Title: Reducing the Experience of Menopausal Symptoms Through Temperature (REST)
NCT: NCT03937466
Date: 3/31/21

Wake Forest® School of Medicine

REST *Reducing the Experience of Menopausal Symptoms through Temperature*

Department of Social Sciences and Health Policy

Reducing the **E**xperience of menopausal **S**ymptoms through **T**emperature (REST)

Informed Consent Form to Participate in Research
Nancy E. Avis, PhD, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research study is to understand if a cooling mattress pad can help women who are experiencing hot flashes. You are invited to be in this study because are a menopausal woman experiencing hot flashes. Your participation in this research will involve 1-3 visits and last about 3 months.

Participation in this study will involve a baseline visit during which we will ask you to complete several questionnaires in-person or via email, You also will be asked to complete a daily diary to keep track of your hot flashes. You will record hot flashes on this diary every day for 2 weeks. If you are still eligible for the study, you will come to the clinic to pick up the mattress pad and cooling cube for your home use. For the next 9 weeks you will use the mattress pad and cooling cube every night and continue to record your daily hot flashes. After 9 weeks, we will ask you to complete additional questionnaires.

All research studies involve some risks. This study involves minimal risk to participants. During the time the participant is using the cooling device, their hot flashes may stay the same, decrease, or increase. Participant's sleep, mood and quality of life may improve, worsen, or stay the same. Participants may feel anxious about answering questions about their well-being, sleep, or menopausal symptoms.

The only risks associated with the cooling device are the following: 1) the possibility of disrupted sleep until you find the temperature that works best for you and the noise of the small fan, 2) the possibility of tripping if you do not place the cube properly, and 3) the possibility of risk of mold or mildew on the mattress pad if unwashed after several months.

There is the possibility that you may benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices may include talking to your doctor about all the choices you have to get relief from your hot flashes. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the

study. The person in charge of this study is Dr. Nancy Avis, PhD. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: [redacted] or [redacted]

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

INTRODUCTION

You are invited to participate in a research study being conducted by investigators at Wake Forest University School of Medicine. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you are a peri- or post-menopausal woman (no periods for at least 3 months) who has daily hot flashes. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask the study staff or your doctor to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to understand if a cooling mattress pad can help women who are experiencing hot flashes. The ChiliPad is a cooling device that you place over your mattress that is designed to keep you cool while you sleep. The portion that you place over your mattress has several small tubes that are attached to a cube. The cube is filled with water that runs through the tubes that cool the mattress pad.

The Chilipad is commercially available, however, has not been approved by the Food and Drug Administration (FDA) for use in this study.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Approximately 24 women will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

We have already asked you some questions to assess your initial eligibility to participate in the study. Based on this initial eligibility, you have been invited to take the next step to assess your eligibility.. At this time, you are being given (or sent) this consent form to read and sign. Once you have consented to participate in the study the following procedures will be performed:

Step 1 (Baseline)

- You or study staff will record a list of your current medications
- You will complete several questionnaires.
- You will be asked to complete a daily diary to keep track of your hot flashes. You will record hot flashes on this diary every day for 2 weeks. If you are still eligible for the study, you will come to the clinic (or other mutually agreed upon location) to pick up the mattress pad and cooling cube for your home use.

Next 9 Weeks

- For the next 9 weeks you will use the mattress pad and cooling cube every night.
- You will continue to record your hot flashes daily.

After Week 9

- You will come to the clinic to complete questionnaires, or complete these by mail.

How Long Will I Be in the Study?

You will be in the study for approximately 3 months. You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first.

What Are the Risks of the Study?

Being in this study involves minimal risk to you.

During the time you use the cooling device, your hot flashes may stay the same, decrease, or increase. Your sleep, mood and quality of life may improve, worsen, or stay the same.

You may feel anxious about answering questions about your well-being, sleep, or menopausal symptoms. You may skip over any questions that you choose not to answer. Study staff is available at all times to discuss any uncomfortable feelings you may have.

The only risks associated with the cooling device are the following: 1) the possibility of disrupted sleep until you find the temperature that works best for you and the noise of the small fan, 2) the possibility of tripping if you do not place the cube properly, and 3) the possibility of risk of mold or mildew on the mattress pad if unwashed after several months.

As part of this study, you will be asked questions about your physical and emotional health. If we learn that you or someone else is in danger of harm, the study team is required to report that information to the proper authorities.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be a direct benefit to you. We hope the information learned from this study will benefit other women in the future. The benefits of participating in this study may be that you experience relief from your hot flashes.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to obtain relief from your hot flashes. You should talk to your doctor about all the choices you have to get relief from your hot flashes.

WHAT ABOUT THE USE, DISCLOSURE AND CONFIDENTIALITY OF 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, such things as 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.

Your personal health information and information that identifies you ("your health information") 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; 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 required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state

privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for an indeterminate period of time. This authorization does not expire. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

When you sign this consent and authorization form you authorize or give permission for the use of your health information as described in the consent form. 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:

Nancy Avis, PhD., Principal Investigator
[redacted]

If you withdraw your authorization you will not be able to be in this study. If you withdraw your authorization, no new health information that identifies you will be gathered after that 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.

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

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.

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.

The purpose of this research study is to obtain data or information on the safety and/or effectiveness of the ChiliPad; the results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

WHAT ARE THE COSTS?

There are no costs to you for taking part in this study. All study materials will be paid for by the study.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive $25 gift card and will be allowed to keep cooling mattress pad upon your completion of the study.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by an internal grant to the Center for Integrative Medicine at Wake Forest University Health Sciences. The researchers do not hold a direct financial interest in the sponsor or the product being studied.

WHAT HAPPENS IF YOU 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, Incorporated do 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 the Principal Investigator, Dr. Nancy Avis at [redacted].

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or 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 have had an unexpected reaction.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

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.

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 investigator, Dr. Nancy Avis at [redacted] anytime.

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, or you would like to discuss problems or concerns, have questions or want to offer input, or you 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 or one will be made available to me. I have had a chance to ask questions about being in this study and have 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.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm
Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm