Consent for Participation in a Research Study

Protocol Title: The General Use of Robots in Stroke Recovery: The Anklebot
Principal Investigator: Bruce T. Volpe, MD
Sponsor: None (Investigator-Initiated with No Funding)

This consent form is written from the point of view of a research subject. If consent will be obtained from a legally authorized representative or next of kin, the words "you" and "your" should be read as "the research subject."

As the subject's legally authorized representative or next of kin, you are being asked to give consent for the subject to be in a research study. You are being asked to do this because the subject is not able to give consent. When making this decision you should take into account the wishes of the subject. If you agree to allow the subject to take part in this research, the subject will also be asked to give consent, but only if he/she regains the ability to make healthcare decisions.

Introduction

You are being asked to join a research study. The following information will explain the purpose of this study, what you will be asked to do, and the potential risks and benefits. It will also explain that you do not have to be in this study to receive medical care. You are encouraged to ask questions before deciding whether you wish to participate, or at any time during the course of the study. You will be told of any new findings that may change your decision to continue to participate.

Why is this research study being done?

The goal of this research study is to improve and better understand movement rehabilitation after stroke with the hope of developing new treatments that maximize this recovery. One effective choice for movement rehabilitation is to use a robot to assist in exercise training. This research study will attempt to determine whether anklebot training improves gait speed and functional ambulation status in individuals after stroke.

You are being asked to participate because you have had a stroke.

How many people will take part in this study?

We hope to enroll a total of 55 subjects in this study.

How long will you be in this study?

If you choose to participate in this research study, the duration of participation will be up to 5 months. During this time, there will be 18 study visits, up to 60 minutes each. These study visits will take place at Transitions of Long Island Outpatient Rehabilitation Center (1554 Northern Blvd, Manhasset, NY). There will additionally be four Gait Evaluations, which will take place at Long Island Pediatric Physical Therapy, PC, 99 Tulip Avenue, Suite 407, Floral Park, NY 11001.

What will happen in this research study?
There are several procedures that you will be asked to complete during the study visits and are described below:

Screening questionnaire
You will be asked to complete a questionnaire about your health history to see if you are a candidate for lower extremity robotic intervention. This will take only a few minutes

Outcome measures
You will complete a series of evaluations to assess the strength and function of your muscles, your physical abilities, and you impression of your functional status. This will take approximately 60 minutes.

Robot-assisted training
You will be seated in a chair facing a video screen and the robot. Your ankle and calf will be placed in a brace and attached to the robot by a foam lined plastic support pad, Velcro straps, and two bolts. You will move, as best you can, the robotic ankle through a series of exercises guided by the visual display on the video screen in front of you. You will be able to see your ankle move and you will see the movements recorded on the video screen. If you cannot move the robotic limb within 1.5 seconds, the device will move your ankle through the exercises. For the ankle movements, the ankle and calf will be supported by a foam padded brace that slides the ankle up and down. The force, speed, and position of the robotic device and whether it is driving the movement of being moved by you will be recorded. This exercise will take approximately 1 hour.

Schedule of Visits
The schedule of study visits is below and describes what procedures will be done at each study visit:

<u>Lead-in Period</u>

- Week 1, Visit 1 (approximately 60 minutes)
    - Clinical outcome measures
    - Medical screening
    - Consent
- Week 2 & 3, Visit 2 & 3 (approximately 60 minutes each)
    - Clincial outcome measures
    - Objective Gait Measures

<u>Training Period</u>

- Week 4-6 Visit 4-11 (approximately 1 hour)
    - Robotic training
- Week 6 Visit 12 (approximately 90 minutes)
    - Robotic training
    - Midpoint Outcome Measures
- Week 7-9 Visit 13-21 (approximately 1 hour)

    - Robotic training
- Week 10, Visit 22 (approximately 1 hour)
    - Discharge Clinical Outcome Measures
    - Discharge Objective Gait Measures

Final Visit

- Week 22, Visit 23 (approximately 60 minutes)
    - Follow Up Clinical outcome measures
    - Follow Up Objective Gait Measures

Participation in this study also allows investigators access to your medical records. They will record your age, gender, date of stroke, and results of the medical imaging you had done following the stroke.

What are the risks of the research study? What could go wrong?
There are no known risks associated with robot-assisted exercise. There may be risks that are unknown at this time.

What are the benefits of this research study?
We cannot predict whether you will experience direct benefits from the robot-assisted training. However, knowledge may be gained which may benefit patients with stroke in the future.

If you do not want to take part in this research study, what are your other choices?
You do not have to participate in this study to receive standard medical care. If you decide not to participate in this study, your doctor will continue to treat you according to standard medical practice.

Will you receive any payments for participating in this research study?
You will not be paid for participating in this study.

Are there any costs for being in this research study?
You will not incur any additional costs associated with this study. All study-related procedures and medications will be provided at no cost to you. Costs related to standard medical practice will be billed as usual to you or your insurance carrier.

What happens if you are injured while participating in this study?
If you are hurt from being in the study, you will receive medical care and treatment as needed from the Northwell Health System. However, you will be responsible for the costs of such medical treatment, directly or through your medical insurance and/or other forms of medical coverage. No money will be given to you.

What are your rights as a research participant?
Your participation in this project is voluntary. The quality of your medical care will be the same, whether you join, refuse to join, or decide to leave the study.

If you do not join the study, you will not be penalized or lose benefits to which you are entitled. If you join the study you may withdraw at any time without prejudice to your future care at Northwell Health. Follow-up examinations may be needed to assure your well-being.

Could you be taken off the study before it is over?
It is also possible that your participation in this study may end without your consent. This decision may be made by an investigator or the IRB. Reasons for withdrawal may include: it is not in your best interests to continue on this study, or the study may be cancelled.

If you withdraw from this study or if you are withdrawn from the study, any data (or samples) already collected will continue to be used. However, no new information will be collected.

What happens if new information is learned?
You will be told of any new findings that may change your decision to continue to participate. Your consent to continue to take part in this study may be obtained again.

What information will be collected and used for this study?
If you agree to be in this study, we will collect health information that identifies you. We may collect the results of tests and interviews. We may also collect information from your medical record. We will only collect information that is needed for research. Such information has been described in this consent form. If you sign this consent form, you are giving us permission to collect, use and share your health information. This permission is called authorization. If you do not want to provide authorization, then you cannot participate in this research study.

Who else will see your information?
Study records that identify you will be kept private. You will not be identified in study records or publications disclosed outside Northwell Health except as detailed below:

- Collaborating investigator, Phil Koch, Physical Therapist at Long Island Pediatric Physical Therapy.
- Investigators might share the results of your study tests and procedures with your doctor or clinical staff not involved in the study, but who may be involved in your treatment.
- Information collected about you, for this study, will also be shared with researchers at MIT, who are helping us with this research project.

The following reviewers may access your study and medical records to make sure that this study is being done properly:

- Representatives from government agencies such as the National Institutes of Health,
- Representatives from the Northwell Health Human Research Protection Program (the committee that reviews research at this institution).

We will do our best to protect the privacy of your records but it is possible that once information is shared with people listed on this form, it will be released to others. If your research record is reviewed by any of these groups, they may also need to view your entire medical record. Please be aware that once private information is disclosed, it is subject to re-disclosure by the recipient and can no longer be considered protected.

In the future, we may publish results of this study in scientific journals and may present it at scientific meetings. If we do we will not identify you.

If the researchers learn about potential serious harm to you or someone else or other public health concerns, it will be shared with the appropriate authorities.

Will you be able to access your records?
If your research records are used for decisions related to your clinical care, you have the right to review this information and request changes. This is limited to information about your treatment and does not include information related to procedures or tests that are for research purposes only. You may access this information only after the study analysis is complete. You have the right to know who has and who will see your records. To request this information, or for any questions related to your health information, you may contact the Research Privacy Officer at (516) 321-2100.

How long will your health information be kept?
There is no limit on the length of time we will keep your information for this research because it may be analyzed for many years. We will keep it as long as it is useful, unless you decide you no longer want to take part or we close the study. You are allowing access to this information indefinitely.

Can you change your mind?
If you change your mind about being in the study, you may withdraw at any time. If you want us to stop collecting your health information, you need to send a letter to the researcher at the following address:

Bruce T. Volpe, MD
Feinstein Institute for Medical Research
350 Community Drive
Manhasset, NY 11030

Your letter needs to say that you have changed your mind and do not want the researcher to collect and share your health information. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those individuals who stay in it.

The information that is collected for research will be analyzed for many years and it is not possible to know how long our analysis will take. Therefore, you are granting access to this information indefinitely.

Data from this study may be used in medical publications or presentations. The information will be de-identified so that individual subjects cannot be recognized and the information will no longer be considered Protected Health Information (PHI).

If the study reveals evidence of abuse or other public health concerns, it will be shared with the appropriate authorities.

Does the investigator of this study receive money if you take part?
The investigators on this study do not receive money for your participation in this study.

Who can answer your questions about this study?
If you have any questions about the study, or about side effects or injury caused by research, call Bruce T. Volpe, MD at (516) 562-3384. If you need emergency care go to the nearest Emergency Department or dial 911. If you have questions about your rights as a research subject you may contact the Office of the Institutional Review Board (the committee that oversees research at this institution) at (516) 719-3100. A signed copy of this consent form will be given to you.

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SUMMATION & SIGNATURES: You have read the above description of the research study. You have been told of the risks and benefits involved and all your questions have been answered to your satisfaction. A member of the research team will answer any future questions you may have. You voluntarily agree to join this study and know that you can withdraw from the study at any time without penalty. By signing this form, you have not given up any of your legal rights.

_____	_____	_____
Subject's Printed Name	Subject's Signature	Date
_____	_____	_____
Witness's Printed Name	Witness's Signature	Date

Investigator's Statement: In addition to advising the above subject about the research study, I have offered an opportunity for further explanation of the risks and discomfort which are, or may be associated with this study and to answer any further questions relating to it.

_____
Investigator's Printed Name

_____	_____
Investigator's Signature	Date

OR

_____ _____
Subject's Printed Name Date

_____ _____ _____
Legally Authorized Representative's Printed Name Legally Authorized Representative's Signature Date

Witness' Statement: I was present during the consent process of the above mentioned research study. A member of the research team explained the research study entirely and allowed ample opportunity for the patient to ask any questions or express any concerns. The patient was unable to sign the consent form due to a physical disability, however, voluntarily agreed to participate in the research study by providing verbal assent. By signing below, I attest to this statement.

_____ _____ _____
Witness Printed Name Witness 1 Signature Date

Investigator's Statement: In addition to advising the above subject about the research study, I have offered an opportunity for further explanation of the risks and discomfort which are, or may be associated with this study and to answer any further questions relating to it.

_____
Investigator's Printed Name

_____ _____
Investigator's Signature Date

OR

_____ _____ _____
Legally Authorized Representative's Printed Name | Legally Authorized Representative's Signature | Date

Description of signer's authority to act on behalf of the subject: _____

_____ _____ _____
Witness's Printed Name | Witness's Signature | Date

☐ Witness signature waived (signed consent emailed, faxed, or mailed to investigator)

Investigator's Statement: In addition to advising the above subject about the research study, I have offered an opportunity for further explanation of the risks and discomfort which are, or may be associated with this study and to answer any further questions relating to it.

_____
Investigator's Printed Name

_____ _____
Investigator's Signature | Date

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ASSENT BY ADULT SUBJECT WITH A LEGALLY AUTHORIZED REPRESENTATIVE

I have been asked to join this research study. I have the right to find out what will or might happen to me if I am in the study. I have the right to tell the doctor, and the person legally allowed to make decisions for me, that I do or do not want to participate.

The person legally allowed to make decisions for me will also be asked to give permission for me to join this study.

(Investigator's name)_____ and _____, the person legally allowed to make decisions for me, have explained what I will have to do in the study.

(Investigator's name)_____ and _____, the person legally allowed to make decisions for me, have explained the discomforts, risks and inconveniences I may have if I join the study.

I have asked any questions I had, and all my questions have been answered.

_____ I agree to be in this study.

_____ I do not want to be in this study.

_____
Subject's name

_____ _____
Put your name here ↑ Date

_____ _____ _____
Witness's Printed Name Witness's Signature Date

All procedures, risks and discomforts have been explained to the subject.

_____
Investigator's printed name

_____ _____
Investigator's Signature Date

Addendum to Consent by Research Proxy
for Continuing Participation in a Research Study

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Principal Investigator: Bruce T. Volpe, MD
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- I have been told that my research proxy gave consent for me to be in the above titled research study.
- I am now able to give my own consent to be in the research study.
- I have been told of the purpose of the research, what my participation will entail, as well as all of the potential risks and benefits.
- I have discussed the research study with the study doctor and have received satisfactory answers to any questions.
- I have been told that I may ask more questions at any time.
- I do not have to stay in this research study. My decision to continue is completely voluntary. If I wish to leave the study, I may have to undergo final follow-up tests to assure my well-being. If I leave the study I will not suffer any penalty or loss of benefits to which I am entitled.
- I have been told that all of the elements of informed consent in the attached consent form, signed by my research proxy, are still applicable.
- I have reviewed the consent document and have discussed all of the elements of informed consent with the study doctor. I agree to stay in the above titled research study.

_____ _____
Signature of Subject Date

_____
Printed Name of Subject

_____ _____
Witness Signature Date

_____
Printed Name of Witness

In addition to advising the above subject about the research study, I have offered an opportunity for further explanation of the risks and discomfort which are, or may be associated with this study and to answer any further questions relating to it.

_____ _____ _____
Investigator's signature Investigator's printed name Date