Caregiver Speaks Protocol
August 7, 2023
NCT04103580

SOCIAL/BEHAVIORAL/EDUCATIONAL RESEARCH PROTOCOL
UNIVERSITY OF MISSOURI

Project Title: Caregiver Speaks: A Technologically Mediated Storytelling Intervention for Family Caregivers of Individuals with Alzheimer's Disease and Other Dementias
IRB Number: 2016062
Version Number: 11
Version Date: 8.7.2023
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Funding Source: National Institute on Aging (NIA)

I. Research Objectives/Background

Over 15 million Americans living with Alzheimer's disease and other dementias (AD/D) receive daily care from family caregivers (unpaid individuals, typically but not always related, who assume responsibility for daily care and decision-making).[1] Caring for a person living with dementia (PLWD) greatly alters caregivers' daily lives, often resulting in depression and anxiety as they labor throughout the illness trajectory.[2-4] Caregiving challenges typically increase as the patient nears death.[5-7] Family caregivers of PLWD often lack support during their most active caregiving and into bereavement. This situation intensifies both caregiving-related distress and caregivers' grief.[8]

Caregivers' pre-bereavement experience is associated with how well they adapt to their post-loss lives.[7,9] Caregivers who experience pre-bereavement depression, anxiety, and inadequate social support are likely to experience more intense grief and distress after their loved one dies.[10,11] Thus, interventions that reduce caregivers' pre-bereavement depression and anxiety may improve the caregiving experience and bereavement journey.[6]

Hospice is one of the few healthcare services that follow caregivers into bereavement. Although Medicare Conditions of Participation require hospice agencies to deliver bereavement services, no standards exist to prescribe how these services are delivered.[12] Furthermore, many hospice agencies lack resources to provide comprehensive services to all bereaved caregivers.[12] Current efforts for supporting hospice caregivers of PLWD show little efficacy at reducing pre- and post-loss depression and anxiety during caregiving and into bereavement.[7] We propose a randomized controlled trial (RCT) of a technologically-mediated, storytelling intervention, Caregiver Speaks. Caregiver Speaks empowers caregivers' self-expression, moderated by increased social support, to make meaning of the caregiving and bereavement experiences, thus reducing depression and anxiety.

Park and Folkman's meaning-making coping model[13] posits that an individual's ability to make sense of, and find benefit in, an adverse life situation (e.g., caregiving and bereavement) will be enhanced by social support, resulting in reduced depression, anxiety, and grief intensity.[13,14] Caregiver Speaks will employ photo-elicitation – using photos to elicit caregivers' thoughts and feelings about their experiences – and a private Facebook (FB) group to enable them to capture and share their stories with one another in a supportive online environment. The overarching goal of this application is to determine the efficacy of Caregiver Speaks in reducing depression and anxiety among hospice family caregivers of people with end-stage AD/D. Our specific aims, qualitative research questions, and quantitative hypotheses are as follows:

Specific Aim 1: Determine the efficacy of the Caregiver Speaks intervention in reducing depression and anxiety among hospice family caregivers of PLWD.

> Research Question (RQ) 1: What is the effect of the Caregiver Speaks intervention on caregivers' depression, anxiety (outcomes of interest)?
>
> Hypothesis (H) 1a: Family caregivers receiving the intervention will report lower levels of depression and anxiety (outcomes of interest), which is facilitated by higher social support (mediating variable) than those in the control group during active caregiving.
>
> H1b: Family caregivers receiving the intervention will report lower levels of depression and anxiety (outcomes of interest), which is facilitated by higher social support (mediating variable) than those in the control group during bereavement.
>
> H1c: Among the intervention group, family caregivers with higher baseline depression scores will experience a larger reduction in depression compared to those with less depression at baseline.

Specific Aim 2: Examine the effect of the Caregiver Speaks intervention on grief intensity among bereaved hospice family caregivers of PLWD.

> H2: Bereaved family caregivers receiving the intervention will report lower grief intensity (outcome of interest) than those in the control group.

Specific Aim 3: Describe how caregivers make meaning of their caregiving and bereavement experiences.

> RQ 2: In what ways do active caregivers find meaning as reflected in their FB posts?
>
> RQ 3: In what ways do bereaved caregivers find meaning as reflected in their FB posts?
>
> RQ 4: In what ways does social validation in an online group facilitate meaning making?
>
> A two-arm multi-site RCT with a mixed-methods analysis will examine the efficacy of a photo-elicitation intervention to reduce caregiver anxiety and depression (Aim 1-2). Qualitative methods will provide insight into how the intervention works to enhance meaning-making and improve caregiver outcomes (Aim 3).

Sub-Study:

> RQ: How are sibling relationships shaped by caring for a parent with dementia?
>
> RQ2: How are sibling relationships shaped by parental death and bereavement in the context of dementia?

II. Recruitment Process

Participants will be hospice family caregivers of PLWD. In the U.S., hospice serves most individuals in their home, which may include nursing homes and other long term care environments, therefore our sample includes these locations. Moreover, we understand that other illnesses often exist alongside an AD/D diagnosis and will account for this in our analysis.

The setting will consist of five hospice agencies in the U.S. These hospice agencies will serve a diverse population, including rural, urban and suburban areas.

We will randomly assign hospice family caregivers to either an intervention group (Caregiver Speaks plus usual care) or control group (usual care). The random assignment will last from active caregiving through bereavement. Upon enrollment in hospice, a hospice staff member will give eligible caregivers a brochure explaining the study. If family caregivers express interest, the staff member will request their verbal permission for a member of our research team to contact them via phone. We have successfully used this recruitment strategy in a prior study.[15]

Prior to study onset, the central Data Manager (RK) will computer-generate a sequence of random group assignments (intervention, usual care) for each hospice site to ensure equal distribution of groups across study sites. Sequences will be generated in randomly chosen blocks of 6, 8, and 10 to prevent any study personnel from being able to forecast group assignment. The randomization schedule for each site will be uploaded into the REDCap database for the study. Upon consent, the next available randomization assignment for the site will be assigned to the patient; all caregivers for that patient will receive the same randomized group to avoid contamination between groups.

During this orientation call, caregivers assigned to the Caregiver Speaks intervention will then receive assistance in setting up Facebook, information regarding privacy concerns for photo taking, and instruction regarding their participation in the intervention from the research staff. Caregivers in the usual care group will receive instruction on how to complete the measures in the REDCap survey.

III. Consent Process

Hospice admission staff will screen eligible participants in compliance with privacy and confidentiality regulations, and briefly explain the study. If an eligible participant is interested and gives consent for a research staff person to contact them, an online orientation session will be scheduled (by the research staff) in order to go over the study in detail, and obtain verbal consent to participate in research activities, and will occur via zoom. During this meeting, an informed consent form will be read aloud to the participant, and they will be given contact numbers for additional information as well as contact information for the University of Missouri Institutional Review Board (IRB). The consent form emphasizes that caregivers can discontinue their participation at any time, and that refusal to participate will not affect their relationship to the hospice agency or the quality of care they receive. The consent form is attached to a follow-up email with the link to complete the baseline measures via REDCap. The baseline survey will not open with the following statement: If you are randomized into the intervention group, participation will require ongoing Facebook use. By checking, ‘yes, I agree to participate’ below, you are acknowledging that Facebook use is part of the intervention activities. You will have many opportunities to ask questions about study involvement, and more specific instructions will be provided to you after you provide consent. If you check, ‘No, I do not want to participate’, the survey will end, and you will no longer be included as a consent in the Caregiver Speaks study.

REDCap Referral and Consent Database Changes as of 9/7/2021:

- Indicator (yes/no) will be added to the consent form that denotes whether or not the intervention 'teach back' was included during the consent process.
- Caregivers will be asked about other family members who might be interested in participating in the study, a notes field will be included so that this information can be added.
- Indicator (yes/no) will be added to the referral form to indicate if the Medical Record (MRN) for the patient was thoroughly searched. A notes field will also be added so that additional MRN info can be noted.
- Indicator (yes/no) added to account for caregivers who initially consent, but subsequently are removed as consents because they did not fill out the baseline and ignored staff contact or opted out of participating wen. If 'yes' is indicated, a notes field is triggered so that the reason for removal can be added as well.

REDCap Referral and Consent Changes as of 6/16/2022:

- When making the initial recruitment call, two questions will be added as a digital literacy screening. If the referral scores 6 or lower on either of the digital literacy screening questions, an alternate recruitment script will be utilized emphasizing the technological assistance the research team can provide to participants.
- Digital literacy screening questions:
  - On a scale of 1-10 with 1 being poor and 10 being excellent, how do you rate your overall skills with technological devices such as cell phones, computers?
  - On a scale of 1-10 with 1 being poor and 10 being excellent, how do you rate your overall skills with social media applications such as Facebook?

IV. Inclusion/Exclusion Criteria

Participants must 1) be a designated family caregiver (i.e., a family member or friend providing unpaid care) of a PLWD who is enrolled in hospice care, 2) be at least 18 years old, 3) be involved in decisions related to their loved one's hospice care, 4) have access to a digital camera or other photo-taking device such as a cell phone, 5) be willing to photograph images they feel capture their caregiving and bereavement experiences, 6) be willing to set up a Facebook account and join the private Facebook group, and 7) have access to e-mail for REDCap survey data collection. Family caregivers without an internet-enabled device will be given a smart phone and data plan restricted to Facebook use for the duration of their participation in the study.

V. Number of Subjects

1. The anticipated enrollment number is 468 subjects (or 234 for intervention group and 234 for control).
2. The PHQ-9 is widely used, has good internal consistency, is well validated, and is commonly used to inquire about the degree to which an individual has experienced depressed mood over the past two weeks.[16] Our power calculations based on our preliminary work hold the following assumptions: 1) attrition rate of 30% 2) 80% power

3) a two-sided alternative for group differences at the 0.05 level of significance for a change in PHQ-9 scores (average of 4 points, variance of 5.5).

VI. Study Procedures/Study Design

Group 1: Usual care. Participants in this group will receive standard hospice care and bereavement support according to the policy of each hospice agency. We considered using an attention match control but chose "usual care" instead, as prior research demonstrated that using attention match control in a behavioral randomized trial is problematic,[17] especially for outcomes such as depression (our primary outcome of interest) and anxiety. This literature advocates that controlling for attention is not necessary and counterproductive in some behavioral intervention trials.[17] Once assigned to an arm, the participant remains in that arm for the entire study, from active caregiving through bereavement. We will not randomize a second time at bereavement. Control group participants will complete study measures electronically through the REDCap system at the same intervals as the intervention group.

Group 2: Caregiver Speaks intervention group. Participants in this group will receive usual care plus the Caregiver Speaks intervention. They will participate in a Facebook group to share their photos and personal stories. During the initial zoom meeting, a research staff person will 1) train caregivers how to set-up and use Facebook, if needed, 2) discuss elements of their story and identify artifacts they may wish to feature in their photo-elicitation process, and 3) enroll them in the pre-bereavement caregiver private Facebook group. Caregivers will participate in this group until the PLWD dies, at which time they will transition (one month) into a bereavement focused group. The bereavement group will include the same components, but the focus of the photos and conversation will be on bereavement. Table 1 provides a summary of the study and intervention participation, as well as the data collection schedule. We will provide caregivers a printed reference guide for using Facebook, including group rules and common Facebook terms, based on materials we have used extensively in our preliminary work.[18]

In an effort to increase retention of participants, the interventionist will now add a follow-up/technical assistance phone call with each NEW intervention participant **after they have completed one full week** of the intervention to assess the following:
a. whether or not there are barriers to accessing/using Facebook.
b. whether or not caregivers are able to share photos.
c. whether or not they know how to set up their notifications to alert them of new posts in the group.
d. whether or not they understand what to share in the group.

Table 1 Summary of Study/Intervention Participation for Caregiver Speaks

Time	Study/Intervention Procedures
Recruitment and Randomization	Flyer given to interested participants by hospice admissions staff, consent given for research staff to contact participant. In addition to that we will send recruitment information packets to some referrals by mail. We will send declines as referrals to another study. Encode (1R01AG069936). Initially consented participants will be given a brief explanation of study-by-study staff and asked

	for verbal consent to participate. Randomization occurs. Zoom meeting (orientation) scheduled.
Zoom (orientation) meeting	Instructions given to intervention group for Facebook and photo-elicitation procedures
Monthly (pre-bereaved caregiver Facebook group)	Research staff will provide ongoing facilitation and encourage discussion of photos and caregiver experiences based on monthly themes. Research staff will encourage participants to post weekly.
1-month bereavement transition	Once bereaved, caregivers will have one month to transition into the bereavement group. Research staff will 1) walk them through the steps of joining the bereavement group, 2) give instructions, and 3) conduct a brief, semi-structured, qualitative interview.
Monthly (bereaved caregiver Facebook group)	Research staff will facilitate discussion of photos based on monthly themes. This will continue up to ~180 days (6 months) after the death of their loved one. Research staff will encourage participants to post weekly.
Study exit	Termination and follow-up: participants will terminate from the group, and will complete 180-day survey and follow-up interview.

The Facebook group will possess the highest privacy level Facebook offers (secret group). Only consented users can search for secret groups; internet searches cannot find them. Membership in a secret Facebook group requires an invitation by a group administrator. Hospice family caregiver participants will be encouraged to log in at least once a week to read content, post photos, and share their stories with other caregivers.

PI Rolbiecki (expert in storytelling and photo-elicitation) and Co-I Teti (photo-elicitation expert) will train and supervise a research team member to serve as the primary Facebook moderator. The moderator will monitor the interactions and discussions among participants daily. Drs. Rolbiecki and Teti and two additional staff will support the facilitation when needed. Based on our pilot work and effectiveness trial (R24HS022140) of photo-elicitation storytelling and Facebook groups, one full-time facilitator will be responsible for up to 100 group members at a time.

Our preliminary work demonstrated that Facebook group members participated more when the moderator asked them to post pictures that captured their experiences, asked questions about the photos, and engaged other members in discussion about the photos. Therefore, the moderator will ask active caregivers to post photos representing their caregiving experiences, their caregiving process, and their meaning structures (e.g., this is what my family dynamic looks like now, while actively caring for my ill family member; this is how my life changed when I assumed the caregiving role; these are the types of things we do as a family now that I am actively caregiving) as related to the month's theme. The moderator will encourage active discussion and posting, weekly (related to the theme). In the bereavement group, the same moderator will ask members to share photos capturing their experiences with death and loss and their post-loss meaning structures (e.g., this is how my family dynamic has changed since the loss; I am now able to do these things again post-loss; this is how my life changed post-loss). The photo-elicitation process is described below.

Caregivers who express a need for additional psychological support will be referred to a hospice social worker (before their family member dies) or hospice bereavement counselor (during bereavement). Although we have found Facebook to be an effective platform where members deliver stories and engage with others with similar experiences, important ethical issues are inherent with this approach. This group is designed for research purposes only. Any caregivers who demonstrate crisis or express intent to harm themselves or others will be dealt with respectfully by the qualified research staff person monitoring the group. Supportive materials (e.g., suicide crisis hotline phone numbers, national information regarding dementia caregiver support) will be made available to any caregiver who expresses interest or demonstrates a need.

Photos are the primary medium through which participants will engage with other group members, responding to the prompts described by the facilitator. Before their loved one dies, caregivers will be asked to take photographs that they feel best capture their daily caregiving and share them with other caregivers in the pre-bereavement Facebook group. The primary group moderator will ask caregivers to focus their photo-taking and discussion on their pre-loss meaning structures (including their pre-caregiving lives) and how this has changed over the course of the illness. For example, caregivers may capture their daily activities caring for their family member, their perceptions of themselves and their interpersonal relationships (including how these changed when they assumed the caregiver role), and how caregiving affects their views of the future and their world. Caregivers who enter the bereavement phase of the study will be asked to take photographs capturing their post-loss meaning structures (e.g., how their sense of self has changed in bereavement, re-examined priorities for life, relationships with the living and continued bonds with the dead, and how their views of the world and future have changed). Members will be asked to discuss these things with others in the bereavement group.

See Table 2 (below) for data collection timing, measures (including psychometric properties), and our specific aims, which focus on key aspects of our conceptual model. Our planned data collection frequency mirrors procedures in our other clinical trials in hospice, allowing us to get measures closest to the patient's death and also through a significant amount of time in bereavement.

Table 2: Aims, Hypotheses, and Associated Measures
Pre-bereavement measures collected at baseline, 14, 30, 90, and 150 days (follow-up data collection post 150 days will occur every 6 weeks until participant transitions to bereavement). Post-death measures collected at transition, 14, 30, 90, 150 and 180 days. During study wind down, participants will complete their final data collection measure based on where they are at in the intervention (e.g., if a participant is on day 90 of 150, they will complete day 90 survey as their final measure).

Specific Aim	**Hypotheses (H) and Research Questions (RQ)**	**Instruments and Variables**	**Description**
Aim 1: Determine the efficacy of the Caregiver Speaks intervention in reducing **depression and anxiety** among hospice family caregivers of PLWD.	***RQ1:*** *What is the effect of the Caregiver Speaks intervention on caregivers' depression, anxiety (outcomes of interest)?* **H1a:** Family caregivers receiving the intervention will	**Primary Outcome: Depression** Patient Health Questionnaire (PHQ-9) **Secondary Outcome: Anxiety** Generalized	PHQ-9: a 9-item screening tool and severity measure for depressive mood.[19] Internal Consistency: .87[20]

	report lower depression and anxiety (outcomes of interest), which is facilitated by higher social support (mediating variable) than those in the control group during active caregiving. **H1b:** Family caregivers receiving the intervention will report lower depression and anxiety (outcomes of interest), which is facilitated by higher social support (mediating variable) than those in the control group during bereavement. **H1c:** the intervention group, family caregivers with higher baseline depression scores will experience a larger reduction in depression compared to those with less depression at baseline.	Anxiety Disorder (GAD-7) **Mediating Variables: Social Validation & Growth:** Social Meaning in Life Events Scale –Social Validation SMILES-SV Integration of Stressful Life Experiences Scale Short Form (ISLES-SF) Caregiver Quality of Life Index (CQLI-R)	GAD-7: a 7-item screening tool and severity measure for generalized anxiety. Internal Consistency: .89[21] SMILES-SV: a 9-item tool for measuring social validation and meaning-making during stressful life events. Internal Reliability: .84[22] ISLES-SF: a 6-item measure that assess meanings made of stress during bereavement.[23] CQLI-R: a 4-item scale that measures physical, social, emotional, and financial quality of life among active caregivers.
Aim 2: Examine the effect of the Caregiver Speaks intervention on **grief intensity** among bereaved hospice family caregivers of PLWD	H2: Bereaved family caregivers receiving the intervention will report lower grief intensity (outcome of interest) than those in the control group.	**Secondary Outcome: Grief Intensity** Texas Revised Inventory of Grief (TRIG)-Present Scale	TRIG-Present: a 13-item scale measuring present grief among bereaved individuals. Internal Consistency: .86[24,25]
Aim 3: Describe how caregivers make meaning of their caregiving and bereavement experiences	RQ2: In what ways do active caregivers find meaning as reflected in their FB posts?	**Caregiver Photos, Discussion of Photos via Facebook Group, Post-intervention**	Qualitative data triangulation and mixed methods analysis.

	RQ3: In what ways do bereaved caregivers find meaning as reflected in their FB posts? RQ4: In what ways does the social support in an online group facilitate meaning making?	**Interviews,** SMILES-SV, ISLES-SF, **and Grief intensity scale**	

Data Analysis Plan:

Statistical Assumptions. We will examine linearity and homoskedasticity by calculating and plotting residuals and Cook's distance for all models. Where data are missing, we will use the Last Observation Carried Forward (LOCF) missing data imputation technique, given that < 30% of data were missing for any particular subject in our prior work. If the proportion of missing data is higher, we will use regression based multiple imputation. Little's MCAR test (missing completely at random) will be used to test that missingness is in no way related to the intervention. Because the sample size is relatively large, we expect that known and unknown confounders will be distributed evenly among the two randomized groups. Additional confounders will only be introduced as covariates if we find evidence of imbalance between groups at baseline. We acknowledge that this study is not powered to detect small interaction effects.

We will test whether randomization created balanced groups by comparing baseline measures and demographic characteristics, using chi-square or t-test analysis for categorical or continuous variables, respectively. Variables that differ significantly between groups will be included in regression models as potential confounders. We will include time from study enrollment to the last observation as a covariate, as well as hospice agency. We will report estimates with 95% confidence intervals. To draw inferences from our study for the likely benefit to an equivalent population, where the intervention under trial is a model of service delivery, all analyses of outcomes will be by intention-to-treat. The intention-to-treat analysis, consistent with the objectives of a pragmatic trial, will minimize the influence of "informative missingness" of the data and preserve groups' comparability.

Statistical Analysis. H1a: Family caregivers receiving the intervention will report lower levels of depression and anxiety (outcomes of interest), which is facilitated by higher social support (mediating variable) than those in the control group during active caregiving.
H1b: Family caregivers receiving the intervention will report lower levels of depression and anxiety (outcomes of interest), which is facilitated by higher social support (mediating variable) than those in the control group during bereavement.

We will examine differences between longitudinal profiles of the two study groups for each of the outcomes (PHQ-9, GAD-7, and grief intensity). We will use linear mixed effect repeated measurement (MMRM) (see model below). This will allow us to draw inferences about how our outcome measures (PHQ-9, GAD-7 and grief intensity) change over time (slope =β_(1,T) and β_(1,C)) between the two study groups. Mixed models are able to accommodate differing numbers of measurements at varying time intervals for participants. Additionally, we will examine how social support mediates our outcomes of interest (depression, anxiety, and grief intensity). As described above, we will also include covariates where indicated.

$$\begin{aligned} Y_{ij} &= \beta_{(0,T)} + \beta_{(1,T)} t_{ij} + b_{oi} + e_{ij} \quad \text{for Treatment group} \\ &= \beta_{(0,C)} + \beta_{(1,C)} t_{ij} + b_{oi} + e_{ij} \quad \text{for Control group} \end{aligned}$$

Where Y_ij represent the depression/anxiety score of the i^th subject at the j^th time, β_(1,T) and β_(1,C) represent the slopes for the treatment and control group respectively with intercepts that vary about the respective mean intercepts β_(0,T) and β_(0,C).

H1c: Among the intervention group, family caregivers with higher baseline depression scores will experience a larger reduction in depression compared to those with less depression at baseline.

A multiple linear regression model will be used as for H1a above to examine the modifying effect of baseline PWBS score. If the β_2 coefficient is negative and statistically significant, we will conclude that the effects of the Caregiver Speaks intervention are conditional on baseline perceptions after adjusting for duration of caregiving (time).
Last post-baseline Anxiety/depression = β0 + β2 * [baseline anxiety/depression] + β3 * [time]

H2: Bereaved family caregivers receiving the intervention will report lower grief intensity (outcome of interest) than those in the control group.
A linear mixed effect model similar to those used for H1a and H1b will be used to examine H2, where the Y_ij will represent the grief intensity score for a subject of the i^th subject at the j^th time.

Subgroup Analysis. We will analyze several subgroups to identify unique attributes that might influence outcomes. Our subgroups are 1) hospice agency, to reflect different organizational structures, 2) older age, gender, race & ethnicity, which might influence use or understanding of Facebook, 3) Caregiver relationship to and residence with the patient, which could affect the meaning and amount of burden and 4) Time from enrollment to last observation, which reflects intervention dose, and 5), co-morbidities in patients, which may impact caregiving outcomes.

Qualitative Analysis. See Table 3 (below) for a detailed qualitative analysis plan. We will enter all photos, qualitative Facebook data, and transcribed interviews into qualitative coding software (Dedoose) for triangulation (use of multiple data sources to ensure a rich and robust dataset)[26,27] and thematic analysis.[28]

Table 3 Qualitative Data Analysis Protocol
Phase 1: **Coding** – We will rely on our preliminary work to inform data coding and categorization. We will begin with a coding frame based on prior research and the theoretical framework.[29] Drs. Rolbiecki, Teti, and Washington will take part in analyzing the triangulated data (i.e., the Facebook discussions, photos, and interviews), including discussing and agreeing on the utterance meanings of each code. Once the final list of codes is complete and agreement on codes is met, each qualitative committee member will code separately and meet to discuss interpretations. The coding frame will be modified throughout

analysis, and the committee will review data as they become available. As a way to guide the thematic analysis process, codes emerging from the data will be labeled by at least two members of this committee and discussed at weekly team meetings. Inter-relator reliability (i.e., a Kappa statistic) will be computed via the Dedoose qualitative coding software. When Kappa is .80, we will divide the data and code individually.

Phase 2: **Pattern Identification and Thematic Analysis** – We will build on Phase 1 by reducing the codes until we can make meaning of the data and identify patterns. This reduction process will consist of grouping the codes into smaller themes, or constructs. We will create a cognitive map of the schema for each dataset (control and intervention). All codes will be further reduced and condensed until we reach a consensus on overarching themes that we feel tell the best story of the data and relate to our research questions.

Phase 3: **Trustworthiness** – Along with data triangulation (which is also used to increase trustworthiness of qualitative data analysis)[30], the qualitative data analysis committee will utilize 1) co-coding, 2) peer debriefing with weekly research team meetings, and 3) a strong audit trail linked in a database.

VII. Potential Risks

Potential Risks: Hospice family caregivers will incur minimal risk by participating in the study. Potential risks could include frustration or anxiety with malfunctioning or technically deficient equipment. Some individuals entering the study might not know how to use Facebook, which may cause some anxiety or frustration. Participants may feel nervous about sharing photos on Facebook and engaging with other hospice family caregivers via the private group. They may also feel uncomfortable discussing their caregiving experiences, as well as their bereavement experiences on this platform. As in most studies, despite efforts to protect confidentiality, potential exists for a privacy breach that could cause distress or embarrassment. All paper forms and computerized data will be stored in secure environments to minimize this possibility. Finally, the potential for frustration exists in that study personnel will have an initial phone meeting (orientation) at the beginning of the study as well as communicate with them by phone at the point they become bereaved. We will continue to minimize these risks by being considerate as we contact family by phone. We also assure participants, both verbally and in writing that they may withdraw from the study at any time. Finally, hospice staff will not release names of any potential participants to the research team without first obtaining consent that the research staff can contact them.

The Facebook platform presents special considerations of risk and privacy. The consent form will make these issues known, and the protocol will require research staff to review participants' privacy settings. We recommend the strictest settings. We will tell potential participants that, if they join the study, their name will be added to a "closed secret" Facebook page, giving them access to other hospice family caregivers of persons living with dementia (PLWD) enrolled in the study. Although the research team controls membership in this group, which is not available to the general public, participants will be advised to protect their personal information and privacy with their individual privacy settings. Members of the Facebook group may contact one another through the Facebook website. However, the research team will not share participants' personal contact information. To participate in the study, participants must join Facebook and have an account. They will be advised to read the Facebook privacy policy and set their Facebook privacy settings with the tightest controls. Our research staff will walk participants through the privacy settings to assist in understanding their meaning. However, participants will decide on their Facebook privacy settings. They will be told that the settings of other group members might affect the privacy of what they share. We also will inform participants of Facebook's policy that it owns all materials placed on the Facebook website, and will advise them to read the policy when posting photos. Should participants feature non-consented individuals in their photos, they will be asked to obtain verbal consent from these individuals before posting the photo in the group. All photos of non-consented individuals will be blurred and de-identified. We will inform participants that, as members of the secret Facebook group, we will encourage them to discuss experiences, share caregiving advice, and access questions and concerns regarding similar issues with others enrolled in the study. Each week, the research staff will provide a new information posting and discussion prompt. We will tell participants that nothing is required of them and that they may log onto the site and read and respond (or not respond) to the discussion as they choose. Our research team will supply discussion information and review all comments and responses to determine members' needs and the helpfulness of the Facebook page. Participants will be given a Rules of Conduct document outlining the ethical conduct expected of the Facebook participants. These rules proscribe giving medical advice to other caregivers or being critical of them. If a participant breaks the rules, the research staff can speak privately with them and, if necessary, after consultation with the Principal Investigators (Drs. Parker-Oliver and Rolbiecki) and research team, revoke their access to the page. The need for this never occurred in our pilot studies. While the Facebook group will not be physically monitored 24/7, all study staff will receive alerts (via Facebook) indicating when and what participant's post. A designated monitoring schedule will be set-up and the Facebook group (and alerts) will be monitored by an actual research staff person between the hours of 7amCST and 10pmCST. Any potential breaches of this code of conduct will be addressed, immediately, the following day. This protocol will be communicated to all participants. This Facebook group does not replace hospice services. Neither the research staff nor any member of the Facebook group will provide mental health services such as counseling. If the research staff becomes concerned about a caregiver's mental well-being, they will contact the hospice social worker to assure the safety of the caregiver and others.

Protection against Risk: Caregiver confidentiality and comfort with the technology are protected, for caregivers must agree to participate in the study's Facebook page on their own account. Training staff to understand their role in recruiting participants, as well as preventing a breach of their confidentiality will address this concern. All paper forms and recordings will be kept in locked cabinets in locked offices within a locked suite. All computerized data will be stored on password-protected and encrypted computers and networks. Only study personnel with a specific need to use data will be granted permission to access it. Finally, all patient/family information taken from the home or hospice office will be identified not with names but with an arbitrary identification code. Hospice family caregivers will participate in recorded interviews, and all recordings will be transcribed and stripped of identifying information. All research data that leave the hospice office will be maintained in a locked file cabinet and secure computer in the PI's office. If written consent is required, the research staff will collect all hard copies of consent forms and hand deliver them to the PI during supervision visits.

VIII. Anticipated Benefits

The proposed project has the potential to improve hospice services by improving hospice support of caregivers from active caregiving and into bereavement. This project's social media platform (Facebook) connects caregivers with other caregivers in a privately moderated group, fostering an environment in which they can obtain additional information and social support that improves both active caregiving and bereavement experiences.

IX. Compensation

Subjects will be compensated $100 total. One payment of $50 will be made via a check at the transition period, and the second $50 payment after completion of their exit interview. During study wind down, all participants will receive their final payment on or around the time of their final survey. Meaning, if participants are on day 90 of 150 and they complete day 90 as their final survey, investigators will initiate final payment. All participants will receive the total amount of their compensation ($100) at the completion of their final survey, regardless of whether they have entered the bereavement phase.

X. Data Safety Monitoring Plan

This project seeks to test the efficacy of the Caregiver Speaks intervention and explore how caregivers' making meaning of their caregiving and bereavement experiences affects their grief intensity. To our knowledge, this is the first hospice intervention offered during active caregiving, following caregivers into bereavement that utilizes the innovative storytelling technique of photo-elicitation. The study will occur in geographically separate hospice programs across the Missouri and in Pennsylvania. The study will use block randomization, with block sizes randomly varying between 6 and 10 to randomize participants into control and Intervention groups, making group allocation difficult to discern. The Data Manager will prepare sequentially numbered, opaque envelopes using a computer to generate random numbers. The total sample will be 468 hospice family caregivers of PLWD in Missouri and Pennsylvania. Participants will be at least 18 years of age, meet the study's inclusion criteria and provide consent to participate. The sample will be referred by hospice admissions staff following a consent-to-contact discussion with the caregiver. Participants in the usual care group will receive traditional hospice care and will be asked questions from the instruments upon enrollment, and every 30 days up to 180 days bereaved. We will conduct a follow-up transition interview with the family caregivers in for the intervention group only at 14-21 days following death of their loved one, then again at ~100-110 days bereaved (for intervention group only). Participants in the Caregiver Speaks intervention group will receive the same measures in addition to the following: participation in a secret Facebook group and facilitated photo-elicitation storytelling intervention. As part of overseeing the Facebook group's psychosocial concerns, Co-investigator Dr. Washington will contact any participant reporting thoughts or actions of harming themselves or others via the Facebook discussion and initiate the participant safety plan.

The Co-Principal Investigators (Drs. Parker-Oliver and Rolbiecki) and Data Manager (Dr. Kruse) will be responsible for monitoring the safety and efficacy of this trial, executing the Data and Safety Monitoring plan, and complying with the reporting requirements. The PIs will provide a summary of the report to the National Institute on Aging (NIA) annually as part of the progress report. The Data and Safety Monitoring report will include participants' socio-demographic characteristics, expected-versus-actual recruitment rates, retention rates, any quality assurance or regulatory issues that occurred during the past year, summary of Adverse Events and Serious Adverse Events, and any actions or changes regarding the protocol.

We will use the Research Electronic Data Capture (REDCap) online database management system that the University of Missouri provides. In this secure network, we will store all study data, data collection instruments, schedule follow-up assessments, monitor enrollment, and manage secure storage. The University of Missouri School of Medicine Bioinformatics Department will provide database management technical support for the data-capture system. Data will be collected via an e-mailed link to all participants with instructions for them to complete the surveys. Based on entered data, the Data Manager will produce reports of apparent data discrepancies and missing data. Data concerns will be addressed through the Data/statistical team and reported to the Steering Committee. Larger concerns with the protocols may be forwarded to the full team or institutional committees depending on their severity. Intervention fidelity will be monitored monthly by Drs. Rolbiecki and Teti. Data quality will be monitored by random inspection of the completed forms by the Data Manager, and any problems detected will be discussed with the Steering Committee.

During screening, study applicants will be assessed to determine their eligibility and safety of their participation in this study. We will use the University of Missouri Institutional Review Board (IRB) definition of serious adverse events. The IRB understands that this definition is unusual in hospice, where deaths are not considered an adverse event because all hospice patients are expected to die. Any adverse event, whether or not related to the study intervention, will be reported to the IRB

All personnel involved with this study will receive appropriate IRB training, including for human subjects training and HIPAA. The PIs will maintain certification of this training.

Responsibilities for data monitoring and safety are outlined below:

- Co- Principal Investigators: The Co- PIs will supervise the study personnel. They will monitor the day-to-day implementation of the intervention and all data collection. They will be in regular contact with each hospice and readily available to identify safety concerns and solve problems. Adverse events that are reported to or observed by the Co-PIs will be reported to the Total Research Team, University of Missouri IRB, and Health Sciences Data Monitoring Safety Board as requested.

- Steering Committee: The research team includes all faculty Co-Is and research staff. Research staff will report all observations, concerns or issues related to the safety of participants or the collection of data. The Co-PIs and Research Specialists will meet weekly to review the status of the intervention, identify problems in the study.
- Each committee meets regularly and reports to the Steering committee any data or safety concerns. All members of the research team are responsible for assuring that any adverse events are reported to the University of Missouri IRB.

XI. Multiple Sites

As we have done in our past clinical trials, all IRB approvals are handled through one institutional IRB. This success has been contingent upon appropriate IRB training by all Co-Is and research staff credentialed through CITI IRB training with customized institutional modules. The IRB application will be submitted to the University of Missouri Institutional Review Board (MU IRB), which will serve as the single IRB with oversight of the study. Drs. Rolbiecki and Parker Oliver, Co- Principal Investigators, will be responsible for all communication between sites and will ensure appropriate IRB approvals are in place prior to the initiation of research activities. MU IRB will maintain records of authorization and of all pertinent communication.

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