

Permission to Take Part in a Human Research Study

Do not sign this consent if today's date is later than the stated expiration date above.

Title of Research Study: Personalized Mobility Interventions using Smart Sensor Resources for Lower-Limb Prosthesis Users

Investigator: Arun Jayaraman, PT. PhD

Supported By: This research is supported by *Department of Defense, Defense Health Program, Congressionally Directed Medical Research Programs Orthotics and Prosthetics Outcomes Research Program.*

Key Information:

The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you have an amputation above or below the knee on one or both sides and you use a prosthesis in your home and community. You will be asked to participate in part or all of this study.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

This study is being done because we want to use cellular phone technology and wearable sensors to monitor the activity, health, and social activities in people with lower limb amputations. Many things affect how well a person can use a prosthesis, e.g., how well the prosthesis fits, how good the person feels, or how many social activities they are involved with.

We want to use sensors that are built into a smartphone and sensors worn on the prosthesis, together with a new app that we have developed, to understand how people use their prostheses in everyday life, and what problems prevent or reduce prosthesis use. The sensors in the phone and those worn by the person will gather data while the person is carrying the phone and going about their daily activities; we can use information from many different sensors to learn about the person's behavior, such as, how often they use their prosthesis and what activities they use it for.

We will also ask participants to perform activities to measure function with their prosthesis, and questionnaires and surveys to learn what the person thinks of their prosthesis and what they would like to be able to do. We will analyze the sensor data and the other testing data to identify areas in which we can help the person do better with their prosthesis – for example, we may find that the prosthesis is uncomfortable after long periods, or that the person feels depressed about their amputation, or that they do not know about any local social activities that they may enjoy. Based on this information

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we will provide interventions or assistance to the study participants who need it. Interventions will not be provided to people who already use their prosthesis well and are satisfied with its performance.

How long will the research last and what will I need to do?

We expect that you will be in this research study for at least 3 months and up to 9 months.

You will be given a cell phone with an unlimited data plan and a sensor will be placed on your most used prosthesis. You will carry the cell phone on your whenever you are out, and the sensor will remain on your prosthesis for 3 months. We may ask you to do specific tasks on this cell phone during this time. You will also be asked to come for a minimum of 2 study visits, one in the beginning and one in the end of 3 months.

If you qualify you will remain in the study for an additional 6 months. During the first 3 months of this time you will receive the assistance you need to help use your device more often or for longer periods of time. After these 3 months you will come into the lab for a day of testing. You will then be sent home with the phone and sensor and data will be collected from these devices for another 3 months. You will then return after this period ends for the same exact testing you've gone through every time. You will return the equipment given to you and the study will be complete.

More detailed information about the study procedures can be found under the section **What happens if I say "Yes, I want to be in this research"?**

Is there any way being in this study could be bad for me?

There are no known risk factors associated with participating in this study. There is no known harm of carrying a cell phone. You may feel some discomfort when asked personal questions, during visits to the hospital.

More detailed information about the risks of this study can be found under **"Is there any way being in this study could be bad for me? (Detailed Risks)"**

Will being in this study help me in any way?

You may not have any direct benefit from taking part in this study. You may be selected to receive an intervention, in which case you may get some benefit; however, not every participant will receive an intervention. Taking part in this study may help researchers to understand whether using smartphone and wearable sensors can provide additional information to help clinicians improve care for people with amputations and enable people to get the most benefit from their prostheses. Improved ability to use a prosthesis may improve the quality of life for individuals with lower limb amputation. In addition, this monitoring system may be helpful for other individuals with disabilities that affect their mobility or social activities.

What happens if I do not want to be in this research?

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.

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

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Detailed Information:

The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team. Arun Jayaraman PT, PhD is the person in charge of this research study. You can call him at 312-238-6875 during normal business hours Monday-Friday. For problems arising evenings or weekends, you may call 352- 246-1166.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu 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.

How many people will be studied?

We expect about 80 people here will be in this research study out of 150 people in the entire study nationally.

What happens if I say “Yes, I want to be in this research”?

As a subject in this study, you will be asked to come to the Shirley Ryan AbilityLab (SRALab), floor 11 Room 1401.

Your participation in this study will last at least three months and up to nine months and will involve several visits to the research lab and/or clinic.

Visit 1: The study will be explained to you. If you are eligible to take part in the study, you will sign a consent form to enroll in the study. You will be provided with a smartphone and a cellular data plan and instructed on how to use an app on the phone that collects sensor data. A wearable sensor will be placed on your primary prosthesis (the one you use for most activities). Trained research staff and clinicians will perform a set of tests and questionnaires with you. This visit will last up to 3 hours.

You will be asked to complete the following tests while you are in the lab:

1. 10 Meter Walk Test: You will be asked to walk for 10 meters while you are timed. You will repeat this 3 times at your normal comfortable pace and 3 times at a fast but safe pace.
2. 6 Minute Walk Test: You will be asked to walk for 6 minutes as fast as you can. You will wear a mask attached to a device that measure how much oxygen you consume with each breath during this time. You are allowed to take rest breaks but the timer will keep running. A clinician and a member of the research team will walk with you.
3. 5-times Sit to Stand: You will be timed as you go from a sitting to standing position and repeat five times with your arms crossed over your chest. You will be timed on how quickly your able to complete this activity.
4. Berg Balance Test: This is a 14-item assessment that measures how well you can balance while performing movements in sitting and standing.

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5. Dynamic Gait Index: You will be tested on your ability to maintain your balance while performing changes in speed, avoiding obstacles, or stopping on command.
6. Functional Gait Assessment: This is a test of balance while moving. You will be asked to perform 10 balance tasks that involve walking or stairs. You may use your assistive device during this test. A physical therapist will monitor you during this test and ensure your safety.
7. Comprehensive High-Activity Mobility Predictor: This test determines your functional ability and changes in these functions over time.

You will be asked to complete the following questionnaires or surveys during your visit:

1. Orthotics Prosthetics User Survey: This is a set of questionnaires that measure satisfaction of services and prosthesis use, maintain awareness of improvement in activities, and evaluate change in function and quality of life.
2. Amputee Mobility Predictor: This test is used to predict your potential level of walking and function after rehabilitation. It involves activities such as transfers, balance, and walking.
3. Modified Falls Efficacy Scale: This questionnaire is designed to measure fear of falling and confidence in balance while completing daily activities.
4. Prosthesis Evaluation Questionnaire: This is a survey designed to gain information about your feelings on fitting and using your prosthesis, feedback regarding your residual limb, the social and emotional parts of using your prosthesis, and your ability to move around.
5. Prosthetic Limb User Survey of Mobility: This questionnaire tests your level of mobility using a prosthesis such as ability to move from one place to another and household and community activities.
6. Patient Reported Outcomes Measurement System: This is a set of questionnaires that measures physical, mental, and social health.
7. Community Predictors Indicators: This is a survey that measures your likelihood of doing different community activities through a normal week.

You will be asked to carry the phone assigned to you every day for 3 months—we will explain to you how and where to carry the smartphone and how to charge it during this first visit. You will be asked to go about your normal business and activities—there will be no restrictions on your activities and you will not be required to do any specific activities. We will ask you to label some of your activities using the app, approximately once per month, and we will instruct you on how to do that and remind you to do it via the smartphone. The smartphone and sensors will record information during your normal daily activities and transmit this data wirelessly to a secure server at the SRALab. The data will be encrypted for additional security and will not be labelled in any way that would allow you to be identified. You will be required to charge the phone at night, and to carry the smartphone (and optionally wear the sensors) at all times for the duration of the study. You will be able to use the phone for personal calls, internet browsing, or email. We will not monitor these activities or in any way record or retain information from your personal communications.

After this first 3-month period you will return to the Shirley Ryan AbilityLab to repeat all the testing you completed at your first visit (listed above). If you are not selected to participate in the second part of the study, you will return all assigned devices and your participation will end on this day.

If you are selected to participate in the second part of the study, you will be assigned to have an intervention to improve your ability to use your prosthesis. You may receive a clinical consultation with a physiatrist who will evaluate your prosthesis fit and function and may

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prescribe adjustments or repair of your device or socket. You may receive psychological counselling with a registered clinical psychologist or other trained personnel. You may receive physical therapy and focused training with your prosthesis. You may receive more than one intervention.

You will receive these interventions for up to 12 weeks, with a maximum of 18-24 sessions as appropriate for you. During this time, we will monitor your activities using the smart phone as before, for a total of three months.

We will then ask you to return to the Shirley Ryan Ability Lab for another visit to repeat the outcome measures and surveys that were conducted at visit 1. This visit will last up to 3 hours. At the end of this period, we will monitor your activities again for three months with no intervention(s), to find out if any effects of the intervention(s) are lost or maintained over time. You will once again repeat all the testing mentioned previously for one final visit at the Shirley Ryan AbilityLab lasting up to 3 hours. At the end of the study you will be required to return the smartphone and sensors; however, you will not be financially responsible for damage or loss of the devices we give to you to use during the study.

What are my responsibilities if I take part in this research?

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

1. Come to the Shirley Ryan AbilityLab for all scheduled visits to complete the previously mentioned activities.
2. Use and care for assigned devices as directed.
3. Label activities while at home as directed by research staff.
4. Report any changes in health, medications, or issues with device use as soon as the present themselves.

What happens if I say “Yes”, but I change my mind later?

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

If you decide to leave the research, contact the investigator so that the investigator can remove you're from the study.

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,

If you agree, this data will be handled the same as research data.

Detailed Risks: Is there any way being in this study could be bad for me?

This is a minimal risk study, meaning participation in this study should not cause you any more harm than if you were normally going about your daily activities or receiving physical or mental health therapy. Possible risks are listed below.

Risk of data security: Since information is being collected from cellular devices, there is a risk in breach of data security which could cause potential loss of sensitive information. A number of steps such as removing all identifying information associated with the you have been taken.

Risk of emotional or mental discomfort: This may occur when answering personal health questions of filling out survey related to physical and mental well-being or depression.

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Risk of soreness or mild discomfort: This may occur due to physical activities required during visits testing at the Shirley Ryan AbilityLab or if physical therapy interventions are assigned to you during the second round of this study.

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. You may be selected to receive an intervention, in which case you may get some benefit; however, not every participant will receive an intervention. Taking part in this study may help researchers to understand whether using smartphone and wearable sensors can provide additional information to help clinicians improve care for people with amputations and enable people to get the most benefit from their prostheses. Improved ability to use a prosthesis may improve the quality of life for individuals with lower limb amputation. In addition, this monitoring system may be helpful for other individuals with disabilities that affect their mobility or social activities.

What happens to the information collected for the research?

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 Department of Defense Health Program: Congressionally Directed Medical Research Programs - Orthotics and Prosthetics Outcomes Research Program.

An exception to our promise of confidentiality is when we in good faith are permitted by law or policy to report evidence of child [or elder] abuse or neglect.

De-identified data (data that does not include any information that can be linked to you) will be kept indefinitely on password protected servers or in locked cabinets accessible only by authorized researcher staff.

Consent forms, personal health information, or any other identifying information will be kept confidential and separate from the data mentioned above in locked cabinets or on password protected servers. It will be destroyed in accordance to IRB policy guidelines unless you agree to be contacted for future studies.

If the sponsor pays any of your medical expenses, we may be required to give the sponsor your name, date of birth, and Medicare ID or social security number.

The sponsor, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), and the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential. **Data Sharing** De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could

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identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include unsatisfactory use of devices or noncompliance with rules of study.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

If you become ill or are injured as a result of this study (medications, devices or procedures), you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study doctor about any illness or injury.

The hospital [university, researchers] will not pay for medical care required because of a bad outcome resulting from your participation in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.

If you agree to take part in this research study, we will pay you \$150 for your time and effort for the first part of the study.

If you qualify for the second part of the study, interventions (i.e. physical therapy, counseling, psychiatry appointments, or prosthetic appointments) will be provided at no cost to you. You will be provided \$20 for each intervention session you have at the Shirley Ryan AbilityLab. You will be paid \$50 for each testing or assessment session that you attend. These funds are provided to help support you with time and travel associated with your participation.

The Shirley Ryan AbilityLab will issue you a ClinCard, which is a specially designed debit card for clinical research. Once a visit that qualifies for compensation is completed, funds will be approved and loaded onto your card. The funds will be available within 1 day after being loaded and can be used at your discretion.

You will be issued one card for the duration of your participation. If your card is lost or stolen, please call (866) 952-3795 or ask a coordinator for a replacement ClinCard.

Fees are incurred if used at an ATM (fees vary by location). However, if the card is used for in-store or online purchases via credit or debit, there are no associated fees and no expiration date.

Please be advised: Inactivity on the card for more than 3 months will incur a monthly fee. However, as long as there is activity on the card within 3 months (funds are added or a transaction is completed), the month period will reset and no monthly fee will be assessed.

If you do incur a monthly fee, please contact Greenphire Support at the number on the back of your card and they will reverse the fee. See "Tips for Using the Attached ClinCard" for more information.

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The Finance Department at the Shirley Ryan AbilityLab will be provided with your information, including your Social Security Number, in order to issue payment for your study participation. Study payments are considered taxable income and reportable to the Internal Revenue Service (IRS). An IRS Form 1099 will be sent to you if your total payments are \$600 or more in a calendar year.

You may be given access to new inventions that are being developed by the investigator, the study sponsor, or other people involved in the study. Certain laws can make it harder to obtain legal protection for a new invention shared with a study participant, unless the study participant agrees to keep information about the invention confidential. You agree to keep confidential information you may receive about new inventions, such as new drugs, new devices, or new methods.

Military personnel should check with their supervisor before accepting payment for participation in this research.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about study devices
- Billing information

You have the right to inspect and copy the mental health and developmental disabilities records that will be collected as part of this study.

The will consent never expire.

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH).

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the

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identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University and the Shirley Ryan AbilityLab workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB).
- Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Clinical affiliates, including but not limited to Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH), for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,
- The Department of Defense Health Program, who is sponsoring the study, and that company's contractors and partners.
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will not expire.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

Arun Jayarman
Shirley Ryan AbilityLab
Max Nader Center for Rehabilitation Technologies and Outcomes, Center for Bionic
Medicine
355 E Erie St, Room 11-1401 Chicago, IL 60611

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

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Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree	I disagree	
_____	_____	The researcher may audio or video record me to aid with data analysis. The researcher will not share these recordings with anyone outside of the immediate study team.
_____	_____	The researcher may audio or video record me for use in scholarly presentations or publications. My identity may be shared as part of this activity, although the researcher will attempt to limit such identification.
_____	_____	The researcher may contact me in the future to see whether I am interested in participating in other research studies by the Principal Investigator of this study.

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

Signature of Participant

Date

Printed Name of Participant

Signature of Person Obtaining Consent

Date

Printed Name of Person Obtaining Consent