Cover Page

Robot-Assisted Therapy and Motor Learning: An Active Learning Program for Stroke

NCT02747433

Informed Consent Document

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Protocol Title: Infusing Robot-Assisted Therapy with Motor Learning Principles: An Active Learning Program for Stroke (ALPS)

Principal Investigator: Susan Fasoli, ScD, OTR/L

Site Principal Investigator: Paolo Bonato, PhD

Description of Subject Population: Adults aged 18-82.

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Why is this research study being done?

The purpose of this study is to develop and test a therapy called the "Active Learning Program for Stroke" (ALPS). We are combining this therapy program with robot-assisted therapy and a home program for your weaker arm. We hope that this therapy will help you to better use your weaker arm after stroke during daily activities.

We are asking you to be part of this study because you are between 18 and 82 years old and had a stroke at least 6 months ago that left you with weakness in your arm and hand. We expect up to 20 people to take part in this study. This study is funded by the Faculty Research Fellowship Program at the MGH Institute of Health Professions.

How long will I take part in this research study?

You will take part in this study for up to 16 weeks. This study involves up to 24 visits in total:

- Up to 6 study visits will be for testing how you move your arm and will be done before you start therapy, when you finish therapy and 1 month after therapy (Assessment visits). You have the choice to complete each of the assessment visits in one or two separate days, depending on your preference. Each visit may take up to 2 hours.
- 18 visits will be therapy for your arm and hand using the Armeo and Amadeo robots and learning ways that you can better use your weaker arm for everyday activities at home. Some people in this study will be assigned to the group that also receives arm therapy using common objects and activities. Each of these visits will be an hour long. They will be scheduled 3 days per week for six weeks. If you are miss a visit, we will reschedule it for a time and date that is convenient for you.

What will happen in this research study?

The testing and therapy will be done in the Motion Analysis Laboratory at Spaulding Rehabilitation Hospital.

At the beginning of the study, we will randomly assign you to one of two groups:

1) **Group 1** will receive the Active Learning Program for Stroke plus robot therapy
2) **Group 2** will receive the Active Learning Program for Stroke plus robot therapy. This group will also receive arm and hand therapy using everyday objects and activities. This will show us whether arm therapy with the robots will be as helpful as therapy that combines robot and arm therapy.

Both groups will have 18 hour-long sessions of arm therapy.

You will be selected by chance (like in a coin toss) to have robot therapy or robot therapy plus arm and hand therapy using everyday objects. Neither you nor your investigator will be able to choose which group you will be in. You will get the same type of therapy for all of your therapy sessions.

The study visits will occur in the Motion Analysis Lab (MAL) and may be scheduled as follows:

MAL Visit Day 1: Screening and enrollment.

MAL Visit Days 2-3: pre-therapy assessments: This part of the study will take part over two or three study visits, depending on your preference. Each visit may take up to 2 hours. During these visits we will:

1) record the stiffness, movement, coordination, and ability to use your weaker arm
2) ask questions about how your stroke has affected your daily life and use of your weaker arm
3) record how well you move and the activity of the muscles of your weaker arm
4) give you sensors to wear on your wrists for three days. These will record movement of both arms during everyday activities at home.

Two of the pre-therapy assessments are used as part of our screening process to be sure that you have enough movement in your arm to safely use the robots and participate in the research study. These tests of the muscle tone (stiffness) and movement in your weaker arm will be given to you first. If these tests show that you are not a good candidate for therapy, then we will stop the testing and will need to exclude you from the study. If this happens, we will explain why and will answer any questions that you have.

MAL Visit Days 4-21: therapy sessions: You will come for 18 visits to do the robot therapy during weekdays (3 days a week for six weeks). If you are in the group that also receives arm and hand therapy with everyday objects, you will do each type of therapy for about half of each session. During all therapy sessions, we will use the Active Learning Program we are developing to help you learn ways to better use your weaker hand. You will receive a home action plan so you can practice activities you would like to do at home with your weaker arm.

MAL Visit Days 22-23: post-therapy assessment: This part of the study will take part over the course of two or three separate study visits, depending on your preference. During these visits we will:

1) record the stiffness, movement, coordination, and ability to use your weaker arm
2) ask questions about how your stroke has affected your daily life and use of your weaker arm
3) record how well you move and the activity of the muscles of your weaker arm
4) give you sensors to wear on your wrists for three days. These will record movement of both arms during everyday activities at home.

MAL Visit Day 24 (Final Visit): follow-up assessment: This part of the study will take part over the course of two or three separate study visits, depending on your preference. During these visits we will:

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IRB Protocol No: 2015P002107 **Sponsor Protocol No: NA**
Consent Form Valid Date: 6/17/2019 **IRB Amendment No: N/A** **Sponsor Amendment No: N/A**
Consent Form Expiration Date: 6/14/2020 **IRB Amendment Approval Date: N/A**

1) record the stiffness, movement, coordination, and ability to use your weaker arm
2) ask questions about how your stroke has affected your daily life and use of your weaker arm
3) give you sensors to wear on your wrists for three days. These will record movement of both arms during everyday activities at home.

ASSESSMENT SESSIONS

The assessment sessions will involve answering questionnaires and tests to measure how much you can move your arm before and after the therapy. All of the devices below are approved by the Food and Drug Administration (FDA) for assessment of arm and hand function, and will be used according to FDA and manufacturer guidelines.

Tests of Arm Movements (about 45 minutes)
We will test the stiffness, movement, coordination and ability to use your weaker arm. We will use tests that are commonly given in stroke rehabilitation research studies.

Questionnaires (about 40 minutes)
We will ask you questions about how well, and how much you use your weaker arm and hand in everyday life. We will also ask how your stroke has impacted your life, and how confident you are when using your weaker arm and hand for daily activities. The questions we ask are from tests that are used in many stroke rehabilitation research studies.

Tests of Reaching Ability and Muscle Activity (Motion Capture & EMG – about 90 minutes)
During two separate assessment visits before therapy and after the last therapy visit, we may use special video cameras and sensors that allow us to precisely monitor your movements and measure when your muscles are active while you are reaching for targets in front of you. During these assessments we will tape small reflective markers to your arm, back and torso. The markers will be seen by the special cameras in the lab. The markers will give us information about how your arm moves during the tests. We will attach EMG sensors on the skin over the muscles of your arms. These sensors will give us information about how your muscles are working while you perform these reaching tasks. We may need to shave and clean your skin with alcohol before attaching the sensors. We may wrap elastic bandages around the sensors to hold them in place. We will ask you to repeat each task at least 3 times. We will give you rest breaks between tasks and we will give you extra time to rest when needed.

Wearable Sensors (about 15 minutes)
We will ask you to wear a sensor each wrist at home for three days before therapy begins, at the end of therapy, and one-month after therapy has ended. These sensors are about the size of a wrist watch and they measure your arm movements during every day activities. We will either

ask you to return these sensors at your next visit, or we will give you a stamped self-addressed envelope to mail them back to us.

<u>THERAPY SESSIONS</u> (about 60 minutes)

You will come for 18 one-hour therapy visits during weekdays (3 days a week for six weeks). During all therapy sessions, we will use cues from the Active Learning Program to help you learn ways to better use your weaker hand. If you miss 1-3 sessions, you may reschedule them and receive therapy for an additional 1-2 weeks so you receive all 18 visits. However, if you miss 4 consecutive appointments you may be removed from the study.

You will receive a home action plan to help you carry-over the Active Learning Program cues you practice in therapy during activities you would like to do at home with your weaker arm. Your completion of the home action plan is voluntary and will not affect your therapy in any way.

Everyone who participates in the study will use two different rehabilitation devices: the Armeo and Amadeo robots. Both devices have been approved by the Food and Drug Administration (FDA) for therapy of the weaker arm and hand after stroke. You will use the Armeo robot during the first 9 therapy visits, and the Amadeo robot during the last 9 therapy visits. The Armeo robot will help you to practice reaching movements with your weaker arm while you play computer games on a screen. The games will be like everyday tasks, such as reaching to pick up items from a shelf and putting them into a basket. When using the Armeo robot, your weaker arm will be strapped to the robot arm. The robot will help support your arm but will not move it as you play these games.

The Amadeo is a hand robot with active motors that can help with finger and thumb movements as you play computer games on a screen. When using the Amadeo robot your forearm will be strapped to the robot base and small magnets will be attached to your fingers with special tape. These magnets connect your fingers to the robot so it can help with opening and closing your hand as needed during the therapy games.

You may be randomly assigned to the group that receives robot therapy plus arm and hand therapy with every-day objects. People in this group will have the same amount of therapy but will do robot therapy for about half of each therapy session and arm and hand therapy with the research staff for the other half of each session. During this therapy you may practice using your weaker arm and hand for tasks such as reaching to turn on light switches, washing dishes, opening doors, etc. The activities you practice will be challenging but achievable, based on your movement abilities.

You may rest after every 10 minutes of therapy, if needed. You can ask for more rest breaks in between if you need to. We may make the games harder to play as you get better at them. We will tell you before we make any changes. We may ask you to stop the study if you can't play the computer games. You may ask to stop taking part in the study at any time.

Videotaping
We may videotape and/or photograph your assessment sessions so we can look at how you move during the session. We will destroy the videotapes/photos after 7 years from the date we close the study. This is the policy of Partners Healthcare System.

- ☐ Initials:___ I agree to be videotaped and photographed during my therapy session.
- ☐ Initials:___I agree to let photographs of me be published in articles about this research study.
- ☐ Initials:___I agree to let videos and photos of me be used in presentations of this study to other researchers.

We can hide your face so that people outside the lab can't recognize you in the videotapes or photos.
Please check one of the boxes:

- ☐ Initials:___I want to be anonymous.
- ☐ Initials:___I do not want to be anonymous.

What are the risks and possible discomforts from being in this research study?

Assessment Sessions
During tests of reaching ability and muscle activity (motion capture & EMG) in the lab, we will apply small reflective markers and EMG sensors to your skin with sticky tape. If you have fragile skin, your skin may become red or irritated from the sticky tape. The risk is similar to wearing a Band-Aid for a few hours and peeling it off. You may experience some discomfort when wearing the wrist sensors at home. The discomfort you may feel will be similar to wearing a watch and bracelet. We will try to decrease these risks by using special tape or soft webbing to increase your comfort and prevent skin irritation.

Therapy Sessions
The risks of arm and hand therapy using real objects and activities are no different than conventional therapy. The known risks involved with the robotic therapy are minimal. Both the

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Armeo and Amadeo robots have excellent safety records. It is possible that you may feel minor fatigue or muscle soreness after therapy sessions. Because the Amadeo is a powered robot that can move independently, it is possible that it could pinch or bruise your hand unexpectedly during therapy. We will be very careful when adjusting the height of the Amadeo robot to be comfortable for you to avoid pinching, and will be sure that your fingers are not attached to the robot when we turn it on. Emergency switches that immediately shut off robot power are within reach during therapy as an extra precaution to prevent injury. The straps and tape that attach your arm and hand to the robot may cause redness of your skin. This will go away. You may take as many rest breaks as you need during the training.

What are the possible benefits from being in this research study?

You may find a small improvement in your arm function after the arm and hand therapy you receive. This may not last, and you may also find no benefit at all. The data that we collect from this study will help us develop and refine the "Active Learning Program for Stroke" (ALPS) that we hope will teach stroke survivors ways to better use their weaker arm during daily activities. If successful, we will use what we have learned from this research to plan larger studies of robot-assisted therapy for persons with stroke. The findings of those larger studies may be helpful in improving the treatment in the future.

What other treatments or procedures are available for my condition?

Depending on your stroke, different treatments may be appropriate at different times in your recovery. Your doctor may recommend occupational therapy, a home exercise program, or no treatment at all may be appropriate.

Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should I do if I want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will I be paid to take part in this research study?

We will pay you $50 if you complete the entire research study. You will be paid $25 if you attend the initial and discharge assessments and all therapy sessions, but do not complete the 1-month follow-up assessment. If you withdraw or do not complete sessions as described above, you will not receive this payment. You may choose not participate if the $50 payment is not acceptable to you. We will cover the cost of parking at SRH and provide cafeteria vouchers for beverages during extended evaluation sessions.

What will I have to pay for if I take part in this research study?

There will be no additional cost to you for participating in this study

What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Susan Fasoli, ScD OTR/L is the principal investigator in charge of this research study. You can call her directly at MGH Institute of Health Professions at 617-643-4777 M-F 9-5 with any questions or concerns.

Paolo Bonato, PhD is Director of the Motion Analysis Lab where the study will take place, and is the on-site person responsible for this research study. You can call him at 617-952-6319 M-F 9-5. You can also call Catherine Adans-Dester, PT at 617-952-6321 M-F 9-5 with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call Dr. Susan Fasoli at 617-643-4777.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 617-424-4100.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my privacy?

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as "health information." In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

In this study, we may collect health information about you from:

- Past, present, and future medical records

- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable health information and why they may need to do so:

- Partners research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within Partners who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The Partners ethics board that oversees the research and the Partners research quality improvement programs.
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your health information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your information for any mailing or marketing list. However, once your information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

Subject	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent	Date	Time (optional)

Consent of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language

Statement of Hospital Medical Interpreter

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Hospital Medical Interpreter	Date	Time (optional)

OR

Statement of Other Individual (Non-Interpreter)

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Name	Date	Time (optional)

Consent Form Version: 5/21/18