Official Title: Virtual Seating Coach on Power Wheelchairs of Persons With ALS
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CAROLINAS HEALTHCARE SYSTEM
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Virtual Seating Coach on Power Wheelchairs of Persons with ALS

INTRODUCTION

Amber Ward, Occupational Therapist (OT), is asking you to participate in this research study of the Permobil Virtual Seating Coach (VSC) at the Neurosciences Institute Neurology, Carolinas Neuromuscular ALS/MDA Center, Carolinas HealthCare System (CHS). The VSC device is an FDA approved module which will be fit to under your power wheelchair seat, and will provide alerts for pressure relief as well as information on power wheelchair use. You are being asked to take part because you have Amyotrophic Lateral Sclerosis (ALS) as well as a Permobil power wheelchair. The purpose of this study is to look at the use of the VSC device with patients with ALS. There is no current research with the VSC with persons with ALS. In this study, we will ask participants to allow their power wheelchair to be fitted with a VSC device to see if it increases power feature use and thereby decreasing pain/pressure injuries and increasing quality of life. A free APP will be added to your Smart phone to assist with the VSC use. You will be one of approximately 20 people involved in this research project at CHS, and your participation will last for up to 36 months (study completion) or until the device no longer is functional for you.

HOW THE STUDY WORKS

After signing the consent, at the screening or baseline visit, we will attach the device under the seat of your power wheelchair and loading the free APP on your Smart phone. We will fully educate you and caregivers on use of the device, set up a home program for use, and have you complete a questionnaire.

For the first month, after the VSC is applied to your power wheelchair and programmed, the VSC will simply record how you use the power wheelchair and the power features. After the first month, the VSC will give alerts via your smart phone to move the power wheelchair seat in prescribed ways for pressure relief, set up by the occupational or physical (OT/PT), for a certain length of time and a certain number of times a day. This seat movement will allow you to change how you sit to a pressure relieving position for a certain length of time. The seat position and power wheelchair will always be under your control, and the VSC does not take over in any way, but simply alerts and tracks seat position. You will be able to ignore the alerts if needed, and the therapist will be willing to assist to make changes as needed at any time.

You will be called, emailed via secure email, or seen in clinic every month for follow up on how use of the VSC is going and any changes which are required to the VSC or the power wheelchair. You, or a caregiver with your assistance, will complete a questionnaire at screening andevery 3 months and identify any items on the VSC or power wheelchair which need to be changed.

Screening Visit and Informed Consent

The screening visit will take approximately 10 minutes.

During this visit, we will discuss the study and requirements. If you don't qualify, the study research staff will tell you why. During this visit, the following will be performed:

- Written consent will be obtained before any study procedures are conducted.
- Completion of questionnaire

, The VSC may be attached to your power wheelchair at the screening visit or may be attached at the baseline visit.

Baseline Visit (DAY 0).
The baseline visit will last approximately 1 hour, and may be at the same clinic visit as the screening or over the phone/by email/private visit.

During this visit, the following will be performed:

- The VSC will be applied to the power wheelchair and programmed (if it was not applied at the screening)
- The free APP will be added to your Smart phone
- You will log onto the APP for the first time
- The researcher will educate you on how the VSC works.

The VSC will be turned on immediately, and will simply record how you use the power wheelchair and power features. You will receive an alert every 6 hours (which can be ignored) until the follow up phone call/email at month one.

Follow-Up Visit (month 1, remotely or clinic/private visit):
The month 1 follow-up visit should last approximately 10 minutes.

During this visit, the following will be performed:

- The VSC alerts will be changed to alert on the smart phone more frequently and to the pre-set angles.
- Participants will receive further instruction and education from an occupational or physical therapist as needed.
- Any problems or issues with the power wheelchair or device will be addressed. A plan for making changes will be implemented.

Follow-Up Visits (month 2, 4, 5, 7, 8, 10, 11, 13, 14, 16, 17, 19, 20, 22, 23, 25, 26, 28, 29, 31, 32, 34, 35 remotely or clinic/ private visit).
The month 2 follow-up visit should last approximately 10-30 minutes.

During this visit, the following will be performed:

- Participants will receive further instruction and device adjustment from an occupational or physical therapist as needed.
- The progress with the device will be assessed by the OT/PT and they may make changes if necessary.

- Any problems or issues with the power wheelchair or device will be addressed. A plan for making changes will be implemented.

Follow-Up Visits (Month 3, 6, 9, 12, 15, 18, 21, 24, 27, 30, 33, 36 at ALS clinic or by private visit/phone/email if unable to attend).
The month 3 follow-up visit should last approximately 10-30 minutes.

During this visit, the following will be performed:

- Participants will receive further instruction and device adjustment from an occupational or physical therapist, manufacturer or vendor as needed.
- The progress with the device will be assessed by the OT/PT, manufacturer or vendor and they may make changes if necessary.
- Any problems or issues with the power wheelchair or device will be addressed. A plan for making changes will be implemented, and any changes which can be addressed immediately, will be.
- Complete questionnaire

You will continue with the same follow-up every month until the device or wheelchair becomes useless to you due to weakness, progression of the disease, lack of desire to use the power wheelchair, or study completion

The VSC will be returned to the ALS clinic whenever you complete the study or withdraw.

RISKS
The study has several risks.

The known possible side effects from the device are:
1. Annoyance or irritation from the alerts
2. Fear of the position the device requests you get in

There may also be risks with use of the device in ALS that we do not yet know.

Questions about your power wheelchair use and your quality of life
You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

Other Risks
Reviewing health related information might be stressful or make you feel uncomfortable. You do not have to answer any questions you do not want to, and you may discontinue the interview at any time if it is too uncomfortable. Withdrawing from the research study will not affect your care now or in the future.

INCLUSION CRITERIA

- Diagnosis of ALS
- Current clinic client at The Carolinas Neuromuscular ALS/MDA Center's multidisciplinary ALS clinic
- Currently using a Permobil power wheelchair with power seating with R-Net electronics that accepts the VSC
- Has a Permobil Corpus 3G (6months old or newer) or who order a new Permobil power wheelchair
- New Permobil chairs which are not obtained through this clinic will also be able to enter the study, such as chairs from other regions or from the Veteran's Administration.

EXCLUSION CRITERIA

- Another diagnosis besides ALS
- Does not have a Smart phone
- Frontotemporal Dementia as noted by a doctor/speech pathologist/social worker in medical records
- Inability/unwillingness to control power wheelchair power features (client)
- Unwillingness to be monitored by study staff and alerted by VSC over time
- Uses other mobility devices indoors (scooter, basic power wheelchair) more than or in addition to Permobil PWC
- Further exclusions may be added in future protocol versions

BENEFITS

This study may or may not improve your condition or pain. The information gained from your case may benefit others with your condition. We expect that more frequent pressure relief and repositioning will assist clients with ALS with decreasing pain and pressure injuries.

ALTERNATIVE PROCEDURE/TREATMENT

The alternative to participation in the study is standard occupational/physical therapy treatment, current power wheelchair use and services as part of the ALS clinic.

ADDITIONAL COST

The VSC, fitting, training, adjustments and labor will be covered by Permobil and the ALS center. All OT/PT visits in the clinic related to the study will be standard of care and will be billed to your insurance if appropriate.

If you would like to have a VSC without being in the study, the OT will assist with that process, although they are generally not covered by insurance.

COMPENSATION

Transportation, time and effort will not be compensated. There is no reimbursement for expenses. The device will belong to the Neurosciences Institute Neurology-Charlotte at the end of its usefulness to you or at the end of the study.

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. This treatment, as well as other medical expenses, will be billed to you or your insurance company in the usual manner.

WITHDRAWAL

Your participation in this study is completely voluntary. You should feel under no pressure to be in the study. If you decide not to be in the study, it will not in any way harm your relations with your doctors, therapists or with Carolinas HealthCare System. You are free to stop being in the study if you change your mind after entering it. This would not harm your relations with your doctors, therapists or Carolinas HealthCare System.

The subject may be withdrawn from the study if they miss 2 clinic visits in a row or refuse contact via phone or email 2 times in a row.

We will tell you about new medical findings that may affect your willingness to continue in the study.

CONFIDENTIALITY:

The records of this study will be kept private. In any sort of report we might publish, we will not include any information that will make it possible to identify a patient. Your record for this study may, however, be reviewed and/or photocopied Permobil, by Carolinas HealthCare System, or by representatives of the Food and Drug Administration or other government agencies. To that extent, confidentiality is not absolute**.**

AUTHORIZATION:

If you wish to take part in this clinical study, you will be asked to sign this consent form. It allows the study investigator to collect, process and pass on to the sponsor organizations any relevant personal health information collected from you during the study. These are activities routinely carried out during all clinical studies.

You have been told that personal information about you (including sensitive personal health information, such as your medical history and your racial/ethnic origin if relevant to the study) will be reviewed, collected on a computer database, stored in electronic or manual files, audited, and/or otherwise processed by:

- the clinical study investigator, and research staff,
- the study sponsor and/or its associated companies,
- regulatory or other governmental authorities of the United States and other countries,
- other persons authorized by the study sponsor,
- Carolinas HealthCare System employees,
- other persons or agencies as required by law or allowed by federal regulations.

You have been told that your personal data are being collected and processed to:

- check your suitability to take part in the study,
- monitor your use of the VSC and power wheelchair,
- compare and pool treatment results with those of other subjects in clinical studies,
- support the marketing, distribution, sale and use of the VSC anywhere in the world.

You have been told that your personal information may be processed within the U.S. or elsewhere in the world or transferred to or from the U.S. for review, processing and/or storage by an associated company or a carefully selected third-party organization. By signing this document, you explicitly consent to the transfer of your personal information, including sensitive personal information, collected during this clinical study, for review, processing and/or storage. Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the Privacy Rule. However, the groups are committed to keeping your personal health confidential.

You may refuse this authorization to transfer your personal information. If you choose not to agree to this authorization, you might be ineligible to participate in the study. If you decide not to sign this authorization, that will not harm your relations with your doctors, therapists or with Carolinas HealthCare System.

You have the right to inspect your medical record at any time. Your research record may be unavailable until the conclusion of the study. At that point, it will be available. Please speak with the study therapist if you desire to access your record.

You have been told whenever your personal information is processed; it will be kept confidential and secure, to the best of our ability. It will be used only for the purpose for which it was collected.

This Authorization does not have an expiration date. You have been told that according to the guidelines for good clinical practice, the study investigator and sponsor will keep your personal information for at least 6 years. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely. If you wish to revoke authorization to use your personal information, you will notify the study therapist Amber Ward, [redacted] in writing. Some of the data obtained from your record prior to your revocation may still be used if considered necessary for the study.

FINANCIAL INTEREST OF INVESTIGATOR

None of the researchers asking you to participate in this study have received or will receive money or other benefits for personal use from the study sponsor. However, the sponsor will give money or other benefits to a research fund, foundation, educational institution, or other organization with which the study staff is associated.

QUESTIONS

The researcher doing the study at Carolinas HealthCare System is Amber Ward, Occupational Therapist. You may ask her any questions you have now. If you have questions later, you may contact Amber Ward, OT at:

Neurosciences Institute Neurology Charlotte- Attn: Amber Ward

[redacted]

The Institutional Review Board is a group of people who review the research to protect your rights. If you have questions about the conduct of this study or about your rights as a research subject, you may call the chairperson of the Institutional Review Board of Carolinas HealthCare System for information regarding patients' rights in a research study. You can obtain the name and number of this person by calling [redacted]

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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 [representative] Print Name	Date	Time
Patient [representative] Signature	Date	Time
Signature of Person Obtaining Consent	Date	Time
Investigator Signature	Date	Time

Identity of representative:
___Next of Kin
___Parent/Guardian
___Healthcare Power of Attorney