Title: CARING: Caregiver Assistance through Resources, Information, and Navigation Guide in Neuro-Oncology

Coordinating Center: H. Lee Moffitt Cancer Center

Principal Investigator: PI: Margaret Byrne, Ph.D.
Moffitt Cancer Center
12902 USF Magnolia Drive, MRC-CANCONT
Tampa, FL 33612
Telephone: 813-745-5569

Research Team: Maija Reblin, PhD, (Co-PI)
Steven K. Sutton, PhD (Collaborator)
Kristen J. Wells, PhD, MPH (Collaborator)
Bradley Zebrack, PhD, MSW (Collaborator)
Peter Forsyth, MD (Collaborator)
Yolanda Piña, MD (Collaborator)

Protocol Version 12 dated 3/22/2024

Table of Contents

Page

1. Study Purposes and Objectives

The aims of this proposal are to:

Aim 1. Assess the preliminary efficacy of eSNAP + Navigator support intervention on Family Caregivers' well-being.

H1: Family caregivers (FCGs) of patients with a primary brain tumor, secondary (metastatic) brain tumor, or leptomeningeal disease who receive the intervention will report less perceived burden and distress when compared with waitlist controls at the Week 8 follow-up.

Aim 2. Assess the preliminary efficacy of eSNAP + Navigator on patient well-being and health care utilization.

H1: Patients whose FCGs receive the intervention will be less distressed and will have fewer unscheduled outpatient visits and hospitalizations when compared with waitlist controls at the Week 8 follow-up.

Exploratory Aim 3. Identify key intervention components using mixed methods to inform future intervention implementation.

Quantitative analysis will identify timing and dosing effects of the intervention and key mechanisms from the conceptual model, including FCG heath care utilization.

Qualitative analysis of FCG interviews about intervention effectiveness will augment quantitative analysis.

2. Background and Introduction

Caregiving is an important public health priority (Family Caregiver Alliance, 2012; Shaji & Reddy, 2012) and the role of informal family caregivers (FCGs) in the health care system is expanding (Redfoot, Feinberg, & Houser, 2013). FCGs relieve demands on the formal health care system by performing care tasks and help patients remain at home (National Alliance for Caregiving, 2016; Taylor, Ostermann, Van Houtven, Tulsky, & Steinhauser, 2007). However, informal caregiving can be burdensome (Bevans & Sternberg, 2012; Burton et al., 2012; Doorenbos et al., 2007) and adversely affect FCG well-being (Given & Given, 1992; Kurtz, Given, Kurtz, & Given, 1994; Robison, Fortinsky, Kleppinger, Shugrue, & Porter, 2009), which is associated with higher patient distress, hospitalization, and mortality(Ankuda et al., 2017; Dionne-Odom et al., 2016; Jacobs et al., 2017). FCGs of patients with primary malignant brain tumor face unique demands and increased burden (P. Sherwood et al., 2004; P. R. Sherwood et al., 2008; Paula R. Sherwood et al., 2006) based on the rapid disease progression, significant physical debilitation, cognitive decline, and personality and behavior changes associated with the disease (Gregg et al., 2014; McConigley, Halkett, Lobb, & Nowak, 2010; Schmer, Ward-Smith, Latham, & Salacz, 2008; Schubart, Kinzie, & Farace, 2008; Paula R. Sherwood et al., 2006). Yet FCGs of patients with primary malignant brain tumor have received very little attention in research, and few interventions have been designed for this population (P. R. Sherwood, Cwiklik, & Donovan, 2016).

FCGs whose informal social network resources (friends, family, acquaintances) provide adequate social support experience lower levels of burden, better health, and improved quality of life (Baron, Cutrona, Hicklin, Russell, & Lubaroff, 1990; Cannuscio et al., 2004; Nabors, Seacat, & Rosenthal, 2002; Newberry et al., 2012; Northouse, Williams, Given, & McCorkle, 2012). This can also positively impact patients, whose psychosocial outcomes are highly interdependent with FCGs' (Kershaw et al., 2015; Kim et al., 2008; Meyler, Stimpson, & Peek, 2007). FCGs with resources to cope are also better able to keep patients at home, decreasing costly hospitalizations (Ankuda et al., 2017; Bidwell, Lyons, & Lee, 2017; Bonin-Guillaume et al., 2015; Longacre, Wong, & Fang, 2014). However, barriers exist for FCG support utilization. For example, FCGs report feeling too overwhelmed to identify or organize available support in the moment, and few formal, comprehensive, proactive FCG support programs exist (Berry, Dalwadi, & Jacobson, 2016; Boele et al., 2017; Northouse et al., 2012; Reblin, Wu, et al., 2017; Warner, Parnell, Cohen, Coleman, & Reblin, 2014). As a result, FCGs may not receive support or may receive support too late to benefit (R. Montgomery & Kwak, 2008; R. J. Montgomery, Marquis, Schaefer, & Kosloski, 2002)

To overcome barriers in FCGs' social support utilization, our team has developed a stepped-care FCG support intervention with input from FCGs of patients with primary malignant brain tumor. The first step includes access to a web-based tool, the **electronic Social Network Assessment Program (eSNAP).** eSNAP quickly collects and organizes social support information entered by FCGs into visualizations of the size, quality, and function of support networks. Visualizations can help FCGs catalogue support resources and present them in a new way, which may make them more salient and remind FCGs of their availability. We have demonstrated the feasibility and acceptability of eSNAP with National Cancer Institute funding (R03 CA 201684-01). FCGs with a lack of existing social support listed in eSNAP will move to the second step: outreach from a **Caregiver Navigator**. The Caregiver Navigator will have social work training and will help FCGs identify and leverage informal and formal social support, including enrolling or directing FCGs to services. For this component, we have adapted the Moffitt Cancer Center's Patient Navigator Research Program (Lee et al., 2013, 2014; Meade et al., 2014; Wells et al., 2012; Wells et al., 2011) with stakeholder feedback.

Our goal is to bring the two intervention components together to conduct a randomized controlled trial. We will test the efficacy of an 8-week eSNAP + Caregiver Navigator support intervention versus a waitlist control for FCGs of patients with a primary brain tumor, secondary (metastatic) brain tumor, or leptomeningeal disease. By intervening with the FCG to increase informal social support and formal service utilization to meet their needs, we anticipate lower FCG burden and distress. We will also leverage the interdependent relationship between FCG and patient; although the intervention is FCG-focused, we anticipate our intervention will also indirectly impact patient well-being and health care utilization outcomes while minimizing patient participation burden.

3. Study Design

3a. Original Study Design

Following the approval of amendment V11 and after consultation with and formal approval from the NIH program officers, we discontinued randomization of subjects to the intervention condition or a waitlist control condition. Participants previously were randomly assigned to the intervention condition or a waitlist control condition, in which the intervention was be made available after the 8-week study period. Randomization was done in REDCap (Research Electronic Data Capture), an online tool which automates random assignment, available through the Participant Research, Interventions, and Measurement (PRISM) Core. To ensure temporal balance between conditions, a randomized block design (blocks of 8) was be used. Participants were stratified by sex (60% female FCGs(Institute, 2015) prior to randomization. Condition was blinded, except to study staff collecting questionnaire data. All enrolled participants now are assigned to receive the intervention. We anticipate this will result in an approximate 2:1 ratio of participants who receive the intervention versus those on the waitlist.

Prior to the approval of amendment V11, we also followed up with FCGs at 6 months and 1 year with brief questionnaires to determine long-term effects of the intervention. We have now discontinued the 6 month and 1 year assessments to focus on retention of participants and data collection through the week 8 primary outcomes assessment.

Finally, we reduced our enrollment to 150 dyads rather than 225 dyads due to projected ability to recruit before the funded study period ends. However, recruitment has moved more quickly than anticipated. We now propose to increase our enrollment to 160 dyads rather than 150 dyads.

3b. Modified Study Design

A prospective, longitudinal 2-group Randomized Controlled Trial design will be delivered to FCGs of patients with a primary brain tumor, secondary (metastatic) brain tumor, or leptomeningeal disease diagnosis. FCG and patient participants will be recruited at/near the patient's first treatment planning appointment – the beginning of the patient's care trajectory. Participants will be assigned to the intervention condition. FCG intervention participants will complete eSNAP at study enrollment. Those with a lack of support identified in eSNAP (at any time as FCGs revisit the app) will be contacted by the Caregiver Navigator, who will conduct sessions by phone, teleconference (e.g. zoom), email or in person to help FCGs identify and problem-solve barriers to finding support resources to meet their needs. Caregiver Navigator procedures also include referral to other professionals for more complex clinical needs. Questionnaires, including support service use and FCG-reported patient hospitalization, will be collected from both groups of FCGs at enrollment and after 4 (F1) and 8 weeks (F2). Patients will complete short questionnaires (<10 minutes) on function and distress at enrollment and 8 weeks (F2), which are timed to routine clinic visits (no visit occurs at F1). In addition, we will conduct interviews with FCGs at F2 to gather qualitative data about the caregiving experience and determine key components of the intervention.

Participants:
We will enroll 160 FCG and patient dyads at Moffitt Cancer Center. We conservatively anticipate a 75% recruitment and 15% attrition rate at each follow up. Our current retention rate is approximately 85%. The research team will occasionally send a study newsletter to communicate with participants (e.g. study updates, enrollment, seasonal topics, etc.). The newsletter will be communicated either electronically (e.g. email, Canva) and/or mailed.

<u>Participant inclusion criteria</u>: 1) age 21+ years, 2) English-speaking/reading/writing, 3) able to complete questionnaires (including by proxy), and 4) not a participant in pilot work. <u>FCGs</u> must self-identify as being a primary FCG of a patient with a primary brain tumor, secondary (metastatic) brain tumor, or leptomeningeal disease diagnosis. A primary caregiver is a family member, friend, or other unpaid person who provides at least some care for a patient at home. <u>Patients</u> must be diagnosed with a new or recurrent primary brain tumor, a secondary (metastatic) brain tumor, or leptomeningeal disease within the last 9 months, receiving at least some evaluation and/or care at Moffitt (i.e. at least one appointment), have a prognosis of at least 9 months. Patients may not participate without consenting FCG. All effort will be made to recruit both members of the dyad, but FCGs may participate without a consenting patient. FCGs may provide proxy data for the patient in these cases (i.e. their own report of the patient's cognitive capacity), but direct patient self-report data will not be obtained from non-consenting patients. Patients are frequently accompanied to their visits by FCGs (> 80% of patients were accompanied by FCGs in pilot work (Reblin et al., Under review)); there are typically frequent opportunities to meet or identify FCGs at the clinic. Only one FCG per patient will be enrolled in the study. If multiple FCGs are identified, the "primary" FCG, or the one who identifies as providing the most hands-on care, will be selected. Patients and FCGs who are experiencing acute distress will be excluded from enrollment and referred directly to social work, per Moffitt policy.

Recruitment: Participants will be recruited through the Moffitt Cancer Center Neuro-Oncology Clinic using processes developed in our prior work.(Reblin et al., Under review; Reblin, Wu, et al., 2017) Patients with upcoming appointments will be contacted by phone via a call or text message, sent a letter, and/or approached by a trained member of the research staff at a scheduled visit to nominate a single primary FCG who typically accompanies them to appointments, provides a majority of hands-on care, and may want to participate in this study. Flyers will also be available in clinic for oncologists and other staff to distribute. A research staff member will introduce the study to nominated individuals at a scheduled visit or will be contacted via telephone. Eligible FCGs and patients interested in participating will be asked to make an appointment with research staff at a convenient time for them (e.g. coinciding with patient treatment schedule, before or after oncologist appointment). FCGs and patients who express interest in the study will be met by research staff in the clinic, other convenient location, or over the phone. In a private space (e.g. consultation room), the research staff member will provide more information about the study and answer any questions before obtaining verbal informed consent, which will be documented by research staff. This waiver of written consent is a concession to two major issues. First, given the population, some patient participants may have physical limitations or loss of motor function that precludes their ability to write, though not their ability to provide informed consent. Second, the waiver of written consent will allow for consenting through means of non-physical contact, protecting this possibly at-risk population from highly-contagious infectious disease. Participants will be provided multiple opportunities to reaffirm or retract their consent throughout the duration of the study, such as when scheduling each Caregiver Navigation session and with the return of completed questionnaires.

Procedures for assignment to study group:
Participants will be assigned by study staff to the intervention (use of eSNAP + Caregiver Navigator). Staff will enter the participant ID number into the system, which will return the assigned condition and track enrollment.

Accrual and retention will be monitored at weekly meetings between study coordinator, recruitment staff, and the PI. Study staff will regularly be in contact with clinic staff to facilitate recruitment and will be available to follow-up with participants in person at the clinic or by telephone/text message/mail/email. We will attend to participant burden by limiting the number of questionnaires for the FCG, but especially for the patient. Further, burden is eased through the use of electronic tools and assessments, telephone/email consultations with the Caregiver Navigator, and timing of the data collection points, eliminating the need for additional visits to the Cancer Center.

Study Period: Enrollment and the first data collection point will be targeted for the patient's first neuro-oncology treatment-planning appointment (or within 2 months of this appointment). This time point was selected to balance the desire to avoid initial distress at diagnosis with our previous work showing that FCGs of patients with primary malignant brain tumor who have high support and low burden early in the care trajectory have better long-term outcomes.(Reblin, Small, Jim, Weimer, & Sherwood, 2017) Similarly, qualitative feedback in our feasibility study suggested a desire for early intervention to set FCGs on the right path.(Reblin et al., Under review; Reblin, Wu, et al., 2017; Warner et al., 2014) Although the treatment planning appointment is still early in the care trajectory, the initial shock of diagnosis has likely passed and a primary FCG is often identified. The study period will continue for 8 weeks, which frequently maps to the first follow-up appointment patients on active treatment have with their oncologists. While patient treatment is not expected to be completed at the 8 week conclusion of the study, our goal is for the intervention to provide FCGs with a foundation of social resources and the tools to problem-solve that they can continue to use throughout the disease course. This includes **transitioning FCG care** to the Moffitt social work service at the end of the study period, which is available to all FCGs of Moffitt patients.

In addition to providing waitlisted participants access to the intervention for 8 weeks (and collecting questionnaire data in that period), all FCG participants recruited in the first 3 years of the study will be asked to complete continued follow-up questionnaires at 6 months and 1 year to explore long-term outcomes and test the timing effects of the intervention.

Procedures**:** At enrollment, participants will complete **baseline questionnaires** on measures drawn from our conceptual model (Figure 1). FCG questionnaires include demographics, burden, and social support measures, and patient questionnaires will include functioning and distress (see Measures, below & Appendix). Questionnaires will be completed electronically using REDCap software,(Harris et al., 2009; "REDCap Software," 2013) a secure data collection and management software. (Paper versions will be available upon request.) Upon completion of questionnaires, FCG participants will be assigned by study staff to the intervention (use of eSNAP + Caregiver Navigator).

FCGs assigned to the **intervention condition** will engage in the stepped-care intervention. In the first stage, FCGs will be asked to use **eSNAP** (using the same tablet as used to complete questionnaires or their own device). Study staff will be available to oversee the eSNAP process and answer questions,(Barnard, Bradley, Hodgson, & Lloyd, 2013) but most FCGs did not require help in our pilot work. If participants are not able to complete eSNAP in the clinic, they may save their input and return to it later. Upon completion (indicated by the user), eSNAP will evaluate the level of support FCGs endorse and make tailored suggestions for resources to augment areas of social support. Intervention participants will be given the web address and login information to access and edit their eSNAP visualization or access resource lists at any time (with reminders to review their eSNAP visualization given during Navigation sessions and at F1 & F2). All FCGs in our pilot study had access to internet at home, and 95% used the internet daily. To assist those FCGs without internet access at home, all participants will be able to use a study tablet while at Moffitt at any point during the study period.

The second level of the Intervention involves support from a **Caregiver Navigator**. The Caregiver Navigator will attempt to contact the FCG within 24 hours of assignment to the intervention (or by other scheduled time) by telephone. FCGs in the intervention condition can also **request a call from the Navigator** at any time during the study period or decline Navigation, request to skip calls or request email sessions. Participants will be made aware that email exchanges may not be encrypted and they should not share PHI. Upon the first contact, the Caregiver Navigator will conduct an **assessment** of factors contributing to the FCG's caregiving burden using the FCG's eSNAP support visualization and through telephone consultation. Second, the Caregiver Navigator will develop a **FCG-specific plan** to address these factors through various types of social support (i.e., informational, instrumental, emotional). The Caregiver Navigator may provide social support directly (e.g. emotional, informational) or may assist FCGs in obtaining support resources from their network or from formal resources through motivational interviewing or problem solving. The Caregiver Navigator will also **work closely with the patient's medical team** to understand the treatment plan for the patient. The Caregiver Navigator may need to provide informational support to the FCG regarding treatment and disease expectations through reinforcement of information delivered by health care providers. As such, the navigator will attend weekly neuro-oncology tumor board meetings and situations where referrals are mandatory (i.e. FCG has acute distress) will be discussed during Caregiver Navigator Training, including the appropriate professional to address the specific need. The Caregiver Navigator will keep in close contact with the FCG (phone, text, email, video conference, per FCG preference) and briefly repeat the assessment of needs weekly. A **log will be made of all Caregiver Navigator contacts**, including date/time, caregiver needs and barriers to obtaining support, and the actions taken by the navigator to meet needs or overcome barriers (see Appendix).(Freund et al., 2008) This log will also be valuable in determining the "active ingredient" or most common/most effective Caregiver Navigator activities. Caregiver Navigator sessions will be recorded (with participant permission) for training or fidelity purposes. Participant consent to audio recording will be assessed in an ongoing manner prior to each session.

In addition to recurring support assessments and general check-ins, the planned suggested topics for weekly Caregiver Navigation sessions include:

1. Identifying barriers and facilitators to obtaining support: reviewing common responses and potential solutions
2. How to broaden the social network: people may be more or less helpful that we expect—sometimes those we think we aren't close to are waiting for an opportunity to help; thinking about future needs and potential support matches; thinking about caregiver support groups
3. How to ask for help: how to identify who to ask; role playing
4. Self-care and respite: What activities help you feel restored? What have you been able to continue to do? Brainstorming how to find time for self-care activities
5. How to set boundaries and eliminate unhelpful support: recognizing unhelpful support; thinking about ways to redirect unhelpful support; strategizing/role playing how to set boundaries
6. Focus on self-efficacy: reflect on previous successes; how to look for new sources of high-quality support; permission to advocate for self and patient
7. Transition of care: learning how to find resources and taking advantage of them.

However, the navigator will be **flexible** given dynamic changes that occur with each patient's functioning, treatment, and prognosis, and FCG resources to handle changes. Navigation calls are anticipated to be 15-20 minutes weekly over 8 weeks, but sessions could vary depending on FCG needs. A major goal of the Caregiver Navigator is to provide FCGs with tools to identify and capitalize on their existing support resources and integrate them with available formal services, including Moffitt social work. This integration will help to transition FCGs from the Caregiver Navigator at the end of the study period. However, this transition may be delayed if FCGs are in crisis at the end of 8 weeks.

All FCG participants will be asked to complete **follow-up questionnaires** by emailed, texted, mailed surveys, or by phone at 4 weeks (F1) and at 8 weeks (F2), including use of services, to show potential change over time (e.g. immediate vs delayed). Patients will complete follow-up questionnaires only at their 8 week clinic visit (F2) to reduce burden. In the intervention condition, FCG questionnaire reminders will be paired with a suggestion to review and update their eSNAP visualization, along with a link to do so, prior to questionnaire completion. Questionnaires will be sent electronically via email using REDCap. Paper questionnaires will also be made available upon request. Every effort will be made to obtain questionnaire data within 2 weeks of each scheduled time point, including follow-up reminder emails, text messages, or phone calls and meeting participants in clinic during patient appointments.

At the conclusion of the 8-week study period, participants will be debriefed by phone, email or in person by trained study staff, which will include a **brief FCG interview**. FCGs who received the intervention will be asked to provide feedback about what they liked and what could be improved. All FCGs will be asked about the barriers they experienced in providing care and what would help or has helped them reduce their caregiving burden. The goal of these interviews will be to provide a qualitative perspective of the caregiving experience in this population, with a specific focus on what worked in the intervention and for whom, with an eye towards identifying factors that may influence the intervention's effectiveness. Previous similar debriefing interviews conducted as part of Dr. Reblin's other research averaged approximately 10-20 minutes.(Terrill et al., 2018) The debriefing interview will be recorded for professional verbatim transcription and qualitative analysis.

Total time for FCGs across the 8 weeks in the study will be less than 120 minutes (excluding navigation). FCG participants may be compensated up to a total of $60, sent either by emailed gift cards or mailed checks. For FCGs, the enrollment visit is expected to be 45 minutes ($20 compensation); questionnaires at F1 and F2 are expected to be 15 minutes with up to 1 hour debriefing at F2 ($20 F1, $20 F2). Total time for patient participants is expected to be 20 minutes (10 at each enrollment and F2); they will be compensated a total of $10 ($5 F1, $5 F2) by emailed gift cards or mailed checks.

Questionnaires: (see appendix for items)

Demographics and Health Characteristics
FCG/Patient Demographics, including relationship status, family composition, frequency of use/comfort with technology, and insurance status, will be assessed at enrollment using an 18-item, purpose-designed measure.
Caregiver and Patient health information will be measured at baseline using a self-reported version of the Charlson Comorbidity Index (Charlson, Pompei, Ales, & MacKenzie, 1987; Chaudhry, Jin, & Meltzer, 2005), Medical Maximizer/Minimizer screener (Scherer, 2019) and selected self-reported health behaviors. Health behavior items will also be used at F1, and F2 (caregivers) and F2 (patients).
Patient medical characteristics, including diagnosis/staging, ECOG, and treatment, will be obtained by chart review.
Patient physical and cognitive functioning will be assessed at baseline and F2 using Neuro-QoL short form (SF) measures(D Cella et al., 2012; David Cella et al., 2011) for Lower Extremity Function-Mobilityand Cognitive Functioning (see description of Neuro-QoL below)
Caregiving Characteristics will be assessed at baseline using purpose-designed questions about the patient/caregiver relationships, living arrangement, duration of caregiving, and weekly amount of caregiving. At Baseline, F1, and F2, caregiver activities will be assessed using modified versions of the Activities of Daily Living (Katz, Ford, Moskowitz, Jackson, & Jaffe, 1963) and Instrumental Activities of Daily Living (Lawton & Brody, 1969). The ADLs measure level of independence across six functions (bathing, dressing, going to toilet, transfer, continence and feeding) in chronically ill and aging populations. This version is a checklist of 8 activities associated with personal care to assess what the FCG helps the patient with because of their health status. IADLs assess the reason that the caregiver helps the patient with various activities (because of their health or not). We adapted it to administer to caregivers (to ask about what they help the patient with and why). The ADLs and IADLs have been validated in proxy for disabled populations (Andresen, Vahle, & Lollar, 2001).
FCG Well-Being
FCG burden will be assessed at baseline, F1, and F2 using the Zarit Burden Interview Short Form(Bedard et al., 2001), a 12-item widely-used measure of burden. Items are summed and higher scores reflect more burden. The scale has been validated in populations of advanced cancer FCGs and has very good internal consistency and discriminative ability (Higginson, Gao, Jackson, Murray, & Harding, 2010). The scale has also been used to identify changes over time (Gaugler, Mittelman, Hepburn, & Newcomer, 2010).
FCG distress will be assessed using the Generalized Anxiety Disorder (GAD-7) (Spitzer, Kroenke, Williams, & Löwe, 2006) and Patient Health Questionnaire (PHQ-8) (Kroenke et al., 2009) at baseline, F1, and F2.
FCG social support will be measured at baseline, F1, and F2 using the 8-item Duke-UNC Functional Social Support Questionnaire (Broadhead, Gehlbach, de Gruy, & Kaplan, 1988). Items are summed and higher scores reflect higher perceived social support. This multi-dimensional questionnaire is used in research to measure amount and type of social support, and used clinically to identify people at risk for isolation. The scale has been shown to be reliable(Broadhead, Gehlbach, deGruy, & Kaplan, 1989) and predictive of psychological and physical health outcomes (Bellon Saameno, Delgado Sanchez, Luna del Castillo, & Lardelli Claret, 1996).

The number of network members entered into eSNAP will also be used as a measure of the size of the FCG social network. If participants use eSNAP over time, we will also capture change.
FCG social support and stress will be measured at baseline, F1, and F2 with Duke Social Support and Stress Scales (DUSOCS-SUP and DUSOCS-STR) (G. Parkerson, 2002). Within each subscale, respondents are prompted with specific family and non-family roles (e.g. significant other, children, neighbors) and asked to report the amount of support or stress provided by that relationship (no such person, none, some, a lot). DUSOCS has been shown to have good internal consistency and reliability, and excellent validity (J. G. Parkerson, Broadhead, & Tse, 1991; Parkerson Jr, Broadhead, & Chiu-Kit, 1992).
FCG coping and self-efficacy will be measured: As a potential covariate at baseline, F1, and F2 using the Coping Self-Efficacy Scale (Chesney, Neilands, Chambers, Taylor, & Folkman, 2006), a 13-item measure of confidence in performing coping behaviors under stress. Items are summed within the scale’s 3 factors: problem-focused coping, emotion-focused coping, and support from friends and family. Internal consistency and reliability are strong and scores are predictive of increased psychological well-being over time. At Baseline, F1, and F2 using the Communication and Attitudinal Self-Efficacy Scale for Cancer (CASE-cancer) (Wolf, Chang, Davis, & Makoul, 2005). The original 12 items have been added upon to create a 19-item scale which measures three factors: understanding and participating in care, maintaining a positive attitude, and seeking and obtaining information. Using the Caregiver Reaction Scale (Qualls & Williams, 2013) at baseline, F1, and F2. The Management of Meaning, Personal Gain, and Relational Deprivation subscales are used with minimal changes.
FCG Preparedness for caregiving is measured at baseline by the 8-item **Preparedness scale of the Family Care Inventory** which assesses the perceived level of preparation for various facets of caregiving such as dealing with physical needs and emotional problems. A five-point Likert-type scale is used ranging from 0 (not at all prepared) to 4 (very well prepared). The scale also assesses previous caregiving experience. Construct validity is shown through negative correlations between preparedness and caregiver worry and Cronbach alpha values range from 0.88 to 0.93(Archbold, Stewart, Greenlick, & Harvath, 1990; Schumacher et al., 2008).
FCG Relationship Quality will be measured using a modified, 4-item version of the Couples Satisfaction Inventory (CSI-4) (Funk & Rogge, 2007) at baseline, F1, and F2.
FCG general health, satisfaction with relationships and ability to carry out social activities will be measured using 3 items from the Patient-Reported Outcomes Measurement Information System (PROMIS-10) (David Cella et al., 2007) at baseline, F1, and F2.
FCG Somatic symptoms will be assessed at baseline, F1, and F2 using the Brief Symptom Inventory (BSI-18) somatic symptoms subscale (Derogatis & Spencer, 1993).
Positive and negative emotions will be assessed at baseline, F1, and F2 using a modification of the Positive and Negative Affect Schedule (Watson, Clark, & Tellegen, 1988). The four items we include are: stressed, in-control, frustrated and hopeful.
For FCGs whose patient passes away during the study period, the TRIG (Texas Revised Inventory of Grief Items)(Faschingbauer, 1981) will be used at all subsequent points to assess cognition, affect and behaviors associated with **bereavement**. Only the 13-item Present Grief section will be used. Likert-type scale with responses from “completely false” to “completely true.”
Patient Well-Being
Patient distress will be assessed using the GAD-7 and PHQ-8 at baseline and F2 (see above).
Patient relationship quality will be assessed at baseline and F2 using a modified 4-item version of the Couples Satisfaction Index (see above).
Health Care Utilization
FCG health care utilization Participants will also be asked for self-reported health care utilization,

including social work or other support services (including referred resources), and whether use was related to the caregiver role or stress at baseline, F1, and F2 using a survey developed in previous research (Byrne, Koru-Sengul, Zhao, Weissfeld, & Roberts, 2010).
Intervention Components
eSNAP use will be gathered using user-log metadata. The system will be designed to capture when and for frequently and for how long individual users are logged in. Changes to eSNAP data will also be captured.
Caregiver Navigator use will be assessed by tracking quantity and length of Navigator visits using a navigator tracking log.(Freund et al., 2008) Referrals and Navigator activities will also be tracked in this log.
FCG Satisfaction with Moffitt, eSNAP intervention, and Caregiver Navigator intervention will be assessed at F2 using a 12-item Client Satisfaction Questionnaire (Larsen, Attkisson, Hargreaves, & Nguyen, 1979).
FCG Satisfaction with care the patient has received will be measured at F2 using the 6-item **Family Satisfaction with Advanced Cancer Care (FAMCARE-6)**(Carter, Lewin, Gianacas, Clover, & Adams, 2011; Kristjanson, 1993), which was developed for clinical administration in ambulatory cancer care.
FCG Debriefing Interview: See Appendix for Draft Guide

4. Statistical Analyses

Effect of modified design: The change in targeted accrual numbers will not change the statistical analyses that will be done. However, our ability to detect differences in outcomes between the waitlist and active intervention may be reduced (hence the need for the word changes in Aims 1 and 2).

Analysis: Our analyses are based on the Caregiver Stress Process Model. Our primary end point is 8-weeks; thus our population of interest is FCGs paired with a patient who survives at least 8 weeks.

Missing Data: Participants who do not submit data at F1 or who decline navigation will continue to be contacted at F2 to complete questionnaires (unless they withdraw from the study) for intent to treat analyses. We plan to begin recruitment early in the care trajectory and anticipate most patients will survive the 8-week study period and will be able to provide the limited amount of data we are collecting. The median survival time for patients with primary malignant brain tumor is 14.6 months.(National Brain Tumor Society) In the unlikely event patients no longer receive care in the neuro-oncology clinic at Moffitt (transition to palliative/hospice care, change providers, death) participants will not be dropped (unless they request to withdraw). Participants in the intervention condition will still have access to eSNAP (and the Navigator) if they wish, with the intent of allowing FCGs to use the intervention to help cope with the new phase of caregiving or bereavement. FCGs will still be asked to complete follow-up questionnaires. If a patient dies, the date of death will be noted, a bereavement card will be sent from the study team, and an abbreviated version of any further surveys will be administered focused on key outcome data for exploratory purposes.

Sample size justification: The analyses for Aims 1 & 2 focus on group differences in parametric variables. A power analysis for an independent-groups t-test with a medium effect size (Cohen's d=0.5) shows that a final sample of 160 (80 per group) would have Power ≥ .80 with alpha=.05 and a two-tailed test. Based on our conservative recruitment and retention estimates, we plan to approach 300 FCGs and enroll 225 to achieve a final sample of 160 dyads completing the 8-week assessment for analyses of hypotheses. However, as the planned recruitment/retention rates are lower than what we achieved in our pilot, we may have a larger sample at F2, which will increase our power. Analyses for exploratory Aim 3 will primarily use path analysis to identify key mechanisms of the intervention on the outcome variable(s) at the 4- and 8-week assessment among the FCGs. The 80 participants in the intervention group will provide the primary data for these analyses, with additional data from participants in the waitlist control group who complete these assessments. It is expected that at least 50% in this group will provide data. Therefore, the expected sample size for the exploratory analyses will be at least 120.

Preliminary analysis: Basic descriptive analyses will be conducted. Chi-square and t-tests will be conducted to determine if the intervention (eSNAP + Caregiver Navigator; both randomized and non-randomized groups) or waitlist control groups significantly differ on demographics, patient medical characteristics, or outcome measures at baseline. Any measure with a group differences of $p<.10$ will be controlled for in primary analyses. Group differences and predictors of attrition will be examined using logistic regression. These results will be used to guide interpretation of primary analyses.

Aim 1 is to assess the preliminary efficacy of eSNAP + Navigator support intervention on FCG well-being. The hypothesis (FCG burden and distress at 8 weeks is lower for intervention group) can be most simply evaluated using independent-samples t-tests if randomization is fully successful. However, Generalized Estimating Equations (GEE) will be used to test the effects of the intervention at F1 and F2 in models that also include the baseline measure of the outcome variable and, if necessary, potential confounds determined by preliminary analyses. This approach handles missing data under the Missing At Random (MAR) assumption and permits analyses beyond those focusing on the outcome variable at 8 weeks (e.g. determining if intervention has an early impact or if effect matures over time). The primary test will be a planned contrast of the 2 conditions at the 8-week assessment within the entire model. The GEE will also assess (1) intervention differences in the primary outcome averaged across the 4 and 8 week assessments, (2) change from 4 to 8 weeks, and (3) group differences in change over time (intervention by time interaction term in the model).

Aim 2 is to assess the preliminary efficacy of interdependent effects of eSNAP + Navigator on patient well-being and health care utilization. We hypothesize that patients with FCGs in the intervention group will report greater well-being and less utilization of health care. The primary outcomes for this aim are (1) patient anxiety and depression scores as (inverse) measures of well-being, and (2) a set of measures for healthcare utilization: the presence of and number of unplanned outpatient visits, the presence of and number of unplanned hospitalizations, and the number of bed days of care in unplanned hospitalizations. For well-being, the simplest test of the hypothesis is an independent samples t-test. If preliminary analyses show that randomization was not fully successful, then linear regression will be used to assess differences between the intervention arms in the context of any potential confounds. For healthcare utilization, the distributions of the outcome variables are expected to warrant 2-stage and/or Poisson regression analyses to assess intervention differences.

Exploratory Aim 3 is to identify key intervention components using mixed methods to inform future intervention implementation. Our quantitative approach will first involve determining the **timing and dose effects of the intervention**. Between-groups GEE analyses will utilize the full dataset to determine if stronger effects of the intervention exist when the intervention is delivered at the first treatment planning appointment (intervention group) or 8 weeks later (waitlist participants who engage in the intervention). We will also analyze data collected from all participants at 6 months and 1 year. Although likely a smaller dataset with some selection bias, these data may provide insight into long term effects on FCG and patient well-being and an opportunity to capture patient hospitalization, a relatively rare but important downstream effect of FCG burden.

We will also explore the dosing of the intervention. Because the intervention is needs-based, FCGs will receive different levels (e.g. eSNAP only; eSNAP plus Caregiver Navigator sessions of differing length/frequency). We will first describe the different levels of intervention used. We will then test the relationship of FCG reported support, distress, and burden and the frequency and time spent engaging in intervention components using repeated measures multilevel modeling. We hypothesize that FCGs who report less support or more distress or burden at enrollment will engage more components of the intervention.

Key mechanisms from the conceptual model (Figure 1) will also be explored using data from all who used the intervention at any time. Planned analyses include describing FCG health care utilization, determining whether intervention components (e.g. eSNAP visualization and resource list/Caregiver Navigator referrals) predict FCG health care utilization, and testing the relationship between FCG health care utilization and FCG well-being. We will also use path analysis to test mediation models mapping FCG support, burden, and distress over time and to test parallel processing models to determine interdependent effects between FCG and patient. For example, we will test whether change in FCG distress is associated with change in patient distress. In addition to identifying key mechanisms of the intervention, these analyses also would contribute to the literature describing the experience of FCGs of patients with a primary brain tumor, secondary (metastatic) brain tumor, or leptomeningeal disease over time.

Qualitative analysis of FCG interviews will augment quantitative analysis. FCGs will be interviewed at 8 weeks about their caregiving experience, including what they liked about the intervention and what could be improved (See Appendix for draft interview guide). Interview audio recordings will be professionally transcribed verbatim. Transcripts will undergo content analysis using open and axial coding by 2 trained coders, led by Dr. Reblin, who has expertise in qualitative analysis.(Dingley et al., 2017; Ellington et al., 2017; Lai et al., 2018; Reblin, Birmingham, Kohlmann, & Graff, 2018; Reblin et al., 2015; Tabler et al., 2015) The goal of the analysis will be to identify aspects of the intervention FCGs found helpful and areas for improvement. Deeper analysis on select transcripts will be conducted to identify themes relevant to findings of the quantitative analysis and emergent themes regarding the caregiving experience.

The audio recordings and transcripts will be stored on secure, password-protected computer servers and will only be accessed by study team members. Audio recordings and transcripts will be retained for at least six years after the study is completed, after which they will be deleted from computer records.

5. Human Subjects Protection

Potential Risks:

There are a few potential risks to the participants. Participants may feel emotional distress when completing questionnaires or thinking about their social networks or caregiving experiences. There is also the possibility of loss of privacy or confidentiality.

Planned strategies for minimizing potential risks

Emotional Distress:

Participants may feel emotional distress when completing questionnaires or thinking about their social networks or caregiving experiences. Some participants may become distressed as a result of their experiences in caregiving. This level of distress is not likely to be more than would occur in daily life or as part of usual care. In the intervention condition (which waitlist control participants may receive after 8 weeks), the Caregiver Navigator will have training to counsel or refer any participant who feels distressed, with support from the interdisciplinary team of investigators and consultants, as well as involvement of the neuro-oncology clinic staff. Part of the role of the Caregiver Navigator is to connect participants with other resources; this will include transitioning care to the neuro-oncology clinic social worker to minimize distress at the end of the study. This social worker is available to all patients and their families, including waitlist control participants, at any time during the patient's care. Emergency procedures, as outlined by Moffitt policy, will be in place should any psychiatric emergency arise. This includes the immediate contact of social work for a risk assessment if a participant is in extreme distress or expresses suicidality. A social worker is on call 24/7 and will make appropriate recommendations for follow-up care in collaboration with the medical team. Although this is likely to be very rare, all study personnel will be trained in these procedures.

Loss of Privacy or Confidentiality:
Precautions will be taken to protect the privacy of all participants contacted to be in the project and for those who participate. Only the study team will have access to participant research data and only trained staff with appropriate approvals will have access to patient medical records when provided consent to do so. All participants will be identified in study files by ID numbers. The study staff will maintain a separate password-protected file behind the Moffitt Cancer Center firewall linking participant IDs to names. Paper questionnaires will have participant IDs and will be stored in a locked file in the study office and entered into an electronic database. Digital audio-recordings will be made only with participant consent. All research data is stored on password-protected computers, secure online platform (REDCap) or in locked cabinets in the PI's office at the Moffitt Cancer Center. All Protected Health Information (e.g. participant names) and identifying data will be kept in a password-protected and encrypted computer or network drive specifically designed for protection of research participant confidentiality at the Moffitt Cancer Center. These systems and devices are all encrypted to protect the research data and participants' privacy. Signed consent forms and participant contact information are kept in password protected and encrypted electronic or physical files within the Moffitt Cancer Center and overseen by the PI. The collection of information about participants is limited to the amount necessary to achieve the aims of the research so that no unneeded information is being collected. Data shared among research team members will be kept confidential. In the course of Caregiver Navigation sessions, the navigator may ask permission to share relevant data with the patient's care team. Caregivers who choose to interact with the Caregiver Navigator or study team by email will be informed that correspondence may not be encrypted and that no PHI should be sent by email. The Caregiver Navigator will be extensively trained and will work closely with the neuro-oncology clinic staff; all effort will be made to support and reinforce information delivered by health care providers. All study staff will receive training in confidentiality safeguards, human subjects and HIPPA certification, research ethics and recruitment, retention and data collection methods and best practices. Throughout the study, periodic updates will be provided at project meetings.

1. Potential Benefits of Proposed research to participants and others

Participants will be told that benefits to participating in research are not guaranteed. Participants may find the eSNAP tool to be helpful in thinking about and organizing their social network resources. Participants may also find benefit in discussing their situation with the Caregiver Navigator and/or discovering or reengaging new and existing support resources. These services are over and above usual care. Although all family caregivers of patients have access to psychosocial care in the form of support groups and the clinic social worker, there is currently no systematic way to make direct referrals in usual care. The organizational exercise of using the eSNAP app, talking to the navigator, and/or using the social resources identified may improve support and reduce caregiver stress, which may in turn improve quality of life. Participants may also feel good about participating in research with the goal of helping other family caregivers and improving the caregiving experience.

Potential benefits to society include development of an intervention to capitalize on existing social resources to reduce caregiver burden as well as improving stress and quality of life outcomes. This intervention, once developed and tested, may be adapted for use with other caregiving populations as well as other populations where visualizing social network resources or facilitating discussions about social network resources may be beneficial.

2. Importance of Knowledge to be Gained:

This proposal addresses the needs of family caregivers of patients with a primary brain tumor, secondary (metastatic) brain tumor, or leptomeningeal disease —a high-need population that is historically underserved and under-studied in research. Family caregivers, especially in this population, are in need of simple, cost-effective ways to reduce burden. However, the primary way to do this identified in the literature, facilitating family caregivers' engagement with their social networks, has not been widely implemented due to barriers in existing methods. We propose to reduce these barriers providing a web-based app to help caregivers organize and prime their existing social support resources, and by providing access to a Caregiver Navigator, who can help problem-solve and make arrangements or referrals. The findings of this study have the potential to inform future interventions with eSNAP and the development of caregiver navigation programs and improve family caregiver outcomes for neuro-oncology family caregivers as well as other groups in need of help harnessing existing social network resources.

6. References

Andresen, E. M., Vahle, V. J., & Lollar, D. (2001). Proxy reliability: health-related quality of life (HRQoL) measures for people with disability. *Quality of Life Research, 10*(7), 609-619.

Ankuda, C. K., Maust, D. T., Kabeto, M. U., McCammon, R. J., Langa, K. M., & Levine, D. A. (2017). Association Between Spousal Caregiver Well-Being and Care Recipient Healthcare Expenditures. *Journal of the American Geriatrics Society, 65*(10), 2220-2226. doi:10.1111/jgs.15039

Archbold, P. G., Stewart, B. J., Greenlick, M. R., & Harvath, T. (1990). Mutuality and preparedness as predictors of caregiver role strain. *Research In Nursing & Health, 13*(6), 375-384.

Barnard, Y., Bradley, M. D., Hodgson, F., & Lloyd, A. D. (2013). Learning to use new technologies by older adults: Perceived difficulties, experimentation behaviour and usability. *Computers in Human Behavior, 29*(4), 1715-1724. doi:http://dx.doi.org/10.1016/j.chb.2013.02.006

Baron, R. S., Cutrona, C. E., Hicklin, D., Russell, D. W., & Lubaroff, D. M. (1990). Social support and immune function among spouses of cancer patients. *Journal of Personality and Social Psychology, 59*(2), 344-352.

Bedard, M., Molloy, D. W., Squire, L., Dubois, S., Lever, J. A., & O'Donnell, M. (2001). The Zarit Burden Interview: a new short version and screening version. *The Gerontologist, 41*(5), 652-657.

Bellon Saameno, J. A., Delgado Sanchez, A., Luna del Castillo, J. D., & Lardelli Claret, P. (1996). [Validity and reliability of the Duke-UNC-11 questionnaire of functional social support]. *Atencion Primaria, 18*(4), 153-156, 158-163.

Berry, L. L., Dalwadi, S. M., & Jacobson, J. O. (2016). Supporting the Supporters: What Family Caregivers Need to Care for a Loved One With Cancer. *Journal of Oncology Practice, 13*(1), 35-41. doi:10.1200/JOP.2016.017913

Bevans, M., & Sternberg, E. M. (2012). Caregiving burden, stress, and health effects among family caregivers of adult cancer patients. *JAMA, 307*(4), 398-403. doi:10.1001/jama.2012.29

Bidwell, J. T., Lyons, K. S., & Lee, C. S. (2017). Caregiver Well-being and Patient Outcomes in Heart Failure: A Meta-analysis. *Journal of Cardiovascular Nursing, 32*(4).

Boele, F. W., van Uden-Kraan, C. F., Hilverda, K., Weimer, J., Donovan, H. S., Drappatz, J., . . . Sherwood, P. R. (2017). Neuro-oncology family caregivers' view on keeping track of care issues using eHealth systems: it's a question of time. *Journal of Neuro-Oncology*, 1-11. doi:10.1007/s11060-017-2504-y

Bonin-Guillaume, S., Durand, A.-C., Yahi, F., Curiel-Berruyer, M., Lacroix, O., Cretel, E., . . . Gentile, S. (2015). Predictive factors for early unplanned rehospitalization of older adults after an ED visit: role of the caregiver burden. *Aging Clinical and Experimental Research, 27*(6), 883-891. doi:10.1007/s40520-015-0347-y

Broadhead, W. E., Gehlbach, S. H., de Gruy, F. V., & Kaplan, B. H. (1988). The Duke-UNC Functional Social Support Questionnaire. Measurement of social support in family medicine patients. *Medical Care, 26*(7), 709-723.

Broadhead, W. E., Gehlbach, S. H., deGruy, F. V., & Kaplan, B. H. (1989). Functional versus structural social support and health care utilization in a family medicine outpatient practice. *Medical Care, 27*(3), 221-233.

Burton, A. M., Sautter, J. M., Tulsky, J. A., Lindquist, J. H., Hays, J. C., Olsen, M. K., . . . Steinhauser, K. E. (2012). Burden and well-being among a diverse sample of cancer, congestive heart failure, and chronic obstructive pulmonary disease caregivers. *Journal of Pain and Symptom Management, 44*(3), 410-420. doi:10.1016/j.jpainsymman.2011.09.018

Byrne, M. M., Koru-Sengul, T., Zhao, W., Weissfeld, J. L., & Roberts, M. S. (2010). Healthcare use after screening for lung cancer. *Cancer, 116*(20), 4793-4799. doi:10.1002/cncr.25466

Cannuscio, C. C., Colditz, G. A., Rimm, E. B., Berkman, L. F., Jones, C. P., & Kawachi, I. (2004). Employment status, social ties, and caregivers' mental health. *Social Science & Medicine, 58*(7), 1247-1256. doi:10.1016/S0277-9536(03)00317-4

Carter, G. L., Lewin, T. J., Gianacas, L., Clover, K., & Adams, C. (2011). Caregiver satisfaction with out-patient oncology services: utility of the FAMCARE instrument and development of the FAMCARE-6. *Supportive Care in Cancer, 19*(4), 565-572.

Cella, D., Lai, J.-S., Nowinski, C., Victorson, D., Peterman, A., Miller, D., . . . Cavazos, J. (2012). Neuro-QOL Brief measures of health-related quality of life for clinical research in neurology. *Neurology, 78*(23), 1860-1867.

Cella, D., Nowinski, C., Peterman, A., Victorson, D., Miller, D., Lai, J.-S., & Moy, C. (2011). The Neurology Quality of Life Measurement Initiative. *Archives of Physical Medicine and Rehabilitation, 92*(10 Suppl), S28-S36. doi:10.1016/j.apmr.2011.01.025

Cella, D., Yount, S., Rothrock, N., Gershon, R., Cook, K., Reeve, B., . . . Rose, M. (2007). The Patient-Reported Outcomes Measurement Information System (PROMIS): progress of an NIH Roadmap cooperative group during its first two years. *Medical care, 45*(5 Suppl 1), S3.

Charlson, M. E., Pompei, P., Ales, K. L., & MacKenzie, C. R. (1987). A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *Journal of chronic diseases, 40*(5), 373-383.

Chaudhry, S., Jin, L., & Meltzer, D. (2005). Use of a self-report-generated Charlson Comorbidity Index for predicting mortality. *Medical care*, 607-615.

Chesney, M. A., Neilands, T. B., Chambers, D. B., Taylor, J. M., & Folkman, S. (2006). A validity and reliability study of the coping self-efficacy scale. *British Journal of Health Psychology, 11*(3), 421-437. doi:10.1348/135910705X53155

Derogatis, L. R., & Spencer, P. (1993). *Brief symptom inventory: BSI* (Vol. 18): Pearson Upper Saddle River, NJ.

Dingley, C. E., Clayton, M., Lai, D., Doyon, K., Reblin, M., & Ellington, L. (2017). Caregiver Activation and Home Hospice Nurse Communication in Advanced Cancer Care. *Cancer Nursing, 40*(5), E38-E50. doi:10.1097/NCC.0000000000000429

Dionne-Odom, J. N., Hull, J. G., Martin, M. Y., Lyons, K. D., Prescott, A. T., Tosteson, T., . . . Bakitas, M. A. (2016). Associations between advanced cancer patients' survival and family caregiver presence and burden. *Cancer Medicine, 5*(5), 853-862. doi:10.1002/cam4.653

Doorenbos, A. Z., Given, B., Given, C. W., Wyatt, G., Gift, A., Rahbar, M., & Jeon, S. (2007). The influence of end-of-life cancer care on caregivers. *Research In Nursing & Health, 30*(3), 270-281.

Ellington, L., Cloyes, K. G., Xu, J., Bellury, L., Berry, P. H., Reblin, M., & Clayton, M. F. (2017). Supporting home hospice family caregivers: Insights from different perspectives. *Palliative & Supportive Care*, 1-11. doi:10.1017/S1478951517000219

Family Caregiver Alliance. (2012). Fact sheet: Selected caregiver statistics. Retrieved from http://www.caregiver.org/caregiver/jsp/home.jsp

Faschingbauer, T. R. (1981). *Texas revised inventory of grief*.

Freund, K. M., Battaglia, T. A., Calhoun, E., Dudley, D. J., Fiscella, K., Paskett, E., . . . The Patient Navigation Research Program, G. (2008). National Cancer Institute Patient Navigation Research Program. *Cancer, 113*(12), 3391-3399. doi:10.1002/cncr.23960

Funk, J. L., & Rogge, R. D. (2007). Testing the ruler with item response theory: increasing precision of measurement for relationship satisfaction with the Couples Satisfaction Index. *Journal of Family Psychology, 21*(4), 572.

Gaugler, J. E., Mittelman, M. S., Hepburn, K., & Newcomer, R. (2010). Clinically significant changes in burden and depression among dementia caregivers following nursing home admission. *BMC Medicine, 8*, 85. doi:10.1186/1741-7015-8-85

Given, B., & Given, C. W. (1992). Patient and family caregiver reaction to new and recurrent breast cancer. *Journal Of The American Medical Women's Association (1972), 47*(5), 201.

Gregg, N., Arber, A., Ashkan, K., Brazil, L., Bhangoo, R., Beaney, R., . . . Yaguez, L. (2014). Neurobehavioural changes in patients following brain tumour: patients and relatives perspective. *Supportive Care in Cancer*. doi:10.1007/s00520-014-2291-3

Harris, P. A., Taylor, R., Thielke, R., Payne, J., Gonzalez, N., & Conde, J. G. (2009). Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *Journal of Biomedical Informatics, 42*(2), 377-381. doi:10.1016/j.jbi.2008.08.010

Higginson, I. J., Gao, W., Jackson, D., Murray, J., & Harding, R. (2010). Short-form Zarit Caregiver Burden Interviews were valid in advanced conditions. *Journal of Clinical Epidemiology, 63*(5), 535-542. doi:10.1016/j.jclinepi.2009.06.014

Institute, N. A. f. C. A. P. P. (2015). *Caregiving in the US 2015*. Retrieved from http://www.caregiving.org/wp-content/uploads/2015/05/2015_CaregivingintheUS_Final-Report-June-4_WEB.pdf

Jacobs, J. M., Shaffer, K. M., Nipp, R. D., Fishbein, J. N., MacDonald, J., El-Jawahri, A., . . . Greer, J. A. (2017). Distress is Interdependent in Patients and Caregivers with Newly Diagnosed Incurable Cancers. *Annals of Behavioral Medicine*. doi:10.1007/s12160-017-9875-3

Katz, S., Ford, A. B., Moskowitz, R. W., Jackson, B. A., & Jaffe, M. W. (1963). Studies of illness in the aged: the index of ADL: a standardized measure of biological and psychosocial function. *Jama, 185*(12), 914-919.

Kershaw, T., Ellis, K. R., Yoon, H., Schafenacker, A., Katapodi, M., & Northouse, L. (2015). The Interdependence of Advanced Cancer Patients' and Their Family Caregivers' Mental Health, Physical Health, and Self-Efficacy over Time. *Annals of Behavioral Medicine, 49*(6), 901-911. doi:10.1007/s12160-015-9743-y

Kim, Y., Kashy, D. A., Wellisch, D. K., Spillers, R. L., Kaw, C. K., & Smith, T. G. (2008). Quality of life of couples dealing with cancer: dyadic and individual adjustment among breast and prostate cancer survivors and their spousal caregivers. *Annals of Behavioral Medicine, 35*(2), 230-238. doi:10.1007/s12160-008-9026-y

Kristjanson, L. J. (1993). Validity and reliability testing of the FAMCARE Scale: measuring family satisfaction with advanced cancer care. *Social science & medicine, 36*(5), 693-701.

Kroenke, K., Strine, T. W., Spitzer, R. L., Williams, J. B., Berry, J. T., & Mokdad, A. H. (2009). The PHQ-8 as a measure of current depression in the general population. *Journal of affective disorders, 114*(1-3), 163-173.

Kurtz, M. E., Given, B., Kurtz, J. C., & Given, C. W. (1994). The interaction of age, symptoms, and survival status on physical and mental health of patients with cancer and their families. *Cancer, 74*(7 Suppl), 2071-2078.

Lai, D., Cloyes, K. G., Clayton, M. F., Doyon, K., Reblin, M., Beck, A. C., & Ellington, L. (2018). We're the Eyes and the Ears, but We Don't Have a Voice: Perspectives of Hospice Aides. *Journal of Hospice & Palliative Nursing, 20*(1), 47-54. doi:10.1097/NJH.0000000000000407

Larsen, D. L., Attkisson, C. C., Hargreaves, W. A., & Nguyen, T. D. (1979). Assessment of client/patient satisfaction: development of a general scale. *Evaluation and program planning, 2*(3), 197-207.

Lawton, M. P., & Brody, E. M. (1969). Assessment of older people: self-maintaining and instrumental activities of daily living. *The gerontologist, 9*(3_Part_1), 179-186.

Lee, J. H., Fulp, W., Wells, K. J., Meade, C. D., Calcano, E., & Roetzheim, R. (2013). Patient navigation and time to diagnostic resolution: results for a cluster randomized trial evaluating the efficacy of patient navigation among patients with breast cancer screening abnormalities, Tampa, FL. *PLoS One, 8*(9), e74542. doi:10.1371/journal.pone.0074542

Lee, J. H., Fulp, W., Wells, K. J., Meade, C. D., Calcano, E., & Roetzheim, R. (2014). Effect of patient navigation on time to diagnostic resolution among patients with colorectal cancer-related abnormalities. *Journal of Cancer Education, 29*(1), 144-150. doi:10.1007/s13187-013-0561-2

Longacre, M. L., Wong, Y.-N., & Fang, C. Y. (2014). An integrative review of US studies: Caregiver psychological health and hospitalization characteristics of older adult care recipients. *Research in Gerontological Nursing, 7*(3), 139.

McConigley, R., Halkett, G., Lobb, E., & Nowak, A. (2010). Caring for someone with high-grade glioma: a time of rapid change for caregivers. *Palliative Medicine, 24*(5), 473-479. doi:10.1177/0269216309360118

Meade, C. D., Wells, K. J., Arevalo, M., Calcano, E. R., Rivera, M., Sarmiento, Y., . . . Roetzheim, R. G. (2014). Lay navigator model for impacting cancer health disparities. *Journal of Cancer Education, 29*(3), 449-457. doi:10.1007/s13187-014-0640-z

Meyler, D., Stimpson, J. P., & Peek, M. K. (2007). Health concordance within couples: A systematic review. *Social Science & Medicine, 64*(11), 2297-2310. doi:https://doi.org/10.1016/j.socscimed.2007.02.007

Montgomery, R., & Kwak, J. (2008). TCARE: TAILORED CAREGIVER ASSESSMENT AND REFERRAL. *Journal of Social Work Education, 44*(sup3), 59-64. doi:10.5175/JSWE.2008.773247713

Montgomery, R. J., Marquis, J., Schaefer, J. P., & Kosloski, K. (2002). Profiles of respite use. *Home Health Care Services Quarterly, 21*(3-4), 33-63.

Nabors, N., Seacat, J., & Rosenthal, M. (2002). Predictors of caregiver burden following traumatic brain injury. *Brain Injury, 16*(12), 1039-1050. doi:10.1080/02699050210155285

National Alliance for Caregiving. (2016). *Cancer Caregiving in the US – An Intense, Episodic, and Challenging Care Experience*. Retrieved from http://www.caregiving.org/wp-content/uploads/2016/06/CancerCaregivingReport_FINAL_June-17-2016.pdf

National Brain Tumor Society. Quick Brain Tumor Facts.

Newberry, A., Kuo, J., Donovan, H., Given, B., Given, C. W., Schulz, R., & Sherwood, P. (2012). Identifying family members who are likely to perceive benefits from providing care to a person with a primary malignant brain tumor. *Oncology Nursing Forum, 39*(3), E226-232. doi:10.1188/12.ONF.E226-E232

Northouse, L., Williams, A.-l., Given, B., & McCorkle, R. (2012). Psychosocial Care for Family Caregivers of Patients With Cancer. *Journal of Clinical Oncology, 30*(11), 1227-1234. doi:10.1200/jco.2011.39.5798

Parkerson, G. (2002). User's guide for Duke health measures. *Durham, NC: Department of Community and Family Medicine, Duke University Medical Center*.

Parkerson, J. G., Broadhead, W., & Tse, C. (1991). Validation of the Duke Social Support and Stress Scale. *Family medicine, 23*(5), 357-360.

Parkerson Jr, G. R., Broadhead, W. E., & Chiu-Kit, J. T. (1992). Quality of life and functional health of primary care patients. *Journal of clinical epidemiology, 45*(11), 1303-1313.

Qualls, S. H., & Williams, A. A. (2013). *Caregiver family therapy: Empowering families to meet the challenges of aging*: American Psychological Association.

Reblin, M., Birmingham, W. C., Kohlmann, W., & Graff, T. (2018). Support and negation of colorectal cancer risk prevention behaviors: analysis of spousal discussions. *Psychology, Health & Medicine, 23*(5), 548-554. doi:10.1080/13548506.2017.1381747

Reblin, M., Cloyes, K. G., Carpenter, J., Berry, P. H., Clayton, M. F., & Ellington, L. (2015). Social support needs: discordance between home hospice nurses and former family caregivers. *Palliative & Supportive Care, 13*(3), 465-472. doi:10.1017/S1478951513001156

Reblin, M., Ketcher, D., Forsyth, P., Mendivil, E., Kane, L., Pok, J., . . . Agutter, J. (Under review). Feasibility of implementing an electronic social support and resource visualization tool for caregivers in a neuro-oncology clinic.

Reblin, M., Small, B., Jim, H., Weimer, J., & Sherwood, P. (2017). Mediating burden and stress over time: Caregivers of patients with primary brain tumor. *Psychooncology*. doi:10.1002/pon.4527

Reblin, M., Wu, Y. P., Pok, J., Kane, L., Colman, H., Cohen, A. L., . . . Agutter, J. (2017). Development of the Electronic Social Network Assessment Program Using the Center for eHealth and Wellbeing Research Roadmap. *JMIR Human Factors, 4*(3), e23. doi:10.2196/humanfactors.7845

. REDCap Software (Version 4.13.17). (2013): Vanderbilt University.

Redfoot, D., Feinberg, L., & Houser, A. (2013). *The Aging of the Baby Boom and the Growing Care Gap: A Look at Future Declines in the Availability of Family Caregivers*. AARP Public Policy Institute Retrieved from http://www.aarp.org/content/dam/aarp/research/public_policy_institute/ltc/2013/baby-boom-and-the-growing-care-gap-insight-AARP-ppi-ltc.pdf.

Robison, J., Fortinsky, R., Kleppinger, A., Shugrue, N., & Porter, M. (2009). A broader view of family caregiving: effects of caregiving and caregiver conditions on depressive symptoms, health, work, and social isolation. *The Journals of Gerontology, Series B: Psychological Sciences and Social Sciences, 64*(6), 788-798. doi:10.1093/geronb/gbp015

Scherer, L. D. Z.-F., Brian J. (2019). *Development of a Single-Item Medical Maximizer-Minimizer Screening Question*.

Schmer, C., Ward-Smith, P., Latham, S., & Salacz, M. (2008). When a family member has a malignant brain tumor: the caregiver perspective. *Journal of Neuroscience Nursing, 40*(2), 78-84.

Schubart, J. R., Kinzie, M. B., & Farace, E. (2008). Caring for the brain tumor patient: family caregiver burden and unmet needs. *Neuro-Oncology, 10*(1), 61-72. doi:10.1215/15228517-2007-040

Schumacher, K. L., Stewart, B. J., Archbold, P. G., Caparro, M., Mutale, F., & Agrawal, S. (2008). Effects of caregiving demand, mutuality, and preparedness on family caregiver outcomes during cancer treatment. *Oncology Nursing Forum, 35*(1), 49-56. doi:10.1188/08.ONF.49-56

Shaji, K. S., & Reddy, M. S. (2012). Caregiving: a public health priority. *Indian Journal of Psychological Medicine, 34*(4), 303-305. doi:10.4103/0253-7176.108191

Sherwood, P., Given, B., Given, C., Schiffman, R., Murman, D., & Lovely, M. (2004). Caregivers of persons with a brain tumor: a conceptual model. *Nursing Inquiry, 11*(1), 43-53. doi:200 [pii]

Sherwood, P. R., Cwiklik, M., & Donovan, H. S. (2016). Neuro-oncology family caregiving: review and directions for future research. *CNS Oncology, 5*(1), 41-48. doi:10.2217/cns.15.43

Sherwood, P. R., Given, B. A., Donovan, H., Baum, A., Given, C. W., Bender, C. M., & Schulz, R. (2008). Guiding research in family care: a new approach to oncology caregiving. *Psychooncology, 17*(10), 986-996. doi:10.1002/pon.1314

Sherwood, P. R., Given, B. A., Given, C. W., Schiffman, R. F., Murman, D. L., Lovely, M., . . . Remer, S. (2006). Predictors of distress in caregivers of persons with a primary malignant brain tumor. *Research In Nursing & Health, 29*(2), 105-120. doi:10.1002/nur.20116

Spitzer, R. L., Kroenke, K., Williams, J. B., & Löwe, B. (2006). A brief measure for assessing generalized anxiety disorder: the GAD-7. *Archives of internal medicine, 166*(10), 1092-1097.

Tabler, J., Utz, R. L., Ellington, L., Reblin, M., Caserta, M., Clayton, M., & Lund, D. (2015). Missed Opportunity: Hospice Care and the Family. *Journal of Social Work in End-of-Life & Palliative Care, 11*(3-4), 224-243. doi:10.1080/15524256.2015.1108896

Taylor, D. H., Jr., Ostermann, J., Van Houtven, C. H., Tulsky, J. A., & Steinhauser, K. (2007). What length of hospice use maximizes reduction in medical expenditures near death in the US Medicare program? *Social Science & Medicine, 65*(7), 1466-1478. doi:S0277-9536(07)00277-8 [pii]

10.1016/j.socscimed.2007.05.028

Terrill, A. L., Reblin, M., MacKenzie, J. J., Cardell, B., Einerson, J., Berg, C. A., . . . Richards, L. (2018). Development of a novel positive psychology-based intervention for couples post-stroke. *Rehabilitation Psychology, 63*(1), 43-54. doi:10.1037/rep0000181

Warner, E. L., Parnell, K., Cohen, A. L., Coleman, H., & Reblin, M. (2014). *Feasibility testing of ecomapping in neuro-oncology caregivers to identify social support networks.* Paper presented at the ASCO Quality and Care Symposium, Boston, MA.

Watson, D., Clark, L. A., & Tellegen, A. (1988). Development and validation of brief measures of positive and negative affect: the PANAS scales. *Journal of personality and social psychology, 54*(6), 1063.

Wells, K. J., Lee, J. H., Calcano, E. R., Meade, C. D., Rivera, M., Fulp, W. J., & Roetzheim, R. G. (2012). A cluster randomized trial evaluating the efficacy of patient navigation in improving quality of diagnostic care for patients with breast or colorectal cancer abnormalities. *Cancer Epidemiology, Biomarkers & Prevention, 21*(10), 1664-1672. doi:10.1158/1055-9965.epi-12-0448

Wells, K. J., Meade, C. D., Calcano, E., Lee, J. H., Rivers, D., & Roetzheim, R. G. (2011). Innovative approaches to reducing cancer health disparities: the Moffitt Cancer Center Patient Navigator Research Program. *Journal of Cancer Education, 26*(4), 649-657. doi:10.1007/s13187-011-0238-7

Wolf, M. S., Chang, C.-H., Davis, T., & Makoul, G. (2005). Development and validation of the Communication and Attitudinal Self-Efficacy scale for cancer (CASE-cancer). *Patient education and counseling, 57*(3), 333-341.