Study title: Sub-Ischial Socket for Transfemoral Amputation and Lower Mobility

NCT number: NCT05662982

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Participant Name: _____ Date:_____

Title of Study: Evaluation of the Northwestern University Sub-Ischial Socket for Persons with Transfemoral Amputation and Lower Mobility Levels

Principal Investigator: Dr. Sara Koehler-McNicholas 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 Defense. 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?

By doing this study, we hope to learn whether a new prosthetic socket design, which is supposed to be more comfortable than current prosthetic socket designs, will help you wear the socket more and therefore walk more. Your participation in this research will last about 10-11 months and involves 7 in person-visits and 11 remote survey assessments.

You will be asked to first, allow us to monitor you for 3 months in your current socket. Then we will make you a new prosthetic socket and we will monitor you for 6 months in your new socket. Monitoring involves wearing a small temperature sensor inside the socket that allows us to measure how much the socket is being worn, wearing a small step counter attached to your prosthesis to measure how much you walk, and completing 10 surveys every 4 weeks that allow us to understand how the socket influences your everyday life.

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

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include receiving a new prosthetic socket that may be more comfortable and may help you walk more. For a complete description of benefits, refer to the Detailed Information section of this informed consent form.

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

Being in this study will expose you to many of the same risks as you are regularly exposed to as an above-the-knee prosthesis user. There is the risk that being asked questions about your everyday life (e.g., depression or mental well-being) may be upsetting. There is also the risk that despite our best-efforts, confidentiality may be compromised. For a complete description of risks, refer to the Detailed 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.

Your alternative to participating in this research study is to not participate.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?
The person in charge of the study is Dr. Sara Koehler-McNicholas at the Minneapolis VA Health Care System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: 612-467-4017.

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?
The purpose of this research is to determine whether a new prosthetic socket design, which is supposed to be more comfortable than current prosthetic socket designs, will help you wear the socket more and therefore walk more.

HOW LONG WILL I BE IN THE STUDY?
This is a multi-site study being conducted at the Hanger Clinic and the Minneapolis VA Health Care System (MVAHCS). Up to 115 participants are expected to be enrolled in this study over the course of approximately 3 years. There may be up to 25 participants enrolled at Minneapolis VA Health Care System.

Your participation in this research will last about 10-11 months and involves a minimum of 7 in person-visits and 11 remote survey assessments. There may be additional in person-visits to adjust socket fit. You will be asked to first, allow us to monitor you for 3 months in your current socket. Then we will make you a new prosthetic socket and we will monitor you for 6 months in your new socket. Monitoring involves wearing a small temperature sensor inside the socket that allows us to measure how much the socket is being worn, wearing a small step counter attached to your prosthesis to measure how much you walk, and completing 10 surveys every 4 weeks that allow us to understand how the socket influences your everyday life.

Participant Name: _____ Date:_____

Title of Study: Evaluation of the Northwestern University Sub-Ischial Socket for Persons with Transfemoral Amputation and Lower Mobility Levels

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WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

Summary of the study sessions:

	Study Session	When	Location	Study Activity	Duration	Payment for completed session
Baseline monitoring period	Session 1	Week 0	Minneapolis VA (in-person)	Answer questions about amputation, current socket, and prothesis; perform physical tasks; sensors/activity monitor attached; 1 survey	2 hours	$60: in-person visit $40: survey
	Sessions 2 - 4	Weeks 4, 8 & 12	Home or place convenient for you	1 survey/session; replace & return sensors	30 minutes/ session	$40/session
Socket fabrication		Up to 4 visits	Minneapolis VA (in-person)	Casting and fitting socket	1-2 hours/visit	$60/visit
Intervention monitoring period	Session 5	Week 0	Minneapolis VA (in-person)	Receive new socket; perform physical tasks; sensors/activity monitor attached; 1 survey	1-2 hours	$60: in-person visit $40: survey
	Sessions 6 - 9	Weeks 4, 8, 12, & 16	Home or place convenient for you	1 survey/session; replace & return sensors	30 minutes/ session	$40/session
	Session 10	Week 20	Minneapolis VA (in-person)	Assess new socket fit; perform physical tasks; sensors/activity monitor attached; 1 survey	1-2 hours	$60: in-person visit $40: survey
	Session 11	Week 24	Home or place convenient for you	1 survey/session; replace & return sensors	30 minutes	$40: survey $50: bonus

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As shown in the diagram above, the study involves 3 phases:

1) A 3-month (12 week) baseline period during which we will monitor you every 4 weeks (4 measurement time points) in your current socket.
2) After the baseline period, you will see a research prosthetist so that he/she can cast, fabricate, and fit you with the new prosthetic socket. We estimate that it will take up to 4 visits of approximately 2 hours for the research prosthetist to cast and fit the new socket.
3) Once you have been fit with the new prosthetic socket and begin wearing it every day, we will monitor you for 6 months (27-week intervention period, 7 measurement time points).

The new prosthetic socket design is called the Northwestern University Sub-Ischial Suction Socket (NU-FlexSIS). It is different from current ischial containment socket designs because it is made to fit over the thigh but without touching your pelvis. The new socket is worn over a gel liner and will be attached to your current prosthetic knee and foot. The process of casting and fitting the socket is the same as you are familiar with from your routine prosthetic care.

Both for the baseline and intervention phases, you will attend an in-person visit with the research prosthetist. These visits will last approximately 2 hours. They will attach a small temperature sensor to the gel liner and a step counter to your prosthesis. These devices will record how much you wear the socket and how much you walk. The temperature sensor and the step counter can record for 4 weeks. To replace the sensors over time, you have the option of going to the research team and letting him/her switch them out, or the research team can show you how to do it yourself at home and we will mail you new sensors to attach along with a pre-paid envelope to mail back the sensors that are full of data.

The study involves a total of 11 measurement time points (every 4 weeks) where we will ask you to complete 10 surveys that allow us to understand how the socket influences your every day life. We expect that it will take about 30 minutes to complete each measurement session. It is your choice whether you wish to complete these surveys online, on paper, or by phone with the assistance of a research assistant. Whichever method you pick, we will send you a reminder the day before that it is time to fill in the surveys.

The 10 surveys include the:
1) Roland-Morris Disability Questionnaire for low-back pain;
2) PROMIS Depression Scale;
3) Self-administered Comorbidities Questionnaire;

4) Socket Comfort Score;
5) Prosthetic Limb Users' Survey of Mobility;
6) Activities-specific Balance Confidence Scale;
7) Community Integration Questionnaire;
8) 36-Item Short Form Health Survey;
9) Dermatology Life Quality Index;
10) OPUS-SwD: Orthotics and Prosthetics Users' Survey Satisfaction with Device.

You can see the research prosthetist as needed over the duration of the study for any adjustments to make sure that the socket fits well or the duration of the study. The process of maintaining socket fit and function is the same as you are familiar with from your routine prosthetic care. At the end of the study, you will attend a final in-person visit with the prosthetist to ensure you are set up with a socket you can wear after the study. This may be the study socket or the socket you had prior to the study. The prosthetist will collect information about your mobility in the socket and remove sensors from your prosthesis. This will take about 1-2 hours.

We will ask you to provide contact information for an alternate contact. We will reach out to this contact if we are unable to reach you after at least 3 attempts. Please inform this contact that you will be giving the study team their contact information and they may receive a call from us if we can not reach you.

We might take pictures of you and your prosthesis to consult with the study team about the fabrication and fit of the socket.

Five months after receiving your new socket, you will attend an in-person visit with the prosthetist to ensure the socket is ok to continue wearing after the study ends. The prosthetist will collect information about your mobility in the socket, similar to the first baseline visit, and attach new sensors and an activity monitor to your socket/prothesis. This visit will take about 1-2 hours.

One month later, you will complete the final survey assessment. You will also use a pre-paid envelope to mail back the sensors and activity monitor. At this point, your participation in this study is complete.

If you like the new sub-ischial socket, you will have the option to keep it at the end of the study and your prosthetist will provide any adjustments needed while you continue wearing it. You and your insurance will not incur any costs for routine socket adjustments needed after the study

ends, but any major repairs or replacement of the socket will incur a cost to you and/or your insurance.

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

If you take part in this research, you will be responsible to participating in all the required measurement sessions and be active in making sure that the socket fits well and that you report any issues to the research prosthetist.

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

This research may hurt you in the following ways:

1) The standard clinical process of making an above-the-knee prosthetic socket involves some loss of modesty and privacy given the intimate fit of the socket with your thigh.
2) It is possible that the new socket may not be comfortable or that it may rub your residual limb and cause redness, blistering, or a sore, just as any new or ill-fitting socket may do. The research prosthetist will work with you to make adjustments to the socket to address these problems.
3) As an above-the-knee amputee you are at a greater risk for stumbling, tripping and falling than people who are not amputees. The risk of stumbling, tripping and falling may be increased when adapting to a new socket.
4) Some survey questions (e.g. about depression, sexual intimacy, or mental well-being, as examples) may be upsetting.
5) If you have not worn a silicone liner before and don't know that you are allergic to silicone, there is the possibility that you may experience itching, brief skin reaction, or an allergic reaction to the silicone liner.
6) It is possible that you may experience fatigue and/or boredom while answering the survey questions
7) It is possible you may experience other issues from transitioning to and wearing a new socket, these include:
    i. low back pain
    ii. residual limb fluid volume loss/shrinkage
    iii. loss of suspension
    iv. muscle cramping, limb discoloration, tingling or numbness from residual limb
    v. constriction/too much compression
    vi. residual limb muscular fatigue
    vii. loosening of prosthetic component

The above issues are usually transient and can be addressed by the prosthetist making adjustments to your socket and/or prosthetic alignment. Some will disappear as you accommodate to wearing and walking in the new socket.

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 research consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: **"How will my private information be protected?".**

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include receiving a new socket that has the potential to be more comfortable and increase your mobility.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution, the US Department of Defense (DOD), the DOD Human Research Protections Office, Food and Drug Administration (FDA) and the Veterans Administration.

With the collection of confidential information, there is always a risk of disclosure. We do not expect this to happen with the measures that will be taken to de-identify the subjects. Full measures will be taken to safeguard your confidentiality. Identifiers might be removed from your identifiable private information and after such removal, your information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent. The study team will use REDCap, an online database to collect and store your information. The information in REDCap will include information that will identify

you, such as your name and contact information. REDCap is a secure system for data storage used in many research studies. REDCap requires a username and password to log-on and is encrypted. REDCap is stored on a secure server. The study team is able to choose who has access to log-on to REDCap and see your information. Access will only be given to Minneapolis VA and University of Washington study team members. The link between your identifying information and study data will be destroyed after the record retention period required by law.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

We will include information about your study participation in your medical record.

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

Taking part in this research study will not lead to any costs to you or your insurance, except if you choose the option to keep the sub-ischial socket after your participation in the study ends, as explained in the preceding 'What Will Happen if I Take Part in the Study' section of this consent form.

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.

Subject Compensation

If you agree to take part in this research study, we will pay you $60 per in-person visit for up to 7 visits and $40 per survey assessment for 11 assessments. We will pay you a bonus of $50 at study completion if you complete all 11 survey assessments. If you complete all study visits you would receive up to $910. Please note that during the course of the research additional visits to the prosthetist may be needed to adjust the socket. If you live 50-150 miles away from the MVAHCS you are eligible for travel reimbursement at a rate of $75 per visit or $150 per visit if you live 150 or more miles away. If you live 150 or more miles away from the MVAHCS, you are also eligible to receive lodging reimbursement at a rate of $150 per night. If you live within 50 miles of the MVAHCS, you will not receive lodging or travel reimbursement.

The Center for Veterans Research and Education (CVRE) will be given your name, address, and Social Security Number in order to issue a check for your study participation. Please allow

three weeks processing time for payments. Study payments are considered taxable income and reportable to the IRS. Research payments to study participants that equal or exceed $600 during any calendar year will result in a FORM 1099 (NEC) being issued to you and a copy 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 should immediately report any injuries resulting from your participation in this study to Dr. Sara Koehler-McNicholas at (612) 467-4017 during the day and during the evenings or week-ends, by calling the VA operator at (612) 725-2000 and ask to have the Physical Medicine/Rehabilitation resident on call paged. Tell the operator you are in a research study. If you do not live in the metropolitan area, you may call the toll-free number: 1-866-414-5058.

DO I HAVE TO TAKE PART IN THE STUDY?
Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION
An investigator may discontinue a participant from the study for the following reasons:

- Significant study intervention non-compliance
- Lost-to-follow up; unable to contact subject
- Any event or medical condition or situation occurs such that continued collection of follow-up study data would not be in the best interest of the participant or might require an additional treatment that would confound the interpretation of the study
- The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation
- If any clinical adverse event (AE), laboratory abnormality, or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the participant
- Disease progression which requires discontinuation of the study intervention

You can leave the research at any time; it will not be held against you.

For female participants, because a pregnancy may affect your ability to wear a prosthetic socket, you will be withdrawn from the study if you become pregnant during the course of this study.

If you decide to leave the research, contact the investigator so that the investigator can organize to get the sensors back from you. Additionally, if you are leaving the research after you have received the new study socket, the investigator will conduct an interview with you so that we can understand if it is a problem with the socket that is contributing to your desire to leave the study.

If you decide to leave the research, you should also contact the research prosthetist so that he/she can reattach your regular socket to your prosthesis if necessary.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

Data obtained in this experiment will become the property of the investigators. If you withdraw from the study, data already collected from you will remain in the study.

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 Minneapolis VA Health Care System IRB office. This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the IRB office at (612) 629-7387 if you have questions, complaints, or concerns about the study or if you would like to obtain information or offer input.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

You will be given any new significant information which is discovered during the course of this study which may influence your willingness to continue the study

WHO COULD PROFIT FROM THE STUDY RESULTS?

We will use the information that we collect for this study only for research purposes, not for profit. Neither you nor your family will gain financially from discoveries made using the data you provide.

FUTURE USE OF DATA

Participant Name: _____ Date:_____

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Principal Investigator: Dr. Sara Koehler-McNicholas VA Facility: Minneapolis VA Health Care System

Data collected for this study will be analyzed and stored at the University of Washington. After the study is completed, the de-identified, archived data will be transmitted to and stored through UW ResearchWorks, for use by other researchers including those outside 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 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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PI/SC Approval Date:

Minneapolis VA Health Care System IRB (Institutional Review Board)
Effective Date: August 1, 2024