Official Title: Education in Clients who are Wheelchair Users and their Caregivers for Promotion of Optimal Pressure Relief

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Wake Forest®
School of Medicine

Education and Training in Clients who are Wheelchair Users and their Caregivers for Promotion of Optimal Pressure Relief
Informed Consent Form to Participate in Research
Amber Ward, OT, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this study is to determine barriers for clients who are complex power wheelchair users for performing pressure relief, and to determine if providing education and training based off the identified barriers in performing pressure relief will better allow clients and caregivers to perform pressure relief and provide insight on the significance of pressure relief. We hope the data will allow us to make better recommendations and give better care to all patients. You are invited to be in this study because you have a complex power wheelchair and have been diagnosed with a neuro-progressive disorder. Your participation in this research will involve 1 initial visit for an interview and survey. Then, education and training will follow. A follow up post-interview 2-4 weeks from the initial interview will occur.

Participation in this study will involve scheduled office or clinic visits or, the investigators may talk to you and/or your caregivers about the research project and determine verbal consent to proceed with process. Current status will be determined through interview, survey, and using standardized measures to determine pain, pressure injuries (staging), sitting tolerance, questionnaire, and current pressure relief timing and practices. The interview will determine if there is a need for further education and training of pressure relief importance, identification of barriers to performance, and options for promotion of pressure relief.

After implementation of the pre-interview and determination/performance of necessity, you will undergo education and training at an occupational therapy clinic visit and/or at home with one or more of the following: handouts, verbal education, hands-on training, and video training. Any additional identified barriers will be addressed as possible with the multidisciplinary team, the wheelchair seating professionals, and with you and/or your caregiver. A post-interview after 2-4 weeks will be performed to determine if the education and training provided you have received has aided in the promotion of pressure relief.

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 Amber Ward, OTR/L. If you have questions, suggestions, or concerns about this study or want to withdraw from it, her contact information is [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].

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How Many People Will Take Part in the Study?
30 people will take part in this study over the course of 2 years.

What Are the Risks of the Study?
The study has a very low level of risk. First, you may have hand tiredness, weakness or cramping due to writing on the form. Second, you may become fatigued by having to think about the responses or in completing the form. You should discuss the risk of being in this study with the study staff.

There is a 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.

As part of this study, you will be asked questions about your current pressure relief practices and abilities. 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?
This study may or may not improve your condition or your ability to perform pressure relief. The information gained from your case may benefit others with your condition in the future.

What Are the Costs?
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 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.

The records of this study will be kept private. In any sort of report published, we will not include any information that will make it possible to identify a patient. Your record for this study would only be accessed as part of standard care by staff.

Will You Be Paid for Participating?
You will receive no payment or other compensation for taking part in this study. It is your choice whether to perform pressure relief and repositioning. In the event that you are harmed as a result of your participation in this study, we will provide or arrange for treatment as necessary.

Alternatives
This is not a treatment study. Your alternative is not to participate.

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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: sensitive personal health information, such as your diagnosis and your racial/ethnic origin if relevant to the study

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will 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.

Your personal health information and information that identifies you 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 Atrium Health Facilities; 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 resulting from this study unless photographs or recorded media 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 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

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records until all activities in the study are finished.

You can tell Amber Ward, OT 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:

Amber Ward, OT
[redacted]

However, if you take away permission to use your Protected Health Information, you will no longer be in the study. We will stop collecting any more information about you, but any information we have already collected can still be used for 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. This could be because it is in your best medical interest, your condition worsened, you failed to follow instructions, or because the entire study has been stopped. 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 health information as described in this consent and authorization 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.

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CONSENT

I have read the above information. I have asked any questions I had, and those questions have been answered. I agree to be in this study and authorize the use of my personal health information. I will be given a copy of this form.

_____	_____	_____
Patient Print Name	Date	Time am/pm
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time am/pm