Clinical Evaluation of Pneumatic Technology for Powered Mobility Devices

NCT03898362

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Subject Name:_____Last 4 SSN:_____Date: _____

Title of Study: Clinical Evaluation of Pneumatic Technology for Power Mobility Devices: Aim 2A

Principal Investigator: Brad Dicianno, MD_____VAMC: Pittsburgh (646)

LAY TITLE: **Evaluating Air Powered Wheelchairs and Scooters**

KEY ELEMENTS: This is a research study to find out whether wheelchairs or scooters that are powered by air are better than those that are powered by batteries. We also want to understand whether it will be easy for people to use these devices in long-term care facilities. Your participation in this study is voluntary.

If you enroll in this study, we will provide a wheelchair or scooter that is similar to the one you already have or will be getting from the VA. We will also provide a similar one that is powered by air instead of batteries. You will use one of the devices that we give you in everyday life for 6 months and then switch over to using the other one for 6 months. We will also ask you to complete questionnaires during the study.

There are minimal risks to this study that are described in this document. Some risks include: breach of confidentiality of your information, falls or injuries when using either device.

If you do not participate in this study, battery powered wheelchairs and scooters are still an option for those needing devices for mobility.

If you are interested in learning more about this study, please continue reading below.

STUDY CONTACT INFORMATION:
If you have a general question about this research study, or if you have any concerns or complaints related to this research study, you may call any of the investigators listed below.

If you experience any illness, injury or other medical problem that you feel may be related to this study, please call Dr. Brad Dicianno at (412) 822-3700 during the day. In the case of a medical emergency contact your local emergency medical service or go to your local emergency room.

PRINCIPAL INVESTIGATOR (S):
Brad E. Dicianno, MD

CO-INVESTIGATOR(S):
Rory A. Cooper, PhD

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STUDY SPONSOR:
The sponsor of this study is the VA Rehabilitation Research and Development Service. Additional information regarding the study sponsor can be provided upon request.

PURPOSE OF THE RESEARCH STUDY: The purpose of this research study is to determine if air powered wheelchairs and scooters can benefit Veterans and others living in long-term care facilities.

Potential Conflict of Interest Disclosure: One of the investigators on this study is listed as the inventor of and has licensed the technology being used in this study. A management plan has been put in place to maintain the integrity of this research.

You are being asked to participate in this research study because you live in a in a long-term Veteran care facility. We will enroll up to 50 participants in this study.

You are being asked to participate in this research study because you:

- are 18 years of age or older
- weigh no more than 250 pounds
- either own or are in the process of receiving a scooter or Group 2 power wheelchair without power seat functions
- live in either the HJ Heinz III Progressive Care Center or the Southwest Veterans Center
- you understand and speak English

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 Website at any time.

DESCRIPTION OF THE RESEARCH STUDY:
This study will last approximately 1 year. The study will involve driving a standard wheelchair or scooter for 6 months, driving an air powered wheelchair or scooter for 6 months, and completing questionnaires at the beginning of the study and about every three months. These questionnaires will collect general information about you, such as gender, age, race, education, and health information such as diagnosis, history of surgeries and pressure ulcers. We will also collect information on your current device, like the manufacturer, its age and how you use it as well as your feelings about and satisfaction with the device.

The surveys will take about 20 minutes to complete and will be completed in person during the initial study visit. Follow up surveys will take approximately 15 minutes and can be completed either in person or over the telephone.

You will be asked to complete a driving course consisting of typical driving tasks like driving forward, turning corners and avoiding obstacles. Information about your driving will be recorded by using sensors attached to the wheelchair or scooters, and you will also participate in driving evaluations in which sensors or motion capture cameras record how your device moves around while you drive.

This study will be carried out at the residential facility where you live. Investigators will provide training on the operation of the air powered device. At the end of the study, you will not be able to keep the devices that you used during the study.

RISKS AND BENEFITS:
There are minor risks associated with participation in this research study. There is a risk of fatigue from participating in surveys or interviews, but they will be kept as brief as possible, and you will be allowed to discontinue at any time, and resume at a later time. There is a risk of fall or injury while driving in the devices or transferring into or out of them. However, the risk of using an air powered device is similar to using a battery powered wheelchair or scooter, and you will be provided with any needed training to use it. There is a risk of running out of air you use an air powered device outside the facility for long distances. However, air tanks will be refilled prior to outings and the air tanks support driving ranges typical for most older adults and long term residents. Backup air tanks will be available and can quickly be used to refill or replace empty tanks. Because there may be other risks associated with participating in multiple research studies, you must tell the research staff about any other studies you are currently participating in, both within and outside of the VA.

You will not directly benefit from participating in this study. You may experience better mobility when using an air-powered device, but this is not guaranteed. You may receive indirect benefit given that you are contributing to medical science or helping to develop mobility devices for Veterans and others who need them.

ALTERNATIVES TO PARTICIPATION:
There may be other studies that you qualify for. Talk to your provider about such options.
You also have the alternative not to participate in this research study. Battery-powered wheelchairs and scooters can be used instead of air powered ones.

NEW FINDINGS: You will be informed of any significant new findings during the course of the study, which may affect your willingness to continue to participate. The final results will not be provided to you at the end of the study, but results of our research are published in scientific journals, updated on the clincialstrials.gov website and may be released on our website at www.herl.pitt.edu.

INVESTIGATOR INITIATED WITHDRAWAL: The investigator(s) may stop your participation in this study without your consent for reasons such as: it will be in your best interest; you do not follow the study plan; or you experience a study-related injury. For example, you may be removed from the study if you do not complete the questionnaires or participate in testing.

VOLUNTARY PARTICIPATION/RIGHT TO WITHDRAW: Your participation in this study is voluntary. You do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled. If you choose to withdraw from the study, simply notify the investigators. You will not be required to complete additional surveys but may opt to do so even if you are not using the air powered devices. If you withdraw from the study, you must return any study wheelchairs or scooters to the investigators.

MEDICAL TREATMENT: In the event that you sustain injury or illness as a result of your participation in this VA approved research study, conducted under the supervision of one or more VA employees, all medical treatment (emergent as well as medical treatment beyond necessary emergent care) will be provided by the VA. Except in limited circumstances, the necessary medical care must be provided in VA medical facilities. However, if such injury or illness occurred as a result of your failure to follow the instructions for this study, you may not be eligible for free care unless you have independent eligibility for such care under Federal Law.

FINANCIAL COMPENSATION: If you sustain an injury or illness as a result of participating in this research study, you may be eligible to receive monetary compensation for your damages pursuant to applicable Federal law. If you believe that you are injured as a result of participation in this study, please contact the Principal Investigator. If compensation is available the Principal Investigator will provide you with an explanation as to what that compensation consists of, or where you can obtain further information regarding it.

COST AND PAYMENTS: You or your insurance will not be charged for any costs related to the research. However, if you are receiving medical care and services from the VA that are not part of this study, and you are a veteran described in federal regulations as a "category 7" veteran, you may be required to make co-payments for the care and services that are not required as part of this research study. You will receive up to $150 for participation in the study. You will receive $50 for completing all testing requirements associated with the first device (6 months) and an additional $100 for completing all testing requirements associated with the second device (12 months). If you leave the study before 6 months you will receive $25. Except in limited circumstances, payments issued through VA are generated by Electronic Funds Transfer (EFT). Therefore, in order to receive payment associated with your participation in this study, you must be willing to receive EFT and to provide banking information to VA, if that information has not already been provided. If you are not able to receive payment through EFT, the Direct Express Debit MasterCard may be issued. The Direct Express Debit MasterCard is a prepaid debit card. Please refer to the flyer that study personnel has provided for more information about which services may require a fee if using your Direct Express Debit MasterCard. In addition, due to limitations in the Financial Management System, payments made to you will generate Internal Revenue Service (IRS) Form 1099 regardless of amount. Payments will be reported to the IRS as income and your social security number will be used for this purpose.

RECORD RETENTION: Your research records will be retained in accordance with the Veterans Health Administration (VHA) Records Control Schedule, or longer, if required by other Federal regulations.

CONFIDENTIALITY AND USE AND DISCLOSURE OF DATA: There are rules to protect your private health information. Federal and State laws and the Federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization', for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including:

Demographic Information such as name, age, race, date of birth

Questionnaire, Survey, and/or Subject Diary

Other (please describe): datalogger driving data (e.x. driving time, average speed, distance traveled)

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the:

Non-VA Institutional Review Board (IRB) who will monitor the study: Institutional Review Board of the Pennsylvania Department of Health

While this study is being conducted, you will not have access to your research related health records. This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

In addition, Institutional Review Board, Food and Drug Administration, Office (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability (GAO) may have access to your research records. Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient. Additionally, any medical information may be shared with your healthcare provider(s) with your consent, and possibly without your consent if permissible under Federal laws and regulations.

Finally, you consent to the publication of the study results or release of the data when published, so long as the information about you is anonymous and/or disguised so that your identity will not be disclosed

Confidentiality risks and precautions to decrease risk:
Every effort will be made to make sure that the information about you obtained from this study will be kept strictly confidential. As private information is collected about you as part of this study, there is a risk to your privacy and confidentiality. The research staff will take every precaution to protect your identity and the confidentiality of the information collected about you. Any electronic data will be stored in a study specific folder on the VAPHS network and hard/paper copies of the information collected about you will be stored in a locked file room. Only those individuals who are authorized to review your information will have access to it. Clinical Coordinators at HERL may periodically audit this study to insure its proper conduct.

Future Use
Your data as generated by this research study will not, even if identifiers are removed, be used or distributed for future research studies.

Revocation: You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Principal Investigator at the address below. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

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Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

RESEARCH SUBJECTS' RIGHTS: You have read or have had read to you all of the above. Dr. Dicianno or his authorized representative has explained the study to you and answered all of your questions. The risks, discomforts, and possible benefits of this research study, as well as alternative treatment choices, have been explained to you.

A description of the study has been provided to you, including an explanation of what this study is about, why it is being done, and the procedures involved. You have the right to ask questions related to this study or your participation in this study at any time. You should be giving your consent only under conditions in which you (or the person representing you) have sufficient opportunity to carefully consider whether or not to participate in this study. Your consent should not be given under conditions that pressure you or try to influence your decision in any way.

Your rights as a research subject have been explained to you, and you voluntarily consent to participate in this research study. You will receive a copy of this signed consent form.

If you have any questions about your rights as a participant in this study or wish to speak more about the

study with someone not associated with the research study, you can call the Associate Chief of Staff for Research and Development at (412) 360-2394. As long as the study is renewed as required by the IRB your signature on this document is valid for the duration of the entire research study. Should any changes occur during the course of the study that may affect your willingness to participate, you will be notified.

By signing this form, you agree to participate in this research study.

_____	_____	_____
Subject's Signature	Subject (Print)	Date

Investigator/Person Obtaining Consent* Researcher (Print) Date

**If person other than the Investigator is obtaining consent, he/she must be approved by the IRB to administer informed consent.*

Version Date Jan 8, 2024