A non-invasive intervention (BreEStim) for management of phantom limb pain (PLP) after limb amputation

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CONSENT TO TAKE PART IN RESEARCH

Full Study Title: A non-invasive intervention (BreEStim) for management of phantom limb pain (PLP) after limb amputation

Study Sponsor: National Institute of Disability, Independent Living, and Rehabilitation Research (NIDILRR)

Principal Investigator: Sheng Li, MD, PhD, Professor, Physical Medicine and Rehabilitation, UTHealth

Study Contact: Shengai Li, MS, research coordinator, [redacted]

The purpose of this study is to compare the effectiveness of innovative intervention of breathing-controlled electrical stimulation (BreEStim) and conventional electrical stimulation (EStim) in management of neuropathic phantom limb pain in patients after limb amputation. If you choose to participate in this study, you will be asked to receive either EStim or BreEStim treatment for one session or for multiple sessions. Each laboratory visit will take about 1 hour. Experiment 1 requires two study visits, which will take place at least three days apart. Experiment 2 also requires two study visits, which will take place at least seven days apart. Experiment 3 requires 20 study visits, which will take place at least two weeks apart. If you participate in all three experiments, you will be part of the study for about one year

The risks associated with this study are minimal. Peripheral electrical stimulation has been used in clinical settings. Risks associated with BreEStim are similar to those clinically commonly used electrical stimulators. You may feel discomfort or even pain during electrical stimulation. You are encouraged to increase or decrease the intensity of electrical stimulation until you are able to tolerate it. The only difference is that electrical stimulation is triggered by voluntary breathing. There are possible minor discomforts associated with putting on the facemask for the BreEStim.

There may be potential benefits to you. You may directly benefit from the new intervention for your phantom limb pain. Also, the findings from the study may provide evidence that the novel approach is feasible and effective in better treating phantom limb pain.

Participation in this research study is voluntary. You may choose not to take part in this research study or may choose to leave the research study at any time. Your decision will not affect the clinical care you receive at the University of Texas Health Science Center at Houston (UTHealth) or Memorial Hermann Health System.

If you are interested in participating, please continue to read below.

What is the purpose of this research study?

The purpose of this study is to see how well BreEStim works at treating people with phantom limb pain after limb amputation. This study will test the safety of the BreEStim. This BreEStim treatment has not been approved by the Food and Drug Administration (FDA); therefore, it is called an investigational device.

The National Institute of Disability, Independent Living, and Rehabilitation Research (NIDILRR) is paying UTHealth for their work on this study.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This will not include information that can identify you. After the study has ended, website will include a summary of the results. You can search this website at any time.

The Principal Investigator (PI) for this study is an inventor of the device, for which a patent may be filed by UTHealth. If the patent is pursued, based on data from this and other research, royalties and other compensation may be received by UTHealth. This means UTHealth has potential financial interests in the outcome of this study.

Who is being asked to take part in this study?
You are being asked to take part in this research study because you have phantom limb pain. This study is being conducted at UTHealth. About 64 people will take part in the study at UTHealth and Memorial Hermann Health System.

What will happen if I take part in this study?
The study has three experiments. You may take part in one or more of the experiments. In experiment 1, you will receive one session of electrical stimulation treatment each time on two different days. Electrical stimulation treatment will be controlled by your breathing (BreEStim) in one session. In another session, the amount of electrical stimulation is predefined (EStim). In experiment 2, you will receive BreEStim treatment at two different (high or low) doses on two different days. In experiment 3, you will receive 10-session BreEStim and 10-session EStim treatment in a random order. The interval between BreEStim and EStim is at least 2 weeks. The following assessment will be made before and after

- Visual analogue scale (VAS). You will inform us the current level of pain.
- Quantitative sensory testing (QST). It includes non-invasive assessment of tactile sensation threshold (TST), electrical sensation threshold (EST), electrical pain threshold (EPT), and thermal thresholds.
- Hear rate variability (HRV). It consists of 5-minute electrocardiogram (ECG) recording before and after a treatment session.

How long will you be in the study?
If you take part in the study, you need to plan the time for experiments. Each laboratory visit will take about 1 hour. Experiment 1 requires two study visits, which will take place at least three days apart. Experiment 2 also requires two study visits, which will take place at least seven days apart. Experiment 3 requires 20 study visits, which will take place at least two weeks apart. If you participate in all three experiments, you will be part of the study for about one year.

What choices do you have other than this study?
You may select other options than being in this research study. You may continue current medication treatments or other alternatives you are using.

What are the risks of taking part in this study?
The risks associated with this study are minimal. Peripheral electrical stimulation has been used in clinical settings. Risks associated with BreEStim are similar to those clinically commonly used electrical stimulators. You may feel discomfort or even pain during electrical stimulation. You are encouraged to

increase or decrease the intensity of electrical stimulation until you are able to tolerate it. The only difference is that electrical stimulation is triggered by voluntary breathing. There are possible minor discomforts associated with putting on the facemask for the BreEStim. Extra rest time will be allowed if the facemask causes discomfort.

There may be some risks that the study doctors do not yet know about.

What are the benefits to taking part in this study?
You may directly benefit from the new intervention for your phantom limb pain. Also, the findings from the study may provide evidence that the novel approach is feasible and effective in better treating phantom limb pain.

Can you stop taking part in this study?
You may decide to stop taking part in the study at any time. To withdraw from the study, please contact Sheng Li, MD, PhD at [redacted].

Your doctor can stop the study at any time. Your doctor or the sponsor may stop your participation in the study if your condition worsens, the study is stopped, the study treatment is no longer available, you do not meet all the requirements of the study, or the study is not in your best interest. If your participation in the study is stopped, your doctor will discuss other options for your treatment.

If you stop participating in this study, the information already collected about you will still be used in the data analysis. However, no further information will be collected without your permission.

While taking part in this study, the study team will notify you of new information that may become available and could affect your willingness to stay in the study.

What happens if you are injured during the study?
If you are injured or have any harmful effects during the course of the research study, treatment will be available to you. You or your insurance company will be billed for any treatment. You should report any such injury to Sheng Li, MD, PhD. You will not give up any of your legal rights by signing this consent form.

What are the costs of taking part in this study?
The treatment will be provided at no cost to you. If you receive a bill that you believe is related to your taking part in this research study, please contact Sheng Li, MD, PhD, or research staff at [redacted] with any questions.

If you take part in the study, you will receive a gift card of $40 for each session for Experiment 1 and 2. For Experiment 3, you will receive a gift card of $40 after the initial session. You will receive the rest of compensation at $40/visit at the end of Experiment 3 (up to 20 sessions) or when you leave the study. All information is stored in a secure fashion and will be deleted from the system once the study has been completed.

If you receive payment for taking part in this study, please be informed that you will be asked to complete a copy W-9 form that will be forwarded to the accounting department as a requirement by the

Internal Revenue Service. You will also be issued a 1099-Misc form from this study for tax reporting purposes.

How will privacy and confidentiality be protected?
Your privacy is important and your participation in this study will be kept confidential. However, absolute confidentiality cannot be guaranteed.

If you sign this document, you give permission to UTHealth and Memorial Hermann Health System to use and disclose (release) your health information. The health information that we may use or disclose for this research may include, for example, all information in a medical record, results of physical examinations, medical history, lab tests, or certain health information indicating or relating to a particular condition. Please understand that health information used and disclosed may include information relating to HIV infection, drug abuse, alcohol abuse, behavioral health, and psychiatric care.

Please understand that research study data will be sent to the sponsor of this research study, NIDILRR. The data that will be sent to the sponsor will not include your name but may include your initials, date of birth, date of study visits, and date of study procedures.

People who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect your health information and may share your information with others without your permission, if permitted by laws governing them. You will not be personally identified in any reports or publications that may result from this study. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

Representatives of the organizations listed below will see your name and other personal identifiers when they review your research records and medical records for the purposes of verifying study data:

- Representatives of UTHealth and/or Memorial Hermann Health System
- Representatives from the U.S. Food and Drug Administration (FDA)
- Representatives of the sponsor of this research including contract research organizations
- Companies engaged with the UTHealth for the commercialization of the results of the research study

Please note that you do not have to sign this Authorization, but if you do not, you may not participate in this research study. UTHealth and Memorial Hermann Health System may not withhold treatment or refuse treating you if you do not sign this Authorization.

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must contact Sheng Li, MD, PhD in writing at 1333 Moursund, Houston TX 77030.

This Authorization will expire 15 years after the end of the study.

Whom can you contact if you have questions about the study?

If you have questions at any time about this research study, please feel free to contact Sheng Li, MD, PhD at [redacted], as they will be glad to answer your questions. You can contact the study team to discuss problems, report injuries, voice concerns, obtain information in addition to asking questions about the research.

The Committee for Protection of Human Subjects at the University of Texas Health Science Center has reviewed this research study. You may contact them for any questions about your rights as a research subject, and to discuss any concerns, comments, or complaints about taking part in a research study at [redacted].

SIGNATURES

Sign below only if you understand the information given to you about the research and you choose to take part in this research study. Make sure that all your questions have been answered. If you decide to take part in this research study, a copy of this signed consent form will be given to you.

Printed Name of Subject	Signature of Subject	Date	Time

Printed Name of Person Obtaining Informed Consent	Signature of Person Obtaining Informed Consent	Date	Time