Official Title: Check yourself before you wreck yourself: A wearable biofeedback device to decrease surgical resident's time in a non-upright posture and work-related musculoskeletal pain

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Department of Surgery

CHECK YOURSELF BEFORE YOU WRECK YOURSELF: A WEARABLE BIOFEEDBACK DEVICE TO DECREASE SURGICAL RESIDENT'S TIME IN A NON-UPRIGHT POSTURE AND WORK-RELATED MUSCULOSKELETAL PAIN

Informed Consent Form to Participate in Research

William C. Sherrill, MD Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to determine whether surgical residents will spend less time in a non-upright position during laparoscopic procedures after wearing a biofeedback device for postural training. You are invited to be in this study because you are a surgical resident completing a rotation at Atrium Health. Your participation in this research will last about one month.

Participation in this study will involve wearing a posture training device and completing online surveys. You will be asked to answer questions about your demographics and complete surveys regarding complaints related to musculoskeletal pain. These questions will be asked at three time points during the study. Each survey should take approximately 5-10 minutes. During the study, you will receive a commercially available posture training device, the Upright Go 2™, to wear around your neck for a two-week tracking period and a two-week training period while you perform laparoscopic procedures. You will need to download the device's free smartphone application and review the application and device's Privacy Policy. The Privacy Policy is available on the website www.uprightpose.com. You should read the terms of use for the application and website. If you use the device, the terms will apply to you.

Before you begin using the device, you will watch a training video. During the tracking period, the device continuously records your posture. During the training period, the device will send biofeedback in the form of a gentle vibration if your posture deviates from a neutral position. At the end of each period, you will be asked to record the percentage of time spent in the upright and non-upright position from the smartphone application into an online survey.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. You will not lose any services, benefits, or rights you would normally have if you choose not to participate. Your decision to participate and any responses you provide will not impact your employment status. If you choose to participate, you will be one of up to twenty-three participants recruited.

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. William Sherrill, PI. If you have questions,

suggestions, or concerns regarding this study or you want to withdraw from the study his email address is William.Sherrill@atriumhealth.org.

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].

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. You should discuss the risk of being in this study with the study staff.

There is the slight risk of a breach of confidentiality. We will do our best to protect your confidential information. 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. Upright, the application and device used in this study, is a third party. Any data breaches by the third party are the responsibility of the third party Upright. Therefore, confidentiality of information entered into the application or recorded by the device cannot be guaranteed. Due to the nature of the study, privacy cannot be guaranteed. Colleagues may notice you wearing the device and be aware of your participation in the study.

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. We hope the information learned from this study will help identify opportunities to improve surgical residents' posture.

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 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.

WILL YOU BE PAID FOR PARTICIPATING?

You will be paid up to $200 in the form of a ClinCard for completing the study. You will receive $10 for completing the first survey, $80 for completing and recording the first two weeks of procedures, $10 for completing the second survey, $80 for completing and recording the second two weeks of procedures, and $20 for completing the final survey, for a total of up to $200. If you complete the entire study, you will have the option to keep the biofeedback training device (approximate $80 value) after the study.

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.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes age, gender, race, height and self-reported Yes or No responses to eligibility criteria asking whether you have been clinically diagnosed with any inflammatory musculoskeletal disorders or undergone any orthopedic surgeries in the last 6 months.

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.

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; 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) or the Office of Human Research Protections (OHRP), 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 unless there are photographs or recorded media which are identifiable.

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 at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified. 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. William Sherrill 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:

William Sherrill, MD
[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.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

You may choose not to take part or you may leave the study at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff. The investigators also have the right to stop your participation in the study at any time. Information about you may be removed from the study data and could be used for future research or shared with other researchers without additional consent from you.

By continuing, I agree to take part in this study. I authorize the use and disclosure of my information as described in this consent form. I have had a chance to ask questions about being in this study and have those questions answered. By taking part in the study, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.