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OREGON HEALTH & SCIENCE UNIVERSITY

Information Sheet and Authorization
(via Telephone or Videoconference)
Care Partner

OHSU Protocol # 22288

TITLE: Using Technology to Support Care Partners for Persons with Alzheimer's Disease: Tele-STELLA

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RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

What should I know about this research?

- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

How long will I be in this research?

We expect that your taking part in this research will last about one year, with most of the activities occurring over 4 months.

Why is this research being done?

The purpose of this research to find out if the intervention, Tele-STELLA, reduces family Care Partner burden and improves quality of life for Care Partners and their family members with dementia. You have been invited to be in this research study because you provide care for a family member with dementia.

What happens to me if I agree to take part in this research?

If you decide to take part in this research study, the general procedures include participating in 16 videoconference-based sessions with professional Guides and other Care Partners. The sessions will address dementia-related behaviors that you and your family member experience and upset you (examples include pacing, irritability or depression). The Guides and other Care Partners will assist you in finding ways to reduce the behaviors. All the visits are done via videoconferencing or telephone, no in-person visits are required. The sessions occur once a week and last about one hour.

We are also asking you to provide information for a data bank called a repository (OHSU IRB #6845). This information will be stored indefinitely and may be used in the future for research, which may include genetic research.

Could being in this research hurt me?

You may find some of the visits personal and this may be distressing for you. Some of the survey questions may be upsetting to you.

Will being in this research benefit me?

The most important benefits that you may expect from taking part in this research include feeling less burdened as a Care Partner.

Possible benefits to others include helping other Care Partners who care for family members with dementia.

What other choices do I have besides taking part in this research?

Instead of being in this research, your choices may include contacting local support programs to learn more about caregiving.

What else should I know about this research?

Other information that may be important for you to consider so you can decide whether to take part in this research is that the sessions may be videotaped and you may share personal information with other Care Partners, thus we cannot guarantee confidentiality.

DETAILED RESEARCH CONSENT

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

What should I know about this research?

- Someone will explain this research to you.

- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research is to find out if the intervention, Tele-STELLA, reduces family Care Partner burden and improves quality of life for Care Partners and their family members with dementia. Tele-STELLA is experimental in this study. You have been invited to be in this research study because you provide care for a family member with dementia.

About 300 subjects will take part in this research (150 Care Partners and their 150 Care Recipients).

How long will I be in this research?

We expect that your taking part in this research will last about one year, with most of the activities occurring over 4 months.

What happens to me if I agree to take part in this research?

You will complete the study procedures listed below and in Table 1. Tele-STELLA is different than standard support groups because we use a specific strategy to help families cope with upsetting behaviors that come with dementia.

Set up and General Communication

We will contact you initially and then as needed via phone, text, email or videoconferencing technology to provide and collect general information, address technical issues, answer questions and communicate concerns. Occasionally we will send you newsletters with study updates. We will send you the newsletters through 2026. Please let us know if you'd like to opt out of receiving these newsletters.

We will send you the Tele-STELLA Handbook (by mail or email). The Handbook provides you with information about the study and our contact information. It includes weekly lessons and pages for you to write your ideas and thoughts. You may keep the Handbook.

After you have consented to this study, we will collect information about you (for example, name, age, address).

This study requires participating in internet-based videoconferencing sessions. During the Tele-STELLA sessions, you will be able to see and talk to the research team and other Care Partners using a camera and a headset connected to your computer. To join the sessions, you may use a personal computer, tablet, smart phone or other device that allows for a reliable connection to the internet. Our technology team may work with you to test your device and your internet

connection to make sure it works for Tele-STELLA.

If you do not have access to a computer, you may have the option to borrow a computer temporarily for this study, subject to availability (please speak to the research team if you have questions about this). If you borrow a computer, the OHSU technology team will manage the information on the device. If you use the computer with your wi-fi network, you may need to configure the computer to join your wi-fi network. You will only be able to use the loaned computer for study-related activities.

Tele-STELLA sessions are accessed through a secure website. You may need to download a software "plug-in" to make the website work. If you use your own computer, phone or tablet, you may need to download the application that allows you to connect to the meetings. This may be available to you from an application store. We may provide you with information about how to download this application and how to remove it after the study is completed. A specific URL (website address) will be generated to connect you with the research team. If your internet connection does not work well, we may ask you to join the Tele-STELLA sessions by phone through the videoconferencing system. If we cannot arrange a reliable connection, you cannot be in the study.

All visits, sessions, and groups will be video-recorded. If there are connection challenges, we may not record all sessions.

Your family member with dementia will not participate in any of the Tele-STELLA sessions. For all Tele-STELLA sessions, you will need to find an activity for your family member while you are engaged in the visits. This may allow you to focus on the material and protect your family member's dignity.

We will ask you to share your contact information (phone number and email) with the other Care Partners and we will encourage you to contact each other.

The study staff are available to answer your questions, help you set up your computer for study activities, and address concerns while you are in the study.

There may be a delay for you to join the Tele-STELLA sessions. This may occur if the Tele-STELLA appointments are full due to high demand, your schedule doesn't allow you to join right away, or if holidays interrupt the normal schedule. Also, The study team may alter the session schedules due to holidays, illness or other scheduling issues.

If you need to wait to join sessions, we will encourage you to seek support from local agencies, such as the Alzheimer's Association. However, if you join another telehealth-based intervention, you will not be able to continue with Tele-STELLA. Please contact us if you have questions about this.The Tele-STELLA program occurs over 16 weeks (4 months). The program is made of up of the "Nova" component (the first 8 weeks) and the "Constellation" component (the next 8 weeks). Between and after the components you will fill out surveys. These components and the surveys are discussed next.

Nova Component (8 weekly sessions)

The first 8 weeks of Tele-STELLA (called "Nova") begin with 4 one-to-one weekly sessions with you and a professional Guide to address your specific needs.

After these first 4 sessions, you meet in small groups (with up to 5 other Care Partners) with a Guide to address the dementia-related behaviors you all face. To accommodate schedules, you might have a week or two off between Sessions 4 and 5.

All sessions are about one hour long and occur once a week. If you need to miss a session, or will be late to a session, please contact us. You may miss up to two sessions of Nova and still be in the study.

During, or immediately after the first Nova session you will document the target problem behaviors you want to work on while in Nova. You will rate how frequently the behaviors occur and how much the behaviors bother you. Your Guide will explain this in your first session and give you instructions on how to do this.

Constellation Sessions (8 weekly sessions)
In the next component of Tele-STELLA, called "Constellation," you will take part in 8 weekly sessions with up to 20 other Care Partners and up to three professional Guides. The Guides will provide brief lessons. You, the other Care Partners and the Guides will discuss concerns and challenges, similar to what you did in Nova. You can skip up to two sessions of Constellation and still be in the study.

During, or immediately after the first Constellation session you will document the target problem behaviors you want to work on while in Constellation. You will rate how frequently the behaviors occur and how much the behaviors bother you. Your Guide will explain this in your first session and give you instructions on how to do this.

Up to four Constellations will be offered per year. You may join any one you want, but you can only join one 8-week session. We ask that you complete Constellation within one year of starting the Nova component. Depending on when you join a Constellation, you may have to complete extra surveys and you may be in Tele-STELLA for more than a year.

Surveys
You will complete 6 surveys and brief weekly surveys. The link to the surveys will be sent to you via email and you can complete them in the privacy of your home on your computer or phone. If you complete the surveys you may be eligible to receive a gift card (see Table 1 for details).

6 Surveys. The 6 "Planet" surveys ask about your family member's behaviors, your coping, your thoughts about placing your family member in long-term care, and your thoughts about the Tele-STELLA experience. The surveys also ask about you and your family member's quality of life. These surveys will occur before and after Tele-STELLA components (Nova and Constellation) (see Table 1). The surveys will take between about 15 minutes to 1 hour to complete. You will need to complete the surveys within one week of receiving them. If you are unable to complete the Planet surveys, you will not be allowed to continue with Tele-STELLA. If you need more time to complete the surveys, please call us--we want to help you stay in the study!

Brief Weekly Surveys. We will ask you to complete brief weekly "Orbit" surveys. This survey asks about caregiving, physical and emotional strain, health care use, and cost of care for your family member with dementia. The Orbit surveys will be sent to you weekly via email until you've completed all study activities (about 1 year). The number of Orbit surveys you complete depends on how many weeks you are in the study. The Orbit survey takes 2-15 minutes to complete and you will have 1 week to complete them. If you need to skip some weeks, please contact the study staff. If you complete at least 80% of the Orbit surveys you may be eligible to receive a gift card (see Table 1 for details). You will start the Orbit surveys after you are enrolled in the study. If you have to wait for a Tele-STELLA session to start, we may ask you to complete the weekly Orbit surveys during this waiting period.

Exit Survey. If you leave the study we will ask you to complete an optional Exit Survey.

Table 1: Tele-STELLA Care Partner Survey Schedule

Activity	Description	When Completed
Mercury Survey (Survey 1)	Assessment of behaviors, mood, quality of life	Before the Nova Session 1
Nova Component (8 weeks)		
Venus Survey (Survey 2)	Assessment of behaviors, mood, quality of life, program satisfaction	Within about one week of completion of Nova Session 8
Earth Survey (Survey 3)	Assessment of behaviors, mood, quality of life	About 1 month after Nova Session 8
(Care Partners who complete all Nova activities may receive $40)		
Constellation Component (8 weeks)		
Earth Survey* (Survey 4)	Assessment of behaviors, mood, quality of life	About 1-2 weeks prior to Constellation start
Mars Survey (Survey 5)	Assessment of behaviors, mood, quality of life, program satisfaction	Within about one week of completion of Constellation Session 8
(Care Partners who complete all Constellation activities may receive $30)		
Earth Survey (Survey 6)	Assessment of behaviors, mood, quality of life	About 2 months after last Constellation session
Weekly Orbit Survey: **Distributed weekly** Orbit surveys start after enrollment and continue until all Planet surveys are completed		
(Care Partners who complete last Earth Survey and 80% of Orbit Surveys may receive $30)		

*Earth Survey should be completed about one week prior to starting Constellation. Depending on timing, Care Partner may need to repeat Earth survey.

Notes from Tele-STELLA Sessions

During Tele-STELLA sessions the Guides may take notes about the session and your comments in the session. These notes will not contain your name or other identifying information and will be kept in a secure computer file.

Optional Focus Group
You may have the option of participating in a focus group with other Care Partners. The purpose of this group is to give us feedback on what you liked and did not like about Tele-STELLA. We will ask you if you want to participate in the focus group at the end of this form. This part of the study is optional. You can still participate in the main study even if you do not participate in the focus group.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to:

- Participate in above activities and surveys
- Notify us if you have questions or concerns
- Follow study guidelines and protocol
- Maintain an internet connection
- Maintain an email account

Could being in this research hurt me?

Some of the conversations about your caregiving experience, and some of the survey questions, 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, or engage in conversations that make you uncomfortable. If the questions and conversations make you very upset, we may help you to find a counselor or other support option.

You will have multiple Tele-STELLA visits, which may be inconvenient. You will need to find an activity for your family member with dementia during the Tele-STELLA sessions, which may cause financial hardship for some. All visits and communication will be via videoconferencing, phone, text or email; there are no travel costs involved.

Although we have made efforts to protect your identity, there is a risk of loss of confidentiality. Tele-STELLA includes group sessions with other Care Partners. You will see and hear the video and audio of all Care Partners who are part of your Tele-STELLA sessions. Thus, your identity will not be confidential. There is a risk that someone you know will be in these groups and your identity would no longer be confidential.

We will ask you to share your email and phone number with other Tele-STELLA Care Partners. Despite our instructions that this information is shared only with Tele-STELLA participants, it is possible that your information will be shared with others who are not in Tele-STELLA and your identity would no longer be confidential. You do not have to share your email or phone number with other Care Partners to stay in the study.

We will record each Tele-STELLA session (Nova and Constellation) and the focus groups. The video will start at the beginning of each session and end when the session ends. The video-recordings will show your face and your name; any information discussed during the sessions and focus group will be heard in the audio. In this case, the information you give us for this study will be identifiable as coming from you and will not be private. It is possible that someone viewing the video may recognize you or your family members and/or hear your names in the audio, and your identities would no longer be confidential. We may use the video-recordings for

staff training, fidelity assessments, study analyses, educational materials, and research publications. You will not be able to watch the recordings before they are used in this way. If you refuse to be video-recorded you cannot be in Tele-STELLA. However, you may turn your camera off during videoconference sessions and still be in Tele-STELLA.

In the future, your video-recordings and information may be given to other researchers for other research studies. These studies may include genetic research.

Will it cost me money to take part in this research?

There will be no cost to you or your insurance company to participate in this study. If you use your own computer to connect to Tele-STELLA, the study will not pay for the computer, Internet service, or any devices (e.g., camera).

Our technical team will review your device (computer, phone, or tablet) and Internet service for your participation in the study. A device or Internet service may be provided for the duration of the study if there has been determined to be a need.

Will being in this research benefit me?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to you include feeling less burdened.

Possible benefits to others include identifying effective ways to help Care Partners for those with dementia.

What other choices do I have besides taking part in this research?

Instead of being in this research, your choices may include contacting local support programs to learn more about caregiving.

What happens to the information collected for this research?

We will take steps to keep your personal information confidential, but we cannot guarantee total privacy because Tele-STELLA involves group sessions, internet-based videoconferencing, and sharing of contact information with other Care Partners. During group sessions we will ask that participants use only their first names. We will remind all participants that the information is private and cannot be shared with others who are not in Tele-STELLA, however, we cannot guarantee that Care Partners will follow these instructions.

Because you will discuss the behaviors of your family member with dementia, we will seek his or her consent. If your family member does not consent to be in the study, you cannot be in Tele-STELLA.

We will create and collect health information about you as described in the “Why is this research being done?” and the “What happens to me if I agree to take part in this research?” sections. Health information is private and is protected under federal 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 may use the information we collect and create about you in order to conduct and oversee this research study and store in a repository.

Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor(s)
- People who work with the research sponsor
- The university who gave us your information
- Government agencies, such as the National Institute on Aging
- OHSU IRB, , the Institutional Review Board (IRB) and WCG IRB (previous IRB) that reviewed this research
- 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.

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

Video-recordings and data from this study may be shared with other investigators for future research studies. A code number will be assigned to you, the video-recordings 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 data and video-recordings for research will be given only the code number which will not identify you. However, the video-recordings will show your face and your name and any information discussed during the sessions and focus group will be heard in the audio. In this case, the information you give us for this study will be identifiable as coming from you and will not be private.

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

The surveys will be completed using cloud software called Qualtrics and REDCap. Both data collection platforms are password protected. Contact information will be collected in order that you may be sent personalized links to the surveys and to enable the research team to manage survey administration. By providing your consent, you give permission for this data to be stored on the Qualtrics and REDCap servers and maintained by the research team, who will be responsible for maintaining the security and confidentiality of the transferred data.

Will any of my information or samples from this study be used for any commercial profit?
The video-recordings that include images and audio of you, or data 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, 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 or information.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We will protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Data or specimens collected in this research might be deidentified and used for future research or distributed to another investigator for future research without your consent.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

Where can I get more information?

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to the OHSU 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).

What if I am injured because of taking part in this research?

If you believe you have been injured or harmed as a result of participating in this research and require treatment, contact Dr. Allison Lindauer at 503-701-8566 or 503-494-8311 (and ask to have Dr. Lindauer paged).

If you are injured or harmed by the study procedures, you will be treated. OHSU and the funder 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 OHSU or its caregivers and researchers for a claim relating to care or research at OHSU, and 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 investigator. Emergency treatment may be available but you or your insurance company will be charged for this treatment.

Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- You are unable to keep your scheduled appointments
- The investigator or funders stop the study
- You do not follow study instructions
- You cannot access the study via phone or Internet
- You do not have access to email
- You do not interact with others in a respectful manner

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

What happens if I agree to be in this research, but I change my mind 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:
Dr. Allison Lindauer
OHSU CR131
3181 SW Sam Jackson Park Road
Portland, Oregon 97239
Email: lindauer@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, we may ask you to complete the remaining electronic surveys as well as an exit survey.

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 data. We will not be able to remove your image or audio from the video-recordings. The material will not be destroyed and we will continue to use it for research.

Will I be paid for taking part in this research?

For taking part in this research, you may be paid up to a total of $100. Your compensation will be broken down as follows:

Debit card payments totaling up to $100 may be provided for study participation. The payments will be pro-rated as noted in Table 1 and as follows:

- Complete all Nova sessions and surveys: $40
- Complete all Constellation sessions and surveys: $30
- Complete final survey and at least 80% of Orbit surveys: $30

You may receive payment via a debit card. There may be fees (for example, if the card is inactive for more than six months), which will be deducted from the balance on your card. Details on how to use the card and any fees are included in the separate card member agreement and “Frequently Asked Questions” sheet.

If you do not complete the surveys within one week, we may not be able to provide you with the

payments.

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

Statement of Consent:

CONSENT:
Do you agree to be in this study? *[Person obtaining consent should initial participant's choice]*

Yes _____ No_____

FOCUS GROUP OPTIONS
_____I give my consent to participate in the optional focus group, which will be video-recorded
_____I DO NOT give my consent to participate in the optional focus group, which will be video-recorded
_____I give my consent to be contacted for future studies about dementia and caregiving

Subject Printed Name Date

As the study staff member obtaining consent, I attest that I have obtained verbal informed consent from the subject listed above.

Person Obtaining Consent Person Obtaining Consent Date

Printed Name Signature