Cover letter for Informed Consent:

Official title: Cooling Leg and Foot Ulcer Skin Post Healing to Prevent Ulcer Recurrence (MUSTCOOL)

NCT02626156

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Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

Monitoring and managing newly healed chronic leg and foot ulcer skin temperature: a cooling intervention (MUSTCOOL) to prevent ulcer recurrence

A. PURPOSE AND BACKGROUND:

You are being asked to volunteer for a research study. The purpose of this study is to find out whether a daily home-care routine of monitoring the skin temperature over newly healed chronic venous leg and/or diabetic foot ulcers and cooling the affected area can prevent the ulcer from coming back, decrease pain from the ulcer, and improve patient functioning and overall quality of life. The study will take place in your home, but you will be asked to come to the clinic four times over the six-month study period to complete some brief surveys and have the affected skin area examined and its temperature taken. You are being asked to participate in this study because you are over 18 years old and have a recently healed chronic venous leg ulcer and/or diabetic foot ulcer. The investigator in charge of the study is Teresa J. Kelechi, PhD, who is a certified wound care nurse and faculty member of the College of Nursing at the Medical University of South Carolina (MUSC). The study is being conducted by MUSC at the Nexus Research Center in Charleston SC, the Spartanburg Regional Healthcare System (SRHS) at the Wound Healing Center in Spartanburg SC, and at the Wound Healing Center at East Carolina University in Greenville North Carolina. Dr. Carolyn Horne is the local investigator in charge of the study at East Carolina University. The study will involve approximately 240 volunteers. This research is sponsored by the National Institute of Nursing Research of the National Institutes of Health.

B. PROCEDURES:

Visit One: Part 1: Screening

To be eligible to participate in this study you must: be aged 18 or older; have had a chronic venous leg (VLU) or diabetic foot ulcer (DFU) that has healed within the past six weeks; be able to speak and write English; have a working freezer and telephone; have no memory loss; be willing and able to perform and complete all required participant study procedures by yourself; be willing and able to wear compression stockings and/or appropriate footwear; have an arterial brachial index (ABI) in the range of 0.8 to 1.3; not have any chronic inflammatory or vascular condition that interferes with blood flow; not have any hypersensitivity to cold or be receiving chemotherapy, and; be willing and able to attend all scheduled visits over the six-month study period.

The following tests and questionnaires will be completed at this visit to make sure you are eligible to participate in the study:

1. You will have your height, weight measured and demographic information recorded, a medical chart review will be performed, and will be asked about your medical history, symptoms and current medication usage.

2. You will have an ankle brachial index (ABI) test of blood pressure in your legs (~15mins), if you have not had one in the past year. To be eligible, your ABI reading must be within the range of 0.8 to 1.3.
3. You will be asked to complete the MiniCog memory test. To be eligible, you must score at least a '2' and have a perfect clock drawing on this test.

Visit One: Part 2: Measures

If you are eligible to participate in the study, you will then be asked to complete the following surveys and have these assessments performed:

1. You will be asked to rate the level of pain in your legs on a 0-10 point Visual Analog Scale (~1min)
2. You will be asked to complete the Brief Pain Inventory survey (~5mins)
3. If you have a VLU, you will be asked to complete the VEINES QOL survey (~5mins)
4. If you have a DFU, you will be asked to complete the NPQ survey (~5mins)
5. You will be asked to complete the International Physical Activity Questionnaire (~5mins)
6. Your skin area over your healed ulcer will be photographed with an infrared thermal camera and the temperature recorded. The image and data will be stored by a third party vendor (WoundVision LLC) and will include your subject ID# and the date of your study visit.

Visit One: Part 3: Enrollment

After these measures are taken, you will be enrolled in the study and randomized by computer into one of two study groups (Group A or Group B), receive study materials, and instructions. You will have a 50/50 chance (like a coin toss) of being assigned to either Group A or Group B. The scheduled study instructions, visits, procedures and requirements are the same for Group A and B. However, Group A and B will receive different cooling patches. Group A will receive a gel filled patch and Group B will receive a non-gel filled patch. During the course of the six-month study, you will be required to:

1. Wear an activity monitoring smart watch on your wrist;
2. Measure your healed ulcer skin temperature over the leg or foot with a handheld infrared thermometer and record the temperature on a study log every morning;
3. Perform the cooling treatment with the patch three days a week for 30 minutes at the same time of day while elevating your legs on a pillow;
4. If prescribed, you are to wear compression stockings (if you had a venous leg ulcer) or any orthopedic shoes (if you had a diabetic foot ulcer); and, to
5. Perform the cooling treatment for five days in a row whenever your skin temperature raises 2^{o}F above its average month one temperature.

6. You will be given a telephone number to call and report if you have any skin changes or problems, and you will also receive monthly telephone calls from the researchers to see how you are doing.

Visit Two

One month after study enrollment, you will be required to return to the clinic for a scheduled study visit and bring the activity watch, the handheld thermometer, and your daily study logs. All of the same measures in Visit One Part 2 will be repeated at this visit. At this visit you will be asked if you have had any changes in your current health status or in the medications that you are taking. You will also be asked to complete a brief satisfaction survey that asks about the how you are finding performing the study procedures and to report any problems that you have had or may be experiencing. The research staff will collect your study logs and download the data from both the activity watch and handheld thermometer. You will be given new daily study logs to complete until the next visit.

Visits Three and Four

All study procedures done in Visit Two will be repeated at Visit Three and Visit 4. Visit Three will occur 3 months after enrollment and Visit Four at 6 months after enrollment. Visit Four marks the end of the study.

You may be withdrawn from the study without your consent if the researchers believe it is in your best interest or if you fail to follow study procedures.

C. DURATION:

Participation in the first visit will take about two hours. The other visits should take about one hour. Daily skin temperature recording and completion of the study log should take about 1 minute to do each day. The cooling part of the study that you will do in your home will take about 40 minutes three days a week. The total duration of the study is six months.

D. RISKS/DISCOMFORT:

Cooling Patch: You may experience uncomfortable cold or hot feelings when initially applying the patch to your skin. These feelings usually go away after a few minutes as your body gets used to the cold patch touching your skin. If these sensations remain after 5 minutes of use, remove the patch and stop. If these sensations still remain after 10 minutes you should immediately call the researchers.

Ankle Brachial Index (ABI): For most people, there are no physical risks involved with an ABI test. You may feel some discomfort when the blood pressure cuffs inflate on your arm and ankle, but this discomfort is temporary and should stop when the air is released from the cuffs.

Other Unknown Risks: There may be other unknown risks associated with cooling recently healed ulcer skin. If your ulcer comes back at any time, or you experience any pain or discomfort, or you notice any changes in the skin color, or have unusual sensations, you should immediately stop using the cooling patch and call the researchers.

Loss of Privacy: Your privacy is very important to us, and the researchers will make every effort to protect it. However, as with any process that collects personal information about you (such as your name, address, and date of birth), there are risks associated for the loss of privacy and confidentiality. Information obtained about you for this study will be kept confidential to the extent allowed by law. Research information that identifies you may be shared with the MUSC Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to conducting research. The information from the research may be published for scientific purposes; however, your identity will not be given out.

You are being assigned to a study group and treatment program by chance. Group A's cooling patch may prove to be less or more effective or have more or less or unknown side effects than Group B's patch or other available treatments. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

E. BENEFITS:
The potential benefit to you is that the treatment you receive may prove to be more effective in preventing the reoccurrence of your ulcer than the usual standard of care, which is wearing compression stockings or orthopedic shoes, elevating the legs, taking good care of the skin, and doing leg exercises, although this cannot be guaranteed.

F. COSTS:
There are no costs to you for participation in this study. You will not be charged for any of the study treatments or study procedures. The costs of the cooling patches, the physical activity watches and all tests associated with this study, and all office visits, will be covered by the study. You and/or your insurance will continue to be billed and will be responsible for your routine standard of care appointments with your medical provider during the study.

G. COMPENSATION:
In return for your time, effort and travel expenses, you will be paid a total of $250.00 for full study participation; after you complete Visit One: Part 1: Screening, you will receive $25.00; after you complete Visit One: Part 2: Measures and Visit One: Part 3: Enrollment you will receive $75.00; after completing each of Visit Two and Visit Three, you will receive another $50.00, and; after you complete the final Visit Four you will receive $75.00. Compensation will be in the form of a check mailed to you after each

visit. In addition, when you come to Visits Two through Four, there will be a “fish bowl”, from which you can draw tokens for additional money.

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

H. ALTERNATIVES:
If you choose not to participate in this study, you will continue to receive the same standard of care from your physician for the management of your venous leg ulcer or diabetic leg ulcer. This standard of care involves compression therapy and/or orthopedic shoes, leg elevation and physical exercise.

I. NEW INFORMATION
If there are significant new findings during the course of the study, you will be notified.

J. STUDENT PARAGRAPH: Your participation or discontinuance will not constitute an element of your academic performance nor will it be a part of your academic record at this Institution.

K. EMPLOYEE PARTICIPATION: Your participation or discontinuance will not constitute an element of your job performance or evaluation nor will it be a part of your personnel record at this Institution.

L. CLINICAL TRIAL REGISTRY DATABANK:
A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time. Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University

Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled. The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Teresa Kelechi at (843) 792-4602. I may contact the Medical University of South Carolina Hospital Medical Director (843) 792-9537 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

At East Carolina University, if you have questions about the sharing of PHI related to this research study, call *Carolyn Horne* at *252-744-6451*. If you have questions about your rights as someone taking part in research, you may call the ECU Office of Research Integrity & Compliance (ORIC) at phone number 252-744-2914 (days). If you would like to report a complaint or concern about this research study, you may call the Director of ORIC, at 252-744-1971. In addition, if you have concerns about confidentiality and privacy rights, you may phone the Privacy Officer at East Carolina University at 252-744-5200.

I agree to participate in this study. I have been given a copy of this form for my own records.

If you wish to participate, you should sign below.

_____	_____	_____	_____
Signature of Person Obtaining Consent	Date	Signature of Participant	Date