Assessing Acceptability, Cost, and Efficacy of STELLA-Support via Technology: Living and Learning with Advancing AD

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Protocol Title:

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Objectives

STELLA (Support via TEchnology: Living and Learning with Advancing Alzheimer's disease and related dementias) is a multicomponent video-conference based intervention designed to facilitate effective management of behavioral and psychological symptoms of dementia (BPSD). In the STELLA intervention, professionals ("Guides") meet with family members ("Care Partners") caring for persons with dementia. Working together, the Care Partners and Guides identify strategies to address upsetting behaviors in the moderate to late stages of dementia. The goal of this intervention is to reduce upsetting behaviors and thus care partner burden including costs.

The specific aims of this study are:

Phase 1

1. Using quantitative and qualitative approaches, assess feasibility and participant acceptability of (a) STELLA, and (b) the assessment methods (subjective measures and unobtrusive objective monitoring).

2. Using quantitative strategies, assess the preliminary effect of STELLA on (a) the affective impact of caregiving, Care Partner cognitive function and person with dementia quality of life, and on (b) Care Partner and person with dementia objective digital behavioral biomarkers (activity, sleep and time together).

3. Test the feasibility of employing digital behavioral biomarker data, combined with qualitative Care Partner feedback, to assess mechanisms of behavior change before, during and after the STELLA intervention.

Phase 2

1. Quantify the costs of delivering the STELLA intervention.

2. Quantify the cost efficacy of STELLA in relation to BPSD frequency and CP reactivity and assess the relationship between costs, BPSD, and care partner burden.

H1: There is a relationship between BPSD and cost: More BPSD behaviors and more CP reactivity to the BPSD are associated with higher out-of-pocket and implicit costs for families living with dementia.

H2: There is a relationship between out-of-pocket and implicit costs and objective measures of burden identified in the ORCASTRAIT Living Lab continuous home assessment. Higher objective burden will correlate with higher implicit and out-of-pocket costs.

STELLA is an ancillary study embedded in the Oregon Roybal Center for CAre Support Translational Research Advantaged by Integrating Technology (ORCASTRAIT) parent study (IRB#20236).

1. Background

Phase 1

Providing care for a family member with Alzheimer's disease or related dementia (ADRD) is both rewarding and risky.[1, 2] Care Partners exposed to chronic stress, often over years, are susceptible to physical and psychological ailments.[2] In addition, the caregiving experience increases the risk of cognitive impairment in Care Partners, with spouses being particularly vulnerable [3-5], thus potentially perpetuating a cycle when yet another family member has to care for the former Care Partner. Effective interventions that reduce Care Partner burden and health risks are available,[6-8] but various factors impede Care Partner participation, including distance, cost, behavioral symptoms of dementia, stigma and social anxiety.[9-12] Recognizing the need to reduce barriers to access, scientists have turned to Internet-based interventions.[13, 14] 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, only a minority of studies allow for health professional engagement, and of these, only a handful provide real-time interaction.[13] Further, Hopwood et al. concluded that, despite the fact that family needs vary across ADRD stages, the interventions reviewed were not targeted to a specific stage of ADRD.[13]

To address the needs of families living with dementia, we have completed two pilot studies using Internet-based Care Partner interventions.[15, 16] These studies tested the feasibility and consumer acceptability of the evidence-based, STAR-C [7] intervention, the precursor to STELLA, when delivered via telehealth. Qualitative data revealed the telehealth intervention was acceptable to Care Partners and preferred over a potential in-home ("live") 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?"[17] 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." [15] Care Partners advised that future interventions should include <u>both</u> one-to-one sessions <u>and</u> one-to-multiple sessions.

Based on the qualitative and quantitative data from the pilot work, [15] STELLA was designed to address the specific needs of families living with moderate to severe dementia. 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.[18] STELLA is designed for families living in the later stages of dementia, where behavioral symptoms are more prominent and distressing for all. [19]

This study is unique in that along with classic measurements of Care Partner burden and depression, we are also measuring these affective symptoms objectively. Further we will assess the effect of STELLA on the person with dementia's objective measures (e.g., sleep time).

STELLA allows all study activities to be done in the Care Partner's homes. This includes assessments of burden and depression using electronic versions of classic measures.

Phase 2

Dementia is the most expensive condition in the United States (US).[1] The high costs are driven in part by the prolonged course and intensity of the disease and heavy care demands on family members.[2] A significant contributor to care demands are the behavioral and psychological symptoms of dementia (BPSD) (e.g., depression, irritability, agitation, anxiety) that the majority of persons with dementia (PwD) experience.[3] These BPSD have been linked to care partner (CP) depression, burden, and grief,[4, 5] and in turn, BPSD frequency increases when CPs are depressed and burdened.[5, 6] De Vugt et al.[7] found that CP reactivity to BPSD predicted skilled care placement, which is concerning

because skilled care makes up the largest portion of the average annual cost per person of US $50,201.(8) Despite evidence that BPSD contribute to care costs, the literature on the cost efficacy of Telehealth-based interventions for BPSD is limited. Further, while numerous technology-based interventions exist, little attention is given to implementation costs or to the potential cost savings of these interventions.

STELLA (Support via TEchnology: Living and Learning with Advancing ADRD) is an intervention designed to address the need for a personalized approach to teach CPs strategies in managing BPSD. This real-time educational intervention is designed for families caring for those in moderate to late-stages of dementia. STELLA uses videoconferencing to connect CPs, in their own homes, with experienced Guides. The Guides use cognitive behavioral techniques to assist CPs in identifying and implementing strategies to reduce distressing behavioral symptoms in the PwD. This in turn diminishes CP burden and depression.(9) Our pilot work found that early versions of -STELLA reduced the frequency BPSD and CP reactivity to them.(10, 11) The subjective and objective outcomes of STELLA are now being tested in the ORCASTRAIT Living Lab, with the goal of scaling STELLA up to address the needs of the 16 million CPs in the US. To prepare for effective future scaling of STELLA, the longer-term costs of implementing the intervention, as well as the cost benefits of the intervention need to be determined.

As many as 90% of all US managed care organizations (MCOs) report using cost in determining coverage of treatments, drugs, and other interventions, while 40% specifically report the use of cost-effectiveness analyses.(12) An increasing awareness of the fiscal challenges confronting the Medicare program and other public payors in the US suggest that interventions which improve outcomes and decrease costs will be well-received.(13) Approval by both public and private payors is therefore a first step in wide dissemination of a new intervention in the US health system. The approval process begins with quantifying an intervention's cost as well as the intervention's cost-efficacy compared to other interventions. Thus, understanding the costs of STELLA will advance the program toward a pragmatic trial and ultimately toward widespread adoption in the US health system.

3. Project Description

Care Partners will participate in an 8-week intervention in which a Guide (e.g., nurse or social worker) will help them identify and modify distressing behavioral symptoms of dementia. We will measure Care Partner affective symptoms, including depression and burden, as well as quality of life for both the Care Partner and the person with dementia. Assessments will occur prior to, during, and after the intervention (Table 3).

This study is ancillary to an existing IRB-approved prospective longitudinal observational study which enables and accelerates the process of developing, translating and disseminating innovative Care Partner interventions facilitated by technology. The ORCASTRAIT study (IRB#20236) is currently enrolling 120 dyads (patients with dementia, and a family Care Partners). ORCASTRAIT uses sensors and other technologies in participants' home setting to monitor and detect (through novel algorithms) early changes in health, cognitive function, activity, and behavioral-functional signatures of patients and Care Partners. The proposed ancillary study will target informal Care Partners enrolled in ORCASTRAIT, and follow changes in their stress and health over the study period. <u>This ancillary study will incorporate data from the parent study, will add the Care Partner (STELLA) intervention and measure Care Partner coping with an additional 5 surveys to the electronic (online) surveys that informal Care Partners are already completing over the parent study period.</u>

4. Study Population

a. Care Partners and Persons with Dementia. Up to 40 Care Partners and their 40 care-recipients with ADRD will participate in this study. The primary focus of this study is on Care Partners, however, we will gather subjective and objective data on participants with ADRD to assess the effect of the intervention on Care Partner affective responses to caregiving and quality of life for both. STELLA participants will be recruited from the existing cohort of patients, and their Care Partners, who are enrolled in the ORCASTRAIT Life Laboratory (OSLL).

There has been no pilot testing of STELLA with non-English speaking care partners, and all materials have been tested in English. Therefore, only English-speaking participants are included in STELLA.

b. Inclusion and exclusion criteria. The research team will assess eligibility of interested parties based on the criteria listed in Table 1. In the event of a screen failure, data collected during screening will be destroyed at the end of the study. The recruitment team will track the number of care partners contacted for the study, the number consented, the number of those that dropped out and the number of those that completed the entire intervention.

Table 1: Inclusion/Exclusion Criteria

Participant	Inclusion	Exclusion
Care Recipient	• Diagnosis of ADRD, moderate to late stages • Exhibits 2 or more behaviors listed on RMBPC[16] that are bothersome to the Care Partner and occur 3 or more times/week at study enrollment • Family member of Care Partner (this can be a relative, spouse or close kin that is considered family)	• Dementia not related to ADRD • Unable to leave Care Partner during Partner training • Early stage dementia, as defined by MoCA of about 15/30 or higher.
Care Partner	• Adult caring for family member with ADRD • Lives with care recipient OR spends at least 4 hours/week with care recipient[(21)] • Age of 18 years or older • Speak English • Own a computer/device with a reliable internet connection and compatible operating system	• Unable to find activity for care recipient during training which would allow Care Partner to work privately, one-on-one during training • Completed similar telehealth intervention within the last year • Hearing and vision problems severe enough to prevent participation • Unwilling or unable to adequately follow study instructions and participate in study procedures
Both	Participate in ORCASTRAIT (IRB#20236)	

c. Vulnerable populations. The primary focus of this study is to assess the feasibility, costs, and efficacy of subjective and objective measurements of Care Partner and person with dementia responses to the STELLA intervention. Therefore, in order for this study to be successful, participants with moderate to late stage ADRD will be recruited. Few interventions address the needs of families in these later stages.

We will ask that a legally authorized representative (LAR) and, if appropriate, the person with ADRD, if the person with ADRD is competent to make a decision about participation. If the LAR and/or the person with ADRD are concerned about competency, the LAR will be asked to make the participation decision. No other vulnerable populations such as children, prisoners, or pregnant women will be included in this study. All Care Partners will be 18 or older.

d. Setting. This study will take place at OHSU. Participants will connect (from their homes or another convenient location) to the research team via direct-to-home, telehealth, video-conferencing and over the telephone at the Layton Aging and Alzheimer's Disease Center. Interventionists will meet with

caregivers via videoconferencing on an OHSU computer and HIPAA secure link. The interventionist may complete the visit from his or her home, OHSU office or other convenient private location. They will use a privacy screen so that participants will not see their home or office environments. No others (e.g., family members of interventionists) will be allowed in the room during the intervention. Please see ORCASTRAIT (IRB#20236) protocol for details of living lab.

e. Recruitment Methods. Participants may be recruited from the OHSU patient population and broader community. Recruitment devices may include websites such as the OHSU Study Participants Opportunities page; newsletters; advertisements; flyers and other printed study materials; social media; institutional communication and events; presentations; and outreach at community events. Direct outreach methods may include telephone contact, mailings, electronic communications, in-person communication, and distribution of recruitment materials.

Potential subjects may be identified from publicly available data (e.g. voter records); from external or internal registries including OHSU databases such as the research data warehouse, NeuroNEXT Department of Neurology Research Contact and Health Information Repository (IRB # 8049), and ACTNOW Research Contact and Health Information Registry (IRB #11606); from existing Layton Center and ORCATECH research participant repositories (IRBs #6845 and (#17189); from word-of-mouth or self-referrals, or via chart review (an IRB-approved HIPAA waiver will be obtained prior to the use or disclosure of any PHI in the recruitment process). We may also recruit by working with community partners and related stakeholders – for example by obtaining physician referrals from outside providers – using IRB approved recruitment materials when applicable.

f. Consent Process. Interested Care Partners and their family members with dementia will be screened prior to consent (either in person, by phone or videoconferencing) to assess eligibility (please see Telephone Script and HIPAA WoA). Information sheets will be made available to the participants. The participants will review the information sheets with the research team and there will be a full informed consent discussion (by phone, videoconference or in person) before verbal consent is obtained. Study staff will conduct a thorough review and discussion of the information sheets, answer any questions the subjects may have, and obtain their verbal consent to participate.

This study requests a waiver of documentation of consent because subjects will have telehealth visits, which means they would have to make a trip to OHSU just to physically sign consent forms; this is unnecessarily burdensome. When the subjects verbally consent to participate in the study, the research team member who conducts the informed consent conversation will sign and date a copy of the information sheets, indicating that the forms were reviewed with the participants and that consent was obtained.

The person with ADRD may not have the cognitive function to understand the study or agree to consent. In this case, we will arrange for a LAR to consent for the person with ADRD. We will adhere to the standards set forth in the OHSU Guidelines for Decisionally Impaired Adults. Similarly, the Care Partner will also be asked to review and agree to the family member's information sheet. The information sheets will be discussed and consent will be obtained prior to the first visit (see *Consent - Information Sheet (Care Partner)* and *Consent – Information Sheet (Family Member)).*

The person with dementia will not partake in any STELLA activities, but we will analyze their data during the study period. Furthermore, our experience has taught us that some family members seek out their Care Partners during the video sessions. Thus, the person with dementia may be video-recorded. Therefore, we will seek the consent of the person with dementia, or their LAR's, to participate in this study.

5. Procedures Involved

Phase 1

Technology. Participants will be enrolled in the ORCASTAIT Life Lab (OSLL) enabling automatic generation of the full suite of digital biomarkers. As per the OSLL protocol, Care Partners and their family members with dementia both wear a long battery life (charged every 6 months) actigraph watch assessing activity (daily steps) and sleep patterns. Passive room sensors will provide activity location information (e.g., time out of home, time together).

Care Partners and their family members with dementia will participate in STELLA for a total of 18 months (Table 3); however, most of the participatory effort will occur in the first two months. In this two-month period, Care Partners will participate in the STELLA intervention and complete surveys listed in Table 4. In the next 16 months, we will ask them to complete on-line surveys per the schedule noted in Table 4. Care Partners will receive an email from the study team asking them to open the Qualtrics or REDCap survey. Once they are in Qualtrics or REDCap, they will receive a welcome message from the PI and study team (see invites and reminder messages). Their family members with dementia will not have any STELLA activities, but we will be analyzing their data during the 18-month period.

All STELLA sessions will occur via videoconferencing and will be video-recorded. The video-conferencing and recording will occur via the OHSU Telehealth Department's HIPAA-compliant, secure systems. Participants will use their own computers to access the study. However, some Care Partners may need to borrow a device. If this is the case, we will lend them a Chromebook. Chromebooks require an internet connection to function and a Google email (Gmail) account to use the STELLA application. We will advise participants in the consent form that they may use their own Gmail account but there is a risk that some of their personal information may be stored on the Chromebook. Alternatively, we can create a Gmail account for them.

Table 2: STELLA Curriculum

Week	Format	Topic
1	One Guide to one Care Partner	Introduction to dementia and behavior management
2		Addressing behaviors
3		Care Partner care
4		ABCs in action
5*	One Guide with up to 4 Care Partners	Communication and dementia
6		Pleasant events
7		Putting it altogether
8		Moving forward, staying connected

*There may be a 2 week break between weeks 4 and 5 if there are scheduling challenges

We will provide them with the secure link to the videoconferencing system. The *direct-to-home* STELLA visits will be done using real-time delivery of telehealth interactions over distance using video-conferencing technology. The basic mode of connectivity between the study participants and the research team will be via the OHSU Telehealth Department's identified interface. This technology allows face-to-face, highly secure video connections to remote locations. Using their existing device (PC, Mac, iPad, smartphone, etc.), with both visual and audio capabilities, participants will be connected with the research team. The visits will be recorded using the OHSU server. The recorded visits will can be used (with participant consent) to teach and instruct students and clinicians in how to conduct high-quality telehealth care, thus facilitating dissemination of the approach in Oregon and nationally. We have successfully used this clinical-grade telehealth technology in our previous intervention studies. [15, 22] On occasion, Care Partners may not be able to connect to the videoconferencing connection due to low bandwidth. In this case, they may meet with the Guide via phone.

The STELLA Intervention. STELLA consists of 8 sessions: 4 sessions one-to-one, with the Care Partner and a Guide, and then 4 sessions with one Guide with up to four Care Partners (total small group will include as few as two and as many as 4 Care Partners) (**Table 2**). Each weekly session takes about 1 hour. The first four sessions allow for development of the Care Partner-Guide working relationship. In these sessions, the Care Partners identify behaviors (both the person with dementia's and the Care Partner's) which are upsetting to the family. Care Partners will be taught to use an "ABC" approach to identify activators of behaviors, the behaviors, and consequences of the behaviors. After they identify the ABCs, they will develop a plan to address the behavior and then test it. Based on Care Partner feedback from our pilots, we adapted the prototype intervention so that STELLA uses the ABC plan for both the person with dementia behaviors *and* Care Partner behaviors. After the four one-to-one sessions, Care Partners will meet in small groups with a Guide. Effective communication strategies, engagement in pleasant events, and coping will be addressed (**Table 2**). [7] The Guide will facilitate conversation and support between the Care Partners. Care Partners will be provided with each other's contact information. They will be encouraged to contact each other during and after the intervention. Due to schedule conflicts, there may be an up to two-week gap between Sessions 4 and 5.

Each Care Partner will have their own STELLA workbook to document their plans and progress (see "The STELLA Collaborative Handbook"). The booklet will be given or mailed to them prior to the first STELLA visit. They will have access to information on caring for person with dementia on the STELLA password-protected website which is under production. STELLA allows for some flexibility in scheduling if Care Partners have to re-schedule. Care Partners will be advised that the one hour sessions may be tiring and that they may end a session early if needed. In addition, Care Partners will need to find an activity for their care-recipients while they are engaged in the training session so they can focus on the material and protect their care-recipients' dignity. Some of the conversations will include discussions about challenging behaviors, which if overheard by the care recipient, may be upsetting.

Surveys and subjective assessments will be administered in person via video conferencing or delivered to Care Partners email via a secure system.

Care Partners will be assigned a study ID number which will be used to identify all documents. The key to study ID numbers will be kept in a secure file on a secure OHSU computer.

After the intervention and the second assessment, Care Partners will be asked to participate in a focus group. No less than 3 and no more than 10 Care Partners will participate in each focus group. Focus group participation will be assigned sequentially (e.g., Care Partners 1 through 6 will be in the first focus group) unless Care Partner availability prevents otherwise. The focus groups will be moderated by the PI or a designated team member.

Care Partners who are unable to complete all 8 training sessions will remain in the study and we may collect the data noted in Table 4. These Care Partners may join a focus group if they choose. Care Partners who do not complete any trainings, or are unwilling or unable to adequately follow study instructions and participate in study procedures, will be withdrawn from the study. We will retain and analyze any data from their participation. They may also be asked to complete the assessments, despite not completing all of the trainings.

For some participants, internet connectivity may be problematic. Every effort will be made to help Care Partner maintain a good connection for each visit. A research team member will test their ability to connect and the quality of their connection prior to Session 1 and later visits if needed. In some cases,

at PI discretion, computer (e.g., Chromebook) may be loaned to the research participant for use in the study if available. If, after multiple efforts, a Care Partner cannot maintain a reliable connection for a telehealth visit, they will be excused from the study. They will be allowed to keep the STELLA Handbook.

Guides will be trained by the PI using the Guide Handbook. The PI or other study staff will review their videos for fidelity, using the Consultant Adherence Checklist. During STELLA, videos will be reviewed by the study team for fidelity and team discussion.

Table 3: STELLA Activities

Activity	Description	Due
Preliminary session	Set up and test videoconferencing link	After consent completed
Mercury Baseline (Survey 1)	Baseline assessment (Table 4)	Prior to intervention start
Intervention (4 weekly sessions)	Meet with for 4 weekly sessions, beginning with **Session 1**. (see Table 2)	After Mercury Baseline survey completed
Starlet Survey (Survey 2)	Electronic assessment of depression, burden	1 month after Session 1
Intervention (4 weekly sessions)	Meet with Guide and up to 4 other Care Partners for 4 more weekly sessions (See Table 2)	After session #8
Venus Survey (Survey 3)	Full assessment, including program survey	2 months after Session 1
Post-STELLA Assessment	Complete personalized target problem assessment via Qualtrics or via video or phone call with a Research Assistant	After Venus survey completed
Focus Groups	Optional focus group to provide study team with feedback	After Venus survey completed
Earth Survey (Survey 4)	Full assessment (Table 4)	6 months post-intervention
Earth Survey (Survey 5)	Full assessment (Table 4)	12 months post intervention
ORCASTAIT Surveys	Cost, burden as described in ORCASTRAIT Protocol	Weekly, while in ORCASTRAIT

Phase 1

Measures. Aim 1: Feasibility will be assessed by measuring how many Care Partners who start the program successfully complete it. Care Partners will fill out our telehealth survey that asks them about acceptability.[23, 24] Acceptability will also be assessed qualitatively using focus groups.[25] The focus groups will be conducted via videoconferencing and will be recorded and transcribed for analysis.[15, 16]

Aim 2: Standard quantitative measures that were used in the earlier pilots [15, 16] will be used to provide preliminary evidence for efficacy. The quantitative measures are grouped into 5 surveys: Mercury Baseline, Starlet,, Venus, Earth (6 months post intervention) and Earth (12 months post intervention). Along with the ORCASTRAIT Living Lab suite of measures (demographics, activity, time with person with dementia, sleep-related behaviors), we assess burden using the RMBPC[26] and the 22-item Zarit Burden Interview (ZBI). To provide focus for the intervention, each Care Partner will identify and rate 2-3 specific target problems to address in STELLA. Pre-death grief will be assessed with the Marwit Meuser Caregiver Grief Index, Short Form (MMCGI-SF). [27] Care Partner plans for person with dementia placement will be assessed with the

revised Desire to Institutionalize (DTI) scale.[28] Care Partner depression will be measured with the CESD-10[30] and role captivity will also be assessed.[31] In addition to subjective assessments, we will evaluate the effect of STELLA on digital behavioral biomarkers (activity, time spent together and sleep) obtained from the ORCASTRAIT platform. Total daily activity, time together and alone, and sleep duration, will be assessed prior to, during, and after the intervention. Care Partners will complete all assessments electronically. A secure link to each assessment will be emailed to each CP. We will ask the CPs to complete the assessments within 5 days of receiving the email. If they do not, we will call them to assess their situation. If they do not complete surveys as outlined on the times listed in Table 3 they may not continue with the intervention.

Aim 3**.** To identify which components of STELLA are most helpful to Care Partners, we will assess the mechanisms of action for reducing burden, depression and grief and improving cognitive function and sleep. Care Partners will complete the surveys (**Table 3**) before the intervention, after Session 4 and after the intervention. An analysis of objective data (**Figure 1**) will also be done during the intervention. We will ask Care Partners in our focus groups to report what they found most helpful about STELLA.

Table 4: Subjective Assessment Descriptions

Measure	Description
Mercury Baseline	
Demographics	Demographics, including hours/week caregiving
Revised Memory & Behavioral Problems Checklist (RMBPC) [23]	Measure of frequency and reactivity to behavioral and psychological symptoms of dementia[23]
Personalized target problem assessment	Care partner-identified targeted problem assessment
Zarit Burden Interview (ZBI)[33]	4-item measure of burden
Center for Epidemiologic Studies Depression Scale (CESD-10)[34]	10-item depression measure
Marwit Meuser Caregiver Grief Index-Short Form (MMCGI-SF)[35]	Care partner pre-death grief[35]
Placement plan scale[37]	One-item assessment of plans for plans for placement for family member with dementia[37]
QoL AD[36]	13-item assessment of quality of life for both the care partner and the person with dementia.
Starlet Survey	
ZBI[33]	
CESD-10[34]	
Venus Survey	
RMBPC[23]	• See Baseline for descriptions • Baseline: + STELLA contact survey + Experience Survey -Demographic survey
Personalized target problem assessment	
ZBI[33]	
CESD-10[34]	
MMCGI-SF[35]	
Placement plan scale[37]	
QoL-AD	
STELLA contact	STELLA care partner contact post intervention
STELLA Experience Survey	16-item + comments on satisfaction, privacy, ease of use
Earth Assessment	
RMBPC[23]	• See Baseline for descriptions • Baseline: + STELLA contact survey -Experience Survey
ZBI[33]	
CESD-10[34]	
MMCGI-SF)[35]	
Placement plan scale[37]	

QoL-AD STELLA contact	-Demographic survey

Phase 2

Aim 1. Quantify the costs of delivering the STELLA intervention. This will measure the direct costs of delivering the intervention (wage multiplied by time of all personnel supporting the intervention) as well costs of technology and equipment, and any in-kind donations of equipment or time to support the intervention.

Aim 2. Quantify the cost efficacy of STELLA in relation to BPSD frequency and CP reactivity and assess the relationship between costs, BPSD, and care partner burden.
Out-of-pocket costs for participating dyads will be collected using an addition to the weekly online ORCASTRAIT survey. CPs will be queried about personal funds spent on health care services, co-pays, medications, or equipment. CP time dedicated to these care-related activities will also be collected. Implicit costs for families will be calculated by multiplying the average weekly hours of care provided by the CP by the average hourly wage of paid caregivers in Portland, Oregon (approx. $29).

Analytic Plan.

Phase 1

Aim 1: Feasibility will be assessed by calculating the proportion of enrolled Care Partners who completed the full intervention. Reasons for drop-out and discontinuation will be investigated carefully. Focus group transcriptions will be analyzed for themes of acceptability using narrative analysis.[25]

Aim 1 Anticipated Results and Implication. We anticipate that the Care Partner will find the STELLA intervention feasible and acceptable. This will provide foundational information for future proposals.

Aim 2: Efficacy will be assessed by calculating changes in the subjective scores before, during and after the intervention using linear regression models and controlling for age, sex and education. Since this is an exploratory (proof-of-concept) study with a small sample size, we do not expect statistically significant findings, but pre-post change and standard deviation of the change will be used to calculate the sample sizes for the next stage, a RCT (NIH Stage II [32], Phase 1) study.

Objective digital behavioral biomarker data collected from the ORCASTRAIT Living Lab (e.g., daily activity (steps), total sleep time, times together) will be assessed before, during and after the intervention and compared to subjective findings. Simple Spearman correlations will be used to explore the relationship of the objective continuous sensor-derived data to the subjective data, where the continuous objective digital data is collapsed to mean values which will serve as a point estimate prior to, during and after the intervention. We will compare the shift in the distribution of each of the digital behavioral biomarkers from baseline to identify relative changes during and after the intervention. We will compare the objective and subjective findings of the dyad to identify trends that correlate with burden (**Figure 1**) [33].

Aim 2 Anticipated Results and Implications. We anticipate that STELLA will reduce Care Partner burden and grief and improve family quality of life. These improvements in turn will decrease

Care Partner desire to place family members in long-term care. We expect these findings will be supported by both subjective and objective data.

Aim 3*:* Before Session 5, subjective and objective data (**Table 4**) will be compared to pre, mid- and post-intervention data to identify trends. Qualitative data will be gathered during the focus groups. Participants will be asked what they thought was most helpful about the intervention and what they thought of the format. The objective and subjective results will be used to identify which components of STELLA were most effective and which need to be modified to improve the potency of future iterations.

Aim 3 Anticipated Results and Implications. We expect to see an improvement in the objectives and subjective data, and we expect that we will need to write revise the STELLA intervention. We will use information from the focus groups and the accrued data to revise as needed.

Other quantitative analyses may be performed if they data reveal important trends.

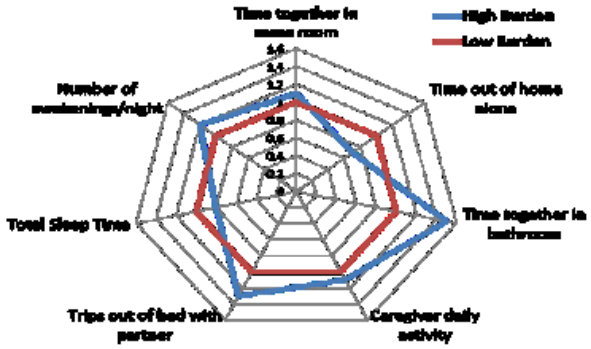

Figure 1: Composite model spider plot of digital behavioral biomarkers in a dyad showing potential domains associated with the degree of caregiver burden (49). Numbers are odds of having the behavior relative to low burden. Similar comparisons can be made relative to baseline (e.g. sleep time or time alone before relative to after intervention).

PHASE 2

Aim 1: We will carry out a costing of the intervention to determine implementation costs of STELLA.

Aim 1 Anticipated Results and Implications. The costing will demonstrate the actual costs of delivering the intervention. This is essential for future pragmatic trials and ultimately for widespread adoption in the US health system.

Aim 2: Assess data collected from CPs for correlations between BPSD frequency and explicit costs to measure the direct cost impact of the intervention. We then assess the relationship between BPSD frequency, CP reactivity, and out-of-pocket costs for families using linear regression models and controlling for salient covariates based on preliminary correlational analysis We will repeat this analysis for implicit costs. We will then compare both the explicit and implicit out-of-pocket costs for participating CPs to those who do not participate.

Aim 2 Anticipated Results and Implications. We expect to see a relationship between BPSD and cost. Specifically, more BPSD behaviors and more CP reactivity to the BPSD will be associated with higher out-of-pocket and implicit costs for families living with dementia. Further, we expect to find a relationship between out-of-pocket and implicit costs and objective measures of burden identified in the ORCASTRAIT Living Lab continuous home assessment. Higher objective burden will correlate with higher implicit and out-of-pocket costs. This will provide much needed data on the intervention's cost-efficacy compared to other interventions to support people living with dementia.

6. Data and Specimens. No genetic material or specimens will be collected in this study.

a. Sharing of Results with Subjects

Results of the RMBPC and the Pre-Treatment Survey will 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 memory, depression, burden or grief scores are abnormal, the Care Partner may be

informed, at the discretion of the PI, that his or her score is of concern. The Care Partner will be referred to appropriate services if deemed necessary (e.g., social worker or other counseling services). The other results will be provided, if asked, after all data is collected and analyzed.

b. Data and Specimen Banking

The video-recordings will ultimately be stored, indefinitely, in the Layton Center and ORCATECH Research Repository (IRB #6845). The video-recordings will show subjects' faces and their names, and any information discussed during the sessions and focus groups will be heard in the audio. Thus, the video-recordings will not be de-identified prior to repository storage. The researchers may use or share this information to conduct future research. Other researchers and those outside of OHSU (who are involved in conducting or overseeing research) may have access to the video-recordings as specified in the *"Privacy, Confidentiality, and Data Security"* section. To obtain this data, researchers must read the *Layton Center for Aging and Alzheimer's Disease Research Data Use and Disclosure and Authorship Policies*, then fill out the Layton Center's "Request for Research Data" form. This form is used across the Center for data requests. The form asks for the PI's information, project name and goals, and a signature (PI) agreeing to comply with the policies. The Data Core team, at the direction of the Data Core Lead (Hiroko Dodge) at the Layton Center reviews and approves these requests.

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 Layton Center. Documents used for the intervention (Individual and Group Logs, Pre-treatment survey, Visit Information Sheet) will be stored with the interventionist and RA in a locked file or briefcase in the staff member's home. All documents will be shredded or returned to the Layton Center at the completion of the intervention. These documents will not contain and PHI, but will contain the participant's study ID #.

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.

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 names, medical record number or other personally identifying information. However, video-recordings will show their faces and their first names and 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. Electronic files for data analysis will contain only the subject code. 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.

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).

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 research team will use the "Invite Collaborators." To ensure the videos cannot be downloaded, the "Invitee Permissions" will be set at "Previewer."

Electronic survey data will be stored in a web-accessible server at Qualtrics or REDCap, though copies of this data will be transferred to a secure OHSU server via API 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.

8. Risks and Benefits

a. Risks to Subjects

There are few risks involved in this study. Care Partners will have to meet (via telehealth) with the research team 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 via telehealth, so there should be no travel costs involved.

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.
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.

b. Potential Benefits to Subjects

Care Partners who complete all 8 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 2 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.

References

1. Lindauer A, Harvath TA. The meanings caregivers ascribe to dementia-related changes in care recipients: A meta-ethnography. Research in Gerontological Nursing. 2015;8(1):39-48. doi: 10.3928/19404921-20141121-01.
2. Fonareva I, Oken BS. Physiological and functional consequences of caregiving for relatives with dementia. International Psychogeriatrics / IPA,. 2014;26(5):725-47. doi: 10.1017/S1041610214000039.
3. Norton MC, Smith KR, Ostbye T, Tschanz JT, Corcoran C, Schwartz S, Piercy KW, Rabins PV, Steffens DC, Skoog I, Breitner JC, Welsh-Bohmer KA, Cache County I. Greater risk of dementia when spouse has dementia? The Cache County study. J Am Geriatr Soc. 2010;58(5):895-900. doi: 10.1111/j.1532-5415.2010.02806.x. PubMed PMID: 20722820; PMCID: PMC2945313.
4. Dassel KB, Carr DC, Vitaliano P. Does caring for a spouse with dementia accelerate cognitive decline? Findings from the Health and Retirement Study. Gerontologist. 2017;57(2):319-28. doi: 10.1093/geront/gnv148. PubMed PMID: 26582383.
5. Mallya S, Fiocco AJ. Impact of informal caregiving on cognitive function and well-being in Canada. Int Psychogeriatr. 2018;30(7):1049-55. doi: 10.1017/S1041610217002605. PubMed PMID: 29235432.
6. Vandepitte S, Van Den Noortgate N, Putman K, Verhaeghe S, Faes K, Annemans L. Effectiveness of Supporting Informal Caregivers of People with Dementia: A Systematic Review of Randomized and Non-Randomized Controlled Trials. J Alzheimers Dis. 2016;52(3):929-65. Epub 2016/04/16. doi: 10.3233/JAD-151011. PubMed PMID: 27079704.
7. Teri L, McCurry SM, Logsdon R, Gibbons LE. Training community consultants to help family members improve dementia care: A randomized controlled trial. The Gerontologist. 2005;45(6):802-11. doi: /10.1093/geront/45.6.802.
8. Mackenzie CS, Wiprzycka UJ, Khatri N, Cheng J. Clinically significant effects of group cognitive behavioral therapy on spouse caregivers' mental health and cognitive functioning: a pilot study. J Gerontol Soc Work. 2013;56(8):675-92. Epub 2013/10/15. doi: 10.1080/01634372.2013.834857. PubMed PMID: 24116878.
9. Karlin NJ, Bell PA, Noah JL, Martichuski DK, Knight BL. Assessing Alzheimer's support group participation: A retrospective follow-up. American Journal of Alzheimer's Disease. 1999;14(6):326-33.
10. Brodaty H, Thomson C, Thompson C, Fine M. Why caregivers of people with dementia and memory loss don't use services. Int J Geriatr Psychiatry. 2005;20(6):537-46. doi: 10.1002/gps.1322. PubMed PMID: 15920707.
11. Karlsson B, Sigström, R., Östling,S., Waern, M., Börjesson-Hanson, A.,Skoog, I. . DSM-IV and DSM-5 prevalence of social anxiety disorder in a population sample of older people. Am J Geriatr Psychiatry. 2016;24:1237-45.
12. Herrmann LK, Welter E, Leverenz J, Lerner AJ, Udelson N, Kanetsky C, Sajatovic M. A systematic review of dementia-related stigma research: Can we move the stigma dial? Am J Geriatr Psychiatry. 2018;26(3):316-31. doi: 10.1016/j.jagp.2017.09.006. PubMed PMID: 29426607.
13. Hopwood J, Walker N, McDonagh L, Rait G, Walters K, Iliffe S, Ross J, Davies N. Internet-based interventions aimed at supporting family caregivers of people with dementia: Systematic review. J Med Internet Res. 2018;20(6):e216. doi: 10.2196/jmir.9548. PubMed PMID: 29895512.

14. Boots LM, de Vugt ME, van Knippenberg RJ, Kempen GI, Verhey FR. A systematic review of Internet-based supportive interventions for caregivers of patients with dementia. International Journal of Geriatric Psychiatry. 2014;29(4):331-44. doi: 10.1002/gps.4016 [doi].
15. Lindauer A, Croff, R., Mincks, K., Mattek, N., Shofner, S.J., Bouranis, N., Teri, L. "It took the stress out of getting help": The STAR-C-Telemedicine mixed methods pilot. Care Weekly. 2018;2:7-14. Epub 7/3/2018. doi: dx.doi.org/10.14283/cw.2018.4.
16. Lindauer A, McKenzie, G., La Fazia, D.M., McNeill, L., Mincks, K., Myers, M., Spoden, N., Mattek, N., Teri, L. , editor. Tele-STAR for dementia caregivers: Methods and preliminary findings (Poster). Alzheimer's Associaion International Conference; 2018 July 2018; Chicago, IL.
17. Caregivers. Focus group transcript, 8-2018. 2018.
18. Drentea P, Clay OJ, Roth DL, Mittelman MS. Predictors of improvement in social support: Five-year effects of a structured intervention for caregivers of spouses with Alzheimer's disease. Soc Sci Med. 2006;63(4):957-67. doi: 10.1016/j.socscimed.2006.02.020. PubMed PMID: 16616406.
19. Garcia-Alberca JM, Lara JP, Garrido V, Gris E, Gonzalez-Herero V, Lara A. Neuropsychiatric Symptoms in Patients With Alzheimer's Disease: The Role of Caregiver Burden and Coping Strategies. Am J Alzheimers Dis Other Demen. 2014;29(4):354-61. doi: 10.1177/1533317513518649. PubMed PMID: 24408750.
20. Onken LS. Cognitive training: Targeting cognitive processes in the development of behavioral interventions. Clinical Psychological Science : A Journal of the Association for Psychological Science. 2015;31(1):39-44. doi: 10.1177/2167702614561512.
21. McCurry SM, Logsdon RG, Mead J, Pike KC, La Fazia DM, Stevens L, Teri L. Adopting evidence-based caregiver training programs in the real world: Outcomes and lessons learned from the STAR-C Oregon Translation Study. Journal of Applied Gerontology : The Official Journal of the Southern Gerontological Society. 2015. Epub 2015. doi: 0733464815581483 [pii].
22. Lindauer A, Seelye, A., Lyons, B., Dodge, H.H., Mattek, N., Mincks,K., Kaye, J., Erten-Lyons, D. Dementia care comes home: Patient and caregiver assessment via telemedicine. The Gerontologist. 2017;Oct(57(5):e85-e93). doi: doi: 10.1093/geront/gnw206.
23. Chang H. Evaluation framework for telemedicine using the logical framework approach and a fishbone diagram. Healthcare Informatics Research,. 2015;21(4):230-8. doi: 10.4258/hir.2015.21.4.230.
24. Poulsen KA, Millen CM, Lakshman UI, Buttner PG, Roberts LJ. Satisfaction with rural rheumatology telemedicine service. International Journal of Rheumatic Diseases. 2015;18(3):304-14. doi: 10.1111/1756-185X.12491.
25. Bowen DJ, Kreuter M, Spring B, Cofta-Woerpel L, Linnan L, Weiner D, Bakken S, Kaplan CP, Squiers L, Fabrizio C, Fernandez M. How we design feasibility studies. Am J Prev Med. 2009;36(5):452-7. doi: 10.1016/j.amepre.2009.02.002. PubMed PMID: 19362699; PMCID: PMC2859314.
26. Teri L, Truax P, Logsdon R, Uomoto J, Zarit S, Vitaliano PP. Assessment of behavioral problems in dementia: The Revised Memory and Behavior Problems Checklist. Psychol Aging. 1992;7(4):622-31. doi: 10.1037//0882-7974.7.4.622. PubMed PMID: 1466831.
27. Marwit SJ, Meuser TM. Development of a short form inventory to assess grief in caregivers of dementia patients. Death Studies. 2005;29:191-205. doi: 10.1080/07481180590916335.
28. Morycz RK. Caregiving strain and the desire to institutionalize family members with Alzheimer's disease. Possible predictors and model development. Research on Aging. 1985;7(3):329-61. doi: 10.1177/0164027585007003002.
29. Logsdon RG, Gibbons LE, McCurry SM, Teri L. Assessing quality of life in older adults with cognitive impairment. Psychosom Med. 2002;64(3):510-9. doi: 10.1097/00006842-200205000-00016. PubMed PMID: 12021425.
30. Andresen EM, Byers K, Friary J, Kosloski K, Montgomery R. Performance of the 10-item Center for Epidemiologic Studies Depression scale for caregiving research. SAGE Open Med. 2013;1:2050312113514576. doi: 10.1177/2050312113514576. PubMed PMID: 26770693; PMCID: PMC4687763.

31. Pearlin LI, Mullan JT, Semple SJ, Skaff MM. Caregiving and the stress process: an overview of concepts and their measures. Gerontologist. 1990;30(5):583-94. doi: 10.1093/geront/30.5.583. PubMed PMID: 2276631.
32. Onken LS, Carroll KM, Shoham V, Cuthbert BN, Riddle M. Reenvisioning clinical science: Unifying the discipline to improve the public health. Clinical Psychological Science : A Journal of the Association for Psychological Science. 2014;2(1):22-34. doi: 10.1177/2167702613497932.
33. Thomas NW, Lindauer, A., Kaye, J. EVALUATE-Tele-STAR: Novel Methodologies for Assessment of Caregiver Burden in a Telehealth Caregiver Intervention: A Case Study. Dementia and geriatric cognitive disorders. in press.
34. Folstein MF, Folstein SE, McHugh PR. "Mini-mental state": A practical method for grading the cognitive state of patients for the clinician. Journal of psychiatric research. 1975;12(3):189-98. doi: 10.1016/0022-3956(75)90026-6.
35. Cummings JL, Mega M, Gray K, Rosenberg-Thompson S, Carusi DA, Gornbein J. The Neuropsychiatric Inventory: comprehensive assessment of psychopathology in dementia. Neurology. 1994;44(12):2308-14. PubMed PMID: 7991117.
36. Pfeffer RI, Kurosaki TT, Harrah CH, Jr., Chance JM, Filos S. Measurement of functional activities in older adults in the community. J Gerontol. 1982;37(3):323-9. PubMed PMID: 7069156.
37. Bédard M, Molloy DW, Squire L, Dubois BA, Lever JA, O'Donnell M. The Zarit Burden Interview: A New Short Version and Screening Version. The Gerontologist. 2001;41(5):652-7.
38. Sheikh JI, Yesavage JA. Geriatric Depression Scale (GDS): Recent evidence and development of a shorter version. Clinical Gerontology. 1986;5:165-73.