Carepartner Collaborative Integrated Therapy in Sub-Acute Stroke

NCT04040751

Consent form for Carepartners dated August 24, 2020

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 80 people who are being studied, at Emory.

Why is this study being done?
This study is being done to answer the question: Does an educational program for caregivers of stroke survivors help improve the use of the stroke survivor's arm? You are being asked to be in this research study because you are a caregiver of a stroke survivor.

Do you have to be in the study?
It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for you or the stroke survivor's condition. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?
If you are eligible and want to be part of the study, you will participate for 3 months (2 evaluation study visits and 2 possible virtual home therapy visits). All study visits will be delivered remotely. The researchers will ask you to do the following: For the evaluations, answer questionnaires about your health, your feelings, your family and what you do to help the person who had a stroke. For the possible treatment sessions, you will be asked to review the online educational intervention. ALL of these procedures will be paid for by the study.

How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study question.

What are the risks or discomforts I should know about before making a decision?
The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include becoming upset as you think about your experiences as a caregiver, loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

Alternatives to Joining This Study
Since this is not a treatment study, the alternative is not to participate.

Costs
You WILL NOT have to pay for any of the study procedures.

What Should I Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.). Make sure you understand which parts of the study are research and which are standard care that you would have even if you did not join the study. Take time to consider this and talk about it with your family and friends.

Emory University
Consent to be a Research Subject / HIPAA Authorization
Caregiver Consent - Remote

Title: **Evaluation of a Carepartner-Integrated Telehealth Rehabilitation Program for Persons with Stroke**

Principal Investigator: Sarah Blanton, PT, DPT, NCS, Associate Professor, Emory School of Medicine, Physical Therapy Division

Sponsor: National Institute of Health/National Institute of Nursing Research

Introduction
You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:
- Please carefully read this form or have it read to you.
- Please listen to the study doctor or study staff explain the study to you.
- Please ask questions about anything that is not clear.

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most the web site will include a summary of the results. You can search this web site at any time.

What is the purpose of this study?
The purpose of this study is to develop an educational program for caregivers of stroke survivors who are receiving an exercise program for their weaker arm. Often after a stroke, an individual may experience weakness on one side of the body and may receive therapy to improve their function and ability to move. Because arm therapy involves activities and exercises that are practiced as part of a home exercise program, the role of the caregiver is very important to help the stroke survivor practice using his/her arm outside of therapy.

What will I be asked to do?

In this study, we will be comparing two groups of caregivers. One group will be asked to review an on-line educational program while their family member who had a stroke receives 2 three hour virtual sessions of arm exercises and goal setting for activities to practice at home. The other group will receive the traditional written educational information on caregiving and stroke.

The on-line caregiver educational program was developed to provide more information that may help caregivers understand more about stroke recovery and therapy and their potential roles in helping the stroke survivor gain as much benefit as possible from therapy. The educational information will be available on a website that can be viewed from

your own computer or tablet. If you do not have access to a computer or tablet, then you will be loaned an electronic tablet for the period of the study so that you can access the information.

Procedures

Evaluations: If you are willing to participate in this study, you will be asked to attend two virtual evaluation visits, one at the beginning of your family member/friend's therapy sessions and one evaluation three months (12 weeks) later. These caregiver evaluation sessions will involve filling out several questionnaires. The questions will be about your health, your feelings, your family, and what you do to help the person who had a stroke. The study team will deliver the packet of questionnaires to your home for you to complete. Once you have completed these forms, the study evaluator will assess some general questions about yourself during the remote evaluation visit. These interview questions and forms will take approximately 1 ½ hours to complete and all sessions will occur at your home. We will also send you an email with links to two electronic questionnaires to complete at week 8 of the study.

Some questions you will answer are about signs of depression. If your answers show that you maybe be helped by an evaluation for depression, we will contact you. We will suggest that you see your health care provider for an evaluation.

After the first evaluation, you will be randomly assigned to either the group that receives the online educational intervention or the group that receives the traditional written instruction about caregiving. The assignment is done randomly, like flipping a coin. If you are in the group that receives the online education intervention, we will invite you to participate in a virtual interview session at the end of the last evaluation to learn more about your experience with study. We will ask you questions about the benefits and challenges of the educational intervention and your suggestions for improving it. These interviews will be video-recorded, will last about 45-60 minutes and are voluntary, you do not have to participate if you do not want to.

Intervention: If you are assigned to the traditional written education group, a research therapist will provide educational materials (brochure and web-based information) on stroke recovery and caregiving after stroke and check in with you over weekly 10 minute phone calls to answer any questions you may have. If you are assigned to the group that will review the CARE-CITE on-line education program, the research therapist will spend time during the first virtual session teaching you how to access the educational information on the CARE-CITE website. You will be asked to review 6 educational modules (workbook chapters) over a period of 4 weeks while your loved one receives the 2 three hour virtual home based therapy sessions. You can review this information on your own time and ask the research therapist during the virtual sessions or weekly phone calls, if you have any questions. You can also email Dr. Blanton (sblanto@emory.edu) if you have any questions. You can look at the CARE-CITE website using your own computer or tablet, or we can loan you an electronic tablet (iPad). We ask that you return the tablet to Dr. Blanton at the end of second evaluation so that other study participants may use the equipment. We will be including a tracking application on each tablet so that we can help you keep track of the tablet just in case it gets lost or stolen.

Who owns my study information and samples?

If you join this study, you will be donating your study information. You will not receive any compensation if your information is used to make a new product. If you withdraw from the study, data that were already collected may be still be used for this study.

What are the possible risks and discomforts?

There may be side effects from the study procedures that are not known at this time.
The most common risks and discomforts expected in this study are: It is possible that thinking about your experience as a caregiver may cause you to be sad or upset. If being in the study causes you to become upset you can contact Dr. Blanton at 404 712-2222. She will talk with you about your feelings. If you need counseling because of being upset about your experiences, Dr. Blanton will talk with you about how to find a counselor.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?

This study is not designed to benefit you directly. This study is designed to learn more about caregivers of persons with stroke. The study results may be used to help others in the future.

Will I be compensated for my time and effort?

Each dyad (stroke survivor and caregiver pair) will receive $100 gift certificate for participating in this study. You (caregiver) will received $50 and your family member/friend will receive $50 individually or $100 as a pair for completing the study. If you (caregiver) and your family member/friend (stroke survivor) do not finish the study, you will be paid for the visits you have completed ($16/evaluation). Please note: The electronic equipment that may be loaned to you during the study is the property of Emory University. Unfortunately, we cannot not give you the electronic tablet for your participation. We can only loan you the electronic tablet for the duration of the study intervention and the tablet must be returned to Dr. Blanton at the second evaluation, so that other study participants may use the equipment.

What are my other options?

If you decide not to enter this study, there is care available to you outside of this research study. Traditionally, caregivers receive family education from therapists to learn how to help the stroke survivor with exercises. Frequently after being in the hospital after the stroke, stroke survivors may receive occupational or physical therapy to help improve the use of his/her weaker arm. The study doctor will discuss these with you. You do not have to be in this study to be treated for stroke or to receive education from therapists about how to help your loved one after a stroke.

Taking part in this study, however, may make you unable to participate in some other research studies, if they exclude people who have taken certain treatments. You should discuss this with the researchers if you have concerns. You may wish to research other study options at websites like clinicaltrials.gov and ResearchMatch.org.

How will you protect my private information that you collect in this study?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

De-identified data from this study (data that has been stripped of all information that can identify you), may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your deidentified data to other researchers. If we do, we will not include any information that could identify you. If your data are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

We will use your data only for research. We will not sell them. However, the results of this research might someday lead to the development of products (such as an educational commercial product) that could be sold by a company. You will not receive money from the sale of any such product.

Once the study has been completed, do you want us to contact you and ask whether you want to receive your results? If so, let the study team know, and they will contact you as the results become available.

Medical Record

If you have been an Emory Healthcare patient before, then you already have an Emory Healthcare medical record. If you have never been an Emory Healthcare patient, you do not have one. An Emory Healthcare medical record will be made for you if an Emory provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory Healthcare medical record you have now or any time during the study.

The results of some study tests and procedures will be used only for research purposes and will *not* be placed in your medical record. For this study, those items include: the CES-D (depression screen), SF-36 (quality of life measure). Family Caregiver Conflict (surrounding stroke recovery) Scale (FCCS), Family Care Climate Questionnaire.

In Case of Injury

If you believe you have become ill or injured from this research, you should contact Dr. Sarah Blanton at telephone number 404-712-2222. You should also let any health care provider who treats you know that you are in a research study.

If you get ill or injured from being in the study, Emory will help you to get medical treatment. Neither Emory nor the sponsor will pay for your medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

Emory and the sponsor have not, however, set aside any money to pay you if you are injured as a result of being in this study or to pay for this medical treatment. For Emory, the only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory employee. "Negligence" is the failure to follow a standard duty of care. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence.

Costs

There will be no costs to you for participating in this study. You will not be charged for any of the research activities.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

For your safety, however, you should consider the study doctor's advice about how to go off the study treatment.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study.

PHI that Will be Used/Disclosed:

The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.

Purposes for Which Your PHI Will be Used/Disclosed:

We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information. We will use and disclose your PHI for the administration and payment of any costs relating to subject injury from the study.

Use and Disclosure of Your Information That is Required by Law:

We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults.

Authorization to Use PHI is Required to Participate:

By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory may use and disclose your PHI to get payment to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- **National Institute of Health/National Institute of Nursing Research** is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Other researchers that are a part of this study.
    - Government agencies that regulate the research including: Office for Human Research Protections
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at: Emory Rehabilitation Hospital, 1441 Clifton Road, Room 213, Atlanta, Ga 30322.

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that

we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

Contact Dr. Sarah Blanton at (404) 712-2222; sblanto@emory.edu if you have any questions about this study or your part in it,

- if you feel you have had a research-related injury or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

Please initial for consent for video recording of evaluation and treatment sessions **_____[initials]**

TO BE FILLED OUT BY STUDY TEAM ONLY

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Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**