Brasthesis Prototype for Women Veterans with Upper Limb Amputations

NCT05179395

7/10/2023

Department of Veterans Affairs

RESEARCH CONSENT FORM

Medical Consent

Participant Name: _____ Date:_____

Title of Study: **Brasthesis™ Prototype for Women Veterans with Upper Limb Amputations**

Principal Investigator: Jeffrey Heckman, DO VA Facility: **James A. Haley Veterans' Hospital**

Informed Consent to Participate in Research

University of South Florida, the IRB of record for the James A. Haley Veterans' Hospital

Information to Consider Before Taking Part in this Research Study

IRB Study # STUDY003630

Doctors and researchers at James A. Haley Veterans' Hospital study diseases and other health problems people may have. Our goal is to try to find better ways to help treat these health problems. To do this, we need the help of people who are willing to take part in a research study.

STUDY OVERVIEW:

1. **WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?**
   We are asking you to choose whether or not to volunteer for a research study conducted by the Department of Veterans Affairs. It is a study being funded by the Department of Veterans Affairs Rehabilitation Research and Development Service. The study is about testing a potentially more comfortable prosthetic harness for women with unilateral amputations. This initial information is to give you key information to help you decide whether to participate. We have included detailed information after this information. Ask the research team questions. Taking part in this study is completely voluntary.

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

   By doing this study, we hope to learn if our new harness is more comfortable than the traditional harness provided to women with unilateral amputations. Our new harness, that we have named Brasthesis, is built into a heavy-duty sports bra. Your participation in this research will last about 4-8 weeks.

   This research study is expected to take approximately one to two years.

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

   The most important reasons for volunteering to participate in this study are (1) to provide a more comfort fit for you and other women with upper limb amputations who wear a prosthesis and (2) to help us with the next steps in the commercialization of Brasthesis.

   For a complete description of benefits, refer to the Detailed Consent Section.

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

   For a complete description of risks, refer to the Detailed Section of the Consent.

Alternatively, you could keep using your prosthesis with your traditional harness or continue not using your prosthesis. For a complete description of alternate treatment/procedures, refer to the Detailed Section of the Consent.

5. 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.

6. WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is **Jeffrey Heckman, DO** of the James A Haley Veterans' Hospital. This person is called the Principal Investigator. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, her contact information is Jeffrey.T.Heckman@va.gov or 813-972-2000 ext. 7506.

After you read this form, you can:

- Take your time to think about the information that has been provided to you.
- Have a friend or family member go over the form with you.
- Talk it over with another health care provider.

It's up to you. If you choose to be in the study, then you can sign the form. If you do not want to take part in this study, you should not sign the form.

DETAILED RESEARCH CONSENT SECTION

WHAT IS THE PURPOSE OF THIS STUDY?

Harnessing is a challenge for individuals with humeral, shoulder, and scapulothoracic amputations and even more of a challenge for women due to female anatomy. We have successfully fit two women with a harness that is integrated into a heavy-duty sports bra.

With this research we hope to fit 5 more women amputees with Brasthesis then see what they think next marketing steps should be. We know that location of the straps that secure the prosthesis to the sports bra vary by individual amputation surgery and resulting area available to accommodate the prosthesis sensor.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About 10 people will take part in this study at James A. Haley Veterans' Hospital. Participants have the option of coming into Tampa (we have funding for travel) or participating with their home prosthestic clinical team and interacting with the research team via Veteran Video Connect videoteleconferencing.

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HOW LONG WILL I BE IN THE STUDY?

We anticipate it will take two to four weeks to order/receive the bra and to fit Brasthesis to your prosthesis. We expect you to wear Brasthesis for 4 weeks. However, if you decide to return to your traditional harness and not wear Brasthesis, you can remain in the study. There may be an additional week to complete data collection after the wearing period. We anticipate that you will be in the study for up to 8 weeks.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

- The project manager will address your questions and obtain your signature on the informed consent document. The project manager is an occupational therapist with extensive experience in amputation and prosthetic research.
- Once you have provided written informed consent, then you and the project manager will order your bra from the sports bra company in your choice of the available colors.
- The project manager will ask you some questions about your satisfaction with your traditional prosthestic harness, the satisfaction, comfort, and activities you are able and not able to do while wearing your traditional prosthesis. This is typically done over the phone.
- Once the bra has been delivered to Tampa or your prosthetic clinical team (we will request overnight delivery), an appointment with your prosthetist or the study prosthetist will be scheduled. If you choose to come to Tampa and need a flight/meals/lodging, the project manager will make travel arrangements for you.
- The Tampa research team will consist of a physician, prosthetist, and an occupational therapist specializing in prosthetic training. The fitting process will begin with introductions. Then you will don your prosthesis with the traditional harness for pressure and range of motion measurement.
- The occupational therapist will measure your range of motion of your shoulders while wearing your traditional harness and prosthesis, or range of motion of your intact and residual limb if you do not use a prosthesis using a goniometer.
- The prosthetist will measure the pressure of the traditional harness at the underarm area of your intact arm and between the socket and residual limb. Pressure measurement is done by applying paper thin sensory onto the skin. See Figure 1.

Figure 1 Green is paper thin sensors

- You will then put the purchased bra on over your traditional harness. We will mark where the traditional harness and sports bra overlap. D-rings will be riveted to the prosthesis at these marks. The individualization of Brathesis begins with you providing feedback to us. We will construct and place the Brasthesis harnessing straps to provide optimal support and comfort. We will add a magnetic one-handed closure in the front, if desired. Last, we will add an activity tracker to your prosthesis to be worn during the 4-week wearing period. The activity tracker will not contain any personal information. We will remove the activity tracker when you return after your 4-week wearing period.
- Once you can use your prosthesis with the Brasthesis harness, your four-week wearing period will begin.

- You may visit your prosthetist at any time during the 4-week wearing period, just like you do now in standard care.
- At the end of the 4-week wearing period, you will return to the prosthetic clinic. We will remove the activity tracker from your prosthesis.
- The range of motion and pressure measurements will be repeated but this time while you are wearing the Brasthesis harness. The project manager, an occupational therapist, or another study team member will lead a discussion with you and your prosthetic team about your experience fitting and wearing Brasthesis. This discussion will be tape-recorded. After we have extracted the text that we need from the recording, the recording will be destroyed. The text will be deidentified, i.e., no one will know who the interviewee was.
- The project manager will ask the same questions as she did at the beginning of the study, about satisfaction, function, and comfort.
- After all five women have completed the 4-weak wear period, we will convene a virtual focus group where as a group, the five participants can discuss the pros and cons of Brasthesis and the next steps in commercialization.

WHAT IS EXPECTED IF I TAKE PART IN THIS STUDY?

- Below is a chronological explanation of the procedures. All procedures are being done solely for the purposes of the research.
  - Timepoint 1: We will mail you an informed consent document that you will take up to a week to review and sign. We will provide you with a postage paid envelop to return the signed document should you choose to volunteer for this study.
  - Timepoint 2: During a phone call with the project manager, we will order a sports bra for you and the program manager will ask you some questions about your satisfaction, comfort and function with your traditional harness. This will take 30-60 minutes.
  - Timepoint 3: You will meet with the research team, and your clinical team if you choose, to fit Brasthesis and take some pressure and range of motion measurements while you are wearing your traditional harness. We will place an activity tracker on your prosthesis. These procedures will take about 2 hours.
  - You will wear Brasthesis for 4 weeks. If you decide not to wear Brasthesis, let us know. We are as interested in why you do not wear Brasthesis as we are in why you do wear Brasthesis. You can continue with the study even if you decide not to wear Brasthesis for the full four weeks.
  - Timepoint 4: At the end of the four-week wearing period, you will return to the clinic to report on your experience with Brasthesis. We will remove the activity tracker from your prosthesis. We will repeat the pressure and range of motion measurements while you are wearing Brasthesis. The PI or project manager will ask a few questions to prompt a discussion with you and the clinical team. This visit will take 1-2 hours. During this visit, photos may be taken for educational and/ or marketing use per your consent.

- Timepoint 5: The project manager will contact you by phone and ask you the same questions about your satisfaction, comfort and function that she asked at timepoint 2 but this time when you are wearing Brasthesis. This will take 30-45 minutes.
- Timepoint 6: After all 5 women have completed their 4-week wearing period, you will be invited to participate in a virtual focus group. This group will last 30-60 minutes.

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

Any procedure has possible risks and discomforts.

- Discomfort. You may find Brasthesis to be uncomfortable. If so, you can discontinue wearing Brasthesis and either return to wearing your traditional harness or no prosthesis.
- Inconvenience. Traveling to a prosthetic clinic for at least two visits is an inconvenience. We are able to reimburse you for travel if you live more than 50 miles from your clinic or the Tampa site or choose to fly to the Tampa site.
- Physical/physiological/psychological/social risks should be less than the standard care harness as Brasthesis uses a trendy sports bra compared the more industrial-medical looking standard harness.
- **Placing the activity tracker on yor prosthesis will have no risk to you.**
- To minimize the described risks and discomforts, please feel free to contact the PI or project manager at any time so that we may address your issues on an individual basis.

Questionnaires

Some people are uncomfortable being asked questions about their amputation. If, for any reason, you wish not to answer specific questions or you wish to terminate the session, you will be able to do so.

Photographs, audiotaping, or videotaping

The study team has explained that by signing this Informed Consent Document, you voluntarily and without separate compensation authorize pictures and/or voice recording(s) to be made of you by the research team while you are participating in this study.

The voice recording is intended for the following purposes:

- To gather data about the experience of using Brasthesis. We will summarize the experiences of all 5 participants. Once the interviews and focus groups recordings are summarized as written text, the original recording will be destroyed. The presentation of findings will be anonymous. Your name will not be used.

The picture and/or video recording is intended for the following purposes:

- Presentation in professional manuscripts and conference presentations. Your face will be blocked out.

- You will have the option to be photographed for technology development purposes by a VA Media photographer. Your face will not be covered. Should you choose this option, a separate photo release will be obtained.

You will not receive any royalty, fee or other compensation for such use. If you refuse to grant consent, there will be no effect on any VA benefits to which you may be entitled. You may at any time exercise the right to cease being filmed, photographed or recorded, and may rescind your consent for up to a reasonable time before the picture, video or voice recording is used.

The video and picture recording is an optional part of the study. You can refuse to be photographed or video recorded but still be an active participant in the study by signing below. Audio recording, however, is not optional as it is an important method of data collection.

Signature: _____ Date: _____

Should you demonstrate a risk for harm or suicide, we will stay with you until we can hand you off to appropriate medical personal.

- A physican will be present during the initial Brasthesis fitting.
- If you are an outpatient at the Tampa location, we will go with you to the Emergency Room for evaluation.
- If we are working with you virtually, we will stay with you until we connect you with the suicide crisis team and/or physician at your facility.
- The PI will be notified.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. However, possible benefits may include increased comfort and function when wearing your prosthesis.

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

You may choose not to participate in this study. If this is your decision, you may continue to use your current prosthesis or not wear your prosthesis. You may discuss these options with your doctor, occupational therapist, and/or prosthetist.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

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

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.

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Health Information Portability and Accountability Act (HIPAA)

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 your name, address, date of birth, social security number (for travel reimbursement if applicable) and information from your medical records such as your medical history as it pertains to your amputation.

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 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).

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.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Principal Investigator of the study at this facility below.

Principal Investigator:
Jeffrey Heckman, DO
James A. Haley Veterans' Hospital
13000 Bruce B. Downs Blvd.
S-117, PM&R
Tampa, FL 33612

You can also ask a member of the research team to give you a form to revoke the authorization. The study team will contact the Release of Information Office. 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, **Dr. Jeffrey Heckman** and his 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.

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.

We will be audio recording interviews and the focus group as a means of data collection. Once we have an anonymous written summary of the content, we will delete the original voice recordings.

We would like to take photos and videos of participants being fitted with and using Brasthesis. However, having photos and video taken is optional to being in the study. The photos and videos will be used in professional publications and conferences. Your face will be blocked out. Also optional is being photographed by VA Media photographers while wearing Brasthesis with your face NOT blocked out that will be used for marketing purposes. You will sign a separate photo release if the photo is used for marketing purposes.

WHAT ARE THE COST 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.

- We will be able to reimburse you and your caregiver (if necessary) for certain expenses such as mileage if you live more than 50 miles from the Tampa (or your local) facility and airfare, lodging, and meals if you fly to the Tampa facility.
- If you choose to travel to Tampa by air, the project will make travel arrangements for you and your caregiver (if necessary).
- Mileage will be reimbursed at the current published GSA rate.
- Meals will be reimbursed per current published GSA rate.
- To receive payment, you and your caregiver (if necessary) will complete VA vendorization forms. Then you and your caregiver (if necessary) will receive reimbursement for meals directly to the account provided on the VA Vendor Form.
- The study will pay for your flight and lodging directly as well as your caregiver's (if necessary). You will not pay then wait for reimbursement.
- You will keep your Brasthesis at no cost to you.
- The VA will be disbursing your reimbursement for meals as well as your caregiver's (if necessary). Due to limitations in the Financial Management System, payments made to subjects through Austin Financial Services Center generate Internal Revenue Service Form 1099 regardless of amount.

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

It is unlikely that you will sustain research-related injuries, lost wages, discomfort or disability from wearing a prosthetic harness, especially as you will have had experience with a traditional prothesis.

Financial compensation for research-related injuries, lost wages, discomfort or disability will not be available. You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

The VA Medical Center is not responsible for any research-related injury treatment costs of a non-Veteran. The non-Veteran and his or her insurance or third-party payer cannot be a responsible party.

DO I HAVE TO TAKE PART IN THE STUDY?

Your participation is voluntary. Refusal to take part in the study will involve no penalty or loss of benefits to which the participant is otherwise entitled.

All that you have to do to withdraw from the research is let the project manager or PI know. Your request must be in writing.

We will continue to use the data already collected but we will not collect any further information.

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 Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the USF IRB at (813) 974-5638 or contact the USF IRB by email at RSCH-IRB@usf.edu] if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

If you would like to contact someone independent of the research study, or cannot reach the research staff, you may contact the James A. Haley Veterans' Hospital Research Compliance Officer at 813-903-4274.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

We will provide any clinically relevant research results to you upon request.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

The project manager 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.

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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 document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

Signature of Person Obtaining Informed Consent/Research Authorization		
_____ Name	_____ Signature	_____ Date