Support via technology: Living and learning with advancing Frontotemporal Degeneration (STELLA-FTD): Phase 2

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1) Protocol Title

Support via technology: Living and learning with advancing Frontotemporal Degeneration (STELLA-FTD): Phase 2

2) Objectives

The purpose of this study is to test the STELLA-FTD intervention that we designed from end-user feedback in Phase 1. The STELLA (Support via Telehealth: Living and Learning with Advancing Alzheimer's Disease) intervention to specifically address the needs of family Care Partners of persons with frontotemporal degeneration (FTD). STELLA-FTD is a multicomponent video-conference based intervention designed to facilitate effective use of community and peer resources to foster effective management of behavioral and psychological symptoms of dementia. In the STELLA-FTD intervention, professionals ("Guides") meet with family members ("Care Partners") caring for persons with FTD conditions. 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. STELLA-FTD has not been tested with families living with FTD and thus, it is not known if it will be helpful to them. **In this study, we will test the new version, STELLA-FTD, to specifically address the needs of family Care Partners for persons with frontotemporal degeneration.**

Aim 1 (Phase 1). Adapt STELLA to the needs of Care Partners for those with FTD

a. Gather FTD Care Partner feedback on STELLA and suggestions for tailoring STELLA for FTD
b. Adapt STELLA for FTD Care Partners based on end-user feedback

Aim 2 (Phase 2). Assess the feasibility and acceptability of STELLA-FTD with FTD Care Partners
Aim 3. Assess the preliminary efficacy of STELLA-FTD on the primary outcomes: reducing the *frequency* of behavioral symptoms and Care Partner *reactivity* to the symptoms as measured on the Revised Memory and Behavior Problems Checklist (RMBPC).[1]

3) Background

Frontotemporal degenerative diseases, such as behavioral variant FTD, primary progressive aphasia and progressive supranuclear palsy (referred to in this proposal as "FTD") place a heavy toll on families.[2] FTD tends to occur in individuals younger than 65, impacting family income and well-being to a greater extent than later-onset dementias.[3,4] Affecting about 60,000 people in the US, FTD often presents with pronounced behavioral symptoms that lead to family Care Partner burden, depression, financial strain, reduced quality of life, and grief.[5,6] Research indicates that Care Partners for persons with FTD experience higher levels of burden and worse sleep quality than Care Partners of persons with ADRD.[7,8] Like Care Partners of persons with other forms of dementia, FTD Care Partners may experience pre-death grief in addition to burden as they perceive their family members changing into "well-known strangers."[9]

The psychological impact of FTD on families has been established, but only a few psychoeducational interventions have been developed to support FTD Care Partners. FTD-focused interventions, such as the Primary Progressive Aphasia education and support group,[10] the telehealth intervention for spouses,[11] the positive affect intervention,[12] and the tailored activity program[13] have shown promising results. These programs are acceptable to Care Partners and have demonstrated efficacy for reducing Care Partner burden. However, most of these interventions were developed for families outside the US, or are limited to specific FTD sub-groups, making them inaccessible to the many Care Partners who need them.

FTD Care Partners have access to support options, including the Alzheimer's Association support groups, but FTD Care Partners often feel these programs are not a good fit for them, as this one noted, "I felt like a zebra in a room of horses." To address this gap, the Association for Frontotemporal Degeneration (AFTD) sponsors support groups, including telephone-based programs.[14] To date, only seven leaders provide these groups across the nation. In-person groups are also available, but there are only five in Oregon and Washington (combined), and none in Idaho and Wyoming. This is concerning, considering that almost 20% of Besser and Galvin's large sample lived in rural areas.[3] For many family Care Partners across the US, distance, care demands, cost, stigma, and depression limit engagement in support and education programs.

Taken together, the literature indicates there are few accessible psychoeducational programs tailored for the unique needs of Care Partners for family members with FTD. Programs that do exist tend to be in the formative stages, require in-person engagement, or are sparsely available, *especially* in the northwestern part of the US. This proposed study addresses these gaps by tailoring the STELLA telehealth intervention specifically for FTD Care Partners.

STELLA was adapted for the well-known STAR-C program.[15] Pilot testing of STELLA prototypes informed revisions, and now STELLA is a telehealth-based, multi-component intervention designed for ADRD Care Partners. STELLA is now being tested on a larger scale, with NIA funding with ADRD Care Partners (R01AG067546)). In two pilot studies the STELLA prototype reduced burden in ADRD Care Partners.[16,17] The qualitative and quantitative data from these studies revealed that the Care Partners felt that it was feasible, acceptable and private. This foundational work indicates that STELLA is primed for modification to meet the unique needs of Care Partners for those with FTD.

4) Study Design

STELLA-FTD is a prospective, mixed methods clinical trial and will occur in two phases. In Phase 1, we gathered FTD Care Partner feedback on STELLA and suggestions for tailoring STELLA for FTD (completed in Fall 2021). We have adapted STELLA for FTD Care Partners based on this feedback. In Phase 2, we will assess feasibility, acceptability and preliminary efficacy of the modified intervention.

STELLA-FTD components and study activities. STELLA-FTD will be adapted from the current STELLA version. Like all STELLA versions, the STELLA-FTD intervention will be provided via videoconferencing and email. *There are no in-person activities.*

Phase 1.

This study employed a convergent mixed-methods design[18] to address the aims. We gathered FTD Care Partner feedback on STELLA and suggestions for tailoring STELLA for FTD through focus groups facilitated by trained STELLA Guides, and elicited written commentary on printed STELLA interventional materials and surveys. We sought Care Partner suggestions for modifications to the intervention so that it meets the unique needs and challenges posed by FTD. The groups were held via videoconferencing. Phase 1 was completed in Fall of 2021.

Table 1. Demographics (N=15)

Age (mean, range, SD)	65.7, 50-79, 8.5
Race (% White)*	86
Gender (% female)*	87
Rural (#, %)	2 (14)
Employed outside home (#, %)	4 (29)
Years caregiving (#, %)	
1-3	3 (20)
3-5	5 (34)
5-7	1 (6)
>7	6 (40)
Diagnosis (#, %)	
BVFTD	4 (27)
FTD	2 (13)
PPA	4 (27)
PSP	1 (6)
Not reported	4 (27)

*n=14

The focus groups were conducted with 15 Care Partners (Table 1). The adaptation and revision suggestions from the participants are nested in the intense caregiving experience of living with complex behavioral symptoms, feeling burdened, isolated, and "living in darkness." Focus group participants offered practical suggestions to create a revised STELLA intervention to address the needs of families living with FTD. Three common themes emerged that will frame Phase 2: FTD and

accompanying behaviors lead to burden; it is difficult to get a diagnosis, and finally, there are barriers to participation in caregiver support programs. Care Partners recommended Phase 2 include a roadmap for navigating FTD.

Phase 2

The Revised Intervention. STELLA-FTD will focus on improving participants' ability to a) identify family stressors and b) subsequently use the ABC approach to address the stressors. Identified stressors may include behavioral, cognitive or language symptoms, but could also involve the need for external services (i.e.: speech and language pathology, social work). STELLA FTD will be entirely group-based, without one-to-one sessions.

All meetings will be via telehealth videoconferencing, phone or chat.

5) Study Population

a) Number of Subjects

Phase 2. We will conduct STELLA-FTD with up to 20 FTD family Care Partners.

b) Inclusion and Exclusion Criteria

Inclusion criteria, Phase 2. The Phase 2 sample will be made up of participants who self-identify as a Care Partner for family member, close friend or kin with FTD, primary progressive aphasia, progressive supranuclear palsy or other frontotemporal degenerative dementia. They must speak English and be able to see and hear the videoconference-based interactions. The Care Partner must provide care for the person with FTD. Participants from Phase 1 may choose to enroll in Phase 2, but they are not obligated to do so.

Table 2. Inclusion/Exclusion Criteria, STELLA-FTD Phase 2

Participants	Inclusion	Exclusion
Care Recipient	• Diagnosis of FTD or FTD-like dementia. • Family member of Care Partner (this can be a relative, spouse, or close kin that is considered family). • Live in OR, WA, CA, ID, MT, TX and WY.	• No Frontotemporal Degeneration diagnosis. • Unable to leave Care Partner during STELLA-FTD sessions.
Care Partner	• Adult caring for family member with FTD-like dementia. • Active or retired family Care Partner (Age 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.	• Unable to find activity for care recipient during STELLA-FTD sessions to allow Care Partner to work privately with Guide and other Care Partners. Hearing and/or vision problems severe enough to prevent participation. • Refuses to be video-recorded during STELLA-FTD sessions. • Unwilling or unable to adequately follow study instructions and participate in study procedures.

Care Partners need to provide care for their family member with FTD. Due to COVID and other unforeseen conditions, this care does not need to be in-person. Care Partners experience burden regardless of the location of the person with dementia, thus they do not have to live with them (Table 2).

Care Partners who attend an external support group can participate.

Exclusion Criteria, Phase 2. See Table 2 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 FTD will die of natural causes while in STELLA-FTD. If this occurs, the Care Partner can remain in the study if he or she chooses to do so.

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

Once identified, the recruitment team will complete the full screen with potential participants, and if eligible, proceed with the consent procedures (below) with the eligible Care Partners. Screening will be completed using paper or electronic (Qualtrics or REDCap) forms.

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 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.

c) Vulnerable Populations

The primary focus of this study is to assess the acceptability, feasibility and efficacy of the STELLA-FTD intervention. Therefore, in order for this study to be successful, Care Partners of care recipients with FTD will be recruited.

There is a risk of loss of confidentiality if the persons with FTD come into view of the Care Partner's computer screen or if they are overheard on the audio during the STELLA-FTD sessions. Care Partners may discuss their family member with behaviors with other study participants. It may be distressing for the person with FTD if they overhear their Care Partner discussing their family's situation.

To minimize these risks, we will ask Care Partners to identify an activity that will keep the person with FTD (and anyone else) occupied and out of computer range during the weekly, hour-long STELLA-FTD visits.

d) Setting

This study will occur at OHSU. All 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.

e) Recruitment Methods

We will take a multi-pronged approach to subject identification and recruitment which includes working with the Association for Frontal Temporal Degeneration to identify participants. Care Partners may be recruited from clinic sites, ADRC research cohorts, electronic registries, community advisory

committees, faith communities and the community at large. We will reach out to families from We will reach out to families in Oregon, California, Washington, Idaho, Montana, Texas and Wyoming.

Up to 10 of the 20 FTD families enrolled in STELLA-FTD will be recruited from UCSF's ALLFTD study. The ALLFTD team has given our team permission to recruit from this cohort.

Respondents to the media or other contact (e.g., clinic patients or calls from the AFTD) will fill out a electronic screening survey, providing their names and contact information, the family member's diagnosis (see Screening Survey in IRB Documents). If the potential participant is eligible, they will be automatically connected to the eConsent.

This data may be stored on Excel files on the OHSU OneDrive, the H or X drives and/or the Qualtrics and REDCap databases.

Advocacy organizations, such as the Association for Frontal Temporal Degeneration, the Alzheimer's Association and CurePSP may be asked to promote STELLA-FTD in their community events. We may present information about STELLA-FTD for these organizations and other community groups.

f) Consent Process

Phase 2. After completing the on-line screen, eligible participants will be given a copy of the Information Sheet. The Information Sheet describes the study in detail. We will ask the Care Partner to confirm that they have received and reviewed the Information Sheet. They may do this electronically via survey questions, in writing (by initialing their own copy of the Information Sheet) or verbally, by informing the STELLA-FTD staff that they agree to be in the study. The participant will retain a copy of the eConsent; the STELLA-FTD study will not retain copies of the individual Information sheets. At the first STELLA-FTD session, the PI will review the key points of the consent with the participants.

Participants will be advised 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.

6) Procedures

STELLA-FTD Intervention. Up to 20 Care Partners for family members with FTD will meet with up to 5 faculty members (called "Guides") and guest speakers on a weekly basis to discuss the strategies to facilitate effective coping with FTD diagnoses across the disease trajectory (Table 4). The lessons will include information on behavioral management and how to access services. We will encourage peer support by including activities that foster conversation.

The STELLA-FTD ABC approach will use the traditional ABC approach, but in the context of living with FTD. We will teach participants how to identify the activators of a behavior, describe the behavior in detail, and discuss the consequences of the behavior. In STELLA-FTD, the "behavior" can be any action that causes distress in the family. With a deeper understanding of the behavior, Care Partners can develop strategies to prevent or modify it. Once the behavioral is described, Care Partners are instructed on how to develop a plan to address the behavior (Box 1).

Each STELLA-FTD videoconference session will begin with a brief didactic lesson presented by the faculty (the "hub") for the Care Partners (the "spokes"). Following the lesson, the faculty and guest speakers will encourage Care Partners will share their questions and stories about their families' experiences with FTD.

The faculty hub team is responsible for ensuring respectful exchange and closes with positive feedback for the Care Partners. Should Care Partners be reluctant to share their experiences, the faculty will

have example stories to discuss. Adult learning is most effective when learners share their knowledge with each other.

Table 3. Example of STELLA-FTD Schedule

Week	Topic	Notes
1 Lindauer	Introduction/ Orientation	• Review program, ground rules, plan for next seven weeks • Participants introduce themselves, discuss challenges, may break into small groups
2 Lindauer	Using the ABCs	• Instruction on how to use the ABC method to identify and address challenging behaviors for all family members. • Discuss how to make an ABC plan
3 Mooney	Communication Challenges	• Using ABC to identify challenging communication issues and emotional responses to the communication issues. • Discuss how speech therapy (SLP) can help with communication • Outline how to request a referral to SLP
4 Foidel*	OT	• Use ABC to identify stressors related to function • Discuss the benefits of working an Occupational Therapist (OT) • Outline steps request a referral to OT
5 Wilhelm*	PT	• Use ABC to identify challenging mobility issues. • Discuss the benefits of working with a physical therapist (PT) • Outline how to request a referral to PT
6 McGuire*	Dietician	• Nutrition and Eating Challenges
7 TBA*	Elder Law Attorney	• Use ABC to identify concerns about long-term care planning • Discuss the benefits of working an elder law specialist • Outline steps to identifying a legal specialist
8 Willis*	Care Partner Self-Care	• Use ABC to identify emotional challenges and caregiving • Discuss the benefits of working a social worker • Outline steps request a referral to Social Work

*Guest speakers will not partake in the research, they will only present their information and entertain questions and answers.

Care Partners who are unable to complete all STELLA-FTD components will remain in the study and we may collect the data noted in Table 5. Care Partners who do not complete any trainings, 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, despite not completing all of the trainings.

We will record the faculty and guest speakers' sessions. The recordings will not have any participants in them, nor identifying information. We will share the recordings with participants who request this.

Focus groups. We may have one focus group of up to 20 participants after the intervention is completed. The format may be the same as the Phase 1 focus group. Any Care Partner who signed a consent, whether or not they participated in the intervention, can participate in this focus group. Focus group leaders will use a semi-structured interview guide to facilitate discussion about the Care Partners' experiences with STELLA-FTD. The focus groups will be video-recorded and transcribed. Transcripts will be analyzed for themes of acceptability.

Implementation. The Care Partners (up to 20) will receive the intervention as described above. Feasibility will be assessed by tracking recruitment patterns, enrollment and retention rates. Acceptability will be assessed in one focus group with Care Partners via videoconferencing.

Table 4: STELLA-FTD Care Partner Activities, Phase 2		
Activity	**Description**	**Due**
Consent	Care Partner and care recipient consent	Prior to any study activities
Preliminary session(s)	Collect enrollment information Set up and test videoconferencing link	After consent completed
STELLA-FTD (8 weeks)		
Mecury Survey (Survey 1)	Baseline surveys (Table 5)	Prior to intervention start
Intervention	Meet with Faculty and Guest Speakers for 7 weekly, 1-hour, sessions	After Baseline Survey completed
Venus Survey (Survey 2)	See Table 5	Within one week of completion of STELLA-FTD
Optional Focus Group		About 1 month after completion of STELLA-FTD
Weekly Orbit Surveys: **Distributed weekly (Table 6)** Orbit surveys start after enrollment and continue until all surveys are completed		

Measures. Please see **Table 5** for descriptions and **Table 4** (Care Partner Activities) for timing of [(1)]distribution to the Care Partners. Demographic information (such as address, age, gender, race / ethnicity, urban / rural status, gender), and information about care tasks performed by Care Partners, and the frequency and duration of providing care may be collected upon enrollment. Care-recipient dementia diagnosis and diagnosis year will be documented. Diagnosis will be identified by Care Partner

The primary outcome, the burden of behavioral symptoms, will be assessed with the 24-item RMBPC, which measures the frequency of BPSD and caregivers' reactions to these behaviors. The RMBPC is among the most commonly-used measures of burden in ADRD caregiver research and has strong internal consistency (α=.86).[1]

Box 1. Example of using ABC's in STELLA-FTD

Activator:
Care Partner asks family member with FTD: "What do you want to do this weekend? Should we visit the kids? Go out for dinner? See a movie?"

Behavior:
Family member with FTD Behavior: Stares, stammers, says, "Don't know."

Care Partner raises voice, asks more questions, and tells family member "You're just not trying."

Consequence:
Person with FTD feels shamed and undervalued, Care Partner feels frustrated, sad.

Identify solutions:
The family, with the help of the STELLA-FTD team, discuss options to improve communication. In the STELLA-FTD session, they learn how to optimize communication in FTD.

Make a plan:
Care Partner writes down a plan in her handbook:

1. Limit questions
2. Use simple statements
3. Ask PCP for referral to Speech Therapist in order to learn strategies that can help with expressive and receptive communication challenges.

Care Partners may 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 Care Partner emotional and physical strain, The 4-item ZBI, a brief measure of burden (α=.78),[31] medication use, likelihood of placing their care recipient into long term care (e.g., assisted living, memory care), 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.

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

Table 5. STELLA-FTD Survey Descriptions	
Enrollment: Demographics etc	
Baseline (complete within one week of orientation)	
Revised Memory & Behavioral Problems Checklist (RMBPC)[1]	Measure of frequency and reactivity to behavioral and psychological symptoms of dementia
Center for Epidemiologic Studies Depression Scale (CESD-10)[26]	10-item depressive symptoms measure
Marwit Meuser Caregiver Grief Index-Short Form (MMCGI-SF) [25]	Care Partner pre-death grief
Quality of life survey(1)	QOL for person with FTD and care Partner
Self-efficacy for symptom management(2)	5-item scale to determine how certain Care Partners are in their ability to manage FTD symptoms
Self-efficacy for community support service use(3)	5-item scale to determine how certain Care Partners' are in their ability to access services.
Ten Item Personality Inventory	Measures intro- and extraversion
Computer self-efficacy scale	Measures comfort with computer use
Computer anxiety scale	Measures anxiety with computer use
Venus-FTD Survey	
RMBPC	(see Baseline for descriptions)
CESD-10	
MMCGI-SF	
QoL (person with FTD and CP; filled out by CP)	
Self-efficacy for symptom management	5-item scale to determine how certain Care Partners are in their ability to manage FTD symptoms
Self-efficacy for community support service use	5-item scale to determine how certain Care Partners' are in their ability to access services.
Sleep Health Survey	Assesses quality of sleep
Service Use Survey	Assesses use of services, such as rehab
STELLA-FTD contact	STELLA-FTD Care Partner contact post intervention
STELLA-FTD 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 contains the 4-item ZBI.	

We will implement the above measures using Qualtrics or REDCap Survey Platforms The surveys will be emailed to the Care Partners. 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 STELLA-FTD coordinator may call them to identify barriers to completing the surveys. The electronic functionality allows Care Partners to complete surveys in the privacy of their homes, at a time that works for them. The Qualtrics and REDCap 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.

Technology. All contacts, surveys and interventions may be completed by phone, email, texting, videoconferencing and/or electronically-administered assessments.

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 Faculty and guest speakers will meet with Care Partners via videoconferencing using either an OHSU computer or their own computer and an OHSU, HIPAA-secure link. Faculty and speakers may complete the STELLA-FTD sessions from their homes, 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 STELLA-FTD 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. The STELLA-FTD study coordinator will teach and support Care Partners in device use and study access. All STELLA-FTD sessions will be video-recorded and the recordings will be stored on a secure server. Content experts will have access to a sample of videos for viewing via the OHSU secure file-sharing system (One Drive).

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

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

7) Data and Specimens

a) Handling of Data and Specimens

No biological or genetic specimens will be collected in this study. Data from the measures described above will be collected via the secure Qualtrics or REDCap systems and then downloaded to a secure OHSU file for analyses. Video-recordings of focus groups and intervention sessions to be used for quality assurance and de-identified transcripts of qualitative data will also be downloaded to a secure OHSU file for analysis.

b) Sharing of Results with Subjects

If the burden or depression scores indicate severe depression or burden, the Care Partner may be informed, at the discretion of the PI. 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.

c) 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.

8) Data Analysis

STELLA-FTD 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.

Phase 1. Audio recordings from focus groups were transcribed, and the resulting transcripts were be audited for accuracy and de-identified to remove any personally identifiable information. Dedoose

qualitative software[32] was used for data management and coding following the approach of classical content analysis to identify themes.[33] The research team discussed emergent themes, and identified areas of convergence and divergence with survey and demographic data.[18] Findings were used to adapt the STELLA intervention to address the preferences and needs identified from our focus groups.

Phase 2. We will assess data from the surveys to characterize the sample and assess program acceptability. We will compare demographic information, computer use, out-of-pocket costs, health-care usage, behavioral symptom frequency, Care Partner reactivity, burden, depression, and daily activities for those that completed the interventions to those that did not.

For acceptability, we will analyze the STELLA-FTD Experience Survey results using descriptive statistics (mean, range, SD). A directed content analysis approach will be used to analyze the qualitative focus group data. 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 STELLA-FTD and the underpinnings of their impressions. These qualitative findings will be considered in relation to the quantitative data using a convergent mixed analysis approach, a widely-used strategy in mixed methods research.[18] This involves separate analyses of the quantitative data (e.g., paired *t* tests, linear regression) and qualitative data, followed by an analysis that looks at areas of data convergence and divergence.

*Aim 2 (*Establish the efficacy of STELLA-FTD 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[1].

We may use linear regression models to examine pre-post changes in primary outcome (RMBPC[1] change scores) utilizing surveys between two points. 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. number of STELLA-FTD sessions each Care Partner attended, b. likelihood of placement, and c. out-of-pocket costs.

Using ANOVA, we may assess pre-post changes in the RMBPC (reactivity subscale)[1] between four groups (rural White, African American; urban African American, White), with the hypothesis that there are no significant differences across groups.[34] 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.

We may also assess efficacy in the domains of Care Partner depression,[26] extraversion and grief[25] before, during and after STELLA-FTD with pre-post paired *t* tests.

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 may assess the relationships between cost, burden and STELLA-FTD 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.

9) 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 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. The video-recordings will show the subjects' faces and the audio will have their voice recordings. Their names and any information discussed during the sessions and focus group will be heard in the audio. The faces, names and audio of any other people who enter the camera/audio zone will also be recorded. We will advise Care Partners that they do not allow anyone (besides themselves) to be in the camera/audio zone during the STELLA-FTD sessions. However, due to the remote nature of the intervention, we will not have control over who is in the camera/audio zone. On the recordings any information subjects (or anyone else) provides will be identifiable as coming from them and will not be private.

We will provide information to subjects on how to set up a false background for their video sessions so that others who may enter the room have less of a chance of showing up on video.

We will use participants' electronic mail, phones and texts for communication and data collection. A key element of STELLA-FTD 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 STELLA-FTD, but we cannot prevent this. The phone numbers and email addresses will not be confidential. We will ask STELLA-FTD participants to only use first names in the intervention.

Electronic mail will be used for data collection and electronic files will be used for storage of the data and may contain some PHI. Each subject will have a unique ID code. 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, 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" or "H" drives in a highly secure, biometrically authenticated data center or shared via OHSU OneDrive.

Electronic survey data will be stored in a web-accessible server at Qualtrics or REDCap. 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.

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, their family members or others 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.

b) 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.

Participants who complete seven STELLA-FTD sessions and all other study activities (e.g., surveys) may receive at $50 ClinCard. We will ask for the participants' social security numbers in order to process the ClinCards.

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