study at nursres@iupui.edu, or by writing her at 600 Barnhill Drive; NU W431 Indianapolis, IN 46202.

Your participation maybe terminated by the investigator without regard to your consent if it is determined to be in your best interest to do so. In addition, your participation may be terminated you fail to follow the instructions given to you or if you are unable to adequately perform the study procedures or if the study is suspended or canceled. You will be told about any new information we learn that may affect your health, welfare, or willingness to stay in the study.

Participant's Consent

In consideration of all of the above, I give my consent to participate in this research study. I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Participant's Printed Name: _____

Participant's Signature: _____

Date: _____ (must be dated by the participant)

Printed Name of Person Obtaining Consent: _____

Signature of Person Obtaining Consent: _____

Date: _____