<Funded by the National Institute on Aging> IRB Protocol#2000032226
NCT05352399

COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH STUDY FOR PARTICIPATION IN A RESEARCH STUDY

YALE UNIVERSITY
YALE UNIVERSITY SCHOOL OF MEDICINE
YALE-NEW HAVEN HOSPITAL
YALE-NEW HAVEN HOSPITAL: SAINT RAPHAEL CAMPUS

Study Title: Improving ED-to-community care transition outcomes for persons living with dementia and their caregivers: development, implementation, and pilot testing of a novel artificial intelligence + care coach intervention

Principal Investigator (the person who is responsible for this research): *Cameron Gettel, MD MHS*
Phone Number: 203-737-4842

Why am I here?

- We are asking you to join a research study.
- The study will look at the use of a digital health intervention to improve your health after an ED visit.
- Your engagement may take approximately 45 minutes.
- This assent form explains the research study and your part in the study.
- Please read it carefully. Take as much time as you need.
- Please ask the study staff questions about anything you do not understand.
- You can ask questions now or anytime during the study.
- If you join the study, you can change your mind later.
- You can quit the study at any time.
- We will also ask your family member for consent for you to be in the study.

Why is this study being offered to me?

We are asking you to join a research study because **we would like to improve your experience after an ED visit**. We are looking for **70** total people to be part of this study.

What is the study about?

The purpose of this study is to evaluate the potential of a digital health app, NeuViCare, and a care coach to help you and your family member caregiver in the time after an ED visit.

What will happen during the study?

If you agree to take part in this study, this is what will happen: **a research assistant will talk with you and your family member about use of the NeuViCare technology, and we will**

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follow-up over 30 days to determine what types of healthcare you use. If you have a family member/caregiver as part of the study, you both will have access to your Care Planner (regarding your ED care plan), local resources, a peer community, and educational information. You and/or your family member/caregiver will complete brief surveys at 7 and 30 days. An occupational therapist care coach will assist with your personalized NeuViCare technology care plan and also be available for questions or assistance you may have during this time period.

How long will I be in the study?

You will be asked to be a part of the study for 30 days after the ED visit.

What are the possible risks of the study?

There is a slight risk regarding the confidentiality of your participation in this study. The researchers are required to keep your study information confidential, however, so the risk of breach of confidentiality is very low. You may feel burdened completing the qualitative interviews or being a part of the Design Thinking workshop. If this is the case, we will stop those phases immediately for you.

How can the study possibly benefit me or other people?

The study might benefit you by providing you and your family member caregiver access to resources in the community that can help you after an ED visit.

The study might help other people by helping us understand more about ED care transitions for older adults and their caregivers after an ED visit.

Will it cost any money for me to be in the study?

You will not have to pay for taking part in this study.

Will I be paid if I join the study?

You will be paid $50 for taking part in this study by a Bank of America gift card. You are responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments.

How do you protect my information?

We will keep information we collect about you confidential. We will share it with others if you agree to it or when we have to do it because U.S. or State law requires it. For example, we will tell somebody if you we learn that you are hurting a child or an older person.

When we publish the results of the research or talk about it in conferences, we will not use your name. If we want to use your name, we would ask you for your permission.
We will also share information about you with other researchers for future research but we will not use your name or other identifiers. We will not ask you for any additional permission.

What Information Will You Collect About Me in this Study?

The information we are asking to use and share is called "Protected Health Information." It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

The specific information about your health that we will collect, use, and share includes:

- Research study records
- Medical and laboratory records of only those services provided in connection with this Study.
- The entire research record and any medical records held by ***Yale New Haven Health System*** created from: ***01/01/2022*** to: ***present day***
- Records about phone calls made as part of this research
- Records about your study visits

How will you use and share my information?

We will use your information to conduct the study described in this consent form.
We may share your information with:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- Principal Investigator of the study
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

Do I have to be in this study?

No, being in this study is up to you. You can say no now if you already know that you do not want to join the study. You can say yes now and if you change your mind later, you can leave the study at any time.

There will be no negative consequences regardless of what you decide to do. Your decision will not change the care you receive or benefits that you would normally get.

What if I have questions?

Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator at **203-737-4842**

If you have questions about your rights as a research participant, or you have complaints about this research, you can call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

Authorization and Permission

Your signature below indicates that you have read this consent document and that you agree to be in this study.

We will give you a copy of this form.

Participant Printed Name	Participant Signature	Date

Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date

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Subject Assent

(if applicable)

My signature signifies that I am willing to participate in the research project described above. Full informed consent for my participation is being provided by my Next of Kin, Caregiver, or Legally Authorized Representative below.

_____ _____

Subject's Name (print) Signature of Subject Date

If subject could not sign, was assent given? Yes No

Next of Kin, Caregiver, or Legally Authorized Representative Informed Consent

I have read this form and decided that_____
(Name of Subject)
will participate in the project described above. Its general purposes, the particulars of involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I will receive a signed copy of this consent form.

_____ _____

NOK/Caregiver/LAR (print) Signature of NOK/Caregiver/LAR Date

Next of Kin (NOK)
Caregiver
Legally Authorized Representative (LAR)

_____
_____

Person Obtaining Consent (print) Signature of Person Obtaining Consent

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