

Telephone Assessment and Skill-Building Intervention for Informal Caregivers

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1.0 Background

Stroke and traumatic brain injury (TBI) are leading causes of long-term disability among Veterans and result in the need for care from informal caregivers after discharge to the home setting. There are very few evidence-based, easy-to-deliver follow-up programs after hospitalization to train caregivers in providing care and to support the relationship between the Veteran and his (her) caregiver. The ANSWERS-VA intervention aims to provide the Veteran and caregiver dyad with a set of practical skills that each can use in coping with and managing symptoms of brain injury.

2.0 Rationale and Specific Aims

Project Objectives. The objectives of this study are to conduct a randomized controlled trial (RCT) to evaluate (a) the efficacy of the “Acquiring New Skills While Enhancing Remaining Strengths for Veterans (ANSWERS-VA)” dyadic intervention with Veterans who have sustained a stroke and/or traumatic brain injury (TBI) and their informal caregivers, and (b) estimate effect sizes for the ANSWERS-VA intervention. The ANSWERS-VA intervention will be compared with an educational intervention that will serve as an attention control group.

Specific Aim 1: To tailor the implementation of the ANSWERS-VA intervention to dyads (n=10) consisting of Veterans with stroke and/or TBI diagnoses and their informal caregivers and modify the implementation processes for the RCT.

Specific Aim 2: To test the short-term, intermediate, and sustained efficacy of the intervention (baseline, 8, 12, 24 weeks, and 1 year) for improving the caregivers’ quality of life, task difficulty, threat appraisal, self-efficacy for caregiving, and optimism.

Specific Aim 3: To complete a cost effectiveness analysis of the intervention in comparison to the attention control.

Exploratory Aim 1: To estimate the effect sizes for the dyad outcomes of depressive symptoms, social participation, and quality of the dyadic relationship.

3.0 Inclusion/Exclusion Criteria

For this study, an eligible, informal caregiver is defined as a family member or significant other who is providing care for a Veteran stroke or a TBI survivor in the home setting. Table 2 provides inclusion and exclusion criteria for Veterans and caregivers. Eligibility will be assessed by Veteran and/or caregiver self-report during a screening telephone interview; however, study personnel may do a basic initial screen by accessing electronic medical records in the Computerized Patient Record System (CPRS) when patient lists are obtained.

Table 2. Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
<p>Informal Caregivers Primary caregiver (family member or significant other) of a Veteran stroke or TBI survivor Plans to be providing care for 1 year or longer Task difficulty (OCBS task difficulty score) of 16 or greater</p>	<p>Informal Caregivers Caregiver does not consider him or herself a caregiver (i.e., believes that the survivor is not impaired or is the same as before the stroke or TBI) Serious medical illness limiting ability to participate</p>

<p>Veterans Must have had a hemorrhagic or ischemic stroke and/or a TBI Stroke occurred within the last 3 years TBI occurred post-9/11/2001</p>	<p>Veterans Resides in a nursing home or long-term care facility Diagnosis of Transient Ischemic Attack (rather than a hemorrhagic or ischemic stroke) Stroke occurred more than 3 years ago TBI prior to 9/11/2001</p>
<p>Both Access to a telephone Willingness to participate in 9 intervention or control calls and 5 data collection interviews at designated study time points Mini-Mental State Examination (MMSE) Score of 4 or above (see Appendix 8.4 in Section 11.0 for MMSE).</p>	<p>Both Unable to contact within 10 calls Age < 18 years Either caregiver or Veteran denies that survivor has had a stroke or a TBI Either the caregiver or Veteran does not want to participate Not fluent in the English language Difficulty hearing or talking by telephone Has a terminal illness (e.g., cancer, end of life condition with decreased life expectancy, renal failure requiring dialysis) History of hospitalization for alcohol or drug abuse History of severe mental illness (e.g., Alzheimer's, dementia, suicidal tendencies, severe untreated depression or manic depressive disorder, or schizophrenia) Prisoner or on house arrest</p>

4.0 Procedures

Recruitment-Participant Identification and Screening: The PI, graduate student interns, and the project manager will be involved in participant identification and screening. We will use several methods to identify Veterans with stroke (hemorrhagic or acute ischemic) and TBI and their caregivers:

- 1) To identify Veterans with recent admissions, we will run lists of patients who were admitted and discharged with stroke or TBI diagnoses. A waiver of consent and HIPAA will be obtained and the patients will be screened for inclusion criteria. After obtaining approval from the provider, we will approach the patient and his/her caregiver (in-person, phone, or mail) about participation in the study;
- 2) We will utilize the Veterans Health Information System (Vista) to establish a list of Veterans/caregivers with a diagnosis of stroke within the past 3 years (10/1/2011 thru present) and TBI post-9/11/2001. A waiver of consent and HIPAA will be obtained and the patients will be screened for inclusion criteria. After obtaining approval from the provider, we will approach the patient and his/her caregiver (in-person, phone, or mail) about participation in the study;
- 3) We will seek provider referrals by regularly contacting all services throughout the hospital and Care Managers in Neurology, PM&R/TBI, and the Caregiver Program Case Manager(s); and
- 4) Advertisements will be placed throughout the VA hospital so that Veterans and/or caregivers can contact the study team.

- 5) We will seek research referrals by utilizing lists of patients from other stroke and/or TBI studies for which the PI has been a collaborator (Co-I, Co-PI, or PI). A waiver of consent and HIPAA will be obtained and the patients will be screened for inclusion criteria. After obtaining approval from the provider, we will approach the patient and his/her caregiver (in-person, phone, or mail) about participation in the study;

After the potential participants have been identified through lists or referrals, we will obtain approval from the Veterans' healthcare providers before we make contact regarding the study. Veterans and their caregivers/next of kin will be contacted in several ways: (1) some may be approached while they are in the hospital being treated for stroke or TBI and given a study brochure and basic information to let them know about the study, and (2) others will be mailed a recruitment packet. When a Veteran with a known caregiver is identified, the recruitment packet will contain a recruitment letter, study brochure, 2 copies of the informed consents (VA Informed Consent Form and the VA Consent for Recording) and HIPAA authorization form (one each for the caregiver and the Veteran), and a Volunteering in Research pamphlet (as required by VA) (see Appendix A1.5). When we are unsure whether or not the Veteran has a caregiver, we will mail a recruitment packet that only contains a recruitment letter and our study pamphlet (see Appendix A 1.1). A telephone number will be provided on the recruitment letter for the recipients to call if they do not wish to be contacted for the study. All recruitment materials can be found in Appendices 1.1-1.5 in section 11.0.

Approximately 1 week after recruitment packets are mailed, Veterans and/or their next of kin will be telephoned by study personnel to determine their interest in the study and to screen for eligibility. We will make approximately 10 attempts to phone each potential participant. If initial contact is made while in the hospital, patient and caregiver will be given the opportunity to be screened for eligibility and/or consented prior to discharge. Otherwise, patient and caregiver will be contacted via phone within 1 week of going home.

We will request a waiver of written informed consent and HIPAA authorization for the purposes of screening the potential participants through medical record review and/or discussions with providers, and potential participants will not be contacted by the study team until those waivers are approved by the IRB. We will obtain approval from the Chief of Medical Services, Neurology, Physical Medicine Rehabilitation (PMR), and the ACOS of Primary Care at both study sites to before we conduct the research. After hospital service approvals, Institutional Review Board (IRB), and VA Research & Development (R&D) approvals are received, we will begin recruitment.

Consent and Enrollment. The informed consents and HIPAA authorization will be explained to interested Veterans and their caregivers over the telephone or in-person. If eligible and they consent, the Veterans and their caregivers will sign and return the consents and HIPAA authorization to the study team by mail, fax, or in-person. Each Veteran and caregiver (i.e., dyad) will receive a copy of the signed consents and HIPAA authorization. Consented dyads will then be scheduled for a baseline data collection telephone interview. Data collection will not occur until the consents and HIPAA authorizations are received by the study team.

Randomization to Groups. Following enrollment, the statistician will randomly assign the dyads to either the ANSWERS-VA intervention or the educational attention control group using a block randomized approach with stratification on diagnosis (stroke dyad/TBI dyad), recruitment site (two for stroke dyads, two for TBI dyads), type of relationship (spouse vs. adult child/other),

PTSD (stroke survivor/TBI survivor), and baseline depressive symptoms (non-depressed vs. depressed PHQ-9 > 5). SAS PROC PLAN⁷⁸ will be used to create the randomized blocks within strata in order to obtain, as closely as possible, similar numbers and composition (balance) between the groups, and facilitate maintenance of blinding of data collectors.

Baseline Data Collection. Veterans and their caregivers will be interviewed by a data collector or the project manager for his (her) baseline interview. This interview will be completed by telephone. Interviews are expected to take approximately 30 minutes for the Veterans, and 60 minutes for the caregivers. Veterans and caregivers will be interviewed separately, either back-to-back or scheduled within a week of one another, whichever is most convenient to the dyad. All data collection instruments including a table which reflects when each instrument is used can be found in Appendices 8.1-8.3 (see section 11.0).

ANSWERS-VA Intervention Procedures. The ANSWERS-VA intervention is delivered completely by telephone. Dyads will receive 8 weekly calls (plus a booster call at 12 weeks) from an ANSWERS intervention specialist located in Indianapolis. The first scheduled intervention call is planned to occur within approximately 1 week of baseline.

The intervention specialist will provide each dyad with educational information on topics such as stroke or TBI as well as cognitive abilities, communication, emotions, behaviors, roles, and social activities all of which may be impacted by the stroke or TBI. Then the intervention specialist will work with each dyad to learn skills and techniques that will help the Veteran and caregiver cope with the symptoms and impairments that resulted from the brain injury. The intervention specialist will also help the dyad apply these lessons to tasks or activities that the dyad selects as being important. Thus, the intervention allows for some flexibility to be able to tailor the sessions to the needs of the dyad. Each session will last approximately 60-90 minutes. Dyads assigned to the intervention group will receive:

- 1) the schedule of upcoming study calls (see Appendix 2.2 in section 11.0),
- 2) ANSWERS-VA workbook (see Appendix 12 in section 11.0),
- 3) Veteran Stroke & TBI Resource Guide (see Appendix 5 in section 11.0),
- 4) Be Involved Brochure (see Appendix 13 in section 11.0),
- 5) if the participants are in the TBI arm, and if they have children, a booklet entitled, "Talking with Children about TBI" or "Talking with Children about Moderate or Severe TBI" (whichever is more applicable to the dyad) (see Appendices 4.2 and 4.3 in section 11.0), and
- 6) if the Veteran has a Post-Traumatic Stress Disorder (PTSD) diagnosis, the Veteran PTSD Booklet (see Appendix 6 in section 11.0).

Attention Control Procedures. The attention control procedures are also delivered completely by telephone. Dyads will receive 8 weekly calls (plus a booster call at 12 weeks) from an ANSWERS intervention specialist who has been cross-trained in the attention control procedures located in Indianapolis. The first scheduled attention control call is planned to occur within approximately 1 week of baseline.

The attention control calls will begin by establishing rapport by asking dyads how they are doing. The intervention specialist will then provide support through the use active listening strategies. These strategies include using (a) conversation starters (e.g., "What would you like to talk about today?"), (b) paraphrasing (e.g., "What you are telling me is..."), (c) clarifying (e.g., "Tell me

more about that”), (d) reflection (e.g., “So, you’re feeling ___ because ___”), and (e) summarizing (e.g., “So, overall...”). These strategies provide the dyad with the opportunity to express their problems and concerns and to use the interventionist as a “sounding board.” Intervention specialists will refer dyads to the ASA or TBI organization, or their health care providers for more information and answers to their questions. These calls are expected to last approximately 15-30 minutes. Dyads assigned to the attention control group will receive:

- 1) the schedule of upcoming study calls (see Appendix 2 in section 11.0 for a complete packet of study letters), and
- 2) educational materials entitled, “Caring for Stroke Survivors” published by the American Stroke Association (ASA) (see Appendix 3 in section 11.0) or “Becoming a Family Caregiver for a Service Member/Veteran with TBI” published by the Defense and Veterans Brain Injury Center (DVBIC) (see Appendix 4.1 in section 11.0).

At the end of the dyad’s participation in the study, the attention control group will receive the ANSWERS-VA workbook, Veteran Stroke & TBI Resource Guide, Be Involved Brochure, and the Talking with Children about TBI and Veteran PTSD Booklet if applicable.

Study Withdrawal/Discontinuation. Any subject is permitted to withdraw from the study at any time or decline to answer any particular question without adverse effects. If a subject withdraws, we will complete a standardized form detailing the reason. If one member of the dyad decides to withdraw, then the other member will have to be withdrawn by the study team because the study intervention relies upon the participation of both the Veteran and caregiver.

Treatment Fidelity Procedures for the ANSWERS-VA Intervention and Attention Control

Procedures. Special efforts will be made to boost and track treatment fidelity of both the ANSWERS-VA intervention and attention control procedures. In order to track and monitor treatment fidelity, the intervention and control calls will be audio-recorded with the permission of the Veteran and caregiver.

Data Collection Procedures. Data collectors and the project manager (baseline data collection only) will be trained to conduct telephone surveys for data collection prior to recruitment. Study personnel will work with the dyad to create a schedule of calls for the study. Response forms (see Appendix 7.1-7.3 in section 11.0) will be mailed to the dyads prior to the data collection calls to facilitate the interview process. Data collectors will be blinded to group assignment and will complete the remainder of the data collection calls which will be scheduled for 8 weeks, 12 weeks, 24 weeks and at 1 year following the baseline interview. These interviews are estimated to take 30 minutes with caregivers and 15 minutes with Veterans. Veterans and caregivers will be interviewed separately, either back-to-back or scheduled within a week of one another, whichever is most convenient to the dyad. Surveys/instruments used for data collection can be found in Appendix 8.1-8.3 (see section 11.0). Data will be collected on paper forms, and then entered into an electronic database.

In order to alleviate some of the interview time and burden on the dyad, and to collect accurate data, Veteran demographics and medical history data (i.e., comorbidities, injury-specific data, health care utilization) will be collected via retrospective medical chart review using the VA electronic medical record known as CPRS. A complete list of variables collected can be found on the Veteran chart abstraction form in Appendix 9 in section 11.0. Please note that the only variables which will contain PHI/PII being collected for the Veterans and caregivers during the course of this study are as follows: name, address, telephone number, MRN (Veteran only-MRN

is SSN at VA), date of discharge (Veteran only), date of diagnosis (Veteran only) and the audio recording of the intervention and control sessions. Methods for ensuring privacy and confidentiality for the Veterans and caregivers are discussed in more detail in section 9.0.

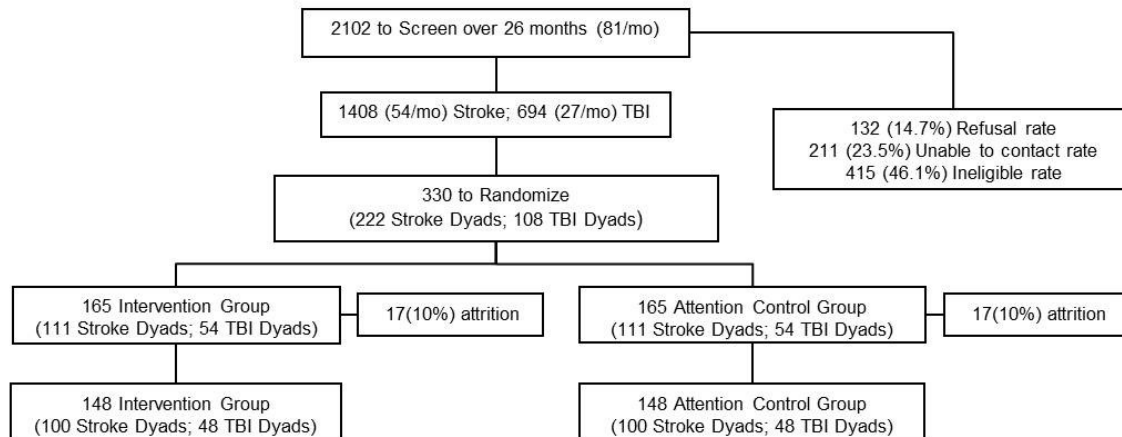
Payment for Participation. Veterans and caregivers will be reimbursed after completing the baseline and 1-year interviews. Reimbursement will be through gift cards unless the VA specifies another payment method must be used. The schedule and amounts for reimbursement for each participant will be as follows: baseline interview - \$15; 1-year interviews - \$15. The total potential reimbursement for each participant in the study is \$30. The VA protocol for research participant reimbursement will be followed.

Project Management Plan. Overall, the coordination of this project will be led by the VA Indianapolis study team with Virginia Daggett, PhD, MSN, RN, the PI, overseeing the project. Dr. Daggett will coordinate the study investigators, and the project manager and will coordinate the research staff and ensure that this study is compliant with all IRB and VA policies and regulations. Study teams from Indianapolis and Houston will have weekly conference calls. Prior to the initiation of this study, Drs. Daggett and Judge will provide training to the intervention specialists for both the ANSWERS-VA intervention and the attention control groups. In addition, all data collectors will undergo training on how to complete the surveys, collect data, and perform data entry to ensure that data from the two sites is being collected in a consistent manner. Yearly face-to-face meetings and weekly calls will ensure that all sites follow the study protocol. The project manager will coordinate prompt and reliable feedback to each site related to any data problems that may occur and likewise, will provide regular recruitment updates. Intervention fidelity will be observed through the review of audio recordings to ensure standardized delivery of the intervention. Data management will be coordinated through the IUSM Biostatistics Department which has coordinated other VA and non-VA multi-site studies.

5.0 Research Design

Sample Size. We plan to recruit Veterans with stroke and TBI diagnoses and their informal caregivers who are enrolled at the Michael E. DeBakey VAMC in Houston and the Richard L. Roudebush VAMC in Indianapolis. Once Veterans and their caregivers have been identified and screened for eligibility, 330 dyads (222 Veterans with stroke and their informal caregivers and 108 Veterans with TBI informal caregivers) will be randomized to either the ANSWERS-VA intervention or an educational attention control group. Based on our proposed sample size, we will need to enroll an average of 13 dyads per month to reach our goal over 2 years (September of 2014 through October 31, 2017). At these two sites combined, we will screen at least 1408 stroke survivors and at least 694 TBI survivors over the course of our study. Figure 3 below outlines our participant flow diagram for this study.

Figure 3. Projected Participant Flow Diagram v5-19-2014

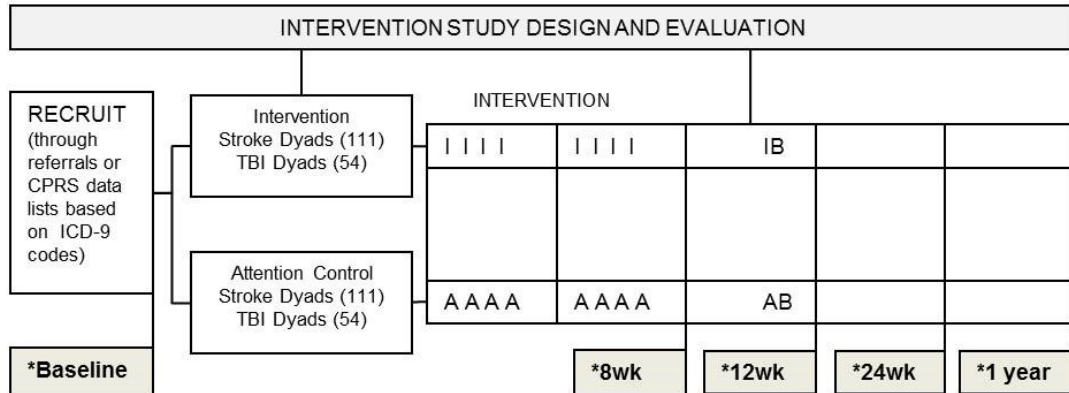


Our sample demographics will represent the Veteran patient population and their caregivers' demographics at the Houston and Indianapolis VAMCs. While we are expecting to recruit a sizable proportion of African American, Hispanic, and women caregivers of Veterans, our sample may be limited in terms of male caregivers and those from other racial groups due to population mix in this region. Specific strategies for the recruitment and retention of both male and female caregivers, as well as those from various ethnic/racial groups, will be used. We will be sure to include written materials that represent multiple ethnic and racial backgrounds as well as depicting both female and male caregivers.

Methods. This is a randomized, controlled trial to evaluate the ANSWERS-VA intervention among Veterans with stroke or TBI and their informal caregivers. Veteran/caregiver dyads in which the Veteran has suffered a stroke (N = 222) or TBI (N = 108), who have received care at the Michael E. DeBakey VAMC (MEDVAMC) in Houston or the Richard L. Roudebush VAMC (RLR VAMC) in Indianapolis, will be randomized to the ANSWERS-VA intervention group or to an educational attention control group. Both the intervention and control procedures involve 8 telephone sessions delivered over 8 weeks, with a booster session at 12 weeks. Data collections will occur at baseline, 8, 12, 24 weeks, and 1 year after baseline.

Data Analysis. Outcomes will be assessed by trained data collectors who are blinded to the treatment. Caregiver task difficulty, optimism, self-efficacy for caregiving and threat appraisal are proposed as mediators for the intervention effect on the primary outcomes of caregiver's quality of life and unhealthy days. We will test the immediate efficacy of the ANSWERS-VA intervention on these mediators and outcomes from baseline to 8 weeks, and long-term, sustained efficacy at (12 and 24 weeks and at 1 year). Veteran and caregiver characteristics (i.e., demographics, co-morbidities, relationship of caregiver to Veteran, and caregiver assessment of the Veteran's impairment) will be controlled by the stratified randomization process and, as necessary, by covariates included in the models. We will assess the exploratory outcomes of effect sizes for the ANSWERS-VA intervention for the Veteran and caregiver on the secondary outcomes of depressive symptoms, social participation, and quality of the dyadic relationship. We will also assess the outcomes of noncaregiving hours and unhealthy days in caregivers to determine the cost effectiveness of this intervention (see Figure 2).

Figure 2. Research Design v5-19-2014



I denotes weekly intervention nurse calls; IB booster at 12 weeks; A denotes weekly attention control nurse calls; AB attention control booster at 12 weeks. *Data collection calls by blinded research assistants.

Study Timeline. The study timeline is planned for four and a half years. We will devote our efforts to start-up, training, and IRB approvals during year 1 and then proceed to recruitment during months 10-36. We complete the 1-year data collection and data analyses on the primary aims in year 4. In the first quarter of year 5, we will complete the follow-up 1-year data analyses to guide our pre-implementation phase of the ANSWERS-VA intervention (see Gantt Chart in Table 6 below).



6.0 Data Management

Database. The REDCap (Research Electronic Data Capture) database system will be implemented to collect data for this study. Study data kept on the REDCap database will not contain any PHI or PII. The project manager, data collectors and/or intervention specialists at Indianapolis and Houston will enter survey data and intervention data in this database. REDCap is a software toolset referred for electronic collection and management of research data. REDCap provides a secure, web-based environment with an intuitive interface for users to enter data and have real time validation rules at the time of entry. The system offers easy data manipulation with logged auditing, functionality for reporting, monitoring and querying patient records, and an automated export mechanism to common statistical packages such as: SPSS,

SAS, Stata, R/S-Plus. Data will be entered into REDCap by the project manager, data collectors and/or intervention specialists in Indianapolis and in Houston.

Data Storage & Security. The servers hosting REDCap are physically located in a secured and environmentally structured computer operations center on the Indiana University (IU) Bloomington campus and are supported by University Information Technology Services (UITS) server and database administrators. To comply with HIPAA guidelines, processes and procedures have been documented and implemented to ensure the security and protection of the study data within the computer operations center, the servers, and the database. There are two secure means of access to the study data for study members who are granted access: 1) via the application by use of IU's Central Authentication Service (CAS) and project database specific permissions; and, 2) via direct access to the database by use of secure database authentication. In each case, the PI will identify who has relevant access to the study data and what permissions each individual shall have. REDCap utilizes SSL (https) encryption for secure connectivity.

We will keep a paper enrollment form that will contain the following PHI/PII: name, MRN, address, and contact information. The enrollment form will be stored in a locked file cabinet in a locked office utilized for the study at the Indianapolis VAMC for patients/caregivers enrolled from the RLRVAMC and at the Houston VAMC for patients/caregivers enrolled at the MEDVAMC. The information from this enrollment form will be added to an electronic crosswalk that ties this information to the study ID that will be established at the coordinating center at the RLR VAMC in Indianapolis in an access-controlled project folder on the secure VA network research drive which is behind the VA firewall. Access to this folder will be given to the study personnel in Houston so that the information can be shared in a secure manner. PHI/PII will not be stored on any other paper research records or in the electronic database (REDCap).

Audio recordings of the calls administered by the intervention specialists will be stored at the Richard L. Roudebush VAMC in the access-controlled project folder on the secure VA network Q. According to the VA's OIS Risk Based Decisions (RBD)Memorandum, recordings will be made with devices that are not technically capable of FIPS 140-2 compliant encryption and at this time there is no cost effective alternative solution that exist. This RBD is permanent or until such a time that a FIPS 140-2 compliant audio recording device is available. Recordings will be uploaded to the VA project folder for backup, and then permanently deleted from the devices.

Missing Data. We will incorporate several strategies to minimize missing data. For example: (a) a tracking database will be incorporated to insure timely follow-up contacts and maintain current contact information; (b) calls with dyads will be scheduled ahead of time and at a time which is convenient for the Veteran and caregiver; (c) essential data fields will force data collectors to provide an appropriate value (including use of special missing codes describing reason data are missing), rather than leave blank; (d) data will be entered into a secure system backed up nightly by the university; (e) paper forms will be available for data collection when direct entry is not possible; and (f) data will be inspected quarterly during data collection for errors and missing values.

Data Transfers. In order to receive the subject lists from Houston, the data collector there will run the list using a template built by a Clinical Applications Coordinator (CAC) from Indianapolis. Then the data collector at Houston will be given access to the Indianapolis study folder on the

secure VA Q-drive and the REDCap database in order to store data collected from that site. Paper data collection forms, including the enrollment form and copies of the Informed Consents and HIPAA Authorizations will be sent to the coordinating center in Indianapolis on a quarterly basis using a trackable courier service.

Data Sharing. We will also make the database available to others when we are finished reporting our primary results. Special measures will be taken to ensure that caregivers and Veterans are not identifiable by any data that are shared. Close collaboration with Dr. Daggett and her research team will be necessary for the use of shared data.

7.0 Risks & Benefits

Risks. The main risks to subjects are loss of confidentiality and discomfort in answering certain questions. Specific steps to minimize these risks are detailed in section 9.0. Should any loss of confidentiality be identified, the study PI will, within 24 hours of the identification of this breach, contact the ACOS for Research, the IRB and R&D committees, and the Information Security Officer (ISO) and Privacy Officer (PO) at the coordinating site as well as the site PI at Houston should the loss of confidentiality occur there.

Benefits to Participants. Our hope is that the ANSWERS-VA intervention will provide Veterans with brain injury and their loved ones with a core set of practical skills that each can use in coping with and managing the symptoms of brain injury. Participants in the intervention group will receive 9 calls from a trained intervention specialist who will work with the dyad on education and counseling-based skills training and cognitive and physical rehabilitation techniques. They will also receive the ANSWERS-VA binder (see Appendix 12 in section 11.0) which contains written educational materials, skills training, worksheets, and additional resources. The control group will also receive the ANSWERS-VA binder, but not until they complete the final data collection interview for the study.

Benefits to Society. The long term goal of this study is to implement this intervention for Veterans with stroke and TBI and their family caregivers across VHA by offering comprehensive training and support. Therefore, this program may also benefit the health-related quality of life of future Veterans with stroke/TBI and their caregivers. The ANSWERS-VA intervention will also foster translation into practice due to eliminating costly in-patient and in-home visits.

8.0 Data Safety and Monitoring

Any ongoing data safety and monitoring issues will be presented to the larger investigators group. This group of investigators is comprised of VA and non-VA representatives with a diverse background in nursing, medicine, traumatic brain injury, biostatistics, stroke and caregiving. This group will monitor recruitment, enrollment, data collection, intervention procedures, and participant safety issues such as adverse events and protocol deviations on an ad hoc basis. This is a minimal risk study, and we do not anticipate any study-related, serious adverse events. However, we will track all adverse events and will report any serious adverse events to the IRB as a reportable VA event per VA policy.. At continuing review, the IRB will receive a copy of all Adverse Events not requiring prompt reporting.

9.0 Privacy/Confidentiality Issues

The only identifiable information this study plans to collect are the subjects' names, addresses, telephone numbers, social security number, hospital discharge date, date of diagnosis, and voice recordings of the intervention and control calls, and all of the PII being collected will be stored at the RLRVAMC and MED VAMC. To add further protections, subjects will be assigned a unique study identification (ID) number. This number will be used as the identifier for the study data that will be stored in the REDCap database and for the audio recordings. The study ID will also connect the Veteran and caregiver data that is abstracted through CPRS chart reviews. The crosswalk file that links the subject ID number with the Veterans and caregivers will be kept at the VA on a network server in a secure file behind the VA firewall and will only be accessible to authorized study personnel. All study forms which contain PHI/PII will be locked and secured in file cabinets only accessible to authorized study personnel. When study personnel are no longer part of the research team, the PI will remove all access to study data from this individual, and the R&D office will be notified so that VA network access can be terminated.

Subjects will be instructed that they may refuse to answer any question with which they are uncomfortable, and they will be assured that they may withdraw from the study at any time without repercussions of their healthcare and the healthcare of the Veteran with whom they have a relationship.

10.0 Follow-up and Record Retention

This study received an award acceptance letter from VA HSR&D in October of 2012. It received funds at the beginning of fiscal year 2014 which was October 1, 2013, and it is anticipated that the study will be completed on March 31, 2018.

All data collected will be stored indefinitely or until the VA Records Control Schedule signifies the destruction timeframe of VA research records. At the time of data discard, all paper will be shredded, and PC hard drives and network files will be sanitized.

After the study is closed, and all analysis and papers are complete, all data that is stored at IU will be returned to the VA.

11.0 Appendices

Appendix 1. Recruitment Materials

- A1.1 ANSWERS recruitment letter 12-19-2014 veteran
- A1.2 Caregiver flyer 12-19-2014
- A1.3 Caregiver brochure 12-19-2014
- A1.4 Volunteering in Research
- A1.5 ANSWERS recruitment letter 12-19-2014 dyad

Appendix 2. Schedule of Calls & Study Letters

- A2.1 Calls and Mailings 12-19-2014
- A2.2 Scheduling Letter 9-22-2014
- A2.3 1st Data Collection Completion Letter-ACG 9-22-2014
- A2.4 1st Data Collection Completion Letter-ANSWERS 9-22-2014
- A2.5 2nd Data Collection Reminder Letter 9-22-2014
- A2.6 3rd Data Collection Reminder Letter 9-22-2014

- A2.7 4th Data Collection Reminder Letter 9-22-2014
- A2.8 5th Data Collection Reminder Letter 9-22-2014
- A2.9 5th Data Collection Completion Letter-ACG 9-22-2014
- A2.10 5th Data Collection Completion Letter-ANSWERS 9-22-2014
- A2.11 Unable to Reach-Intervention Calls 6-6-2014
- A2.12 Unable to Reach-Data Collection Calls 9-22-2014
- A2.13 ANSWERS Withdraw during IC1-IC8 6-6-2014
- A2.14 Gift Card Receipt 1st Interview – different addresses 7-23-2014
- A2.15 Gift Card Receipt 1st Interview – same address 7-23-2014
- A2.16 Gift Card Receipt 5th Interview – different addresses 7-23-2014
- A2.17 Gift Card Receipt 5th Interview – same address 7-23-2014
- A2.18 No Phone Number 12-2-2014

Appendix 3. ASA-Caring for Stroke Survivors 11-1-2013

Appendix 4. DVBIC Materials

- A4.1 DVBIC Manual 11-1-2013
- A4.2 Talking with Children mild
- A4.3 Talking with Children moderate to severe

Appendix 5. Veteran Stroke & TBI Resource Guide – Indianapolis 10-31-2014

Appendix 6. Veteran PTSD Booklet 12-8-2014

Appendix 7. Response Forms

- A7.1 Veteran Response Forms-All Data Calls 12-19-2014
- A7.2 Caregiver Response Forms-1st Data Call 12-19-2014
- A7.3 Caregiver Response Forms-2nd-5th Data Calls 12-19-2014

Appendix 8. Data Collection Measures

- A8.1 Table of Data Collection Measures 9-22-2014
- A8.2 Veteran Data Collection Instruments 12-16-2014
- A8.3 Caregiver Data Collection Instruments 12-16-2014
- A8.4 Recruitment Screening Form VANRI Caregiver 12-15-2014

Appendix 9. Veteran Chart Abstraction Form 12-16-2014

Appendix 10. Scripts-Recruitment & Data Collection

- A10.1 Recruitment Script for Phone Calls 12-19-2014
- A10.2 Data Collection Script-Baseline 9-22-2014
- A10.3 Data Collection Script-2nd to 5th 9-22-2014

Appendix 11. Suicide Protocol Indy 3-25-2015

Appendix 12. ANSWERS-VA Intervention 12-16-2014

Appendix 13. Indy Be Involved Brochure 10-31-2014