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

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Minimal Risk Protocol Template

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1) Objectives

The purpose of this study is to test a revised psychoeducational intervention to help Care Partners for family members with dementia understand and reduce the distressing behaviors that come with progressive dementia. Tele-STELLA (Support via TEchnology: Living and Learning with Advancing Alzheimer's disease and related dementias) is a multicomponent videoconference-based intervention designed to facilitate effective management of behavioral and psychological symptoms that are common in the later stages of dementia. In the Tele-STELLA intervention, professionals ("Guides") meet with family members ("Care Partners") who care for persons with dementia. Working together, the Care Partners and Guides identify strategies to address upsetting behaviors. The goal of this intervention is to reduce upsetting behaviors and, thus, Care Partner burden.

The NIA-approved specific aims of this study are:

Aim 1. Establish the feasibility and acceptability of Tele-STELLA

a. Assess the feasibility of implementing Tele-STELLA with a national participant pool, including participants from multiple Alzheimer's Disease Research Centers.
b. Assess feasibility and acceptability of the Constellation component of Tele-STELLA.
c. Assess user acceptability of Tele-STELLA and fidelity to the intervention protocol. Refine and optimize Tele-STELLA, as needed, based on above findings.

Aim 2. Establish the efficacy of Tele-STELLA in reducing the *frequency* of behavioral and psychological symptoms of dementia (BPSD) and Care Partner *reactivity* to the symptoms.

H1: Participants who completed the Tele-STELLA intervention will report a significant reduction in the frequency of BPSD and Care Partner reactivity to the BPSD.

2) Background

Providing care for a family member with Alzheimer's disease and related dementias (ADRD, aka, "dementia") is both rewarding and risky.[1,2] Care Partners exposed to chronic stress, often over years, are susceptible to physical and psychological ailments.[2] Effective interventions that reduce Care Partner burden and health risks are available,[3-5] but various factors impede participation, including distance, cost, behavioral symptoms of dementia, stigma and social anxiety.[6-9] Recognizing the need to reduce barriers to access, scientists have turned to Internet-based interventions.[10,11] Recent research indicates that multi-component, technology-facilitated interventions which allow Care Partner engagement with health professionals are effective and favored by Care Partners. However, a minority of telehealth-based interventions allow for health professional engagement and, of these, only a handful provide real-time interaction.[10] Further, Hopwood et al. concluded that, despite the fact that family needs vary across ADRD stages, the interventions reviewed were not targeted to specific stages of dementia.[10]

To address the needs of families living with dementia, we have completed two pilot studies using Internet-based Care Partner interventions.[12,13] These studies tested the feasibility and consumer acceptability of the evidence-based, STAR-C [4] intervention, the precursor to Tele-STELLA, when delivered via telehealth. Qualitative data revealed the telehealth intervention was acceptable to Care Partners and preferred over a potential in-home intervention. We found that burden was reduced, but depression was not. This may be because the interaction with the Guide formally ended after Session 8, leaving Care Partners with a sense of isolation, as this one commented: "I went through withdrawals… I wanted to call her (the Guide)—who can I turn to?"[14] The prototype interventions did not include meaningful opportunities for Care Partners to interact with each other post-intervention.

Care Partners felt their support vanished and did not like "the fact that it was over."[12] Care Partners advised that future interventions should include both one-to-one sessions and one-to-multiple sessions.

Based on the qualitative and quantitative data from the pilot work,[12] Tele-STELLA was designed to address the specific needs of families living with moderate to severe dementia. Tele-STELLA is a multi-component, tailored intervention that begins with one-to-one sessions with each Care Partner and Guide, then links Care Partners to each other in a meaningful way to sustain support post intervention.[15] Tele-STELLA is designed for families living in the later stages of dementia, where behavioral symptoms are more prominent and distressing. [16]

The ultimate goal of this study is to diminish the *frequency* of behavioral symptoms that persons with dementia experience, and Care Partner *reactivity* to these symptoms. Based on Kales et al.[17] framework, behavioral symptoms arise from unmet needs, overburdened Care Partners and environmental factors, all within the context of cultural background and beliefs. Behavioral symptoms are bidirectional in that the person with dementia's behaviors affects the Care Partner's behaviors and vice versa.[18-20] We hypothesize that addressing these factors will reduce behavioral symptom frequency, and, in turn, Care Partner reactivity to them, resulting in reduced Care Partner burden, depression and grief**.**

Tele-STELLA allows all study activities to be done in Care Partners' homes, using videoconferencing, email and phones. This includes assessments of burden and depression using electronic versions of classic measures. No visits to university sites are needed.

3) Study Design

Tele-STELLA is a prospective, mixed methods clinical trial. Care Partners for people with dementia will receive a psychoeducational intervention to facilitate effective management of behavioral symptoms of dementia. We will assess efficacy with pre/post measures.

4) Study Population

a) Number of Subjects

A power analysis was performed to determine sample size. Based on previous work, we will need 124 care partners to find a significant difference of 2 points using paired *t*-tests on the reactivity portion of the RMBPC, as well as significant differences in depression and grief. With 124 participants, we'll have 90% power to detect a 2-point reduction in CP reactivity over the Tele-STELLA intervention period, using multiple comparison adjusted p-value of p=0.016 (0.05/3). In the pilot studies, the attrition rates were as high as 15%. Our current attrition rate is 30, thus we will aim to enroll 200 CPs. We will also enroll the 200 Care Recipients of the CPs, but will not collect data *from* them. We will collect data *about* them (demographics, Quality of Life) from the CPs.

Based on previous work, we will recruit up to 200 Care Partners and their 200 care recipients with dementia. This allows for 30% attrition. We will recruit participants nationally, including those from the catchment areas from national Alzheimer's Disease Research Centers.

b) Inclusion and Exclusion Criteria

Inclusion criteria. The Tele-STELLA sample will be made up of participants who self-identify as a Care Partner for a family member, close friend or fictive kin [21] with moderate to severe ADRD, and their care Recipients with dementia. The care recipients will be enrolled with their Care Partners, but will not engage in the intervention. We will collect data such as demographics, health care use and quality of life. We will seek their consent for data management and confidentiality.

The Care Partner must speak English in order to participate in Tele-STELLA. However, the person with dementia does not need to speak English, as long as the person with dementia can consent, or the LAR can consent on their behalf.

The Care Partner must be able to see and hear the videoconference-based interactions.

The Care Partner must provide care for the person with dementia (e.g., assistance with ADLs, transportation, medication management, care oversight) for at least 4 hours/week. Due to COVID and other unforeseen conditions, this care does not need to be in-person. For example, a daughter may talk with her mother with dementia on the phone every night and supervise her care in a memory unit. Care Partners experience burden regardless of the location of the person with dementia, thus they do not have to live with them (Table 1).[22]

To be included, all Care Partners must be able to identify two or more behavioral symptoms that are distressing for him or her (the Care Partner) as described on the Revised Memory and Behavioral Problems Checklist (RMBPC), or other commonly cited behavioral symptoms related to dementia.[23] We will enroll Care Partners whose care recipients are in the moderate to late stages of dementia. To assess stage, the Care Partners will be given information describing the three stages of dementia, as identified by the Alzheimer's Association (Box 1).[24] They will be asked to choose the stage that best aligns with their care recipient's current state.

Care Partners who attend an external support group can participate, however, it cannot be a STAR-C [4] (or a version thereof) intervention. We found in our earlier work that support group attendance did not affect our outcome (RMBPC) scores.[12,25]

Box 1: Stages of Dementia
Mild: Able to function independently, but some problems with memory (e.g., difficulty finding the right words, remembering names). May have trouble with losing items, planning and organization.
Moderate: Memory problems prominent (forgetting important facts about personal history, difficulty recalling basic information, such as home address, confusion about time or season). Behavioral symptoms notable: Anger, suspiciousness, frustration. May wander, have problems with incontinence. May need help with dressing, toileting.
Severe: Memory and functional problems impaired. Needs assistance with bathing, dressing, toileting. Difficulty with communication, expressing needs. Personality changes more apparent (agitation, apathy, aggression).

Exclusion Criteria. Care Partners with hearing and/or vision problems severe enough to prevent participation will be excluded. See Table 1 for detailed Inclusion/Exclusion Criteria. It should be noted that this study includes Care Partners for those with advanced dementia. Thus, it is possible, but not likely, that the care recipient with advanced dementia will die of natural causes while in Tele-STELLA. If this occurs, the Care Partner may remain in the study with PI approval. We may reduce the number of surveys for these Care Partners.

If a Care Recipient does not consent to be in Tele-STELLA, the Care Partner cannot enroll in Tele-STELLA.

Care Partners must consent to be video-recorded while in Tele-STELLA sessions. They may turn off their cameras if they prefer.

5) **Screening and enrollment.** Care partners will be recruited from across the United States, from ADRCs, other professionals, and the community at large The teams at the OHSU, University of Kentucky, Emory and UTHSCA ADRCs and other sites will support recruitment in the following ways:

- Inform prospective subjects about the availability of the research
- Provide prospective subjects information about the research which may include IRB-approved recruitment materials
- Inform prospective subjects about the Tele-STELLA website (www.tele-stella.org) and pre-screening link
- Provide prospective subjects with information about contacting the investigators for information
- Seek or obtain the prospective subjects' permission for the investigators to contact them
- Provide OHSU the prospective subjects' contact information. Remote teams and community contacts may email OHSU with information or enter it into a secure file on OneDrive (see Partial Waiver of Authorization, 3/10/2021). Per the HIPAA waiver, OHSU teams will not email information PHI to referring entities.

The University of Kentucky, Emory, and UTHSCA teams will **not:**

- Pre-screen prospective subjects for Tele-STELLA
- Answer specific questions about study details (they will refer to the OHSU team for detailed information)
- Consent participants
- Participate in any research activities

When the OHSU team is notified of a prospective subject, they will complete a full screen.If the prospective participant is not eligible, the OHSU team will ask the subject permission to share their contact information with the recruitment teams and document their permission. They will also be given the phone number of the OHSU recruitment specialist for further information on other studies.

If eligible, the OHSU team will proceed with the consent procedures (below). Screening will be completed using telephone or videoconferencing and documented on paper (Fillable PDF) or electronic (Qualtrics[26] or REDCap[27]) forms.

In the event of a screen failure, data collected during screening will be destroyed prior to the end of the study. The recruitment team will track the number of Care Partners screened for the study, the number consented, the number of those that dropped out, the number who completed some of the intervention, and the number of those that completed the entire intervention.

The remote ADRC locations will only recruit participants for this study. The remote locations including Emory, UK, UTHSCSA, will not participate in any research activities (e.g., full screening, consent, intervention, assessment, identified data analysis). They may participate in analysis of deidentified data, research presentations and manuscript production.

a) Vulnerable Populations

The primary focus of this study is to assess the acceptability, feasibility and efficacy of the Tele-STELLA intervention. Therefore, in order for this study to be successful, Care Partners of care recipients with moderate-to-late stage ADRD will be recruited. The care recipients with dementia will not partake in the intervention, but we will collect data about them, such as their health system use and expenses, behavioral symptoms and their quality of life. Further, if they inadvertently enter Care Partners' rooms during the recorded Tele-STELLA sessions, they may be recorded. Care recipients in this study will be in the moderate to late stages of dementia. They will likely be decisionally impaired and unable to provide informed consent. Thus, we may obtain the informed consent of the care recipient's legally authorized representative (LAR) prior to the Care Partner engaging in any study activities.

Table 1: Inclusion/Exclusion Criteria		
Participant	**Inclusion**	**Exclusion**
Care Recipient with Dementia	• Diagnosis of ADRD, moderate to late stages as defined by family member (Box 1) • Exhibits 2 or more behaviors, including those listed on RMBPC[16], that occur 3 or more times/ week at study enrollment that are bothersome to the Care Partner • Family member of Care Partner (this can be a relative, spouse or close kin that is considered family) • Provides informed consent to participate in the Research, or has LAR who can consent on their behalf • Lives in ADRC catchment area at enrollment	• Dementia not related to ADRD • Unable to leave Care Partner during Tele-STELLA sessions • Early stage dementia, as defined by family member (Box 1)
Care Partner	• Adult caring for family member with ADRD • Provides care for at least 4 hours/week[28] • Age of 18 years or older • Speaks and understands English to be able to participate in intervention • Owns a telephone (smartphone, cell phone or landline) • Has email and mailing address to receive computer, study materials and surveys • Provides informed consent to participate in the research • Lives in ADRC catchment area at enrollment	• Unable to find activity for care recipient during Tele-STELLA sessions to allow Care Partner to work privately with Guide and other Care Partners • Completed similar telehealth intervention within the last year • Hearing and/or vision problems severe enough to prevent participation • Refuses to be video-recorded during Tele-STELLA sessions. • Unwilling or unable to adequately follow study instructions and participate in study procedures

The risks of persons with dementia participating in Tele-STELLA are limited to loss of confidentiality (if they come into view of the Care Partner's computer screen). Care Partners will discuss their family member with dementia's behaviors with other study participants. They will fill out demographic, mood and behavioral surveys on their behalf. It may be distressing for the person with dementia if they overhear their Care Partner discussing difficult behaviors.

To minimize these risks, we will ask Care Partners to identify an activity that will keep the person with dementia occupied and out of computer range during the weekly Tele-STELLA visits.

We will follow OHSU's POLICY HRP-021 to identify appropriate LARs.

a) Setting

This study will occur primarily at OHSU. The University of Kentucky, and the Emory University, and the UTHSCA ADRC research teams will recruit and pre-screen Care Partners from their regions. We will send the recruitment flyer to other ADRC's around the nation and use national registries (ResearchMatch, RISE) to recruit nationwide. All other study activities (screening, consent, intervention, surveys, etc.) will be conducted by the OHSU team.

All study activities will occur via phone, videoconferencing, mail, email and/or text. No in-person visits are required.

b) Recruitment Methods

We will take a multi-pronged approach to subject identification and recruitment. . Care Partners may be recruited from across the US from clinics, electronic medical record systems, ADRC research cohorts,

Researchmatchand other electronic registries, community advisory committees, faith communities and the community at large. We will use social media (e.g., Facebook, Twitter) advertisements to recruit Care Partners from the ADRC regions. "This study will also recruit from the Research Inclusion Supports Equity (RISE) Registry (Emory IRB No. 3337)." All media will receive IRB approval prior to use.

Potential volunteers will be contacted by ResearchMatch via an email contact message containing IRB-approved recruitment language for this study (not including direct study contact information such as study phone number). Volunteers will then have the option of replying by clicking 'yes' or 'no' in the contact message. If a volunteer chooses to respond in the affirmative, they will authorize ResearchMatch to release their contact information to the PI (or ResearchMatch designee) who will be responsible for managing that information according to institutional guidelines.

The RAs at the ADRCs will provide interested parties with information about the study and provide them with the website link. The website (www.tele-stella.org) contains a pre-screening tool that asks interested individuals for basic information such as: Do you care for a family member with dementia (like Alzheimer's disease) for at least 4 hours per week? (by "care" we mean physical care, and/or oversight, for example, managing the care of a family member in memory care); Does your family member with dementia do things that upset you? Do you livein the US? ? If yes to all three, they will be asked to provide their contact information (see Facebook Ad, HIPAA waiver). Recruitment screening responses will be documented in a secure Qualtrics[26] or REDCap[27] survey system, within a secure Excel file on the OHSU Box or OneDrive site, or by phone to an identified Tele-STELLA RA. Advocacy organizations, such as the Alzheimer's Association and the Lewy Body Dementia Association may be asked to promote Tele-STELLA in their community events. We may present information about Tele-STELLA for these organizations and other community groups.

d) Retention Methods

Payment for Participation. Care Partners will receive gift cards from OHSU for participation. They will receive a ClinCard for a total of $100. They will receive the first installment of $40 after completing the first component of Tele-STELLA, the second installment of $30 after completing the second component, and the third installment of compensation of $30 after completing all study activities (Table 2). In order to receive the payments, the subjects will need complete the surveys within the allotted time window (1 week) and provide OHSU with their social security number. The PI may allow provisional compensation if a participant does not complete all the required activities but otherwise demonstrates commitment to the study processes.

Emails and Letters. We may send periodic emails, newsletters, letters or cards to Care Partners to thank them for their participation and to wish them happy holidays. We may send these communications to current and past participants as long as the study is active.

We may send emails and/or texts to Care Partners to communicate appointment times, address technology issues, or address concerns.

e) Consent Process

If the screening process finds the Care Partner is eligible to participate, the OHSU coordinator or research assistant (RA) will send the consent information to the Care Partner and the Care Recipient with dementia via

traditional mail or email, depending on the family's choice. RA will schedule a consent appointment with the Care Partner and ask them to read the consent information prior to appointment.

The RA will arrange a follow up appointment to review the consent forms. This will start with the "Consent Knowledge Check." If the care partner provides two or more incorrect answers, the RA will contact the PI or her delegate. If the PI judges the care partner unable to consent, they will not be enrolled in Tele-STELLA.

If the Care Partner passes the Consent Knowledge Check, the RA will review the key points of the consent information sheet and answer any questions they may have.

The consent process will occur by phone or videoconferencing by the OHSU team. Prior to consenting, the identified Tele-STELLA RA will confirm that the potential Care Partner participant is comfortable and actively listening to the conversation. The RA will begin by asking if the Care Partner has any questions about the consent information or process. RA will then administer the knowledge consent check. If 4 or more questions are answers correctly, RA can assume the Care Partner has read and comprehended the consent information, and continue consent process.
Care Partners are responsible for the safe care of their family member with dementia. It is assumed they will have the capacity to consent. However, if the study team has concerns about a Care Partner's cognitive capacity, they will not consent them and will inform the PI (Lindauer). The PI will contact the potential participant to further assess their trial comprehension and consent capacity.

After comprehension is verified, the RA will ask the Care Partner to verbally consent to the study. When the Care Partner verbally consents to participate in the study, the research team member who conducts the informed consent conversation will sign and date a copy of the forms, indicating that the forms were reviewed with the Care Partner and that consent/assent was obtained. A copy of the forms will be sent to the participants (email or traditional mail). We have used this process with our other studies and it has worked well. If the consent is revised, care partners will be sent the updated consent for both them and their care recipient. They will be advised to contact us if any concerns or if they want to withdraw. The revised consent will not be reviewed with the care partner by the RA or signed by the RA.

If a Care Partner withdraws they will receive an email or letter confirming their withdrawal and thanking them for their participation. All study activities will end; however, if they consented to be in a focus group, we will contact them after they withdraw to give them the option to participate in a focus group. They will have the option to decline focus group participation.

The person with dementia will not partake in the Tele-STELLA intervention, but we will collect and analyze data about them from their Care Partner (see Care Partner Consent) during the study period. Our previous experience has taught us that the person with dementia may enter the room of the Care Partner during Tele-STELLA sessions and inadvertently appear in the videoconferencing recordings. We will seek the consent of the person with dementia or their LAR to participate in this study using an Information Sheet. Care Recipients who are not able to provide informed consent are given the option to assent for the study; this decision will ideally be discussed between the Care Recipient and their LAR, but the final decision is the LAR's to make. If we are unable to obtain the Care Recipient's consent (from them or the LAR), the Care Partner cannot be in the study.

The Information Sheet for the person with dementia advises them of their family member's involvement in the study, the data we collect on them, and the risk of loss of confidentiality if the person with dementia enters their family member's camera field (on their computer) during the live videoconferencing sessions. We will ask the Care Partner or LAR if their family member would be able to understand the information sheet. If the Care Partner or LAR identifies the person with dementia is unable to consent for themselves, , we will ask the LAR to accept responsibility for understanding and communicating the information provided on the Information Sheet.

If the Care Recipient and LAR agrees to assent, RA will complete the assent process over the phone with both parties present. RA will highlight key information in each section of the Care Recipient consent form and ask Care Recipient if they have any questions or concerns about the participation of their Care Partners or selves. In our similar studies, many of the participants with dementia were not capable of consenting. The extra step of a full formal consent for the person with dementia was stressful for Care Partners (often the LARs). The Information Sheet provides the family with information they need to safely participate in Tele-STELLA, while at the same time removing a barrier (full consent of the person with dementia) for study participation.
The study team has the legal and ethical obligation to ensure that prospective subjects, or their LARs, have the sufficient knowledge and comprehension of the information contained in the consent/assent documents to enable them to make an informed decision about whether or not to participate in Tele-STELLA. Participants will be advised in the consenting process that the study team is obliged to report any elder abuse. Participation in this research is not meant in any way to replace regular care.

Procedures

Enrollment and Set-up. After consenting to the study, Care Partners will be contacted by the study research assistants (RA) to collect enrollment information (e.g., demographics, contact information) and orient them to logging on to the Tele-STELLA on their computers (see "Technology" below). The RA's will mail or email the "Tele-STELLA Care Partner Handbook" and ClinCard to the Care Partner, which provides details about all study activities as well as contact information for nationally-available support programs (e.g., the Alzheimer's Association).

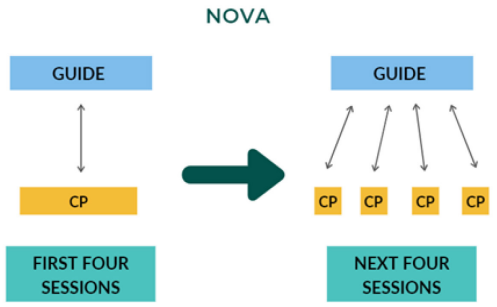

Figure 1. Nova Component of Tele-STELLA

The RA will manage all scheduling with participants using telephone, text, and email (see Table 5).

Tele-STELLA Components. Tele-STELLA consists of two components: **Nova** and **Constellation** (Figures 1 and 2). Each component is made of up of approximately one-hour sessions over about eight weeks. The sessions are taught by the professional "Guides" (e.g., nurses, social workers) or trained lay personnel. The Nova component is designed to introduce Care Partners to Tele-STELLA, first in a one-to-one format, then in small groups (Figure 1). The Constellation component is the same intervention, but provided at a group level, after Nova. IRB-approved PowerPoint slides will be shared with Care Partners as needed. The study coordinator may join any if needed.

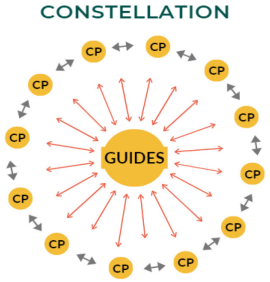

Figure 2. Constellation Component of Tele STELLA

The Nova component. In the first **four** weeks of Nova, **one** Care Partner will meet with **one** Guide via synchronous videoconferencing (Figure 1). The one-to-one sessions orient the Care Partners to the learning environment, allow for mutual trust to develop between the Care Partners and Guide, and give Care Partners the authority to select the behavioral symptoms they want to address.[29]

During, or after the first Nova session the Care Partners and Guides will document the problem behaviors the Care Partners want to work on while in Nova. They will rate how frequently the behaviors occur and how much the behaviors bother the Care Partner. This information will be entered into the Qualtrics[26] or REDCap[27] program.

In the first weeks of Nova, the Care Partner will learn the Tele-STELLA ABC approach, which focuses on identifying the activator of a behavior, describing the behavior in detail, and discussing the

consequences of the behavior. With a deeper understanding of the behavior, Care Partners can develop strategies to prevent or modify it.[30] While Tele-STELLA encourages Care Partners to consider and address their own behavioral symptoms (e.g., depression, grief), the intervention starts with focusing on at least two behavioral symptoms experienced by the family member with dementia.

At **Week 5**, after the 4-week induction period, up to five Care Partners will join one Guide, via videoconferencing, for the remaining four weeks in Nova (Figure 1). In these small group sessions the Guide presents didactic information on pleasant events,[31] affective symptoms of caregiving and Care Partner coping. After the didactic section, Care Partners will be encouraged to share their stories about their experiences, their ABC plans and their successes.

The Constellation component. After completing the Nova component, Care Partners will join the Tele-STELLA Constellation via synchronous videoconferencing (Figure 2). Here up to 20 Care Partners meet as a group with up to three Tele-STELLA Guides for 8 weeks to review and discuss the key lessons of Tele-STELLA. Any Care Partner who completes the Nova component can join a Constellation. The Constellation allows experiential adult learning by having Care Partners practice what they learned in Nova and to provide support for their Care Partner colleagues.[29] Up to four Constellations will be provided/year. Care Partners can join any Constellation, but they need to start it within 1 year of starting Nova. If they delay participation, they may be in the study longer than a year.

During, or after the first Constellation session the Care Partners and Guides will document the problem behaviors the Care Partners want to work on while in Constellation. They will rate how frequently the behaviors occur and how much the behaviors bother the Care Partner. This information will be entered into the Qualtrics[26] or REDCap[27] programs.

Each Constellation session starts with a brief didactic lesson presented by the Guides (the "hub") for the Care Partners in the "spokes" (Figure 2). Following the lesson, a Care Partner will share their story about their family's experience with dementia and distressing symptoms. The participating spokes and the hub may seek more details about the Care Partner's story and discuss approaches to the symptoms. This approach encourages dialogue between all Care Partners to gain a fuller understanding of each Care Partner's experience. The Guides responsible for ensuring respectful exchange and closes with positive feedback for the Care Partners. Should Care Partners be reluctant to share their experiences, the Guides will have example stories to discuss.

Adult learning is most effective when learners share their knowledge with each other.[29] Thus, the Constellation sessions are designed to allow Care Partners to practice and discuss their ABC plans with a larger group of peers.

Care Partners who are unable to complete all Tele-STELLA components may remain in the study and we may collect the data noted in Table 4. Care Partners who do not complete any sessions, or are unwilling or unable to adequately follow study instructions and participate in study procedures, may be withdrawn from the study. We will retain and analyze any data from their participation. They may also be asked to complete the surveys and attend focus groups, despite not completing all of the sessions.

Anticipated challenges. Scheduling Care Partners may be difficult. Thus, the protocol allows the following concessions:

- The study team may alter the session schedules due to holidays, illness or other scheduling issues.
- Up to two weeks break between Nova session #4 (one-to-one) and #5 (small group).
- Nova and Constellation sessions may be doubled in a week if scheduling challenges.
- Care Partners can delay joining a Constellation for up to a year after starting Nova. However, they will need to repeat the Earth Survey (which they complete 1 month after the last Nova session) prior to starting the Constellation.

- If Care Partners delay joining a Constellation, they may be in the study longer than one year.
- Care Partners can skip up to 2 Nova sessions and 2 Constellation sessions and still remain in the study.
- If a Care Partner misses a session, they can catch up by doing two sessions in one week.
- There may be two Constellation sessions in one week if schedules conflict with holidays or other challenges.
- If there are more Care Partners than available Guides, the Care Partners may have to wait to join the Nova or Constellations components. We will enroll them and have them do the weekly survey until there is space for them in the sessions. We will provide them with "usual care" which includes referral to local support agencies, such as the Alzheimer's Association.

Focus groups. Any Care Partner who signed a consent, whether or not they participated in the intervention, can participate in a focus group. Focus groups may be held about twice a year. Focus group leaders will use a semi-structured interview guide to facilitate discussion about the Care Partners' experiences with Tele-STELLA. The focus groups will be video-recorded and transcribed. Transcripts will be analyzed for themes of acceptability. We have successfully used videoconferencing for focus groups in the previous two pilots.[12,25]

Table 2: Tele-STELLA Care Partner Activities

Activity	Description	Due
Screen	Screen for study eligibility (see HIPAA waiver)	Prior to consent
Consent	Care Partner and care recipient consent	Prior to study activities
Preliminary session(s)	Collect enrollment information Set up and test videoconferencing link Mail handbook and email PDF Handbook	After consent completed
Nova Component (8 weeks)		
MecurySurvey (Survey 1)	Baseline surveys (Table 4)	Prior to intervention start
Target Problem Assessment		Guides complete during or after Session 1
Intervention: Nova 1	Meet with Guide for 4 weekly one-to-one sessions	After Mercury Survey completed
Intervention: Nova 2	Meet with Guide and up to 5 other Care Partners for 4 more weekly sessions	After Nova session #4
Venus Survey (Survey 2)	See Table 4	Within one week of completion of Nova
Target Problem Assessment		
Earth Survey (Survey 3)	Assessment of behaviors, mood, quality of life	1 month after last Nova Session
Target Problem Assessment		
(Subjects who complete all above activities will receive $40)		
Constellation Component (8 weeks)		
Earth Survey* (Survey 4)	See Table 4	About 1 week prior to Constellation start
Target Problem Assessment		Prior to or during Constellation Week 1
Intervention	Meet with up to 20 Care Partners for 8 weekly Sessions	After Earth Survey completed
Mars Survey (Survey 5)	See Table 4	Within one week of completion of Constellation
Target Problem Assessment		
(Subjects who complete all Constellation activities will receive $30)		

Earth Survey (Survey 6)	See Table 4	2 months after last Constellation session.
Target Problem Assessment		
Weekly Orbit Surveys: **Distributed weekly (Table 4)** Orbit surveys start after enrollment and continue until all surveys are completed		
(Subjects who complete last Earth Survey and 80% of Orbit Surveys may receive $30)		

*Earth Survey should be completed within approximately two weeks of starting Constellation. If Constellation start is delayed, Care Partner will need to repeat Earth Survey.

Guide training. Guides will be trained by the principal investigator (PI), Project Director (PD), andother Guides. Guides will participate in standardized didactic and experiential training. Best practices in managing and facilitating both individual and group sessions will be emphasized.

Guides will review the Guide Handbook and recordings of other Guides. . They will record mock sessions with models acting as a Care Partner. The models (e.g., staff, Tele-STELLA Community Advisors) will use a scripted format, "stage" names and false stories. Models will be advised not to use any PHI. Mock practice sessions will allow guides to practice group strategies such as management of inappropriate behavior (e.g. use of disparaging comments), and inclusion of reticent participants. Guides will demonstrate essential competencies in behavior identification, intervention delivery and data documentation prior to implementing Tele-STELLA. The PI and PD will determine when Guides are adequately trained to do the Tele-STELLA intervention. All training will be completed via videoconferencing and recorded to maintain consistency across guides. The PI/PD may join any Tele-STELLA session to assess Guide competency.

Fidelity Assessment. The Tele- STELLA trial utilizes a vigorous fidelity assessment protocol that examines interventionist (Guide) adherence to protocols during delivery monitoring. This protocol is informed by evidence-based standards, including recommendations from the NIH Treatment Fidelity Workgroup Behavior Change Consortium and advised by Onken et al.[30] We utilize this protocol to reduce threats to internal validity and facilitate dissemination of findings and procedures

We will videotape all Tele-STELLA sessions and recordings will be stored on a secure server (OneDrive) that the fidelity assessment team can access via the OHSU secure filesharing system. The fidelity assessment team will consist of content experts, including experienced Guides. They may view a randomly-identified subsample of up to 20% of videos. The assessment will evaluate procedural fidelity, documentation fidelity, and theoretical fidelity. Fidelity items are scored using a binary rating of "1" (present) or "0" (absent), with clearly defined characteristics required for either rating. Inter-rater agreement on video assessments will be measured (77).

STAR Council. The STELLA Team Advisory Resource (STAR) Council is made up of former study participants, caregivers, and community members with lived experience and an interest in dementia caregiver well-being. The Council provides structured input to ensure study activities reflect community perspectives and are culturally and contextually appropriate.

STAR Council members may:

1. Review study materials, communication tools, and recruitment strategies and provide user-centered feedback.
2. Participate in beta testing of websites and technology tools (via Webex; sessions may be recorded for internal review by authorized staff).
3. Attend mock intervention sessions as practice participants to support staff training (via Webex; may be recorded for internal review).
4. Review dissemination products (e.g., manuscripts, posters, newsletters).
5. Participate in selected recruitment and outreach events with study staff.

6. Provide guidance on community outreach and dissemination of study findings to community members in ways that are meaningful, engaging, and culturally appropriate for the communities the study aims to benefit.

The Council will primarily meet via Webex. All members will complete a brief orientation covering STAR Council goals, expectations, use of technology, and compensation procedures. Ongoing training and support will be provided to promote meaningful engagement. The STAR Council members will be provided with up to $50/hour of service as funds allow. No PHI of any study participants will be shared with STAR Council members. Council feedback will be reviewed by the study team to inform materials, procedures, and dissemination. Engagement quality will be assessed annually.

Implementation. Tele-STELLA will be implemented in two phases. *Phase 1* will be a pilot phase to address the goals stated in Aim 1 ("Establish the feasibility and acceptability of Tele-STELLA"). In *Phase 2,* we will complete the intervention with the remaining Care Partners to address Aim 2 ("Establish the efficacy of Tele-STELLA in reducing the *frequency* of BPSD and Care Partner *reactivity* to the symptoms").

Table 3. Plan for Refining and Optimizing Tele-STELLA (Aim 1)

Aim	Criteria	Possible Modifications
Feasibility	• 80% of Care Partners will complete Tele-STELLA within 12 months of starting the intervention • 70% of Care Partners will complete at least one Constellation component • 80% will report accessing internet with minimal challenges.	• Identify barriers to participation in focus groups and modify as indicated. • Discuss and address technology challenges with ORCATECH team
Acceptability	• 80% will report overall satisfaction with program on the Tele-STELLA Satisfaction Survey • 50% will attend focus groups • In their focus groups, Care Partners will report positive experiences with Tele-STELLA	• Address concerns in focus groups • Implement changes, if they align with Tele-STELLA theory and principles, as suggested by focus groups
Fidelity	• There will be moderate to high protocol adherence as measured on the Protocol Adherence Checklist • Inter-rater agreement on video assessments will range from 0.42-1.00[34]	• Identify and address areas of poor adherence, re-train Guides as needed • Review video rating protocol and adjust as needed
Preliminary Efficacy	• Trends will suggest improvement in behavioral symptom frequency, Care Partner reactivity, burden and grief. We may see improvements in quality of life for both the person with dementia and the Care Partner.	• Identify where improvement (or lack thereof) was seen across the intervention • Work with Consultant (Teri) and/or co-investigators to modify intervention to target areas of weakness

Phase 1. The first Care Partners (up to 36) will receive the intervention as described above. Feasibility will be assessed by tracking recruitment patterns across the ADRCs, as well as enrollment and retention rates. We will document and compare completion rates for both the Nova and Constellation components. We will compare completion rates for each location. Acceptability will be assessed by engaging focus groups with Care Partners via videoconferencing, and fidelity will be assessed using the procedures discussed above.

Should findings from Phase 1 indicate a need for substantial revisions, the study team will discuss the revisions and implement changes that align with the theoretical basis of the intervention.[17] We will repeat procedures with another sample of Care Partners. We will repeat this process until we meet the criteria outlined in Table 3.

Phase 2. Once the intervention is refined, and meets the criteria in Table 3, we will implement Tele-STELLA until up to 124 Care Partners have completed the full intervention. We will assess the efficacy of Tele-STELLA as described in Aim 2 (Establish the efficacy of Tele-STELLA in reducing the *frequency* of behavioral symptoms and Care Partner *reactivity* to the symptoms).

Measures. For all measures, please see **Table 4** for descriptions and **Table 2** (Care Partner Activities) for timing of distribution to the Care Partners. Demographic information (such as address, age, sex, race, rural status) will be collected upon enrollment. Care-recipient dementia diagnosis and diagnosis year will be documented. Dementia stage will be identified by Care Partner report (Box 1). The number of years and hours of caregiving will be recorded.[12,25]

The primary outcome, caregiver burden will be assessed with the RMBPC,[23] which measures the frequency of BPSD and caregivers' reactions to these behaviors. The RMBPC is among the most commonly-used measures of burden in caregiver research and has strong internal consistency (α=.86).[35] Six questions additional questions as about care recipient behaviors.

Tele-STELLA requires Care Partners to work on their specific family behavioral symptoms. This information is documented in Qualtrics[26] or REDCap.[27] The Guide and Care Partner discuss the behavioral symptoms in the first Tele-STELLA Nova sessions and document them for reference during and after the Nova sessions. The Care Partners will complete their own assessments at the end of Nova and in Constellation.

We will assess burden with the 4-item ZBI, a brief measure of burden (α=.78).[36] Pre-death grief will be assessed with the Marwit Meuser Caregiver Grief Index-Short Form (MMCGI-SF).[37] The MMCGI-SF is an 18-item assessment of pre-death grief with high internal consistency (α=.80).[37] The Ten-Item Personality Inventory provides information on extraversion and introversion.[38]

Quality of life (QOL) will be assessed with the QOL in Alzheimer's Disease (QOL-AD) [39] scale, a 13-item measure of factors such as physical health and energy. Care Partners will complete their own QOL-AD. The Care Partner may complete the QoL AD for the care recipient. The QOL-AD has high internal consistency (α=.80) with those with high cognitive function. Internal consistency is high when Care Partners reports on their care recipient's QOL (α=.86). Care Partner depression will be measured with the CESD-10 (α=.88).[40] We will assess satisfaction with Tele-STELLA using the Tele-STELLA Experience Survey.[12,25]

Table 4. Tele-STELLA Survey Descriptions	
Target Problem Assessment: Care partner documents target problems prior to and after Nova and Constellation	
Mercury (Baseline)	
Revised Memory & Behavioral Problems Checklist (RMBPC) [23]	Measure of frequency and reactivity to behavioral and psychological symptoms of dementia[23]
Center for Epidemiologic Studies Depression Scale (CESD-10)[41]	10-item depression measure
Marwit Meuser Caregiver Grief Index-Short Form (MMCGI-SF)[37]	Care Partner pre-death grief[37]
Placement plan scale[42]	One-item assessment of plans for placement of family member with dementia[42]
QoL AD[39]	13-item assessment of quality of life for the Care Partner
QoL AD[39] (person with dementia)	13-item assessment of quality of life for completed by the Care Partner on behalf of the person with dementia.

Venus Survey	
RMBPC[23]	(see Baseline for descriptions)
CESD-10[41]	
MMCGI-SF[37]	
Placement plan scale[42]	
QoL-AD[39]	
QoL-AD[39] (person with dementia)	
Tele-STELLA contact (includes TIPI)[38]	Tele-STELLA Care Partner contact post intervention, extraversion, introversion
Tele-STELLA Nova Experience Survey	16-item + comments on satisfaction, privacy, ease of use
Earth Survey	
RMBPC[23]	(same as "Venus" but without Experience Survey)
CESD-10[41]	
MMCGI-SF[37]	
Placement plan scale[42]	
QoL-AD[39]	
QoL-AD[39] (person with dementia)	
Tele-STELLA contact	
Mars Survey	
RMBPC[23]	(see Baseline for descriptions)
CESD-10[41]	
MMCGI-SF[37]	
Placement plan scale[42]	
QoL-AD[39]	
QoL-AD[39] (person with dementia)	
Tele-STELLA contact	Tele-STELLA Care Partner contact post intervention
Tele-STELLA Constellation Experience Survey	16-item + comments on satisfaction, privacy, ease of use
Weekly Orbit Survey: **Distributed weekly during full intervention**	
Measures Care Partner emotional and physical strain and frequency of contact with both their and their family member with dementia's clinical providers. It measures the frequency of as-needed medication use for behavioral symptoms; measures out-of- pocket costs, and use of ABC plans.	

Care Partners will fill out weekly "Orbit" surveys that were developed by the Oregon Roybal Center for CAre Support Translational Research Advantaged by Integrating Technology (ORCASTRAIT), housed at the Oregon Alzheimer's Disease Research Center. The survey includes the "ORCASTRAIT Care Partner Weekly Survey," which measures such variables as Care Partner emotional and physical strain, medication use and frequency of contact with both their and their family member with dementia's clinical providers. Also included in the Orbit survey is the "ORCASTRAIT Caregiver Cost Survey," which measures out-of- pocket costs. The two surveys will take approximately 1-15 minutes (total) to fill out and will be emailed to the Care Partners weekly.

We will assess Care Partner likelihood of placing their family member into long-term care (e.g., assisted living, memory care) using a single item question ("In the next 6 months, how likely are you to move your care recipient to another living arrangement?"). Care Partners will rate this on a scale of 1 (not at all likely) to 5 (very likely).

If the Care Partners drop out of the study, we will ask them to complete the Exit Survey so we can get their feedback.

The Guides may collect qualitative data during the intervention that highlights challenges for the Guides, technological issues, and/or provides insightful comments from the Care Partners (see Guide Tracking Sheet). A notes section is provided for each session on the Attendance and Content Checklist.

We will implement the above measures using Qualtrics[26] or REDCap[27] Survey Platforms[26] The surveys will be emailed to the Care Partners.[26] Auto-reminders will be sent to the Care Partners until they complete the surveys. If they do not complete the surveys within 5 working days, the Tele-STELLA coordinator may call, email or text them to identify barriers to completing the surveys. If they would like to stay in the study, they will need to complete at least 80% of each survey and submit survey responses within two weeks of receiving them. However, final disenrollment of a participant due to incomplete surveys is subject to PI discretion.

Care Partners will need to complete their first planet survey (Mercury) the week prior to their first Nova session with the Guide. They are not allowed to begin the intervention until they complete the Mercury survey. If they do not complete their Mercury survey within one month of receiving it, they may be removed from the study. The electronic functionality allows Care Partners to complete surveys in the privacy of their homes, at a time that works for them. The Qualtrics[26] and REDCap[27] platforms are HIPAA compliant and secure. We will assess completion rates and internal consistency of the online platform surveys. Focus group participants will be queried about their experience with the platform.

g) Technology and Participant Communication. All contacts, surveys and interventions may be completed by phone, email, texting, videoconferencing and/or electronically-administered assessments (see Table 5). The pre-screen will be online at www.tele-stella.org. All other study activities (screening, consenting, intervention and surveys) will be done at OHSU by OHSU scientists, interventionists and staff. There are no in-person research activities. We will send occasional newsletters with study updates via OHSU's Marketing Cloud system. Marketing Cloud is managed within OHSU and is HIPAA compliant..We will send the newsletters through 2026. Care partners will have the option of opting out if they do not want to receive the newsletters.

This study will be using interactive, real-time delivery of telehealth care over distance using video-conferencing equipment. The basic mode of connectivity between the study subjects and the research team will be via OHSU's Webex system. This platform is secure as independently validated by OHSU's IT and legal department.

The Webex recording system will be used to record the telehealth visits. This service can securely record all visits as needed. There is no limit as to how many visits can be recorded concurrently. Visit recordings will be managed through the Webex secure web portal requiring OHSU credentials and multi-factor authentication. OHSU Security Engineering department has agreed to ensure that this study's policies and procedures meet strict Information Security Directives (ISDs).

The Guides will meet with Care Partners via videoconferencing using either an OHSU computer or their own computer and an OHSU, HIPAA-secure link. The Guides will not contact the Care Partners outside of the videoconferencing sessions without making a reasonable effort to have the study coordinator contact the Care Partner first. The Guide may complete the visit from his or her home, OHSU office or other convenient private location. They may use headphones and a privacy screen so that participants will not see their home or office environments. During the Tele-STELLA sessions, Care Partners can connect to the videoconference-based sessions from their home or another private location.

Care Partners may use their own computers, tablet or smartphones for this study. We will provide them with a secure OHSU-generated link to access the study's videoconferencing site. Some Care Partners may not have a device to access the study. These Care Partners will be loaned a Chromebook with a simplified user interface allowing for only study activities to be conducted using the device. Care Partners will access the intervention using the OHSU secure videoconferencing link which will be visible upon opening the Chromebook. Chromebooks will be mailed to Care Partners and pre-paid postage and packaging will be provided for the return mailing. Care Partners can keep the Chromebooks while they participate in the Tele-STELLA intervention, the post-intervention survey, and a focus group.

Care Partners who use their own computers, and those using the loaner Chromebooks, may need a hotspot device that uses cellular service to access the internet. The study will provide this device. Whether they use their own devices or the Chromebooks, Care Partners will have the option to use internet or cellular service to access the study, but the study will only pay for cellular service. If all efforts to correct connection issues fails, the Care Partner may participate in Tele-STELLA via phone.

We will work with the Oregon Roybal Aging & Technology Team (ORCATECH) to manage the computers and accompanying technology. A Tele-STELLA research assistant may teach and support Care Partners in device use and study access. All Tele-STELLA sessions may be video-recorded and the recordings will be stored on a secure server and/or OneDrive. Videos that are not needed for fidelity assessments may be deleted. Videos saved on staff webex accounts will be deleted should the staff member leave OHSU. Content experts will have access to a sample of videos for viewing via the OHSU secure file-sharing system (Box[43] or OneDrive).

Care Partners will access all electronic surveys on their Chromebooks, their own computers, tablets, their smartphones, or other devices.

Care Partner surveys will be administered via the REDCap[27] or Qualtrics[26] Survey Platform[26] (FIPS 140-2 compliant transfer). This platform provides HIPAA secure, easy-to-use surveys that Care Partners can complete on their Chromebook, laptop or smartphone. We used Qualtrics[26] in our previous pilot, with 100% Care Partner completion of surveys.[25]

6) Data and Specimens

h) Handling of Data

No biological or genetic specimens will be collected in this study. Data from the measures described above will be collected via the secure Qualtrics[26] or REDCap[27] systems and then downloaded to a secure OHSU file for analysis.

i) Sharing of Results with Subjects

Results of the RMBPC and the Personalized Target Behavior Problem Assessment may be shared with the Care Partner prior to the intervention. This will help the Care Partner identify behaviors they want to target in the training sessions. If the burden or depression scores indicate severe depression or burden, the Care Partner may be informed, at the discretion of the PI (see DSMP) The Care Partner may be referred to appropriate services if deemed necessary (e.g., social worker or other counseling services). The other results may be provided, if asked, after all data is collected, analyzed and published.

j) Data and Specimen Banking

Data from this study may be shared with other investigators for future research studies through the data repository. Data from the repository will be shared with other investigators according to the IRB approved repository policy (OHSU IRB # 6845).

6) Data Analysis

Tele-STELLA will use a mixed-methods approach to assess and refine the intervention. Along with classic quantitative measures, we will engage focus groups to examine program acceptability.

Aim 1(Establish the feasibility and acceptability of Tele-STELLA). We will assess data from the surveys to characterize the sample, assess program acceptability, and measure treatment fidelity. We will compare demographic information, computer use, out-of-pocket costs, health-care usage, behavioral symptom frequency, Care Partner reactivity, burden, depression, quality of life and daily activities for those that completed the interventions to those that did not.

For acceptability, we will analyze the Tele-STELLA Experience Survey results using descriptive statistics. A narrative analysis approach may be used to analyze the qualitative focus group data and the data from the Guide Tracking Sheet. The transcripts from the video recordings may be examined to identify contextual features, Care Partners' goals, the influences of the other Care Partners and Guides and the results the Care Partners experienced. We will identify themes of acceptance, or lack thereof, of Tele-STELLA and the underpinnings of their impressions.[45] These qualitative findings will be considered in relation to the quantitative data using a parallel mixed analysis approach, a widely-used strategy in mixed methods research.[46] This involves separate analyses of the quantitative data (e.g., paired *t* tests, linear regression) and qualitative data. This may be followed by an analysis that looks at areas of data convergence and divergence. We have used this approach in our pilots [12,25] where we found that Care Partners with higher reactivity scores on the RMBPC[23] voiced in the focus groups preference for a one-to-one intervention. Those with lower scores were inclined to prefer a group intervention.[47] These findings informed our decision to include both one-to-one and group sessions in Tele-STELLA. Similarly, the parallel mixed analysis findings may be incorporated into any needed revisions of Tele-STELLA.

For treatment fidelity, we will document the proportion of Care Partners who completed the full Tele-STELLA intervention. For the video assessments, Cohen's kappa coefficient will be used to calculate inter-rater agreement, with the following coefficients: Almost perfect 0.81-1.00; Substantial 0.61-0.80; Moderate, 0.41-0.60, Fair 0.21-0.40; Slight/poor, <0.[34]

*Aim 2 (*Establish the efficacy of Tele-STELLA in reducing the *frequency* of behavioral symptoms and Care Partner *reactivity* to the symptoms)*.*

Efficacy will be assessed by measuring pre/post changes on the RMBPC (frequency and reactivity) after NOVA (primary analyses) and after Constellation (exploratory analyses). We may also assess efficacy in the domains of Care Partner depression, QOL and grief before and after each component (Nova and Constellation), with pre-post paired *t* tests.[46]

Using hierarchical linear modeling, we may assess the effect of Tele-STELLA controlling for number of days between the end of Nova and the beginning of Constellation as a sensitivity analysis.

We may use linear regression models to examine pre-post changes in primary outcome (RMBPC change scores) utilizing surveys between two points. We may assess relationships between the Care Partner reactivity subscale and other variables, controlling for variables such as age, sex, number of hours caregiving, rural status and education: a. number of Tele-STELLA sessions each Care Partner attended, b. likelihood of placement, and c. out-of-pocket costs. Other linear regression models will be used as indicated.

Using linear regression modeling, we may assess relationships between the Care Partner reactivity subscale and the following variables, controlling for age, sex, number of hours caregiving, rural status and education: a. the number of days prior to starting Nova sessions, b. the number of days prior to starting Constellation sessions.

We may assess differences in the RMBPC (reactivity subscale) between four groups (rural White, African American; urban African American, White) with multiple comparisons assessed post-hoc using Tukeys HSD correction. We may test whether the efficacy of our intervention differs across racial and ethnic groups using interaction terms (e.g., time*groups) in linear regression.

Using ANOVA, we may assess pre-post changes in the RMBPC[23] (reactivity subscale) between four groups (rural White, African American; urban African American, White), with the hypothesis that there are no significant differences across groups. We may test whether the efficacy of our intervention differs across racial and ethnic groups using interaction terms (e.g., time*groups) in linear regression.

If some participants participate by phone only, we may compare their scores with those completing the study via videoconferencing using appropriate statistical measures (e.g., ANOVA).

We will summarize costs and may assess the relationships between cost, burden and Tele-STELLA participation using linear regression models and other statistical analyses deemed appropriate for cost analyses.

Other statistical analyses may be completed if the data suggest important relationships.

7) Privacy, Confidentiality and Data Security

Standard institutional practices will be followed as described in the OHSU Information Security and Research Data Resource Guide to maintain the confidentiality and security of data collected in this study. Study staff will be trained with regard to these procedures.

All scales will be de-identified and a participant number will be assigned to each scale for data management. All data will be kept on the limited-access drives or computers at OHSU or in a locked location in the OHSU ADRC. Documents used for the intervention (Individual and Group Logs, Pre-treatment survey, Visit Information Sheet) may be stored with the interventionist and RA in a secure location in the staff member's home. All documents will be shredded or returned to the OHSU ADRC at the completion of the intervention. These documents will not contain any PHI, but will contain the participant's study ID #.

To help us protect subjects' privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers can refuse to disclose information that may identify subjects, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify subjects, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the FDA. A Certificate of Confidentiality does not prevent subjects or members of subjects' families from voluntarily releasing information about them or their involvement in this research. If an insurer, employer, or other person obtains subjects' written consent to receive research information, then the researchers may not use the Certificate to withhold that information. However, if we learn about abuse of a child or elderly person or that a subject intends to harm him or herself or others, or about certain communicable diseases, we will report that to the proper authorities.

Upon enrollment, subjects will be assigned a code that will be used instead of their name, medical record number or other personally identifying information. However, video-recordings will show their faces and their names--any information discussed during the sessions will be heard in the audio. In this case, the information subjects give us will be identifiable as coming from them and will not be private.

We will use participants' electronic mail, phones and texts for communication and data collection. A key element of Tele-STELLA is to foster peer support. Care Partners will be asked to share their phone numbers and email addresses with other participants. We will ask all participants to refrain from sharing this information with others outside Tele-STELLA, but we cannot prevent this. The phone numbers and email addresses will not be confidential. We will ask Tele-STELLA participants to only use first names in the intervention. Care Partners can opt out of sharing their contact information.

Electronic mail for data collection, and electronic files for data analysis may not contain any PHI. Codes will not contain any of the 18 HIPPA identifiers. The key associating the codes and the subjects personally identifying information will be restricted to the PI and study staff. The key will be kept secure

on a restricted OHSU network drive in a limited access folder. Any paper files will be stored in the restricted-access offices at the Layton Center.

Electronic data will be stored on restricted computers and/or drives on the OHSU network, to which access will require OHSU/ID password authentication.

Video-recordings may be shared with other researchers and those outside of OHSU who are involved in conducting or overseeing research via the secure Webex portal, or via OHSU Box.com or OneDrive. Using Webex, video streaming links can be sent to identified users via email (which will require a password to access). Study coordinators can download the video files outright from the Webex portal and saved on OHSU's "X" drive in a highly secure, biometrically authenticated data center or shared via OHSU Box.com or OneDrive. Using OHSU Box.com (or OneDrive).The transcripts of the videos will be available to study staff to review sessions and address any concerns.

Electronic survey data will be stored in a web-accessible server (e.g., Qualtrics[26] or REDCap[27]). Copies of this data will be transferred to a secure OHSU server via Application Programming Interface call. Other electronic data will be stored on a secure, password protected OHSU server. Access to data is restricted to study personnel. Access to data requires username/password authentication.

10) Risks and Benefits

a) Risks to Subjects

There are few risks involved in this study. Care Partners will have to meet (via videoconferencing) with the research team and other Care Partners for multiple visits, which may be inconvenient. Care Partners will need to find an activity for their care recipients during the sessions, which may cause financial hardship for some. All visits will be virtual, so there should be no travel costs.

Some of the questions on the scales may seem very personal or embarrassing and fatiguing to participants and may upset them. They may refuse to answer any of the questions that they do not wish to answer. If the questions make them very upset, we will refer them to a social worker or similar professional.

There is a risk that the video-recordings may be seen by someone they know. It is possible that someone viewing the videos may recognize them or their family members and/or hear their names in the audio, and their identities would no longer be confidential. The Care Partners will see each other's' video and audio and share contact information, thus, their identities will not be confidential.

No part of Tele-STELLA study participation for the Care Partners *should* result in a serious adverse event as defined by the NIA Adverse Event and Serious Adverse Event Guidelines: [86]

> Any adverse event that results in death; is life threatening or places the participant at immediate risk of death from the event as it occurred; requires or prolongs hospitalization; causes persistent or significant disability or incapacity; results in congenital anomalies or birth defects; and/or is another condition which investigators just to represent significant hazard.

There may be other adverse events for Care Partners as defined by the NIA Adverse Event and Serious Adverse Event Guidelines[86]

> Any untoward or unfavorable medical occurrence in a human study participant, including any abnormal sign (e.g. abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the participants' involvement in the research, whether or not considered related to participation in the research.

Due to the known strain of caregiving, Care Partners may report mental health issues (e.g., anxiety, depression) or physical manifestations of stress (e.g., hypertension, low back pain). These will likely not be related to the intervention, however, emotional distress is a potential risk of study participation,

thus training will be provided to all study team members (including all study investigators, Guides and research assistants) to (a) sensitize them to the signs, symptoms and/or indicators of extreme emotional upset, (b) enable them to make an appropriate immediate response and (c) ensure that project protocol, below, for providing information about resources is carried out appropriately.

> Brief Description of the Emergency Response Protocol: In the event that any participant displays significant psychological stress as identified by any member of the study team, the Principal Investigator will be notified within 24 hours (Lindauer) (off hours and on weekends, one of the co-PIs or experienced Guides will be notified). Dr. Lindauer (or her delegate) will reach out to the participant with appropriate resources (hotlines, websites, etc.). To the extent possible, these resources will be local to the participant in question. Resources provided to Care Partners are detailed in section 1.3 "Protection Against Study Risks." Dr. Lindauer (or her delegate) will be responsible for reporting adverse events to SO, NIA, IRB during normal reporting intervals.

It is possible that the **persons with dementia** who are enrolled in Tele-STELLA may experience a serious adverse event as defined by the NIA Adverse Event and Serious Adverse Event Guidelines. These SAEs would not be a result of the intervention (the persons with dementia do not participate the intervention). Rather, these events will likely be due to advancing dementia and/or health concerns that come with advancing age (e.g., agitation, falls, urinary tract infections, pneumonia) and are expected. It is expected that some participants with dementia will die, and/or be placed in hospice while they are enrolled in the study.

Hospitalizations and deaths in persons with dementia will be considered expected SAEs for the participants with advancing dementia or conditions associated with aging and therefore reported in quarterly reports

We also expect adverse events for the **persons with dementia** as defined by the NIA Adverse Event and Serious Adverse Event Guidelines.[86] These AEs would not be a result of the intervention (the persons with dementia do not participate the intervention). Rather, these events will likely be due to advancing dementia and/or health concerns that come with advancing age (e.g., agitation, urinary tract infections, pneumonia).

We will report SAEs and AE's per directions laid out by the NIA:

- Only Unexpected SAEs *for those who participate in the intervention* (i.e., only care partners and not the persons with dementia, who are still considered research participants due to measures being collected about them but do not receive the intervention) will be reportable to the IRB, SO and NIA via expedited reporting (i.e., within 48 hours).

- Expedited reporting to NIA PO, SO and IRB (i.e., within 48 hours of study team's awareness) will **only be required for care partners who experience adverse events that are both serious (SAE) and unexpected** (i.e., have not been previously reported for the study's intervention).

- The summary of all other SAEs will be reported to NIA Program Officer and to the Safety Officer **quarterly**, unless otherwise requested by the Safety Officer. SAEs for those who do not participate in the intervention (i.e., persons with dementia) will be reportable quarterly (i.e., in quarterly summary reports).

- Hospitalizations and deaths will be considered expected SAEs for the participants with advancing dementia or conditions associated with aging (i.e., PLWD) and therefore reported in quarterly reports.

a. Potential Benefits to Subjects

Care Partners who complete all training sessions may experience a reduction in their feelings of burden and depression. They may feel less likely to want to place their care recipients in long-term care. It is possible that these benefits will last up to 6 months. In general, they may feel better about caregiving. Care recipients may experience less psychological stress as their Care Partners learn to communicate and manage behaviors.

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