Title: Assessing an Animal-Assisted Treatment Program for Adults With Aphasia: The Persons With Aphasia Training Dogs Program

NCT Number: NCT04610346

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Consent to Participate in a Research Study and
Authorization for Release of Health Information for the Research Study Purposes

Jefferson Office of Human Research

Department of Rehabilitation Medicine
Moss Rehabilitation Research Institute (MRRI)

Research Study Title: Assessing an animal-assisted treatment program for adults with aphasia: The persons with aphasia training dogs program

Joining through the PSPCA

Research Study Sponsor: National Institutes of Health

Principal Investigator: Sharon Antonucci, Ph.D. CCC-SLP
215-663-6561

Key Information about this Research Study

This section gives an overview of this research study. There is a more complete description of this study in the pages that follow.

In this study, participants are trained how to teach dogs basic obedience skills like SIT or STAY. We want to see whether learning how to teach dogs is good for people who have had a stroke and have aphasia.

If you consent to being in this study, the first thing you will do is become a volunteer at the PSPCA main headquarters on Erie Avenue in Philadelphia. We can help you with the paperwork, but we will not communicate with the PSPCA about you.

Next, you will have a session at Moss Rehabilitation Research Institute. You will meet with a speech therapist to complete tests of your thinking and language skills and to talk about life with aphasia.

If you are eligible to continue, we will schedule dog training classes for you with dogs at the Pennsylvania SPCA (PSPCA). Research staff will meet with you at the PSCPA for the classes. There will be one class a week for 5 weeks. Assistance with transportation may be available. You will come to Moss and meet with a speech therapist for more testing a few days after dog training classes are over and 3 months later.

All sessions will be video recorded. You will be paid for research visits at MRRI. Assistance with transportation for these visits may be available.

There is always some unavoidable risk of injury involved when working with animals. To join this study, you must sign a separate release form saying you will not hold anyone associated with Moss Rehabilitation Research Institute responsible because of something that happens related to participating in the Persons with Aphasia Training Dogs Program.

Your participation in this study is voluntary. You do not have to join this study if you do not want to. You will not lose any services, benefits, or rights you would normally have if you do not participate.

General Information

This form has important information about this research study. The study will be done at Moss Rehabilitation Research Institute (MRRI), part of Jefferson Health.

'You' refers to the person who takes part in the research study. You will have a chance to read over the information and think about it before you are asked to decide if you want to take part. A member of the research team will talk to you about taking part in this research and answer any questions that you may have.

What is some general information you should know before joining a research study?

- Someone will explain the research study to you. You can ask all the questions you want before you decide.
- You volunteer to be in a research study. Whether you participate is up to you.
- You can choose not to take part in the research study.
- You can agree to take part now and later change your mind.
- Whatever you decide will not be held against you or change the care you receive.
- If you do not understand something about the research study, ask for an explanation before you agree to take part and sign this form. You can continue to ask questions even after you have made your decision at any time during the research study.
- You get a copy of this form once it is signed and dated.

How is being in a research study different from your regular healthcare?

Research is <u>different</u> from medical treatment. Medical treatment tries to make *you* better. Research tries to learn more about medical problems and treatments for a *group of people*. Research may or may not help you or make you better.

Who can you talk to about the research study?

For Questions About:	Person or Office	Contact Information
The Study or Research Related Injury	Main Investigator: Sharon Antonucci, Ph.D. CCC-SLP	215-663-6561
If you need to contact someone other than the study personnel about a concern or your rights as a research subject	Jefferson Center City Institutional Review Board (Ethics Committee)	215-503-0203 215-503-8966 215-955-4239

Study Specific Information

How is this study funded?

This study is funded by the National Institutes of Health (NIH). The NIH is a public agency that promotes and funds health related research.

Why is this study being done?

Scientists who work at Moss Rehabilitation Research Institute (MRRI) and study stroke are called the Brain Behavior Relationship (BBR) Research Group. Our research enrolls people who have had a stroke, as well as those who have never had a stroke. We study how the brain works and how problems caused by stroke affect people. We study behaviors like speech, attention, memory, and movement to find out what therapies work best and how the brain recovers.

This project looks at factors related to living with aphasia including social and psychological factors following stroke. We will use the results of this study to plan future research on animal-assisted treatment following stroke.

Do we use your medical information?

Yes, but only if it concerns research about brain functioning or stroke-related difficulties. For your convenience, we use available records when possible. This includes different types of tests you may have or already had (like memory tests or MRI scans). These results can come from tests done as part of your treatment at an Einstein Healthcare Network facility, or, tests that took place during your participation in MRRI research projects that study stroke. If your records are from a different facility, you will be asked to sign a separate release form. If we cannot use available imaging records, we may ask you to have a scan of your brain at the University of Pennsylvania; details on this scan study will be discussed with you at a later time if you are eligible and interested.

More information about how your medical information is protected and shared can be found in the Confidentiality Section of this form.

About how many people will take part in this research study?
About 20 people may complete this study.

Why are you being invited to take part in the research study?
You have had a stroke and now experience aphasia (problems talking or understanding language). You are also interested in working with dogs.

Where will your research visits take place?

- Dog training, practice and observation sessions will take place at the PSPCA.
- The Assessment visits with the Speech Therapist will take place at:
  Moss Rehabilitation Research Institute
  Medical Arts Building
  50 Township Line Road
  Elkins Park, PA
  A friend or family member can come with you.

Do you have to take part in this research study? What happens if you say no?
You do not have to take part in this research study. If you decide you do not want to take part in the research study:

- There is no penalty or change to any benefits that you are otherwise entitled to.
- You can still see your doctors and have therapy at Jefferson Health.
- Your medical care and the relationship you have with your healthcare team or Jefferson Health will not change.
- Your medical benefits will not change.

What if you decide not to take part in the study? Are there other treatment choices?
Whether or not you take part in this study has no bearing on the standard of care treatment choices available to you. However, if you currently receive rehabilitation therapy, please tell the researcher. This could help us decide when to schedule the start of dog-training classes. After the dog-training classes have begun, please talk to Dr. Antonucci before starting speech and language therapy or psychological counseling services. We ask that you do not join other dog training classes until this study has ended. We also ask that you do not participate in other research until the assessments for this study have been completed.

What will you do if you join this research study?

Becoming a PSPCA volunteer

The first thing you will do is become a PSPCA volunteer. This involves completing an application and doing some training online and in-person. We can help you with the paperwork, but we will not communicate with the PSPCA about you.

Intake and Baseline Testing

Once you are an official PSPCA volunteer, you will be then be seen for an intake session. You will be asked about your medical history related to stroke and your current health. You will complete some tests of your thinking and language skills and be interviewed about living with aphasia. The visit will last about 2-3 hours and you will be paid for participating. If you are eligible to continue, dog training classes will be scheduled to begin as soon as possible after the intake session.

Dog Training, Practice and Observation Sessions

You and a dog living at the Pennsylvania SPCA (PSPCA) on Erie Avenue in Philadelphia, PA will work together. Research team members will work with you to conduct dog training classes and observation sessions. It is possible that you will work with a different dog each week.

- You must complete the official PSPCA volunteer training process before you can begin dog training sessions. You can only work with dogs at your color level or 'easier'.
- Dog Training: Classes will be held 1 time a week for 5 weeks. Each week you will be taught how to teach a dog a new obedience skill. These skills are LOOK, TOUCH, SIT, STAY, and COME. A Training Class will usually last about 75 minutes.
- Skills Practice: You are asked to practice obedience skills with a dog at least 3 times a week. You will be given a log sheet to keep track of your practice times. You may only work with dogs who are at your color level or an easier color level. Help with transportation may be available.
- Observation: A certified dog trainer will watch you and your dog after the dog training classes have ended. These visits will be a few days after the last class and again 3 months later. You will show how to use the obedience skills taught during the classes and the dog trainer will assess how you do.

Outcome Testing

You will meet with a Speech Therapist at MRRI after the dog training classes have ended. There will be 2 sessions: one a few days after the dog training classes end, the

second about 3 months later. You will complete some tests of your thinking skills and be interviewed about living with aphasia. The visits will last about 2-3 hours and you will be paid for participating.

Many of the tasks you complete will be audio and video recorded. More information about how recordings are used, protected, and shared can be found in the Audio and Video Recording Section of this form.

How long will your participation in the research study last?
All study activities will take place over 5-6 months. Dog training classes and observations last about 75 minutes. Research visits to MRRI may last up to 2-3 hours.

What if you decide you want to take part in the study but change your mind later?
If you decide to take part in the research study, you always have the right to change your mind. You can decide you no longer want to take part in the research study at any time. No matter what your choice is, there will be no penalty to you. Your choice will not affect the care that you receive, your benefits or the relationship you have with your healthcare team or Jefferson Health. It is important that you talk to the study team if you are thinking about leaving this study before it ends.

If you do change your mind about taking part in the research study:

- Any information that has already been collected about you will remain part of the research records and cannot be removed.
- No new information will be collected about you after you tell the research study team you have changed your mind about being in the study.

Could taking part in this research study put you at risk or cause any discomfort?

- <u>Dog Training Classes, Practices and Observations</u>
  There are always some unavoidable risks involved when working with animals.
  - Risks that a dog may cause injury to you or other persons;
  - Risks that a dog may cause damage to the location;
  - Risks that saliva, water, food, snow and/or other debris may be present in the training area.

  To join this study, you must sign a separate release form saying you will not hold anyone associated with Moss Rehabilitation Research Institute responsible because of something that happens related to participating in the Persons with Aphasia Training Dogs Program.

- Research Testing Visits at MRRI
  There is a chance that you might get frustrated or tired during the testing visits. Sometimes things we ask you to do may be hard for you. But, we will take as many rest breaks as you need. You might feel uncomfortable while discussing your mood and personal issues. You may decline to answer questions as you wish. If you are or become pregnant, there are no additional risks to you or your baby.

Could taking part in this research study help you or others in any way?
We cannot promise that being in this study will help you feel better about living with aphasia. You will not receive any official certificate for completing the dog training; Dr. Antonucci is not a certified professional dog trainer. The information we get may help us plan animal-assisted treatment for people with aphasia in the future.

Could your taking part in this research study end early or be stopped for any reason?
Your participation in the research study can end early or stop at any time. Some of the reasons this might happen include:

- If you decide you no longer want to take part in the study
- If you are not able to or do not do the things that the study requires
  - For example, if you miss 3 dog training sessions in a row
- If your health or other circumstances change and the research team feels that it is no longer in your best interest
- If the study is ended by the sponsor

Is there any cost to you for taking part in this research study?
Neither you, nor your insurance provider, will be charged for research visits related to this study. However, your standard medical care remains your responsibility or the responsibility of your insurance provider.

Will you be paid or receive anything for taking part in this study?
Yes. We will give you $15 per hour for your time and effort during the assessment sessions conducted in our offices at MRRI. You will be paid for each session you attend. Because you can work at your own pace, the total amount may vary from person to person. Most people will earn between $90-$135 over the course of the whole study.

Payment will be made using a pre-paid debit card. It works like a bank debit card except you do not need to have a bank account. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after each completed visit. You may use this card at any store that accepts a credit card or you

can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals and inactivity. You will receive additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, will be given your name, address, and date of birth. They will use this information only as part of the payment system. Your information will not be used for any other purposes and will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating.

You will be asked to fill out a W-9 form that asks for your name, address, and social security number. The information will be given to our accounting department and will be used to meet tax reporting responsibilities.

Depending on your situation and the availability of funds, our researchers may offer to schedule your transportation to and from study visits. Accepting this service is completely optional. If we schedule your travel, we will provide your name, address and phone number to the transportation company. Payment for the ride service will be made directly to the transportation company by our office. If you use transportation that is scheduled by us, please understand that we are not responsible for anything that may occur during that transportation, just like we would not be responsible if you were to make your own transportation arrangements. If we do not schedule your travel and costs make it impossible for you to attend research sessions, we can offset your travel expenses up to $20 per session (credited to your Clincard at the time of your visit). The maximum number of visits to the PSPCA that will be arranged or reimbursed is 20. This provides for all 'required' evaluation and training sessions, plus 12 additional practice visits. You are welcome to travel more frequently to the PSPCA, but no more than 20 visits to the PSPCA will be funded by the study.

What happens if you get hurt or get sick from taking part in this research study?

- To help avoid injury or illness, it is very important to follow all research study directions
- If you have an emergency, call 911 right away or go to the emergency room (ER)

If you are injured or get sick because of this research study, you can get medical care at any of the Jefferson Health facilities, your local doctor or provider, or any other healthcare facilities, when needed. You choose when and where to get medical care. It is also important that you tell the research team about any research study-related illness or injury.

In the event of an injury or illness resulting from your participation in this research project, you will be provided with clinically appropriate medical care for that injury or illness within the capabilities of Jefferson Health. However, Jefferson Health cannot assure that the medical care and treatment will be provided without charge, and the costs incurred may, ultimately be your responsibility.

Confidentiality (privacy) Of Your Personal Information

This study is covered by Certificate of Confidentiality from the National Institutes of Health. The Certificate means that we do not have to give out identifying information about you even if we are asked by a court of law. We will use the Certificate to resist any demands for identifying information, but there are some limits to this protection. We may voluntarily provide the information to authorities if we learn of or observe child abuse, elder abuse, animal abuse, or the intent to harm yourself or others.

We will also share your research information with your written permission. You or a member of your family can share information about your part in this research if you wish.

Who sees the information collected about you?
Your information may be viewed by the individuals involved in conducting this research, including those collaborating, funding, and regulating the study. We share the minimum amount of information necessary on a need to know basis (only when we have to) and ask anyone who receives it from us to protect your privacy. Even though we are very careful, there is a chance that if we share your information with someone else, it could then be used or shared in a way that it will no longer be protected like we protect it here.

We cannot promise complete confidentiality. If you agree to be in this study, federal or state laws may permit or require us to show information to others who may or may not be part of the research study.

The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you that we create, collect, or use as part of the research. This permission is called an Authorization. If you sign this form, the following people may access, use, store or share your research and personal health information collected as part of this study:

- Members of the Jefferson Health / MRRI research team
- Other MRRI staff members: Other researchers who work here can sometimes help us understand the information we get from you during the study. They also help us

plan future studies. Sometimes these researchers may know you, if you have been in their studies. Sometimes the researchers may not know you.

- The Study Sponsor: The National Institutes of Health pays for this study and may need to look at your study record.
- Regulatory Agencies: The Office of Human Research Protections is a government agency that provides research oversight. The Institutional Review Board at Thomas Jefferson University looks over the results of this study every year to make sure all the rules are being followed. Regulatory agencies may conduct audits that look at your study records and may photocopy records that have your name listed.
- Government officials and the staff of Thomas Jefferson University and its Affiliates who need to see this information as part of their job.
- The MRRI Research Registry: If you are a member of the Registry, we will let the Registry team know when you started and finished this study. We will send them updated information about you, such as a new phone number. We will send them results from some of the research surveys and tests you complete.
- Transportation Companies: If you ask that we make travel arrangements for you, we will provide your name, address and phone number to the ride service. We will also let them know of any special travel related needs you may have.
- The BBR Research Group: Your study records may be also shared with MRRI researchers for use in other projects that study brain-behavior relationships and address stroke-related issues. These projects will be approved by an authorized IRB prior to your research information being shared.

Additionally, your research results may be shared with other laboratories or individuals who provide services or analyze health information in connection with this study. The information shared with these researchers will not include your name or other information that can identify you and will be used for one or both of the following specific purposes: (1) to assist the project team in interpreting research information; or (2) to assist the project team in planning future studies.

The PSPCA is a public place. PSPCA staff will not be involved in your sessions. The research team will not identify you to PSPCA staff or share your study information with PSPCA staff. But, there are no completely private spaces within the PSPCA. It is possible that PSPCA staff or volunteers who see you with the research team may guess that you are in the PATD program. This may identify you as having had a stroke or having aphasia.

The research team may let the PSPCA staff know which dogs have worked on each skill.

You can talk about the program with anyone you want. The research team cannot guarantee that other people will keep your information confidential.

What research and personal health information will be collected as part of this study?

If you sign this form, you are authorizing (allowing) the study's team members to collect certain kinds of information:

- We collect your contact information so we can get in touch with you by phone, cell phone, letter, text or email.
- We collect general information, such as if you're male or female, your age, work experience and education.
- We collect research information, such as notes that the research team makes about you during this study and results of any surveys, questionnaires or tests you did for the study.
- We collect health information, such as images of your brain and information about stroke-related problems that you may experience. This information includes findings from tests you complete for medical or research purposes. Information may collected be from your past, present or future medical and research records.

How is your research and personal health information protected?

The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you that we create, collect, or use as part of the research. This permission is called an Authorization. Jefferson Health follows the rules of the federal law (HIPAA) and all other related laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it will no longer be protected. Our Notice of Privacy Practices (a separate document) explains how we protect your information. A copy of the Notice will be given to you if you have not already received a copy.

Will your authorization ever expire?

This Authorization does not have an expiration date. The study team may need to correct or provide missing information about you even after your study participation is over. A review of your research or medical records may also take place after the study is over.

May you take back your authorization?
You have the right to take back (revoke) your Authorization at any time by writing to:

Sharon Antonucci, Ph.D. CCC-SLP
Moss Rehabilitation Research Institute
Medical Arts Building
50 Township Line Road
Elkins Park, PA 19027

If you revoke your Authorization, the study team will not collect any new health information about you. However, they can continue to use and disclose any already-collected information if that is necessary for the reliability of this study. If you revoke your Authorization, you can no longer continue to participate in the study.

What if the information from this study is published?
We may publish reports about this study that describe results of this study. In those reports, we will not use your name, and there will be no way to identify you.

We may publish results from this study on a website that other researchers and clinicians can use in their studies. These results may describe what you did in this study. But we will not use your name, and there will be no way to identify you.

How will the information that is collected from you during the research study be kept confidential?

- Research files and records are not labeled with your name. We use a subject code on all research information. Only the study staff at MRRI can link that code to your name or other information that can directly identify you.
- Your signed consent document will be stored in a locked file that only the research team can access.
- The 'paper' research record created from your information will be stored in a locked file that only authorized individuals can access.
- Your electronic research information, including video recordings, is stored on internal computer systems. Electronic files may also be saved to a secure location through a subscription to a private web-based cloud service. Video recordings will be moved from the video camera to a secure location as soon as possible.
- Only authorized members of our research staff will have electronic access to your information. This is true whether the files are saved at our facility or on a web-based platform.
- Your electronic research information is kept safe by password protection and other information security practices.

- Research staff may use their personal telephones or devices to contact you or to get driving directions to your location if necessary. Your contact information and/or text messages will not be saved to a staff member's personal device.
- Information is kept only as long as necessary and will be destroyed according to hospital policy.

Will your information be used for other research?

Information obtained about you in this study may also be used for other research studies here at Einstein.

Your information may also be shared with institutions outside of Jefferson for other research projects. Before your study record is shared with other institutions for further research, information that identifies you will be removed. The individuals performing the additional research will not know who the information came from. You will not be asked for additional consent to use your information for such research projects.

What else do you need to know if you decide to take part in this research study?

- 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
- You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.
- You have the right to see and get a copy of your health information that is used or shared as part of this research study. Tell the person in charge of this research study if you would like this information.
- You have a right to refuse to sign this form. If you do not sign the form, you may not be in the research study, but refusing to sign will not affect your health care outside the study.
- Signing this form does not mean that you are giving up your legal rights.

Audio and video recording

Audio and video recording are a required part of this research project. Study staff will watch and listen to these recordings in order to transcribe your speech and to observe your skills.

You will be told when you are being recorded, the recordings are digital. They may be used indefinitely but will be stored for a minimum of 6 years after the study has ended. The recordings will not use your full name, but since they may include your voice and images of your face, it is possible that you could be recognized by a viewer.

By signing this consent form, you allow us to record your research sessions and to use these recordings for research purposes. These recording will be shared and protected as described in the Confidentiality Section of this form.

Additionally, we may present reports about this study for educational reasons and may wish to show recordings of you during these presentations. Use of your video for educational purposes is optional. Please indicate below whether or not we have your permission do so.

_____ (initial) YES, I allow video recordings created during my research sessions to be shown for educational purposes. I understand that the audience may include health care providers, researchers and students from inside and outside Jefferson Health. I understand that I can withdraw my permission for these recordings to be used at any time.

_____ (initial) NO, I do not allow videos created during my research sessions to be used for educational purposes.

Email Communications

We are asking for your email address so we can arrange appointments and answer your questions about this research project. Email is generally not a secure way to communicate about your health. You should not send sensitive, detailed personal information by email.

You do not have to provide your email address to participate in this study. Please initial one of the lines below.

_____ (initial) Yes, I may be contacted by email.
My email address is _____

_____ (initial) No, I do not want to be contacted by email.

How do you indicate your decision about taking part in this research study?

If you decide you want to take part in this research study, you must sign and date this form.

Patient/Subject: By signing this form, you are agreeing that:

- You were given the opportunity to read this form.
- All of the information in this form was discussed with you by an investigator or other research personnel to your satisfaction.
- All your questions have been answered to your satisfaction.
- You were not pressured and you voluntarily agree to take part in this research.

_____	_____	_____
Your Name	Your **Signature**	Date
_____	_____	_____
Name of Person Obtaining/ Assisting with Consent	Signature of Person Obtaining/ Assisting with Consent	Date

By signing below, you the **investigator**, certify that you, a co-investigator, or other properly trained and qualified key personnel, reviewed the elements of consent with the study participant.

_____	_____	_____
Name of Investigator	Signature of Investigator	Date
_____	_____	_____
Name of Witness	Signature of Witness	Date

(Witness required if the only language the subject speaks and understands is English, but the subject cannot read English, or if the subject is blind or cannot physically sign the consent form.)

☐ **Copy of Signed and Dated Consent Form Given to the Subject/Parent/LAR**