Internet-based Conversational Engagement Clinical Trial

NCT02871921

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IRB#: 15937

CLINICAL RESEARCH CONSENT AND AUTHORIZATION SUMMARY OF KEY INFORMATION ABOUT THIS STUDY

TITLE: Internet-based Conversational Engagement Clinical Trial (**I-CONECT**)

PRINCIPAL INVESTIGATOR: Hiroko Dodge, PhD (503) 494-9043

You are being asked to join a research study. This consent form contains important information to help you decide if you want to join the study or not.

This study is being conducted at the University of Michigan (UM) and at Oregon Health & Science University (OHSU). OHSU is coordinating the study, so this consent form is based on the rules and regulations of OHSU.

PURPOSE:

This study is trying to answer questions about how the brain functions in older adults, how social interaction affects the mind and brain, and how to prevent memory decline and dementia.

DURATION:

The research study will take 6 months. This study includes approximately 4 telephone appointments. Participation also involves regular communication with staff on the telephone, and possibly face-to-face via video chat device.

PROCEDURES:

If you decide to participate, you will be asked to do several activities such as:

- Answering surveys and questionnaires
- Telling us about your medical history and medications
- Completing memory and thinking tasks
- Giving saliva for genetic testing (this is optional)
- Possibly participating in a Video Chat Program (half of study participants will be assigned to this program).

RISKS: There is a risk that the Video Chat Program may not be as good as any treatment prescribed by your doctor for memory problems or social isolation.

BENEFITS: Regular social engagement through video chat may help slow the decline of memory and thinking skills in older adults. However, we do not know if you will directly benefit from being in this study. This study may help us learn things that will help people in the future.

ALTERNATIVES: You may choose not to participate in this study. If you have concerns about your memory, you may talk to your doctor. In some cases, doctors may prescribe medications to treat memory decline in older adults.

Taking part in this study is your choice. You do not have to join the study. Even if you decide to join now, you can change your mind later. Please ask the study staff if you have any questions about the study or about this consent form.

END OF CONSENT SUMMARY

Research Consent and Authorization Form

TITLE: Internet-based Conversational Engagement Clinical Trial (I-CONECT)

PRINCIPAL INVESTIGATORS: UM: Laura Struble, PhD, GNP-BC (734) 615-5750
Kathleen Potempa, PhD (734) 615-0085
OHSU: Hiroko Dodge, PhD (503) 494-9043

WHO IS PAYING FOR THE STUDY?

The National Institute on Aging (NIA), which is one of the National Institutes of Health (NIH).

WHY IS THIS STUDY BEING DONE?

You have been invited to be in this research study because you are 75 years or older and you have limited social interactions.

The purpose of this study is to learn more about social interaction, memory, and mental function in older adults. Many older adults are at risk of developing dementia and social isolation. It is possible that increasing social interaction could slow the decline of thinking abilities and improve the brain's structure and function in older adults.

The Video Chat Program in this study is experimental. We do not know if it works, or if it is better than other ways of preventing or treating decline in memory and thinking skills.

This study will take 6 months. It includes approximately 4 telephone calls, as well as additional technology troubleshooting calls if needed. Participation also involves short weekly telephone calls with staff, and possibly face-to-face via video chat device.

We are trying to learn if social interaction may help delay the onset of dementia, including Alzheimer's disease. A particular version of a gene,

APOE4, increases a person's risk of Alzheimer's disease. In this study, we are testing to see whether people with this version of the gene could benefit from the Video Chat Program.

Genes are the units of DNA--the chemical structure carrying your genetic information—that determine many human characteristics such as the color of your eyes, your height, and whether you are male or female.

To learn more about the APOE4 gene, we will ask you to give a saliva sample for a biospecimen bank, also called a repository. The saliva sample and basic demographic information about you (sex, year of birth, ethnicity and race) will be sent and stored at the National Centralized Repository for Alzheimer's Disease and Related Dementias (NCRAD) at Indiana University. Your sample and information will be coded and not identifiable by your name. We may determine your complete DNA sequence, called whole genome sequencing. Other genetic and genomic data may be generated, as well. These samples will be stored indefinitely and may be used and disclosed in the future for research, which may include genetic research.

Giving this saliva sample is optional. You can still be in the study even if you do not give the sample for genetic testing.

We are also asking you to provide your study information for a repository at OHSU. This information will be stored indefinitely and may be used and disclosed in the future for research, which may include genetic research.

If you decide to participate, the repository parts of the study are not optional.

Approximately 180 people will be enrolled in the study at Oregon Health & Science University (OHSU) and other universities in the United States, including the University of Michigan (UM).

WHAT EXAMS, TESTS AND PROCEDURES ARE INVOLVED IN THIS STUDY?

For COVID-19 safety, we will not interact with you face-to-face in person at your home for this study. When we need to give you study materials or equipment, we will either mail them or deliver them to your home. If

we deliver items, we will plan with you to drop them off outside your home, so we will not see you in person.

Screening Home Visit *(3 hours, may be split into more than one phone call)*

At this call, study staff will explain the study and ask if you want to participate. You will complete several surveys and tasks that measure memory, attention, and other thinking and mental functions. Some of these tasks will be audio recorded. You will be asked about your feelings, social connections, medications, health history and demographics.

We will ask whether you are comfortable having magnetic resonance imaging (MRI) scans, and if you able to have an MRI scan safely. If we are not sure whether you can have an MRI scan safely, we may ask you to give permission for us to review related records from your doctor.

We will give you a set of surveys about your personality, feelings, and relationships. You will be asked to fill these out on your own after the call. The surveys will take another hour of time, in addition to the call time. If you have a computer or other device that allows you to go online, we may ask you to do the surveys online, rather than on paper. If you can complete the surveys online, we will request your email address to send you a link to the surveys.

You will have the option of giving us a name and phone number for an emergency contact person we can call if we cannot reach you for more than two days after a scheduled appointment. You may also share your primary care doctor’s information with us, in case we learn anything during the study about your health that you would like us to share with your doctor. Providing this information is optional; you may still participate in the study even if you do not wish to provide this information.

You will also have the option to be contacted for future research participation opportunities. You may still participate in the study even if you do not wish to volunteer to be contacted in the future.

After the visit, we will review your information and call you to let you know if you are eligible to participate in the study.

Baseline Call *(30 minutes)*

At this call, we will ask you about physical measures like height and weight. We will assess your vision and hearing. If you agree to saliva testing, you will provide ½ teaspoon of saliva by spitting into a plastic tube. (We will give you a kit for this.)

You will be asked to give us general health information about your relatives (family history of memory problems). Any information you give us will be kept confidential as described in this consent form. We will not contact your relatives, unless you provide them as an emergency contact (an optional portion of this study).

After this call, study staff will contact you to tell you whether you were randomly selected to receive the Video Chat Program or be in the control group (no video chats). There is a 50/50 chance of being put into the Video Chat Program or control group. Neither you nor the study staff have control over the group assignment—it is done by a computer program. If you are assigned to the control group, you will not receive video chats; however, you will still receive a weekly phone call (see below for more details).

Technology Installation *(30-90 mins)*
(ONLY participants in the Video Chat Program)

If you are in the Video Chat Program, we will provide you with the study technology before your technology installation call.

We will then schedule a phone call to set up the video chat device with you. At the call, we will help you learn how to use the device and answer any questions.

The video chat device needs an internet connection to work. You will need to connect the video chat device to your current internet connection.

You will need to put the video chat device close to the internet box, and you may not have much control over where the internet box is installed. Therefore, the location of the video chat device in your home may not be convenient or preferable.

Video Chats ***(26 weeks/about 6 months)***
(ONLY participants in the Video Chat Program)

You will video chat with our study staff for 26 weeks. For most of the study (the first 24 weeks), you will have a video chat with study staff 4 times per week. Toward the end of the study (the last two weeks), you will only have 2 chats per week.

Video chats will be scheduled at a regular time Monday-Thursday between 1 pm to 5 pm EST. Each chat will last for 30 minutes. Chats will happen using the video chat device, but in case of technical problems a chat may be done over the telephone.

These chats will be casual conversations. You will talk about a variety of topics that are meant to be interesting and thought-provoking. The video chats will be audio and video recorded.

We will ask you questions about how you are feeling before and after the first conversation each week. At the end of six months, you will be asked for your thoughts and opinions about your experience with the chats.

Weekly Phone Call ***(26 weeks/about 6 months)***

You will have a regularly scheduled telephone call with study staff each week to ask about your health and social interactions. The calls take approximately 10-15 minutes and are audio recorded. These calls will happen for about 6 months.

Month 6 Call ***(2 hours, may be split into more than one call)***

After about six months, we will return to your home to repeat the same questionnaires and tests to measure memory, attention, and problem solving that were done at the beginning of the study. You will not need to provide your medical history or give saliva samples again, but most other study tasks will be repeated.

The person who gives you tests will not know whether or not you are participating in the Video Chat Program. The study is done this way because knowing whether you are doing the video chats may change the results of the study. Please do NOT tell the person testing you whether or not you are doing the video chats.

We will ask you to fill out the same surveys about you personality, feelings, and relationships that you filled out at the beginning of the study. The surveys will take another hour of time, in addition to the call time.

Technology Pick-up *(30-60 minutes)*
(ONLY participants in the Video Chat Program)

Toward the end of the study, we will collect the video chat device and any related equipment.

Follow-Up Call *(20 minutes)*

About a month after the last weekly health call, we will call you to ask you about your social interactions and your mood.

On the next page, there is a table showing a simple view of these study activities.

STUDY ACTIVITIES:	**Initial CallsCalls**	**Weekly Calls & Possible Video Chats**	**6-Month Calls**	**Follow-Up Call**
Consent, medical history, saliva collection	**X**			
Surveys about personality, feelings, and relationships	**X**		**X**	
Memory and thinking tasks, surveys	**X**		**X**	**X**
Possible technology install/uninstall	**X**			**X**
Possible video chats with study staff *(30 minutes per chat, 4 chats per week)*		**X**		
Weekly telephone call on health and social interactions		**X**		
TOTAL HOURS PER TIME PERIOD (COLUMN)	*4½-5½ hours*	*6½ hours for calls + 50 hours for chats*	*3 hours*	*20 minutes*

All video chats in this study will be video and audio recorded. Parts of the testing calls will be audio recorded. The weekly phone call will also be audio recorded. We will use these recordings for educational materials and research analysis.

In the future, your saliva and information and recordings may be given to researchers for other research studies. These studies may include genetic research. The saliva and information will be labeled as described in the **WHO WILL SEE MY PERSONAL INFORMATION?** section.

WILL I RECEIVE RESULTS FROM THE TESTING IN THIS STUDY?

If you are not eligible for the study, we will tell you why. If appropriate, we will suggest that you see your health care provider.

We do not plan to share any of your individual test results with you. The results of all other research tests, including genetic testing, will not be made available to you because the research is still in an early phase and the reliability of the results is unknown.

WHAT RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?

Some of the surveys we ask you to fill out or questions we ask may seem very personal or embarrassing. They may upset you. You may refuse to answer any of the questions that you do not wish to answer. If the questions make you very upset, we will help you to find a counselor.

If you participate in the video chats, you may feel close to the study staff you talk to. You might feel sad or lonely, or feel a sense loss when the study ends. We will give you resources for other social connection at the end of the study.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination if you have already been diagnosed with the genetic disease being tested.

Although we have made efforts to protect your identity, there is a small risk of loss of confidentiality. If the results of these studies of your genetic makeup were to be accidentally released, it might be possible that the information we will gather about you as part of this study could become available to an insurer or an employer, or a relative, or someone else outside the study. Even though there are certain genetic discrimination and confidentiality protections in both Oregon law and federal law, there is still a small chance that you could be harmed if a release occurred.

WHO WILL SEE MY PERSONAL INFORMATION?

We will take steps to keep your personal information confidential, but we cannot guarantee total privacy. Samples and information about you are collected during this study. When this information is stored at the end of the study, a unique code will be used to label your information, instead of your name or other identifying information.

We will create and collect health information about you as described in the **WHY IS THIS STUDY BEING DONE?** and the **WHAT EXAMS, TESTS AND PROCEDURES ARE INVOLVED IN THIS STUDY?** sections of this form. Health information is private and is protected under federal law, Michigan law and Oregon law. By agreeing to be in this study, you are giving permission (also called authorization) for us to use and disclose your health information as described in this form.

The investigators, study staff, and others at OHSU and UM may use the information we collect and create about you in order to conduct and oversee this research study. Information and saliva samples will also be stored in research data banks, also called repositories. Contributing information to the repositories is not optional. Contributing your saliva is optional.

We may release this information to others outside of OHSU and UM who are involved in conducting or overseeing research, including:

- The funder of this study, the National Institutes of Health, and the funder's representatives.
- The Office for Human Research Protections, a federal agency that oversees research involving humans.

Those listed above may also be permitted to review and copy your records.

We may also share your information with other researchers, who may use it for future research studies.

We will not release information about you to others not listed above, unless required or permitted by law. We will not use your name or your identity for publication or publicity purposes, unless we have your special permission.

To help us protect your privacy, we have obtained a Certificate of Confidentiality to protect your privacy even from people who try to get your information using a court order. One exception is if you agree that we can give out research information with your name on it. Another exception is information about child or elder abuse or neglect and harm to yourself or others or communicable disease reporting. Note that this doesn't prevent you from releasing the information yourself.

Under Oregon and Michigan law, suspected child or elder abuse must be reported to appropriate authorities.

OHSU complies with Oregon state requirements for reporting certain diseases and conditions to local health departments. UM complies with Michigan state requirements for reporting certain diseases and conditions to local health departments.

When we send specimens or information outside of OHSU, they may no longer be protected under federal, Michigan law, or Oregon law. In this case, your specimens or information could be used and re-released without your permission.

Data and specimens from this study may be shared with other investigators for future research studies. A code number will be assigned to you, your cells and genetic information, as well as to information about you. Only the investigators and people involved in the conduct of the study will be authorized to link the code number to you. Other investigators who may receive samples of your saliva, genetic information, medical information and study data for research will be given only the code number which will not identify you.

We will protect your privacy when sharing audio recordings by only sharing the recordings with approved researchers. We will not share any parts of the audio recordings that contain identifying information like your name, telephone number, or other information we think could be used to tell your identity. However, because everyone's voice is unique, it's possible that someone listening to the recording could identify you from the sound or pattern of your voice.

Your genetic information may be shared in a public online database for future research. The database will not contain any information that directly identifies you, such as your name, address, or birth date, so it is unlikely that someone would know the genetic information came from you. In the future, people may develop ways to identify you or your blood relatives from this information, but currently, there is not a way to identify you without having additional information to compare to it, such as information from your DNA sample.

Results of the saliva analysis, along with your basic demographic information, may be submitted to the NCRAD database that will assist other researchers investigating various diseases, including Alzheimer's disease and dementia. This government health research database will have access limited to approved researchers. Your data may be withdrawn from the database at any time, upon your request. However, data that has already been distributed for approved research will not be retrieved.

The saliva samples provide genetic material, which could be used for studies designed to identify the genes contributing to diseases, such as Alzheimer's disease. In addition, the information and samples may also be used to study other diseases.

If you would like us to contact you about future studies, we may keep your contact information on file, and we may share it with other researchers who are doing research at OHSU. If you are contacted in the future, you may choose not to participate. You may also choose at any time to be removed from the list.

We may continue to use and disclose your information as described above indefinitely.

WILL ANY OF MY INFORMATION OR SAMPLES FROM THIS STUDY BE USED FOR ANY COMMERCIAL PROFIT?

Samples and information, including any video recordings and audio recordings, about you or obtained from you in this research may be used for commercial purposes, such as making a discovery that could, in the future, be patented or licensed to a company, which could result in a possible financial benefit to that company, OHSU, UM, and its researchers. There are no plans to pay you if this happens. You will not have any property rights or ownership or financial interest in or arising from products or data that may result from your participation in this study. Further, you will have no responsibility or liability for any use that may be made of your samples, information, video recordings, or audio recordings.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There will be no cost to you or your insurance company to participate in this study.

If you decide to join the study, you will receive $50 after Screening, and another $50 after completing the Month 6 activities. You may choose to drop out of the study at any point of time. You will not receive prorated compensation.

In addition, if we have to use your personal internet for the video chat device, we will compensate you $35 per month for each month you are video chatting up to a total of $210. You will receive this along with your other compensation at Month 6. If you drop out of the study early, we will still compensate you for the months of internet we used for this study.

We may request your social security number in order to process any payments for participation.

Payment received as compensation for participation in research is considered taxable income for a research subject. If payments are more than $600 in any one calendar year, UM is required to report this information to the Internal Revenue Service (IRS). Research subject payments exceeding $600 during any calendar year will result in a 1099 (Miscellaneous Income) form being issued to the research subject and a copy will be sent to the IRS.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

If you believe you have been injured or harmed as a result of participating in this research and require treatment, please contact Principal Investigators Laura Struble, PhD, GNP-BC, at (734) 615-5750, or Kathleen Potempa, PhD, at (734) 615-0085.

If you are injured or harmed by the study procedures, you will be treated. OHSU, UM and the National Institutes of Health do not offer any financial compensation or payment for the cost of treatment if you are injured or harmed as a result of participating in this research. Therefore, any medical treatment you need may be billed to you or your insurance. However, you are not prevented from seeking to collect compensation for injury related to negligence on the part of those involved in the research. Oregon law (Oregon Tort Claims Act (ORS 30.260 through 30.300)) may limit the dollar amount that you may recover from the study institutions or their caregivers and researchers for a claim relating to care or research at OHSU, as well as the time you have to bring a claim.

If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

This federally funded study also does not have the ability to provide compensation for research-related injury. If you are injured or become ill from taking part in this study, it is important to tell your study doctor. Emergency treatment may be available, but you or your insurance company will be charged for this treatment.

WHERE CAN I GET MORE INFORMATION?

If you have any questions, concerns, or complaints regarding this study now or in the future, please contact Principal Investigators Laura Struble, PhD, GNP-BC, at (734) 615-5750, or Kathleen Potempa, PhD, at (734) 615-0085.

This research has been approved and is overseen by an Institutional Review Board (“IRB”), a committee that protects the rights and welfare of research subjects. You may talk to the IRB at (503) 494-7887 or irb@ohsu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.

- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get more information or provide input about this research.

You may also submit a report to the OHSU Integrity Hotline online at https://secure.ethicspoint.com/domain/media/en/gui/18915/index.html or by calling toll-free (877) 733-8313 (anonymous and available 24 hours a day, 7 days a week).

DO I HAVE TO TAKE PART IN THIS STUDY?

Your participation in this study is voluntary. You do not have to join this or any research study. You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study. Some parts of the study are optional. You can choose not to participate in some or all of the optional parts but still participate in the rest of the study.

Your health care provider may be one of the investigators of this research study and, as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another doctor who is in no way involved in this project. You do not have to be in any research study offered by your physician.

IF I DECIDE TO TAKE PART IN THIS STUDY, CAN I STOP LATER?

If you do join the study and later change your mind, you have the right to quit at any time. This includes the right to withdraw your authorization to use and disclose your health information. You can choose to withdraw from some or all of the optional parts of this study without withdrawing from the whole study. If you choose not to join any or all parts of this study, or if you withdraw early from any or all parts of the study, there will be no penalty or loss of benefits to which you are otherwise entitled, including being able to receive health care services or insurance coverage for services. Talk to the investigator if you want to withdraw from the study or change which parts of the study you are participating in.

If you no longer want your health information to be used and disclosed as described in this form, you must send a written request or email stating that you are revoking your authorization to:

Hiroko Dodge, PhD
Oregon Health & Science University
3181 SW Sam Jackson Park Rd CR-131
Portland, OR 97239
dodgeh@ohsu.edu

Your request will be effective as of the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that we have already acted based on your authorization.

If you choose to withdraw from the study, you will be asked to return the video chat device and accessories (e.g., headphones), if applicable.

If in the future you decide you no longer want to participate in this research, we will remove your name and any other identifiers from your samples and information, but the material will not be destroyed and we will continue to use it for research. Some data, like the recordings, may not be able to be completely de-identified.

If study staff become aware of a clinically relevant issue, such as development of dementia, someone will discuss this with you and refer you to your primary care provider for follow-up. Participation in this research is not meant in any way to replace regular clinical care, but the researchers will address any relevant issues to try and ensure your health and safety.

You may be removed from the study if the funder or investigator stops the study, if you develop dementia, or if you do not follow study instructions.

We will give you any new information during the course of this research study that might change the way you feel about being in the study.

SIGNATURES:

PARTICIPANT OPTIONS

You have the option to provide contact information for your doctor and/or an emergency contact. If you would like to share this information with the study team, you may do so. You can still participate in the study even if you choose not to share this information.

You have the option to be contacted for future study participation opportunities. You can still participate in the study even if you choose not to be contacted for future studies. Please initial by your choice below:

_____ I give my consent to have my contact information kept on file indefinitely so that I can be contacted for future research participation opportunities.

_____ I do **not** wish to be contacted for future research participation opportunities.

You have the option to give a saliva sample for genetic research and future research. You can still participate in the study even if you choose not to give this sample. Please initial by your choice below:

_____ I consent to give a saliva sample for genetic research and future research.

_____ I do **not** wish to give a saliva sample.

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

We will give you a copy of this form.

Subject Printed Name	Subject Signature	Date
Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date