# Online Information and Support for Distance Caregivers

# NCT02666183

# 12.13.21

# Study Protocol and Statistical Analysis Plan

## DISTANCE CAREGIVER STUDY PROTOCOL

### OBJECTIVES

The primary goal of this RCT is to compare outcomes (anxiety, distress, depression) for DCGs of patients with advanced cancer and/or patients receiving ongoing care from a medical oncologist who are randomly assigned to either the full intervention arm (Closer), the video-only intervention arm (Video-C Only), or the control group (Web-Only). The goal is to determine which is most efficacious in improving outcomes over time for these caregivers.

### RESEARCH SUBJECT SELECTION AND ELIGIBILITY

The sample will consist of patients with advanced cancer and/or patients receiving ongoing care from a medical oncologist and distance caregivers of these patients. Patients with any metastatic solid tumor will be recruited for participation in the study. Subject(s) selection will involve two phases: first eligible patients must be identified and second, they must have eligible DCGs as well.

Inclusion and exclusion criteria include:

**Patient inclusion criteria** are: 1) a new diagnosis (within 3 months) of advanced cancer and/or patients receiving ongoing care from a medical oncologist (solid tumors) or a new recurrence of the primary cancer in an advanced stage; 2) receives ongoing care from a medical oncologist at the Seidman Cancer Center (SCC); 3) has English as the primary language; 4) has a life expectancy of >6 months; 5) provides consent for his/her own treatment and procedures; and 6) identifies a DCG involved in his/her care, support, or care planning.
**Exclusion**: The patient sample is limited to patients with advanced cancer and/or patients receiving ongoing care from a medical oncologist because the full intervention is tailored to meet the needs of DCGs of patients with advanced cancer and/or patients receiving ongoing care from a medical oncologist.

The second stage of selection and eligibility will involve DCGs.

**DCG inclusion criteria** are: 1) is an adult family member (at least 18 years old) of a patient with an advanced-stage cancer; 2) identifies himself/herself as a DCG for the patient; 3) lives >1 hour travel time away from the patient; 4) has English as his/her primary language; 5) is capable of providing informed consent; and 6) will be able to access Internet (phone, computer, etc.). The sole **exclusion** criterion is cognitive impairment.

For this study, DCGs will be defined as anyone who self-identifies as providing informal, unpaid care to a family member with advanced cancer and/or patients receiving ongoing care from a medical oncologist, who provides support to the patient, and who lives >1 hour away in travel time; a definition commonly used to define DCGs [1,2,4,77].

### RESEARCH SUBJECT ENTRY

**Subject recruitment:** Potential **patient subjects** will be obtained from a list of patients who have appointments to be seen in the outpatient clinic at the Seidman Comprehensive Cancer Center (main campus). Research Assistants (RAs) will obtain a list of patients who meet eligibility criteria each week from the outpatient clinic staff. RAs will review subject charts to confirm eligibility of these subjects prior to their outpatient appointment.

**Informed Consent for patient and DCG:** At their outpatient clinic visit, all subjects who meet eligibility criteria will be approached by the RA and asked if they have a DCG. For those who have a DCG, the RA will describe the study and ask if the RA if he/she (RA) can contact the DCG to talk about the study and to invite participation. The RA will then obtain contact information from the DCG and contact them, describe the study, and ask for consent. Only after the DCG consents, will the RA obtain written consent from the patient. The RA will contact the DCG by telephone within a week of meeting with the patient. If the patient does not give the RA permission to contact the DCG or if the DCG does not consent to participate then neither the patient nor the DCG will be enrolled in the study. In our pilot, 90% of patients agreed to let the RA contact the DCG. Using this procedure in our pilot study, we were able to obtain consent and enrollment data from the patient and the DCG within 7 days of one another.

**Subject randomization**: Once consent has been obtained, the DCG subject will be randomly assigned by the Project Director to one of three arms of the study. Randomized to one of the three study groups will involve using the minimization stratified randomization technique. Minimization is designed to balance pre-identified stratifying covariates across treatment assignments more effectively than simple randomization[79]. Stratification variables will be DCG age, gender and patient cancer stage. We will use the free online program MinimPy[97].

Allocation concealment: For DCGs assigned to the Closer or Video-C Only groups, the Project Director will email the link to download the free WebEx application that will be needed for all videoconference sessions. For subjects in the Web-Only group, the Project Director will email them to download an application that will allow the DCG to click on an icon and be directly connected to the DCG website used for this group. This procedure will blind RAs to group assignment.

## STUDY DESIGN AND METHODS

### Design/Study Type

This proposed three group RCT will examine the effects of videoconference technology (information) during patient-oncologist office visits and the added effects of from RN coaching sessions (information + emotional support) using videoconference technology. The study will use an experimental design with random assignment of DCGs to groups.

### Selection of Instruments

Study measures will be obtained at enrollment and 4 months later (Table 1).

**Table 1. Study Tools and Measures**

| Variable | Measure | Time of measure Enroll | 4M | Reliability |
|---|---|---|---|---|
| **Outcome Variables** | | | | |
| Distance Caregiver | PROMIS$^{R*}$ (SFv1.0-ED-Anxiety-SF8a) | X | X | r=.96 |
| Distance Caregiver | NCCN Distress Thermometer | X | X | r=.80 test-retest |
| Distance Caregiver | PROMIS$^{R}$ (SFv1.0-ED-Depression-SF8a) | X | X | r=.83 |
| Distance Caregiver Health Status | MOS-SF12** (GSRH-Item 1) | X | X | r=.79 test-retest |
| Patient Anxiety | PROMIS$^{R}$ (SFv1.0-ED-Anxiety-SF8a) | X | X | r=.96 |
| Patient Distress | NCCN Distress Thermometer | X | X | r=.80 test-retest |
| Patient Depression | PROMIS$^{R}$ (SFv1.0-ED-Depression-SF8a) | X | X | r=.83 |
| **Appraisal Variable** | | | | |
| Caregiver Burden | Zarit Burden Interview-12 | X | X | α=.88-.99 |
| **Covariates** | | **Enroll** | **4M** | |
| Distance Caregiver demographics (age, race, gender) | Enrollment form | X | | NA |
| **Mechanisms of Intervention Variables** | | | | |
| Self-Efficacy | Caregiving Self-Efficacy Scale | X | X | α=.82-.91 |
| Emotional Support | PROMIS$^{R}$(Item Bankv2.0-Emotional support) | X | X | α=.90-.99 |
| **Descriptive Variables** | | **Enroll** | **4M** | |
| Patient: Age, gender. | Enrollment form | X | | NA |
| Distance Caregiver: Socioeconomic & marital status, work productivity, computer competence/literacy. | Enrollment form | X | | |
| Recovery Experience Questionnaire: Psychological Detachment Subscale | Enrollment form | X | | |

*PROMIS$^{R}$: Patient Reported Outcomes Measurement Information System; **MOS-SF: Medical Outcomes Study Short-Form 12; GSRH: General self-rated health (Item 1).

### Description of Intervention

***Closer* Intervention**. The full intervention (*Closer*) is a tested intervention that uses videoconferencing technology (WebEx) for delivery and delivers the highest dose of the intervention. This arm of the intervention will deliver personalized information (aimed at enhancing self-efficacy) and emotional support via RN or SW coaching as well as the opportunity to talk with the oncologist and patient in "real time" during a minimum of four patient-oncologist office visits over a 4-month period (at least once/month). For patients who have more than one

oncologist-patient meeting/month, we will use the videoconference technology to allow the DCG to join as many of the oncologist-patient office visits as desired.

After study enrollment, DCGs will be contacted by the interventionist who will conduct baseline assessments. Afterwards, each DCG will schedule a videoconference coaching session with the interventionist (each lasting 20-30 minutes)[46,51] approximately once/month depending upon caregiver's need and availability.

**Table 2: Key Components of *Closer* Intervention**

| Videoconference Coaching & Office Visit Sessions | Information to Enhance Self-Efficacy as a DCG | Emotional Support |
|---|---|---|
| **Session 1** [At study enrollment] | • Interventionist performs baseline assessment of DCG using **PAL-23-25** Guidelines from NCCN[62] (understanding of course of disease, amount of information desired, values with respect to QoL). | • Interventionist performs baseline assessment of caregiver distress, practical, family, emotional concerns (**NCCN Assessment: DIS-A**) & caregiver spirituality (**Facit-Sp Assessment**) |
| **Sessions 2 – 4** [Focus & amount of services provided over time is determined by assessment and caregiver need and will vary over time] | • Based upon assessment results:<br>1. Develop a plan of care for DCG to provide tailored information and assistance that is needed.<br>2. Provide information (after HIPAA release provided by patient) regarding test results, changes in treatment plan, and care transition information.<br>3. Provide referrals for information or other community services as needed.<br>4. Assist the DCG with coordinating services or care for patient among multiple providers (if needed).<br>5. Discussions related to advance care planning.(See **NCCN Guide: PAL-27**)<br>6. Provide any information needed in terms of what to expect along the disease trajectory, additional information as patient's disease progresses, and resources that may be needed in the future. Assist DCG in obtaining information about resources.<br>7. Demonstrate online resources such as NCCN (www.nccn.org/patients/resources/life_with_cancer/distress.aspx)<br>8. Provide information & discuss self-care strategies that may be of help to DCG (e.g. diet, exercise, stress reduction). (**NCCN Guide: PAL-25**) | • Based upon assessment results:<br>1. Make referrals for spiritual and/or psychological counseling if indicated. (See **NCCN Guide: DIS 16, 20-28**) If no referrals available locally for DCG, arrange videoconference meetings with SCC social workers, spiritual counselors, chaplin etc.<br>2. Provide emotional support to DCG as needed.<br>3. Provide anticipatory grief support and end-of-life education as needed. (**NCCN: DIS-22**).<br>4. Identify resources for ongoing emotional and social support (online groups, local support groups, ways to utilize existing support systems). (e.g. www.nccn.org/)<br>5. Conduct *ongoing assessment* in key areas identified at baseline as areas of concern to monitor. Provide additional feedback, support, or guidance as needed for DCG to obtain various types of support as needed. (See **NCCN Guide: PAL-25**) |
| **Videoconference Office Visit Meetings with Oncologist, Patient, DCG (minimum 1/month x 4 months)** | 1. Interventionist will be linked via videoconference to the oncologist-patient-DCG meetings and will provide the DCG feedback at subsequent coaching sessions regarding ways to enhance the caregiver's role as patient advocate and ways to communicate with the healthcare team should these issues be of concern.<br>2. Interventionist will follow up in subsequent coaching sessions with DCG on clarifying any information | 1. Interventionist will be able to provide emotional support to DCG as needed as it relates to discussions that occurred in the oncologist-patient-DCG videoconference meetings.<br>2. Topics discussed at the videoconference meetings that have raised emotional issues with the DCG or that the |

| | | |
|---|---|---|
| | discussed at the meetings, providing more information as relevant to issues discussed with patient and oncologist at the prior office visit meeting | Interventionist feels might warrant follow-up discussion (e.g. EOL issues) can be further explored at subsequent coaching sessions. |

**Video-C Only**. This arm will involve the delivery of information solely via the use of videoconference technology during the patient-oncologist-DCG visit. As with the Closer intervention, the DCG will be able to participate in the patient-oncologist visit in "real time" during a minimum of four office visits over the 4-month study period (total dose ~5 hours). The procedure for these meetings will be the same as outlined for Closer (above) but will not involve having the interventionist involved.

**Web-Only**. This group will be provided access to a website that will provide the following major links: a) Caregiving Resources (links to "National Family Caregiver Association", etc), b) Resources for DCGs (links to "Caregiving from a Distance", etc), c) Cancer Information (links to National Cancer Institute, etc.). DCGs will be told that we will track usage of the website in order to assess which areas of the website are used most frequently. Any questions or concerns regarding use of the website can be sent online to the study's technical site, and the support staff will respond within 24 hours.

**Data Collection**

As seen in Table 1, data (patient and DCG) will be collected by the RA at student enrollment (after consent is obtained from patient and DCG) and 4 months later (after the end of the intervention period).

**Description of Study Process**

At study enrollment, patient demographic information will be obtained through a brief 5 minute interview conducted by the RA during an outpatient clinic visit. Instruments for patients will be interviewer-administered (10-20 minutes maximum). Interviews with patients will be conducted in person when possible at the time of the patient oncology visit, and the order of tool administration will be randomized. If this is not feasible, patients will be interviewed by phone. Instruments for DCGs will be conducted by the RAs via telephone at a time convenient for the DCGs. Interviews will be scheduled to take place at the time of enrollment, and then 4 after enrollment. The interviews will include administration of study tools (Table 1) in a random order. The RAs (blind to study arm assignment) will use established interview protocols from our prior research that have shown a minimum of subject burden. From prior work, these interviews are estimated to last 10-20 minutes[46].

**Adverse Reactions and Their Management**

As they occur, all unanticipated events and adverse events will immediately be reported to the principal investigator who will report them to the IRB according to the IRB protocol for both serious and non-serious adverse event and unanticipated problem reporting. These will be summarized in the twice annual reports Annual progress reports to the IRB and NINR/NIH will include a summary of the Data and Safety Monitoring Committee's activities and findings as well as any adverse events regarding human subjects. Program officials at NINR will be informed within 3 business days of unanticipated problems (e.g. data breach) or unexpected serious adverse events that may be related to the study protocol or IRB-approved revisions to the study protocol that indicate a change in risk for participants.

**Patients** will be interviewed in person during a clinic visit at the Seidman Cancer Center (SCC) at study enrollment and then 4 months after study enrollment. During these interviews, data will be obtained related to patient anxiety (PROMIS Anxiety-SF8a), distress (NCCN Distress Thermometer), and Patient Depression (PROMIS Depression-SF8a). If, during the interviews, the research assistant (RA) obtains data from the patient that indicates that their NCCN Distress Thermometer score is >5, the RA will refer the patient to the social worker at the SCC for further evaluation and referral as needed. The SCC has this procedure as part of their standard of practice and our research team will utilize this existing pattern of referral. For patients with anxiety scores >60[83] or depression scores $\geq$ 58.6[98] the RA (or a member of the research team) will contact the patient's primary oncologist and will collaborate to determine the appropriate referral (SCC psychiatrist or other mental health professional) on the day of the interview.

**Distance Caregivers** (DCGs) will also be interviewed at study enrollment and then 4 months after study enrollment. These interviews will take place on the phone with the caregivers being at varying distances from the SCC. If, during the interview, their scores on the anxiety, depression or distress measures (same as for patient) exceed the thresholds established (same as for patient), the RA will reflect to the DCG that their score(s) indicate distress (or anxiety, depression) and the RA will encourage them to contact their primary care physician or a local mental health professional. We will tell the DCG that if it would be helpful, we could try to identify some contact/facilities in their area and if the DCG is interested, the RA will contact the Project Director who will identify some appropriate contacts for the DCG. The RA will call the DCG and share that information within 48 hours of the interview. If the DCG depression score falls within the "severe" range (>70.3)[98] the RA will follow the protocol outlined but will make a follow-up call within 24 hours.

Serious adverse events that have any possible relation to the study be reported immediately to the IRB. Less significant events and events that have no relation to the study procedures will also be reported to the IRB in a timely fashion.

Anticipated Reactions

A risk involved in the study is that patients and/or caregivers might become tired during the interview or they may find talking about feelings to be upsetting. The interviews will be scheduled at the convenience of the patients and/or caregivers and they may stop the interviews at any time if they become tired or simply wish to stop talking. They can elect to not answer any question they find upsetting and can choose to stop participating completely in the study at any time. Participation or non –participation will have no effect on the type or quality of care that the patient receives. A research assistant who is not employed by the hospital will obtain all research data.

Reaction Management

This study involves an intervention—thus a Data and Safety Monitoring Committee (DSMC) will be formed for this study. This committee will be comprised of members outside the study team and the Chair of the committee will be responsible for submitting reports to NINR within 2 weeks of the meeting. The committee who are outside the study team will review data on the study as provided by the PI. Twice annually throughout the project, this committee will review data on this study regarding: (1) study safety including auditing selected cases for compliance with IRB requirements, (2) conformance with informed consent requirements, verification of source documents, and investigator compliance, (3) minimizing research-associated risk, and (4) protecting the confidentiality of participant data. In addition, it will review all causes of mortality and issues with participation. The rate of recruitment refusal (percent and reasons) and subject attrition (percent and reasons) will be tracked and reported at these reviews. Differential attrition form all study groups will be monitored. If concerns or problems are identified by the DSMC, they will be reported to the IRB and NINR/NIH via email by the Chair of the DSMC within 3 business days after they are identified.

## STATISTICAL ANALYSIS

This study is an evaluation of a randomized three group trial. The major aim is listed, followed by hypotheses and analyses.

Aim 1: Compare the direct effects of Closer, Video-C Only, and Web-Only on DCG outcomes (anxiety, distress, depression) over time, controlling for DCG demographic variables.

H1: DCGs in the Closer arm will show significantly greater reductions, over time, in DCG outcomes (anxiety, distress, and depression) and significantly greater improvement in health status than subjects in the Video-C Only and Web-Only groups.

**Primary endpoints**

The primary purpose of the study is to examine the effectiveness of two videoconference-based interventions (Closer, Video-C Only) when compared to a control group (Web-Only) upon psychological outcomes for DCGs of patients with advanced cancer.

**Power Analysis for Sample Size**

Using a repeated measures analysis with within-between interaction, 3 repeated measures, Type I error of 0.05, and a correlation among repeated measures of 0.5, 104 subjects in each of the three arms would have a power of .95 to detect a difference in the rate of improvement between the control and intervention groups, assuming an effect size of .15 or greater[78].

**Stratification factors and intervention allocation plan for randomized studies**

Randomized to one of the three study groups will involve using the minimization stratified randomization technique. Minimization is designed to balance pre-identified stratifying covariates across treatment assignments more effectively than simple randomization[79]. Stratification variables will be DCG age, gender and patient cancer stage. We will use the free online program MinimPy[97].

Allocation concealment: For DCGs assigned to the Closer or Video-C Only groups, the Project Director will email the link to download the free WebEx application that will be needed for all videoconference sessions. For subjects in the Web-Only group, the Project Director will email them to download an application that will allow the DCG to click on an icon and be directly connected to the DCG website used for this group. This procedure will blind RAs to group assignment.

**Analysis plan**

Preliminary steps will include examining the frequencies of items to identify the range of variability of each item (e.g., having a range of responses and not having any one category account for >90% of all possible category responses), determine coding inaccuracies, check for outliers, and missing data, and to verify sample size, and normality of data. Descriptive statistics will include examining means, standard deviations, and testing for normality using skewness and kurtosis.

Prior to testing the Aims, additional correlational analyses will be run as the first step to identifying potential relationships among the components identified in the study model. These correlations will be used to prescreen potential violations of the assumptions of correlation. Additionally, scatter plots between the two variables can help identify influential cases, as well as patterns of nonlinearity and non-constant error variance that may reduce a Pearson's *r*. To remedy the potential violation of the assumptions, influential cases can be removed and models retested to determine Pearson's *r* improvement. Data transformations can be used to remedy issues concerning non-linearity, non-constant error variance, and non-normal error variance. These prescreening techniques will help prevent potential problems that may occur when these relationships are tested in our main analyses.

Analyses. Two types of analyses are planned. The first will be a preliminary analysis using exploratory techniques to examine univariate characteristics and bivariate relationships among covariates and between covariates with outcomes. These exploratory techniques will be based upon proportions, medians and/or means. The change in each of the DCG outcomes (anxiety, distress, depression) with time over the 4-month study period will be examined by a repeated measures multivariate regression analysis with covariates entered into the model. A time variable will be created to represent the time of measurement (enrollment, 4 months); and the intervention variable will be expressed using the indicator variables (representing Closer, Video-C Only, Web-Only). The regression coefficient term representing the interaction between time and intervention will indicate whether there are differences in changes over time between the two intervention groups and the attention control group within the context of each of the outcome.

A preliminary step of the multivariate analysis will be to characterize and estimate the relationship of each outcome as measured in Aim1 with the intervention indicator variable, controlling for DCG demographics (age, race, gender). The intervention indicator variable will be the focal independent variable. For continuous variables that do not have a linear relationship with a specific outcome, appropriate transformations or categorization will be considered. For nominal and ordinal variables, the number and type of categories will be considered to obtain the optimum relationship, if any, with the outcome. After this initial step, any variable found to have a significance level less than 0.30 will be retained for further consideration in the model building process. A backward elimination process will be used to assess the relationship between each outcome and available covariates. Goodness of fit tests will be examined to determine the soundness of the models and the relative importance of the various factors present on each outcome. Estimates of regression coefficients and

their variance-covariance matrix will serve as the basis for testing hypotheses. Once a preliminary model containing significant main factors is obtained, interaction terms between the main factors and the intervention variable will be considered. For the major aim, the outcome variables are: DCG anxiety, distress, and depression. In addition, we will be able to classify differences in outcomes by groups using criteria of minimally important differences for PROMIS scales for patient with advanced stage cancer[93]. This will facilitate our interpretation—not only of statistically significant findings but of clinically significant findings as well.

**Handling missing data in the analysis.**

Missing data is a problematic issue when dealing with longitudinal data sets. Some individuals may quit the study or not participate at a specific data collection point. AMOS will allow for analysis of incomplete data using Full Information Maximum Likelihood (FIML) estimation. Issues of nonrandom missing data are of particular interest in longitudinal data because dropout rates are not a random process; to the extent this is predicted by variables included in the data analysis, FIML will provide unbiased parametric estimates.

## REFERENCES


1. Cagle JG, Munn JC. Long-distance caregiving: A systematic review of the literature. *Journal of Gerontological Social Work 2012*;55:682-707.
2. Wagner D. Caring across the miles: Findings of a survey of long distance caregivers. *Final report for the national council on the aging*. Washington, DC; 1997.
3. MetLife. Miles away: The Metlife study of long-distance caregiving. New York: Mature Market Institute; 2004.
4. Baldock CV. Migrants and their parents: Caregiving from a distance. *Journal of Family Issues 2000*;21:205-224.
5. Harringan MP, Koerin BB. Long distance caregiving: Personal realities and practice implications. *Reflections 2007*;13:5-16.
6. Heath A. Creating partnerships with long distance caregivers. *Caring 1995*;14:48-49.
7. Parker MW, Call VR, Dunkle R, Vaitkus M. "Out of sight" but not "out of mind": Parent care contact and worry among military officers who live long distances from parents. *Military Psychology 2002*;14:257-277.
8. Collins WL, Holt TA, Moore SE, Bledsoe LK. Long-distance caregiving: A case study of an African-American family. *American Journal of Alzheimer's Disease and Other Dementias 2003*;18:309-316.
9. National Alliance for Caregiving & American Association of Retired Persons. *Caregiving in the US 2009*. Retrieved from www.caregiving.org/data/Caregiving_in_the_US_2009_full_report.pdf.
10. McMillan SC. Interventions to facilitate family caregiving at end of life. *J Pall Med 2005*;8:S132-39.
11. Given B, Wyatt G, Given C, et al. Burden and depression among caregivers of patients with cancer at the end of life. *Oncol Nurs Forum 2004*;31:1105-17.
12. Robinson-Whelan S, Tada Y, MacCallum R, McGuide L, Kiecolt-Glaser JK. Longterm caregiving: what happens when it ends? *J Abnorm Psychol 2001*;110:573-584.
13. DuBenske LL, et al. CHESS improves cancer caregivers' burden and mood: results of an eHealth RCT. *Health Psychology 2014*;33:1261-1272.
14. Badr H, Carmack CL, Diefenbach MA. Psychosocial interventions for patients and caregivers in the age of new communication technologies: opportunities and challenges in cancer care. *J Health Commun 2015*;Jan28:1-15.
15. Williams A, Bakitas M. Cancer family caregivers: a new direction for interventions. *J Pall Med 2012*; 15:775-783.
16. Northouse L et al. A tailored web-based psychoeducational intervention for cancer patients and their family caregivers. *Cancer Nursing 2014*;37:321-330.
17. Northouse LL, Mood D, Templin T, Mellon S, George T. Couples' patterns of adjustment to colon cancer. *Soc Sci Med 2000*; 50(2): 271-84.
18. Hodges LJ, Humphris GM, Macfarlane G. A meta-analytic investigation of the relationship between the psychological distress of cancer patients and their carers. *Soc Sci Med 2005*;60:1-12.
19. Northouse LL, Katapodi MC, Schafenacker AM, Weiss D. The impact of caregiving on the psychological well-being of family caregivers and cancer patients. *Seminars in Oncology Nursing 2012*;28:236-245.
20. Egan J. Long-distance caregivers embrace technology. Technorati, Blog Post: January 9, 2011. National Council on Aging (2006, March). *Nearly 7 million long-distance caregivers make work and personal sacrifices.* Retrieved from: http://www.ncoa.org/content.cfm?sectionID=105&detail=49.
21. Family Caregiver Alliance Fact Sheet. Administration on Aging (AoA), 2012. http://www.caregiver.org/caregiver/jsp/. Accessed: October 7, 2013.
22. Gaugler JE, Linder J, Given CW, Kataria R, Tucker G, Regine WF. Family cancer caregiving and negative outcomes: the direct and mediational effects of psychosocial resources. *J Fam Nurs 2009*;15:417-44.
23. Given B, Sherwood PR. Family care for the older person with cancer. *Semin Oncol Nurs 2006*;22:43-50.
24. Goldstein NE, Concato J, Fried TR, Kasl SV, Johnson-Hurzeler R, Bradley EH. Factors associated with caregiver burden among caregivers of terminally ill patients with cancer. *J Palliat Care 2004*;20:38-43.
25. Haley WE, LaMonde LA, Han B, Burton AM, Schonwetter R. Predictors of depression and life satisfaction among spousal caregivers in hospice: application of a stress process model. *J Palliat Med 2003*;6:215-24.
26. Klemm P, Wheeler E. Cancer caregivers online: hope, emotional roller coaster, and physical/emotional/psychological responses. *Comput Inform Nurs 2005*;23:38-45.
27. Braun M, Mikulincer M, Rydall A, Walsh A, Rodin G. Hidden morbidity in cancer: spouse caregivers. *J Clin Oncology 2007*;25(30):4829-4834.
28. Carey PJ, Oberst MT, McCubbin MA, Hughes SH. Appraisal and caregiving burden in family members caring for patients receiving chemotherapy. *Oncol Nurs Forum 1991*;18:1341-8.
29. Sherwood P, Given C, Given B, von Eye A. Caregiver burden and depressive symptoms: Analysis of common outcomes in caregivers of elderly patients. *J Aging & Health 2005*;17:125-147. Doi: 10.1177/0890264304274179.
30. Stetz KM. Caregiving demands during advanced cancer: the spouse's needs. *Cancer Nurs 1987*;10: 260-268.

31. Grov EK, Dahl AA, Moum T, Fossa SD. Anxiety, depression, and quality of life in caregivers of patients with cancer in late palliative phase. *Ann Oncol 2005*;16:1185-91.
32. Hagedoorn M, Sanderman R, Bolks HN, et al. Distress in couples coping with cancer: A meta-analysis and critical review of role and gender effects. *Psychol Bull 2008*;134:1-30.
33. NINR National Institute of Nursing Research. 2001. Research in informal caregiving: State of the science workgroup meeting. URL: http://www.ninr.nih.gov/NR/rdonlyres/5B7C2DB8-9C63-4F26-A26B-13DIF947FFCB/4868/WorkingGrouponInformalCaregiving.pdf
34. Fiegl C. IOM report brief. http://www.ama-assn.org/amednews/m/2011/04/25/gl10425htm; accessed April 25, 2014.
35. Mazanec P. Distance caregiving a parent with cancer. *Seminars in Oncology Nursing 2012*;28:271-278.
36. AARP Public Policy Institute Valuing the Invaluable: 201 Update. The Economic Value of Family Caregiving. http://www.aarp.org/relationships/caregiving/info-07-2011/valuing-the-invaluable.html.
37. Bevan JL, Sparks L. Communication in the context of long-distance family caregiving: An integrated review and practical applications. *Patient Education & Counseling 2011*;85:26-30.
38. van Ryn M, Sanders S, Kahn K, van Houtven C, Griffin JM, Martin M, Atienza AA, Phelan S, Finstad D, Rowland J. Objective burden, resources, and other stressors among informal cancer caregivers: a hidden quality issue? *Psychooncology. 2011*;20:44-52. doi: 10.1002/pon.1703.
39. Yates ME, Tennstedt S, Chang BH. Contributors to and mediators of psychological well-being for informal caregivers. *J Gerontol B Psychol Sci Soc Sci 1999*;54:P12-22.
40. Mazanec P, Daly BJ, Ferrell BR, Prince-Paul MJ. Lack of communication and control: experiences of distance caregivers of parents with advanced cancer. *ONF 2011*;38(3):307-313.DOI:10.1188/11.ONF.307-313.
41. Joseph AE, Hallman BC. Over the hill and far away: distance as a barrier to the provision of assistance to elderly relatives. *Soc Sci Med 1998*;46:631-9.
42. Benefield LE, Beck C. Reducing the distance in distance-caregiving by technology innovation. *Clin Interv Aging 2007*;2:267-72.
43. Seigel R, Naishadham D, Jemal A. Cancer Statistics 2012. *CA: A Cancer Journal for Clinicians 2012*;62(1):10-29.
44. Bevans M & Sternberg E. Caregiving burden, stress, and health effects among family caregivers of adult cancer patients. *JAMA 2012*;307(4):398-403.
45. Ferrell BR, Grant N, Borneman T, Juarez G, & terVeer A. Family caregiving in pain management. *J Palliative Med 1999*;2:185-195.
46. Douglas SL, Daly BJ. Effect of an integrated cancer support team on caregiver satisfaction with end-of-life care. *ONF 2014*;41:E248-255.
47. Northouse, L.L., Mood, D.W., Montie, J.E., Sandler, H.M., Forman, J.D., Hussain, M., Pienta, K.J., Smith, D.C., Sanda, M.G., Kershaw, T. Living with prostate cancer: Patients' and spouses' psychosocial status and quality of life. *Journal of Clinical Oncology 2007*;25:4171-4177.
48. Barg F, et al. A description of a psychoeducational intervention for family caregivers of cancer patients. *Journal of Family Nursing 1998*;4:394-413.
49. Northouse L, Williams AL, Given B, McCorkle R. Psychosocial care for family caregivers of patients with cancer. *J Clin Oncol 2012*;30:1227-34.
50. Harding R, List S, Epiphaniou E, Jones H. How can informal caregivers in cancer and palliative care be supported? An updated systematic literature review of interventions and their effectiveness. *Palliat Med 2012*;26:7-22.
51. Daly BJ, Douglas SL, Gunzler D, Lipson AR. Clinical trial of a supportive care team for patients with advanced cancer. *J Pain Symptom Manage. 2013* Mar 22.
52. Douglas SL, Daly BJ, Kelley CG, O'Toole E, Montenegro H. Impact of a disease management program upon caregivers of chronically critically ill patients. *Chest 2005*;128(6):3925-36.
53. Northouse LL, Katapodi MC, Song L, Zhang L, Mood DW. Interventions with family caregivers of cancer patients: meta-analysis of randomized trials. *CA Cancer J Clin 2010*;60:317-39.
54. NCCN Treatment Guidelines, 2014. Accessed at: http://www.nccn.org/professionals/physician_gls/f_guidelines.asp
55. Candy B, Jones L, Drake R, Leurent B, King M. Interventions for supporting informal caregivers of patients in the terminal phase of a disease. *The Cochrane Library 2011*; 6:1-63.
56. Brown RS, Peikes D, Peterson G, Schore J, Razafindrakoto CM. Six features of Medicare coordinated care demonstration programs that cut hospital admissions of high-risk patients. *Health Aff 2012*; 31(6):1156-66.
57. Gentles SJ, Lokker C, McKibbon KA. Health information technology to facilitate communication involving health care providers, caregivers, and pediatric patients: a scoping review. *J Med Internet Res 2010*;

12(2):E22-46.
58. Dyer EA, Kansagara D, McInnes DK, Freeman M, Woods S. Mobile applications and internet-based approaches for supporting non-professional caregivers: A systematic review. VA-ESP Project #05-225; 2012.
59. Savolainen L, Hanson E, Magnusson L, Gustavsson T. An internet-based videoconferencing system for supporting frail elderly people and their carers. *J Telemed Telecare 2008*;14(2):79-82. doi:10.1258/jtt.2007.070601.
60. e-Connected Family Caregiver: Bringing Caregiving into the 21st Century. January 2011. Funded by: January 2011. Funded by UnitedHealthcare and National Alliance for Caregiving. http://www.caregiving.org/data/FINAL_eConnected_Family_Caregiver_Study_Jan%202011.pdf
61. Beauchamp N, Irvine AB, Seeley J, Johnson B. Worksite-based internet multimedia program for family caregivers of persons with dementia. *Gerontologist 2005*;45(6):793-801.
62. Dew MA, Goycoolea JM, Harris RC, et al. An internet-based intervention to improve psychosocial outcomes in heart transplant recipients and family caregivers: development and evaluation. *J Heart Lung Transplant 2004*;23(6):745-758.
63. Brennan PF, Moore SM, Smyth KA. The effects of a special computer network on caregivers of persons with Alzheimer's disease. *Nursing Research 1995*;44(3):166-172.
64. Glynn SM, Randolph ET, Garrick T. A proof of concept trial of an online psychoeducational program for relatives of both veterans and civilians living with schizophrenia. *Psychiatr Rehabil J 2010*;33(4):278-287.
65. Wade SL, Walz NC, Carey JC, Williams KM. Preliminary efficacy of a Web-based family problem-solving treatment program for adolescents with traumatic brain injury. *J Head Trauma Rehabil 2008*;23(6):369-377.
66. Wade SL, Walz NC, Carey JC, Williams KM. Brief report: Description of feasibility and satisfaction findings from an innovative online family problem-solving intervention for adolescents following traumatic brain injury. *J Pediatr Psychol 2009*;34(5):517-522.
67. Demiris G, Oliver DR, Hensel B, Dickey G, Rantz M, Skubic M. Use of videophones for distant caregiving: an enriching experience for families and residents in long-term care. *J Gerontol Nurs 2008*;34:50-5.
68. Oliver DP, Albright DL, Kruse RL, Wittenberg-Lyles E, Washington K, Demiris G. Caregiver Evaluation of the ACTIVE Intervention: "It was Like We Were Sitting at the Table With Everyone". *Am J Hosp Palliat Care 2013* May 26. [Epub ahead of print]
69. Rogers WA, Mynatt ED. How can technology contribute to the quality of life of older adults? In, Mitchell ME (Ed), 2003, *The technology of humanity: Can technology contribute to the quality of life*? Chicago, IL: Illinois Institute of Technology.
70. Dishman E, Matthews J, Dunbar-Jacob J. Everyday health: Technology for adaptive aging. In: Pew R, Van Hemel S, editors. Technology for adaptive aging. Washington, DC: *National Academies Pr* 2004; 179–208.
71. Kamen C et al. The association between partner support and psychological distress among prostate cancer survivors in a nationwide study. *J Cancer Surviv 2015*; Epub. DOI 10.1007/s11764-015-0425-3.
72. Siston AK et al. Psychosocial adjustment of patients and caregivers prior to allogenic bone marrow transplantation. *Bone Marrow Transplantation 2001*;27:1181-1188.
73. Mazanec P. Distance caregivers of parents with advanced cancer. (Doctoral dissertation). [Dissertation Abstracts International: AAT 3383485]. Cleveland: Case Western Reserve University; 2009.
74. Daly BJ, Douglas SL, O'Toole E, Gordon NH, Hejal R, Peerless J, Rowbottom J, Garland A, Lilly C, Wiencek C, Hickman R. Effectiveness trial of an intensive communication structure for families of long-stay ICU patients. *Chest. 2010;*138(6):1340-8. doi: 10.1378/chest.10-0292. Epub 2010 Jun 24.
75. Douglas SL, Daly BJ, Gordon N, Brennan PF. Survival and quality of life: short-term versus long-term ventilator patients. *Crit Care Med 2002*;30:2655-62.
76. Given BA, Given CW, Kozachik S. Family support in advanced cancer. *CA Cancer J Clin 2001*;51:213-31.
77. Kodow-Nyameazea Y, Nguyen PV. Immigrants and long-distance elder care: An exploratory study. *Ageing International 2008*;32:279-297.
78. Buchner, A., Erdfelder, E., & Faul, F. How to Use G*Power (1997). http://www.psycho.uni-duesseldorf.de/aap/projects/gpower/how_to_use_gpower.html. Accessed February, 2015.
79. Pocock SJ, Simon R. Sequential treatment assignment with balancing for prognostic factors in the controlled clinical trial. *Biometrics 1975*; 31:102-115.
80. Bland J. Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet 1988*;8:307-10.
81. Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics 1977*;33:159-74.
82. Bellg AJ, Borrelli B, Resnick B, et al. Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychol 2004*;23:443-51.

83. Cella D, Riley W, Stone A, Rothrock N, Reeve B, Yount S, Amtmann D, Bode R, Buysse DJ, Choi SW, Cook KF, DeVellis R, DeWalt D, Fries JF, Gershon R, Hahn E, Pilkonis P, Revicki D, Rose M, Weinfurt K, Hays RD on behalf of the PROMIS Cooperative Group. (2010). Initial item banks and first wave testing of the Patient–Reported Outcomes Measurement Information System (PROMIS) network: 2005– 2008. Journal of Clinical Epidemiology, 63(11), 1179-94.
84. Recognition and alleviation of distress in laboratory animals. National Research Council. National Acadamies Press: Washington, DC. 2008. Accessed at: http://www.nap.edu/catalog.php?record_id=11931
85. Ware JE, Kosinski M, and Keller SD. A 12-Item Short-Form Health Survey: Construction of scales and preliminary tests of reliability and validity. Medical Care, 1996;34(3):220-233. Tool accessed at: http://www.sf-36.org/tools/sf12.shtml
86. DeSalvo KB, Fisher WP, Tran K, Bloser N, Merrill W, Peabody J. Assessing measurement properties of two single-item general health measures. *Quality of Life Research 2006*;15:191-201.
87. Zarit S, Femia E. Behavioral and psychosocial interventions for family caregivers. *Am J Nurs. 2008*;108(9 Suppl):47-53.
88. O'Rourke N, Tuokko HA. Psychometric properties of an abridged version of the Zarit Burden Interview within a representative Canadian caregiver sample. *The Gerontologist 2003;43*(1):121–127.
89. Wood RE, Bandura A. Social cognitive theory of organizational management. *Academy of Management Review 1989*;14(3):361-384.
90. Ann M Steffen; Christine McKibbin; Antonette M Zeiss; Dolores Gallagher-Thompson, Bandura A. The revised scale for caregiving self-efficacy: Reliability and validity studies. *The Journals of Gerontology 2002*;57B:74-86.
91. Pearlin L, Mullan JT, Semple S, Skaff M. Caregiving and the stress process: an overview of concepts and their measures. *The Gerontologist 1990*;30: 583-594.
92. SAS/STAT® User's Guide (2014). SAS Institute Inc., Cary, NC, USA.
93. Yost KJ, Eton DT, Garcia SF, Cella D. Minimally important differences were estimated for six PROMIS-Reported Outcomes Measurement Information System-Cancer scales in advanced-stage cancer patients. *J Clinical Epidemiology 2011*; 64(5), 507-16.
94. Patient-Reported Outcomes Measurement Information System-Emotional Support Manual. Accessed at: http://www.assessmentcenter.net/documents/PROMIS%20Emotional%20Support%20Scoring%20Manual.pdf. 2.10.15.
95. Jansen J1, Butow PN, van Weert JC, van Dulmen S, Devine RJ, Heeren TJ, Bensing JM, Tattersall MH. Does age really matter? Recall of information presented to newly referred patients with cancer. *J Clin Oncol 2008* Nov 20;26(33):5450-7. doi: 10.1200/JCO.2007.15.2322. Epub 2008 Oct 20.
96. Collins FS, Tabak LA. NIH plans to enhance reproducibility. *Nature 2014*;505:612-613.
97. MinumPy. Accessed at: http://sourceforge.net/projects/minimpy/. 6.15.15.
98. Amtmann D, Kim J, Chung H, Barner A, Askew, R, Wu S, Cook K, Johnson K. Comparing CESD-10, PHQ-9, and PROMIS depression instruments in individuals with multiple sclerosis. *Rehabilitation Psychology 2014*; 59(2), 220-229.