Use of Socially Assistive Robots for Long Term Care Older Adults With Cognitive Impairment and Apathy

NCT05178992

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The Ohio State University Consent to Participate in Research

Aim 2: Evaluate Robot Activities in Long Term Care Settings

Study Title:	**Impact of a novel socially assistive robotic architecture on engaging older adults with mild cognitive impairment, Alzheimer's Disease, and Related Dementia in Long Term Care Settings.**
Researcher:	**Judith Tate, PhD, RN**
Sponsor:	**National Institute on Aging**

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.

Your participation is voluntary. You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

You may or may not benefit as a result of participating in this study. Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.

You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate. If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Purpose: Why is this study being done?

This study is being done by researchers at Ohio State University and Vanderbilt University. The purpose of the overall study is to see how robots might be used to help older adults in physical and social activities. Many have suggested that robots might be used to help older adults with physical and social activities. We would like to study how well robots can work with older adults and what older adults think about working with robots.

You are being asked to take part in this research study because you are an older adult and can provide us important suggestions as we test the use of robots in activities with older adults.

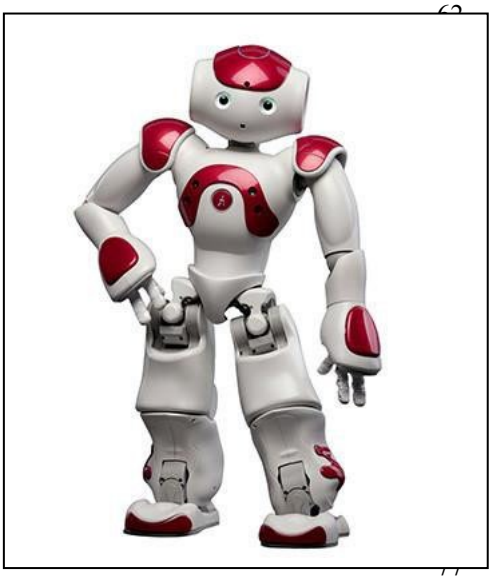
2. How many people will take part in this study?

We are asking 188 older adults who were not part of Aim 1 to take part in the study. Half will be randomized (like the flip of a coin) to test the robot activities. The other half will participate in non-robot activities.

3. Procedures/Tasks: What will happen if i take part in this study?

- You will be asked to complete some questionnaires about your thinking and memory, and thoughts about working with robots. You will complete these questionnaires three times: before you start the activity session, at four weeks, and at 8 weeks after the last activity session. This will take about 45 minutes each time.
- We will gather information from the nursing staff on your diseases and medications and physical activity. By consenting, you are agreeing to have them obtain this information from your medical records and provide to the study team for research purposes.
- You will be randomly assigned (like the flip of a coin) to test the robot (Group A) or have no contact with the robots (Group B).
- If you are in the robot group (Group A), you will be asked to participate in robot activities of your choice with another older adult two times a week. Each activity session will take about 30 minutes. If you get tired, we can take a break during the session. These sessions will take place over 8 weeks (2 months) for a total of 16 sessions.

We have several robots that we are testing. We do not know if you will be working with a robot.



This robot is called Nao and stands about two feet tall. It will be placed on a table in front of you. At no time will you be in physical contact with this robot.

This robot is called Aibo. It is about the size of small poodle dog. If you want, you can touch this one or pick it up.

This robot is called Misty. It stands about two feet tall and can move about on the floor or table.

If you are selected to work with a robot, you can choose the activity, depending upon your interests. These can include any of the following:

- Chair exercises
- Games using a TV monitor
- Drawing and painting using a TV monitor
- Participating in music
- Commands and responses from the 'dog' robot

- We will monitor your body's responses constantly during the activity session. We will ask you to wear a wristband that will give us your heart rate and skin temperature.

- You will be observed for your interactions and attention during the activity session by a trained research assistant. We will also be videotaping the session.

If you are in the group that does not work with a robot (Group B), you can choose any activity of your choice offered at your facility.

Once a week, all participants (Group A and Group B) will be observed for their interactions and attention during an activity at the facility.

4. Duration: How long will I be in the study?

You will be in the study for 8 weeks (2 months). Each robot activity session will take approximately 30 minutes. You will participate in 2 sessions a week for 8 weeks.

5. Can I Stop Being in the Study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

Questionnaires: Before the first session and again after the last session, you will be asked a series of questions on your thinking and memory, and perceptions about robots. Those in Group A will be asked about their perceptions of the robots. These topics may make you upset. You can skip questions if you do not want to answer them. There is a potential risk of loss of confidentiality; we will make every effort to keep your information secured.

Activity Sessions: Spending the time with us may be an inconvenience.

You may become bored, annoyed or anxious with some of the activities. If at any time you get tired or annoyed, let us know and we will stop the session. You can take a break at any time when filling out the questionnaires or attending the activity session.

Rarely, people may have itching or skin reddening from the wristband. If the wristband feels uncomfortable, you can remove it.

7. What benefits can I expect from being in the study?

There may be no direct benefit to you for participating in this study. The knowledge we gain will help us find new ways to use robots for helping older adults.

You may find participating in the activity sessions and being with another person an enjoyable experience.

Confidentiality: Will My Information Be Kept Private?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law. Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor, **National Institute of Aging,** supporting the study;
- Vanderbilt University Institutional Review Board or Office of Responsible Research Practices.

We will work to make sure that no one sees your survey responses without approval. But, because we are using the Internet, there is a chance that someone could access your online responses without permission. In some cases, this information could be used to identify you.

Prior to sharing recordings with other researchers, we will modify the video to block the view of your face.

Certificate of Confidentiality

The NIH has issued a Certificate of Confidentiality for this study. This Certificate provides extra protection for you and your study information, documents, or samples (blood, tissue, etc.). The Certificates are issued so that we cannot be required to disclose any identifiable, sensitive information collected about you as a part of this study in a lawsuit or legal proceeding. We are also prevented from releasing your study information without your consent. This is a layer of protection over and above the already existing protections in place for you and your information, documents, or samples.

However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, the Agency that is funding this study requests the information, or if the FDA tells us to release this information. We may also use your information to conduct other scientific research as allowed by federal regulations.

Study information that has health implications may be placed in your medical record where authorized employees may see the information. Further, authorized requests for your records (medical record release for continuity of care) may result in research-related information being released.

Please talk to your study team, or contact the Office of Responsible Research Practices at 614-688-8641, if you have questions.

You may also visit the NIH website at https://grants.nih.gov/policy/humansubjects/coc.htm to learn more.

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.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. What are the costs of taking part in this study?

There are no costs to you or your family associated with this study.

10. Incentives: Will I Be Paid for Taking Part in this Study?

By law, payments to participants are considered taxable income.

If you are in the group that has the robot activities (Group A), we will give you a $25 Amazon gift card after you have completed the first eight sessions. We will also give you another $25 Amazon gift card after you have completed the last eight sessions.

Everyone (Group A and Group B) will get a $25 Amazon gift card for completing the baseline interviews, the week 4 interviews and the week 8 interviews (for a total of $75).

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. Participant Rights: What Are my Rights if I Take Part in this Study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

13. Will my de-identified information be used or shared for future research?

We de-identify information by removing all information that could be used to identify you, including your name, date of birth and address. Prior to sharing recordings with other researchers, we will modify the video to block the view of your face.

We may use or share de-identified with other researchers without your additional informed consent.

14. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law. We will work to make sure that no one sees your survey responses without approval. But, because we are using the Internet, there is a chance that someone could access your online responses without permission. In some cases, this information could be used to identify you

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor (National Institute on Aging) supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

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 the website at any time.

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Research records;
- Information gathered for this research about:
  - Your age and gender
  - Your physical function
  - Your medical conditions
  - Medications you take
  - Questionnaires

II. Who may use and give out information about you?

Designated researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office record;
- Others:
  - National Institute on Aging
  - Data Safety Monitoring Board
  - Vanderbilt University Institutional Review Board or Office of Responsible Research Practices.

IV. Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by

sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

You will not be able to be in this research study.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

16. Contacts and Questions: Who Can Answer Questions About the Study?

For questions, concerns, or complaints about the study, or you feel you have been harmed as a result of study participation, you may contact the principal investigator of this study, **Judith Tate, PhD, RN at 614-292-4907 or by email attate.230@osu.edu.** For questions related to your privacy rights under HIPAA or related to this research authorization, please contact Kathleen Ojala at 614-293-6482 or by email at ojala.3@osu.edu.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact **Lorraine Mion, PhD, RN at 614-688-3734 or by email at mion.3@osu.edu.**

17. Use of my photos in my facility's website and newsletters. You may be asked by the staff at your residence to use photos of you interacting with the robot in their newsletters or on their website. You can approve or refuse the use of your photos for this publicity as you would be identifiable in the pictures. Please indicate your preference in how you want publicity photos handled and initial.

☐ I **do not** want my picture(s) used for publicity. Initial: _____

☐ I wish to see the picture(s) first before I decide whether they can be used. Initial: _____

☐ I **approve** the use of my picture(s) for publicity. Initial: _____

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form. If you are completing this form online and wish to print or save a copy of this page, select the print button on your web browser.

Printed name of participant	**Signature of participant**
	AM/PM
	Date and time
Printed name of person authorized to consent for participant (when applicable)	**Signature of person authorized to consent for participant (when applicable)**
	AM/PM
Relationship to the participant	**Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time