Refinement of the Comprehensive Mobile Assessment of Pressure (CMAP) System for Prevention of Pressure Injuries

NCT04309864

March 19, 2024

Participant Name: _____ Date:_____

Title of Study: CMAP Phase 3: Refinement of the Comprehensive Mobile Assessment of Pressure System

Principal Investigator: **NAME** VA Facility: Minneapolis VA Health Care System

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by the Department of Veteran Affairs. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The purpose of this research is to assess and refine our CMAP system (Comprehensive Mobile Assessment of Pressure) with Veterans who have a spinal cord injury (SCI). We want to ensure wheelchair users learn and maintain healthy pressure distribution behaviors to prevent pressure injuries. The entire research study is expected to last approximately 1 year, your participation will last approximately 1 month.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

There are no direct/personal benefits to you from your taking part in this research study. However, the information we get from this study might help others with your condition(s).

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You may not want to participate if you are unfamiliar with smartphones or unwilling to try new technology. For a complete description of risks and alternate treatment/procedures, refer to the Detailed Information section of this consent.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is **NAME** at the Minneapolis VA Medical Center. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, the mailing address is 1 Veterans Drive (151), Minneapolis MN 55417, and phone number is **PHONE**.

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DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

By conducting this research project, we hope to learn about how this mobile assessment system can be used by Veterans and their therapists to help individualize education about preventing pressure injuries to meet your lifestyle.

HOW LONG WILL I BE IN THE STUDY?

It is expected that your participation will last approximately 1 month, and the study is expected to last about 1 year. We expect that up to 17 Veterans will participate in this phase of the study at the Minneapolis VA, no other VA sites are taking part in this study.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

Shifting your weight regularly can prevent the chance of getting a pressure injury on your seated area. This study will allow for you to work closely with the SCI physical or occupational therapist seating specialist to test the pressure mapping system which consists of a pressure mat and smartphone application (app). You will be sitting on the pressure mat for about 21 days of in-seat testing period and interacting with the phone app. The pressure mat will detect seated pressures, changes in those pressures as you move around in your seat and give you notifications to shift your weight in your wheelchair throughout the day. The notifications will be based on your arrangement with the therapist.

During the study you will be interacting with **NAME** who is leading the study, as well as a physical therapist or occupational therapist, and a study coordinator.

Timeline of events:

- We will arrange a time for you to come to the VA SCI clinic to meet with the research team and a therapist for about 2 hours. First, we will go over the consent materials for the study, and then you will work with study staff to learn about the pressure mapping system. We will send the system home with you. You will also complete several short surveys. You won't have to answer any questions that you don't want to answer.
- For 3 weeks you will sit on the mat system in your wheelchair. For some days you will be monitoring information about your seating pressure on your phone. Other days you won't see information on your phone but it will be monitoring your seating movements.
- A research team member will call you most weekdays to check in on how the system is working. These calls will usually take less than 10 minutes.
- If you are having any skin problems in your seating area you will report these to the study team immediately.
- After 2 weeks you will meet over VA Video Connect (or other secure virtual method) with the therapist to talk about your seating movement and pressure relief.

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- After about 3 weeks on the system the study staff will meet with you by video to hear about your experiences and to get your feedback. This video interview will take about 30 minutes and it will be recorded so we don't miss any of your comments. You will also complete the same surveys. You will then ship the system back to us in a provided box.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

If you take part in this research, you will be responsible for:

- Learning to use the pressure mapping system with the study staff.
- Asking questions as you think of them.
- Working with the seating specialist therapist to learn seating behavior using the study mapping system.
- Using the pressure mapping system for the agreed upon time (about 21 days) whenever you are in your wheelchair.
- Filling out survey forms as instructed.
- Providing informal feedback about the mapping system to the study team.
- Keeping your study appointments, virtual or in person. If you must miss or change an agreed upon appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment.
- Returning the mapping system to the study team at the end of your participation in the provided box. It is not yours to keep.

While participating in this research study, do not take part in any other research project without approval from the investigators. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

Transfers

One potential risk could be the possibility of falling during a transfer in and out of your wheelchair. This risk is no greater than falling from transfers in your daily life. Any transfers done in the clinic will be done under the care and observation of qualified study staff.

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Skin Integrity
It is possible that impaired skin integrity could occur due to the addition of pressure mat material between you and your seat cushion. The pressure mat materials could lead to increased heat and/or moisture, which are contributing factors to some pressure injuries. A fold in the material could also occur, creating increased pressure, which could also lead to a pressure injury. Based on preliminary studies that assessed the effect of the mat on skin, the risk of developing a pressure injury due to use of the mat on your wheelchair cushion is minimal. We will remind you to do daily visual skin checks to identify possible any skin problems as early as possible. If you found a skin issue, you would follow up with your primary care team and stop using the pressure mat until your providers decide that you could continue sitting on the pressure map.

Personal Identifiable Information
We may record audio of participants during the study for data analysis by the study team. De-identified audio may be used in publications and presentations. Other de-identified data may be shared with study collaborators (University of Texas, Galveston and University of Minnesota). There is a risk that your identity will be disclosed by being recognized in these publications and presentations or by the study collaborators. To protect against your information being exposed, we keep all of the information we collect about you secure using the VA standards for security of data.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There are no direct/personal benefits to you from your taking part in this research study. However, the information we get from this study might help others with spinal cord injury or those that are at higher risk for pressure injuries.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

Alternatives to treatment would be your normal standard of care for pressure injury relief and monitoring.

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HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Any information obtained about you in this study will be treated as confidential and will be safeguarded in accordance with the Privacy Act of 1974. Information published or presented about the results of the study will be in a form that does not identify any particular participant. By joining this study, you give the investigators your permission for them to collect data from your medical records to determine if you are eligible and if you remain eligible to participate in the study.

Participation in this study will involve a loss of privacy, but information about you will be handled as confidentially as possible. Your research records will be labeled with a coded number. Data collected from the pressure maps and surveys obtained in this study will be stored as de-identified data. That means it will be stored with a coded number and not have your name or any other information linking it to you in the data file.

The list that matches your name with the coded number will be kept in locked files and/or electronic secure study data folders. The research records will be kept in a secured file that only the study team has access to. Your information will be combined with information from other people taking part in the study. We will write about the combined information we have gathered. Any presentations or publications from this information will not identify you.

When your information is given to other researchers working with this study, your information will be labeled with a unique code. Only **NAME**, the study coordinator and IRB-approved study staff will be able to identify you. The paper research records will be kept in a locked filing cabinet in a locked office. The electronic research records will be kept on a password-protected computer in a secure study folder.

Records will be kept according to the current VA policies. Protections will be put in place to be sure that this information is kept confidential.

In order to comply with federal regulations, records identifying you may be reviewed by the authorized representatives of the Institutional Review Board of the VA, including the Office of Research Oversight (ORO), Federal Agencies such as the Government Accounting Office (GAO), VA Office of Inspector General (OIG), and the Office for Human Research Protections (OHRP) or other federal regulatory officials responsible for oversight of human subject protection. By signing this document, you consent to such inspection.

Your information collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private information. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form, you provide your

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permission called your 'authorization,' for the use and disclosure of information protected by the 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. The study team may also collect other information including your name, address, date of birth, and information from your medical records such as your phone number, injury level and information needed for payments such as bank routing, account number and SSN.

The research team may also need to disclose the information to others as part of the study progress. Others may include the following: Food and Drug Administration, Office (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), the Government Accountability Office (GAO; Sponsors; Contractors, Affiliates as appropriate) or any other entity required to oversee research, as well as the VA Institutional Review Board, and the local VA medical facility Human Research Protections Program.

We will be sharing certified de-identified data with Co-Investigators from the University of Minnesota and the University of Texas, Galveston.

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.
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.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility, or you can ask a member of the research team to give you a form to revoke the authorization. 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.

If you revoke this authorization, **NAME** and their research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

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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.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

WILL THERE BE PAYMENT FOR MY PARTICIPATION?

If you agree to take part in this research study, we will pay you a total of $100 by electronic funds transfer (EFT) for your time and effort upon completion of participation. Your SSN will be required for this method of payment. The first $50 will be given after consent and initial training on the app, if you continue, the second $50 will be given at the completion of participation. Compensation for participation in research is considered taxable income. We will also provide a $25 stipend to cover the costs of your transportation for the visit to the Minneapolis VA at the start of the study.

If you receive $600 or more in any one calendar year, the VA is required to report this information to the Internal Revenue Service (IRS). FORM 1099 (Miscellaneous Income) will be issued to you and a copy will be sent to the IRS.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

You do not give up any legal rights or release the VA from any liability by signing this form. If you are injured from this research study, treatment will be available, including first aid, emergency treatment and follow-up care, as needed, by the VA Medical Center. In the event you cannot reach a VA facility, the VA will pay for necessary medical care for any injury or illness directly related to your participation in this research study.

If you should have a medical concern or get hurt or sick resulting from participation in this study, please immediately report this to **NAME** at PHONE during the day and by calling PHONE during nights or weekends and ask for the PM&R resident on call. Also call those numbers if you

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should have a medical concern or get hurt or sick because of taking part in this study. If you do not live in the metropolitan area, you may call the toll-free number: PHONE.

DO I HAVE TO TAKE PART IN THE STUDY?

Your participation is voluntary, any refusal to take part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you are a VA employee or student, any refusal to take part in the study will in no way influence your employment, ratings, subsequent recommendations, or academic progress as applicable.
You may discontinue taking part in this study at any time without any penalty or loss of benefits. You can withdraw and still receive the same standard of care that you would have otherwise received.
For data already collected prior to your withdrawal, the investigator may continue to review the data already collected for the study but cannot collect further information, except from public records, such as survival data.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

Certain circumstances may arise where termination for all or part of your participation would be necessary, this could include extreme health events such as a new or developing pressure injury or any other condition that we have deemed unsafe to have you participate in this study. **NAME** will discuss with you the options and guide you through an orderly termination process if withdrawal is warranted.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the local IRB office at (612) 629-7387. This is the Board that is responsible for overseeing the safety of human participants in this study. You may call our local IRB if you have questions, complaints, or concerns about the study or if you would like to obtain information or offer input. You may contact the Patient Representative at (612) 725-2106 at any time if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

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Sometimes during the course of a research study, new information becomes available about the pressure mapping system that is being studied that might change a person's decision to stay in the study. If this happens, **NAME** will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw from the study, **NAME** will arrange for your medical care to continue. If you decide to continue in the study, you might be asked to sign an updated informed consent form. **NAME** could also decide it to be in your best interests to withdraw you from the study. If so, they will explain the reasons and arrange for your usual medical care to continue.

You will not receive relevant research results during the course of the study.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

_____has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.
By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

`I agree to participate in this research study as has been explained in this form.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

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