Development of Vision-Guided Shared Control for Assistive Robotic Manipulators

NCT04323449

October 9, 2023

Subject Name: _____ Last 4 SSN: _____ Date: _____

Title of Study: Evaluation of Vision-Guided Shared Control for Assistive Robotics Manipulators

Principal Investigator: Dan Ding, PhD VAMC: Pittsburgh (646)

LAY TITLE: **Evaluation of Vision-Guided Control for a Robotic Arm**

KEY ELEMENTS:

This is a research study to evaluate a new control method for a wheelchair-mounted robotic arm among powered wheelchair users. Your participation in this study is voluntary.

This research study will consist of a questionnaire about general demographics (such as age, and race), health information, and previous experience with assistive technology. You have the option of completing these surveys verbally or on paper. Several tests will also be administered to test upper extremity function and ability as well as to test your ability to view a two- and three-dimensional object. You will then undergo a training phase with the assistive robotic arm mounted on a table to assess if you will be eligible for participation in the study. If you are eligible you will move on to a second training phase where you will be asked to learn and practice slightly more complex tasks while using the new control interface. After this training, the assistive robotic arm will be mounted to your wheelchair, a table or a stand and you will be asked to complete several everyday tasks from a task list. Portions of the study will be videotaped if you provide permission to do so. At the conclusion of the study, we will conduct a brief interview with you and obtain more insight on how you perceive the ease-of-use and usefulness of the new control. The location of this study will be conducted either at the lab or at your home. You have the options of scheduling a single lab or home visit no more than 6 hours or multiple 2-3 hour lab or home visits where the combined visitation time will take 6 hours at most. If it is not possible to do a 6 hour visitation, you have the options of a single 3 hour visitation.

There are risks to this study device that are described in this document. Some risks include: frustration , a device malfunction, damage to the object and leaving tape trail on the object. You will not directly benefit from participating in this study. You may however, receive indirect benefit given that you are contributing to medical science or helping to advance future understanding of Assistive Robotic Manipulators.

You have the right not to participate.

If you are interested in learning more about this study, please continue reading below.

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STUDY CONTACT INFORMATION: If you have a general question about this research study, or if you have any concerns or complaints related to this research study, you may call any of the investigators listed below.

If you experience any illness, injury or other medical problem that you feel may be related to this study, please call 412-822-3700 during the day. In the case of a medical emergency contact your local emergency medical service or go to your local emergency room.

Principal Investigator: Dan Ding, PhD

Co-Investigators: Rory Cooper, PhD
Cheng-Shiu Chung, PhD
Breelyn Styler, PhD
Lindsey Morris, OTD OTR/L

Contact Information: Human Engineering Research Laboratories
VA Pittsburgh Healthcare System
6425 Penn Avenue, Suite 400
Pittsburgh, PA., 15206
412-822-3700

STUDY SPONSOR:
Department of Veterans Affairs: Merit Review (CC 103)
Additional information regarding the study sponsor can be provided upon request

PURPOSE OF THE RESEARCH STUDY: The purpose of this research study is to evaluate a new control method for a wheelchair-mounted robotic arm among powered wheelchair users.

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You are being asked to participate in this research study because you are 18 years of age or older, use a power wheelchair as primary means of mobility, and have self-reported difficulties in performing everyday manipulation tasks such as reaching for a glass of water, opening a refrigerator, and picking up a toothbrush. Up to 21 subjects will be recruited to participate in this study at the Human Engineering Research Laboratories.

DESCRIPTION OF THE RESEARCH STUDY:
This research study will require a single visit or multiple visits to the Human Engineering Research Laboratories in Bakery Square, Pittsburgh, PA or at your home that will last no more than 6 hours.

The following study procedures will be conducted:

You will first be asked to complete a basic questionnaire which includes questions about general demographics, injury and health information, and assistive technology experience. You will then be asked to answer a survey for upper limb function and symptoms. Then we will administer two tests (including a paper folding test and a cube comparison test) to examine your spatial visualization and orientation abilities.

Training Sessions
You will then go through a basic training session. In this session, we will explain the basic operation principle of the robotic arm, and you will learn to operate the arm and practice the basic movements. You will also be given opportunities to try different control interface options. You will start with the method you use to control your power wheelchair and could explore other options such as the touch interface. This session will last for about one hour. At the end of the training, we will ask you to perform three simple tasks on a task board including pushing a large round button, flipping a toggle switch, and pushing down a door handle using the robotic arm mounted on a table. If you can complete each task within 2 minutes, you will be considered eligible for participating in the study and move to the next training session. Otherwise, more practice and training will be provided. Investigators may also decide whether you have proficient skills to move onto the next session or if the trial should be concluded.

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In the 2nd training session, we will explain more advanced features of the robotic arm, and also introduce new control interface. This session will last approximately 1.5 hours. After training, we will install the robotic arm to your wheelchair, a table, or a stand and configure the control interface for you.

Testing Session
Prior to testing, you will be given a task list that including a list of typical everyday living manipulation tasks. You will be first asked to rate the task in terms of type of assistance needed, levels of difficulty, and levels of satisfaction. You will then be asked to select 5-10 tasks that you cannot complete on their own. You will then complete the selected tasks with two interventions, the default control and the new control. There will be a break after each intervention, and you can also request resting periods at task transitions. The testing session will last about 2 hours. The testing session will be video recorded so that they may be viewed by the study team during data analysis. We will collect a number of measures after each intervention such as task completion time, task success rate, your cognitive load, and usability of each control.

At the conclusion of the study, we will conduct a brief interview with you to obtain more insight on how you perceive the ease-of-use and usefulness of the new control as well as obtain suggestions you may have for further development and deployment. The interviews will be audio-recorded for later transcription. The recordings will not be shared outside of the VA.

RISKS AND BENEFITS: This research study involves minimal risks. All necessary precautions will be taken to minimize the possible risks.

- Device Malfunction: There is the risk that the device/control could malfunction. To minimize this risk, the investigators will be working on your side and provide supervision as needed. The device is designed to operate under slow speeds and allows investigators to specify safety zones where the arm cannot reach. In addition, safety switches are installed, and investigators have the ability to completely shut down the operation of the device for any reason. Thus, no physical injury (e.g., swinging around and hitting you) can occur using this device.

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- Frustration: You may experience frustration while learning to use a new device. You will be provided with extensive training and allowed to take a break and/or discontinue the study at any time. You will also have the option to decline to complete a task if they are unable or choose not to.

- Object damage: If the study is conducted at your home, the object for robotic arm testing might be damaged. To minimize the risk, we will not use any fragile items. The investigator will also be working on your side, giving you instructions on the robotic arm operation when needed to reduce the risk.

- Tape trail on the object: If the study is conducted at your home, a tape trail may be left on the testing object. We will use tapes that do not leave marks when peeling off to reduce the risk.

You will not directly benefit from participating in this study. You may however, receive indirect benefit given that you are contributing to medical science or helping to advance future understanding of assistive robotic manipulators and assistive technology.

ALTERNATIVES TO PARTICIPATION:
There may be other studies that you qualify for. Talk to your provider about such options. You also have the alternative not to participate in this research study.

NEW FINDINGS: You will be informed of any significant new findings during the course of the study, which may affect your willingness to continue to participate. This study will not generate any clinical findings.

INVESTIGATOR INITIATED WITHDRAWAL: The investigator(s) may stop your participation in this study without your consent for reasons such as: it will be in your best interest; you do not follow the study plan; or you experience a study-related injury.

VOLUNTARY PARTICIPATION/RIGHT TO WITHDRAW: Your participation in this study is voluntary. You do not have to take part in this study, and your refusal to participate will involve no

penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled.

MEDICAL TREATMENT: In the event that you sustain injury or illness as a result of your participation in this VA approved research study, conducted under the supervision of one or more VA employees, all medical treatment (emergent as well as medical treatment beyond necessary emergent care) will be provided by the VA. Except in limited circumstances, the necessary medical care must be provided in VA medical facilities.

However, if such injury or illness occurred as a result of your failure to follow the instructions for this study, you may not be eligible for free care unless you have independent eligibility for such care under Federal Law.

FINANCIAL COMPENSATION: If you sustain an injury or illness as a result of participating in this research study, you may be eligible to receive monetary compensation for your damages pursuant to applicable federal law. If you believe that you are injured as a result of participation in this study, please contact the Principal Investigator. If compensation is available the Principal Investigator will provide you with an explanation as to what that compensation consists of, or where you can obtain further information regarding it.

COST AND PAYMENTS: You or your insurance will not be charged for any costs related to the research. However, if you are receiving medical care and services from the VA that are not part of this study, and you are a veteran described in Federal regulations as a "category 7" veteran, you may be required to make co-payments for the care and services that are not required as part of this research study.

You will be compensated $25/hour up to $150, if you complete the full 6 hour study, for your time and effort in completing this study.

Except in limited circumstances, payments issued through VA are generated by Electronic Funds Transfer (EFT). Therefore, in order to receive payment associated with your participation in this study, you must be willing to receive EFT and to provide banking information to VA, if that information has not already been provided. If you are not able to receive payment through EFT, the Direct Express Debit MasterCard

may be issued. The Direct Express Debit MasterCard is a prepaid debit card. Please refer to the flyer that study personnel has provided for more information about which services may require a fee if using your Direct Express Debit MasterCard.

In addition, due to limitations in the Financial Management System, payments made to you will generate Internal Revenue Service (IRS) Form 1099 regardless of amount. Payments will be reported to the IRS as income and your social security number will be used for this purpose.

RECORD RETENTION: Your research records will be retained in accordance with the Veterans Health Administration (VHA) Records Control Schedule, or longer, if required by other Federal regulations.

CONFIDENTIALITY AND USE AND DISCLOSURE OF DATA: There are rules to protect your private health information. Federal and State laws and the Federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization', for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including:

Demographic Information such as name, age, race, date of birth

Photographs, Digital Images, Video, or Audio Recordings

Questionnaire

Other: difficulties in everyday life; impaired vision; history of pressure sores;

The research team may also need to disclose your health information and the information it collects to others as part of the study progress.

In addition, Institutional Review Board, Food and Drug Administration, Office (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government

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Accountability (GAO) may have access to your research records. Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient. Additionally, any medical information may be shared with your healthcare provider(s) with your consent, and possibly without your consent if permissible under Federal laws and regulations.

Finally, you consent to the publication of the study results or release of the data when published, so long as the information about you is anonymous and/or disguised so that your identity will not be disclosed

Confidentiality risks and precautions to decrease risk:
Every effort will be made to make sure that the information about you obtained from this study will be kept strictly confidential. As private information is collected about you as part of this study, there is a risk to your privacy and confidentiality. The research staff will take every precaution to protect your identity and the confidentiality of the information collected about you.

Any electronic or hard/paper copies of the information collected about you will be stored in a secured location. Any copies that contain information that could be used to identify you (such as your name, address, date of birth, etc.), will be stored separately from any information that does not contain identifiers. Only those individuals who are authorized to review your information will have access to it.

Future Use
Information from this study will be kept for future studies. A copy of coded research data (with your subject ID) may be shared with other investigators studying wheelchairs or combined with other data sets related to wheelchair use and development.

Future use is part of this study. By signing this form, you are authorizing and permitting uses and/or disclosures of your data for future research purposes (e.g., future studies). We will ensure that any data that can be used to identify you is not shared.

All data will be stored within secure VAPHS network with restricted access to the study team and will be maintained in accordance with the Veterans Health Administration (VHA) records control schedule.

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Revocation: You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Principal Investigator at the address below. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

Dan Ding, PhD
Human Engineering Research Laboratories
VA Pittsburgh Healthcare System
6425 Penn Avenue, Suite 400
Pittsburgh, PA., 15206
412-822-3700

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

RESEARCH SUBJECTS' RIGHTS: You have read or have had read to you all of the above. Dr. Ding or his/her authorized representative has explained the study to you and answered all of your questions. The risks, discomforts, and possible benefits of this research study, as well as alternative treatment choices, have been explained to you.

A description of the study has been provided to you, including an explanation of what this study is about, why it is being done, and the procedures involved. You have the right to ask questions related to this study or your participation in this study at any time. You should be giving your consent only under conditions in which you (or the person representing you) have sufficient opportunity to carefully consider whether or not to participate in this study. Your consent should not be given under conditions that pressure you or try to influence your decision in any way.

Your rights as a research subject have been explained to you, and you voluntarily consent to participate in this research study. You will receive a copy of this signed consent form.

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If you have any questions about your rights as a participant in this study or wish to speak more about the study with someone not associated with the research study, you can call the Associate Chief of Staff for Research and Development at (412) 360-2394.

As long as the study is renewed as required by the IRB, your signature on this document is valid for the duration of the entire research study. Should any changes occur during the course of the study that may affect your willingness to participate, you will be notified.

By signing this form, you agree to participate in this research study.

_____	_____	_____
Subject's Signature	Date	Time
_____	_____	_____
Investigator/Person Obtaining Consent*	Researcher (Print)	Date

**If person other than the Investigator is obtaining consent, he/she must be approved by the IRB to administer informed consent.*

Version Date: Oct 9th, 2023