Caregiver Self-Management Needs Through Skill-Building

ClinicalTrials.gov Identifier: NCT03635151

NIH NINR: R21NR016992

Document Date: 12/04/19

Study Protocol and Statistical Analysis Plan

Study Protocol

Study Description

Brief Summary: Caring for a family member after a stroke can be very difficult and worsen the physical and mental health of untrained caregivers. The Telephone Assessment and Skill-Building Kit (TASK III) intervention is a unique, comprehensive caregiver intervention program that enables caregivers to develop the necessary skills to manage care for the survivor, while also taking care of themselves. The long-term goal of this study is to offer training and support for family caregivers through an efficacious, cost-effective program.

Detailed Description: Stroke is a leading cause of serious, long-term disability, and has a very sudden onset; families are often thrust into providing care without any training from health care providers. Studies have shown that caregiving without training can be detrimental to caregiver's physical and mental health, which can impede survivor rehabilitation and lead to institutionalization and higher societal costs. Unlike existing stroke caregiver interventions that require costly face to face interactions, and that focus primarily on the survivor's care, the Telephone Assessment and Skill-Building Kit (TASK II) is delivered completely by telephone, and empowers caregivers to address both their own and the survivor's needs using innovative skill-building strategies. Aligned with current patient and caregiver guidelines, TASK II has demonstrated evidence of content validity, treatment fidelity, caregiver satisfaction, and efficacy for reducing depressive symptoms; however, future development of TASK II requires a stronger focus on self-management strategies to improve caregiver health, and enhanced use of other telehealth modes of delivery prior to implementation into ongoing stroke systems of care. The purpose of this study is to optimize the TASK III intervention through the innovative leveraging of technologies and theoretically-based self-management strategies to improve caregiver health. Specific Aim 1 consists of focus groups and individual interviews with 40 experts (10 interdisciplinary researchers, 10 technology experts, 10 clinicians and clinical leaders, and 10 stroke family caregivers) to provide preferences about essential areas of new self-management content, proposed technologies (e.g., iBook, eBook, interactive website, FaceTime, Zoom), and future implementation strategies to inform a novel TASK III prototype. Specific Aim 2 will determine feasibility of the TASK III intervention with a pilot study of 74 stroke caregivers randomized to TASK III or an Information, Support, and Referral (ISR) group in preparation for a larger randomized controlled clinical trial. Recruitment, retention, treatment fidelity, satisfaction, and technology ratings will be obtained for both TASK III and ISR groups who will receive 8 weekly sessions with a booster session 4 weeks later. Outcome measures will be explored at baseline, 8 weeks (end of intervention), and 12 weeks (after booster). If TASK III is shown to be efficacious in a future randomized controlled clinical trial, our next goal will be to translate TASK III into ongoing stroke systems of care; and, someday to adapt it for use among caregivers with other debilitating/chronic conditions providing a strong public health impact.

Study Design

Study Type: Interventional (Clinical Trial)
Actual Enrollment: 74 Participants
Allocation – Randomized
Intervention Model: Parallel Assignment
Masking – Single (Outcomes Assessor)
Primary Purpose – Supportive Care
Enrollment – 74 stroke family caregivers

Arms and Interventions

Arm	Intervention/Treatment
Telephone Assessment and Skill-Building Kit (TASK III) Group	The TASK III group will receive a TASK III Resource Guide that we developed and 8 weekly calls from a nurse. The nurse will call again a month later. The TASK III nurse will help you assess your needs and concerns, build your skills as a caregiver, and refer you to community resources.
Information Support and Referral (ISR) Group	The ISR group will receive an American Heart Association brochure and 8 weekly calls from a nurse. The nurse will call again a month later. The ISR nurse will provide information, support, and referral to community resources.

Randomization

Caregivers will be randomized 1:1 to the TASK III or ISR group using a permuted block randomization stratified by type of relationship (spouse vs adult child/other) and baseline depressive symptoms (non-depressed vs depressed PHQ-9 ≥ 5) as in the TASK II trial. Random permutations within each block within each stratum will be generated using a random number generator (SAS Proc Plan). Data collectors will be blinded to group assignment to mitigate potential bias. The randomization scheme will be accessed by the project manager by logging into the REDCap website and entering type of relationship and baseline depressive symptoms for group assignment.

Outcome Measures

Primary Outcome Measure	**Description**
Caregiver satisfaction ratings for both TASK III and ISR programs measured by the Caregiver Satisfaction Scale (CSS). [Time Frame: 12 weeks]	Caregiver satisfaction ratings (usability, ease of use, acceptability) for both TASK III and ISR programs are measured using the Caregiver Satisfaction Scale (CSS). The CSS consists of 9 items rated on a response scale ranging from 1 = Strongly Disagree to 5 = Strongly Agree. Items are summed for a total score with a possible range of 9 to 45. Higher scores indicate greater satisfaction.
Secondary Outcome Measures	**Descriptions**
Depressive symptoms measured by the Patient Health Questionnaire Depression Scale (PHQ-9). [Time Frame: Baseline to 8 and 12 weeks]	Caregiver depressive symptoms are measured by the Patient Health Questionnaire Depression Scale (PHQ-9) consisting of 9 items rated on a response scale ranging from 0 = Not at all to 3 = Nearly every day. Items are summed for a total score with a possible range of 0 to 27. Higher scores indicate higher depressive symptoms.
Life Changes (i.e., changes in social functioning, subjective well-being, and physical health as a result of providing care) measured by the Bakas Caregiving Outcomes Scale (BCOS). [Time Frame: Baseline to 8 and 12 weeks]	Caregiver life changes (i.e., changes in social functioning, subjective well-being, and physical health as a result of providing care) are measured by the Bakas Caregiving Outcomes Scale (BCOS). The BCOS consists of 15 items rated on a response scale ranging from -3 (changed for the worst) to +3 (Changed for the best). The items are recoded (-3 = 1) (-2 = 2) (-1 = 3) (0 = 4) (1 = 5) (2 = 6) (3 = 7) so that positive numbers can be obtained for analysis. The recoded responses to the 15 items are summed for a total score with a possible range of 15-105. Higher scores indicate more positive life changes as a result of providing care.
Unhealthy Days measured by the number of unhealthy days in the past 30 days. [Time Frame: Baseline to 8 and 12 weeks]	Caregiver unhealthy days are measured using the Unhealthy Days (UD) measure consisting of two items: How many days during the past 30 days was your physical health not good?; How many days during the past 30 days was your mental health not good? These items range from 0 = no unhealthy days to 30 = 30 unhealthy days. The two items are summed for a total score, with a cap of 30 days. Higher scores indicate more unhealthy days in the past 30 days.

Inclusion Criteria	**Exclusion Criteria**
• 21 years or older • Primary caregiver (unpaid family member or significant other providing care for a stroke survivor) • Must be providing care after discharge to the home setting (for Specific Aim 2) • Fluent in the English language • Access to telephone or computer • No difficulties hearing or talking by telephone or computer • (Specific Aim 1) Willing to participate in an online or telephone focus group or an online or telephone individual interview. Some interviews or focus groups may be offered face to face. • (Specific Aim 2) Willing to participate in 9 calls from a nurse and 3 data collection interviews.	• Survivor had not had a stroke • Survivor did not need help from the caregiver • Survivor going to reside in a nursing home or long-term care facility • Caregiver scores <16 on the Oberst Caregiving Burden Scale Task Difficulty Subscale (for Specific Aim 2) • Caregiver scores <4 on a 6-item cognitive impairment screener • Caregiver or survivor is: • Prisoner or on house arrest • Pregnant • Terminal illness • History of Alzheimer's, dementia, or severe mental illness • History of hospitalization for alcohol or drug abuse

Statistical Analysis Plan

Statistical Analysis

Data Management. All study data and tracking will be entered into an electronic data system, REDCap (www.REDCap.org), a secure research electronic data management system with validated data entry, audit trails for tracking data manipulation and export procedures. It is HIPAA complaint satisfying all local, state, and federal regulation for the capture and storage of private health information for research purposes.

Sample Size. Sample size is based on satisfaction measures. For evaluating caregiver satisfaction and technology ratings, a sample size of 30 in each group will achieve 80% power to detect a mean difference in satisfaction of 0.44 between groups, TASK III of 4.4 and ISR of 3.96, with an estimated standard deviation (SD) of 0.60 in both groups using a two-sample t-test with a significance level of 0.05. This detectable difference is lower than satisfaction scale differences observed in the original TASK study with a total satisfaction scale score mean (SD) of 4.41 (0.57) in the TASK group and 3.94 (0.60) in the ISR control group. For evaluating outcome trends, group sample sizes of 30 and 30 will produce two-sided 95% CI with a distance from the difference in means of ± 0.52 standard deviation of the outcome.

Missing Data. We will make every effort to avoid missing data. We will assess the reasons, patterns, and distribution of missing data, allowing us to assess whether an assumption of missing completely at random is reasonable or whether missingness is conditional on another variable in the dataset (i.e. missing at random). Descriptive statistics will compare characteristics of patients with and without missing data. If missing at random, we will incorporate variables that are identified to be related to the missingness in the analysis using multiple imputation, if the amount of missing data affects the study results.

Recruitment, attrition rates, and fidelity ratings of data collection and intervention procedures. Using procedures similar to the TASK II study, we will monitor screening and recruitment rates, attrition rates, and fidelity ratings of all data collection and intervention procedures. We will compute the numbers screened and enrolled per month, proportion of screened eligible who enroll, intervention assignment specific retention rates at each follow-up visit, and proportion of outcome measures completed. ***Fidelity ratings:*** We will utilize an itemized checklist for monitoring adherence to the unique components of the TASK III study. Adherence will be scored with dichotomous responses for presence or absence of each item. Frequencies and percentages will be calculated for each item by group. Intervention dosage will be calculated for nurse call duration (minutes) and time caregivers spend reading study materials (minutes) for each group. Descriptive statistics for intervention dosage will be computed by group and between group mean differences will be evaluated using two-sample t-tests or non-parametric alternative, if normality assumption is violated.

Caregiver satisfaction and evaluation of technology ratings. Satisfaction ratings from the Caregiver Satisfaction Scale (CSS) (usability, ease of use, acceptability) and evaluation of technology ratings will be summarized at the item and scale levels by intervention group using descriptive statistics, including mean and 95% confidence interval (CI). Cronbach alpha will be calculated as a measure of internal consistency. CSS scores, total and subscales, will be compared between groups using two-sample t-tests or nonparametric alternative, if the normality assumption appears violated. We will explore sex differences by careful description of subgroup effects.

Outcome measures by TASK III and ISR groups. Descriptive statistics and graphics will be used to evaluate outcomes from baseline to 8 and 12 weeks by intervention group. By intervention group, stick plots will be used to show individual caregiver outcomes at baseline, 8 and 12 weeks and we will compute a mean and 95% CI for the change from baseline to 8 and 12 weeks for each outcome. In computing the 95% CI, we will specify an appropriate distribution, if a Gaussian-based approximation for the interval estimation does not appear to be valid. At each follow-up time-point, 8 and 12 weeks, we will compute mean differences and 95% CI between groups to evaluate trends in outcomes. We will not test for statistically significant differences between groups in outcome measures or estimate effect sizes in this pilot study, because the primary purpose is to determine feasibility of our procedures to inform the planning and design of a larger trial. Estimating effect

sizes using small pilot samples has been scrutinized in the literature, as such, our effect size estimates for a larger efficacy trial will be based on clinically meaningful treatment effect. We will explore sex differences in intervention effect by careful description of subgroup effects.

Anticipated Results and Interpretation: This study will enable us to 1) provide the necessary preliminary data, recruitment procedures, and training protocols to successfully conduct a large efficacy trial of the TASK III; 2) further refine the TASK III intervention via program evaluation data (satisfaction, technology ratings); and 3) demonstrate our capacity to measure outcomes and estimate changes from baseline.