Official Title: The Effect of Pain on Short Term Cognitive Performance Using a Computer Assisted/Ipad Game Interface

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Wake Forest®
School of Medicine

Department/Section of *Anesthesiology*

The Effect of Pain on short term cognitive performance using computer/iPAD assisted game interface

Informed Consent Form to Participate in Research
Douglas Ririe, M.D., Ph.D., Principal Investigator

INTRODUCTION

You are invited to be in a research study. 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 healthy individual. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study 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 discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to evaluate the impact pain from heat or cold has on your ability to pay attention.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

At total of 60 people at Wake Forest Baptist Medical Center will take part in this study.
In order to identify the 60 subjects needed, we may need to screen as many as 150 because some people will not qualify to be included in the study.

WHAT IS INVOLVED IN THE STUDY?

In this study game success will be compared in subjects exposed to heat on the leg and cold on the foot by placing it in cold water or body temperature water. This will be done using an iPad games that require 2-3 minutes to play. You will be asked to play the game before, during, and after the cold or heat. Just prior to playing the games and just after playing the games, you will be asked to score your pain on a scale from 0- 10.
The study will be conducted at Piedmont Plaza II in the Migraine and Pain Research Unit (MPRU).
You will be randomized (like a flip of a coin) to either the Thermal Group or Control Group. You will have a 1 in 3 chance of being in the Control Group and a 2 in 3 chance of being in the Thermal Group.

Group 1(Thermal Group): We will administer thermal heat temperatures in sequences of a low and a higher temperature to your forearm(s) and ask you to rate the pain by using a sliding rating score from 0-10. We will use a thermal probe with a tip about the size of a penny which

will be placed on the skin of your forearm and the temperatures will be applied and held constant for 5 seconds. The probe temperature will vary from skin temperature up to a temperature that is hot (105.8° F to 122.2° F) and uncomfortable, but does not burn your skin.

Next will use a thermal probe with a tip about the size of a quarter which will be placed on the skin of your leg and a temperature 116.6° F will be applied for 90 seconds.

Lastly, we will ask you to place your foot into a bucket of cold (50°F) water for 90 seconds or a bucket of normal body temperature (100.4°F) water for 90 seconds.

We will ask you to play a computerized game on an iPad before, during and after the thermal testing.

Group 2 (Control Group): No thermal testing will be performed, we will ask you to play a game on the iPad using the same time intervals as the Thermal Group.

How Long Will I Be in the Study?

You will be in the study for 30-60 minutes.

You can stop participating at any time.

What Are the Risks of the Study?

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests or iPad based games. This may include frustration, excitement, anxiety or headache. You should discuss the risk of being in this study with the study staff. There is also the possibility of the sensation of slight sunburn the size of a quarter. Exposure of the foot to cold water could result in short duration of decreased circulation, reduced sensation, and anxiety.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as 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?

You are not expected to receive any direct benefit from taking part in this research study. There is no benefit to you from participating in the study. However, benefits may be for future patients by understanding the effects pain on the ability to pay attention and helping us to reduce the impact of surgery and anesthesia for future patients.

What Other Choices Are There?

This is not a treatment study. Your alternative is to not participate in this study.

What About My Health Information?

In this research study, any new information we collect from you and/or information we get from

your medical records about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:**
Name
Age
Medications
Medical History

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study may be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer. Only the following people or organizations will be granted access to your Protected Health Information:

1) The study investigator and his/her staff, or others at Wake Forest University Health Sciences who oversee research

2) Other people or laboratories providing services for this research project on behalf of Wake Forest University Health Sciences and Wake Forest University Baptist Medical Center

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 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.

You can tell Dr. Douglas Ririe that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Dr. Douglas Ririe
[redacted]

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.

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 anyway to ensure that this important 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.

WHAT ARE THE COSTS?

There are no costs to you for taking part in this study. All study costs 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 YOU BE PAID FOR PARTICIPATING?

We will compensate $25 for the thermal heat testing, $25 for the application and subsequent thermal cold testing. Subjects will receive a gift card in the amount of $50 for their participation in the Study. Control subjects will receive 25$ gift card.

To receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not let them know what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study but you will not be paid.

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 Anesthesiology at Wake Forest University Health Sciences. The researchers do not, however, 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].

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

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 Dr. Douglas G. Ririe at [redacted] during regular business hours and after hours you may call the study coordinator 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.

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

This study may be enrolling students from the Wake Forest University and/or Wake Forest University Medical Center campus. In addition to your rights as a research participant noted in the previous section, as a student, you are under no obligation to participate in this study. You may refuse to participate or withdraw from the study at any time and for any reason without affecting your grades, performance evaluations, or assignments. You will not be pressured into participating in this research study by any statements or implied statements that your grades, performance evaluations or assignments will be affected by your willingness to enroll in the study. Your medical records/information will not be used by the faculty, administration or study staff to make decisions regarding the status of your medical benefits. If you have questions regarding your enrollment in the study and your status as a medical student, please contact the Office of Student Services for additional information.

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. Douglas G. Ririe, M.D, Ph.D. at office: [redacted], pager: [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, 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. I have been satisfactorily informed of the above described procedure with its possible risks and benefits. I give permission for my participation in this study. I know Dr. Ririe or his associates will be available to answer any questions that I may have and may be reached in the Department of Anesthesiology [redacted]. If I feel my questions have not been adequately answered, I may request to speak to a member of the Institutional Review Board by calling [redacted]. I understand that participation in this study is voluntary and I am free to withdraw this consent and discontinue participation in this project at any time, even after signing this form, and it will not affect my care. 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:_____ Date:_____ Time:_____ am pm