Telephone Assessment and Skill-Building Intervention for Informal Caregivers

NCT#: 02398409

Date: 3/24/16

Protocol 1304011277 IRB Approved

Department of Veterans Affairs	**VA Research Consent Form**

Subject Name:		**Date:**	
Title of Study:	IRB# 1304011277 - Telephone Assessment and Skill-Building Intervention for Informal Caregivers		
Sponsor:	VA Health Services Research & Development (HSR&D), Nursing Research Initiative (NRI)		
Principal Investigator:	Virginia S. Daggett, PhD, RN	**VAMC:**	Roudebush VA Indianapolis

Purpose:
You are invited to participate in a research study of Veterans who have suffered a stroke or traumatic brain injury (TBI), and their Caregivers. The purpose of this study is to test an intervention program called ANSWERS-VA which aims to provide Veterans and Caregivers with a set of practical skills that each can use in coping with and managing symptoms of stroke or TBI. This study will last for 3.5 years; however, your participation in it will only last for 1 year.

Description:
If you agree to participate, you will be one of 330 Veteran/Caregiver pairs who will be participating in this research. If you agree to be in the study, you can expect the following things:

After enrollment, you will be randomly assigned (like flipping a coin) to 1 of 2 groups: the ANSWERS-VA intervention group or the control group which receives basic education and support.

You will be contacted by a member of the study team who will work with you and your Veteran to schedule a baseline interview for a time that is convenient to you. The baseline interview will be conducted over the telephone or in-person at the Roudebush VA Medical Center (whichever is most convenient for you). The baseline interview will last approximately 60 minutes. We will also work with you to draft a schedule of future study calls which can be modified as needed.

Within 1 week of the baseline call, you will be mailed your call schedule and your educational materials. If you are randomized to the ANSWERS-VA intervention, you will also receive the ANSWERS-VA Workbook.

After the baseline interview, you will receive 4 calls from a study Data Collector at 8 weeks, 12 weeks, 24 weeks and 1 year (i.e., 2 months, 3 months, 6 months and 1 year). Each call will last approximately 30 minutes. The content of all of the data collection calls will be about your perception of your Veteran's level of impairment, the types of caregiving activities that you do, as well as questions regarding your feelings about caregiving, your life and your relationship to the Veteran.

You will also receive 9 calls from an Intervention Specialist. These calls will begin 1 week after the baseline interview and each call will last approximately 60-90 minutes for the intervention group and 15-30 minutes for the control group. The first 8 calls will occur weekly, and the last call will occur approximately 3 months after the baseline interview.

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Your calls with the Intervention Specialist will be audio recorded, but these recordings will only be reviewed for quality assurance purposes to make sure that the research study protocol is being followed and not for data collection purposes.

A description of this clinical trial will be available on **ClinicalTrials.gov**, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Risks:
While on the study, the risks are that you may feel uncomfortable answering some of the questions, and there is a minimal risk of loss of confidentiality regarding the information that you may share. The study team will follow VA policy and regulations to minimize these risks.
In order to protect your confidentiality, all documents that contain your individually identifiable information will be locked and secured in file cabinets only accessible to authorized study personnel. Study data collected will be kept in a secure database and in secure files. You will also be assigned a unique study ID number which will be used to link your data and the data of your Veteran.

To minimize any discomfort, you may refuse to answer any question with which you feel uncomfortable, and your may withdraw from the study at any time without repercussions to your healthcare or to the healthcare your Veteran. However, if you choose to withdraw, the study team will have to withdraw your Veteran as well since the intervention relies upon the participation of the pair.

Benefits:
This study is evaluating a stroke program that may benefit the health-related quality of life, functioning, and well-being of you and future veterans with stroke/TBI and their Caregivers. While this program has demonstrated preliminary success, these benefits cannot be guaranteed.

Statement of Use of Research Results:
The results of this study may be published, but your records or identity will not be revealed unless required by law.

Confidentiality:
Efforts will be made to keep your personal information confidential, but we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published.

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Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the investigator and his/her research associates, the study sponsor, the Indiana University (IU) Institutional Review Board or its designees, the VA Research and Development (R&D) Committee's designees, and federal agencies, including but not limited to the Office for Human Research Protections, the Office of Research Oversight, and VA Office of the Inspector General.

Retention of Research Records:
Research records will be maintained by the investigator in accordance with the VHA Records Control Schedule which currently requires that all research records be stored indefinitely.
You will be assigned a unique study identification (ID) number which will be linked to your data. The only individually identifiable data that we will be collecting is your name, address, telephone number, and the audio recording of your intervention or control calls. The file that links your study ID to your data and your identifiable data will be kept at the Richard L. Roudebush VAMC on a secure network research server behind the VA firewall.

The database we will be using to store all of the other study data is called REDCap (Research Electronic Data Capture). The database servers are physically located at the IU Bloomington campus in a secured computer operations center and are supported by the IU University Information Technology Services (UITS) server and database administrators. All data will only be accessible to authorized study personnel.

Research Subject Costs:

1. There will be no costs to you for any of the treatment or testing done as part of this research study. Eligibility for medical care at a VA Medical Center is based upon the usual VA eligibility policy and is not guaranteed by participation in a research study.
2. The study is sponsored by the Veterans Administration through a Nursing Research Initiative (NRI) grant through Health Services Research and Development (HSR&D).
3. You will not be required to pay for medical care or services received as a participant in a VA research project except as follows:
   Some veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are **not** part of this study.

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Compensation & Treatment for Injury:

1. You will receive payment for taking part in this study. After completing the **baseline interview**, you will receive a gift card worth $15, and after completing the final, **1-year interview**, you will receive another gift card worth $15. Therefore, you are eligible to receive $30 if you complete the baseline and 1-year interviews. There is no compensation offered for completing the other 3 interviews at 2 months, 3 months, and 6 months or for each of the 9 intervention and control calls.
2. The VA medical facilities shall provide necessary medical treatment to a research subject injured as a result of participation in a research project approved by a VA R&D Committee and conducted under the supervision of one or more VA employees. This does not apply to: (1) treatment for injuries due to noncompliance by a subject with study procedures; or (2) research conducted for VA under a contract with an individual or a non-VA institution.
3. Financial compensation for research-related injuries is not available. However, by signing this form, you do not give up your legal rights to seek such compensation through the courts.

RESEARCH SUBJECT'S RIGHTS:

Participation in this study is entirely voluntary. You may refuse to participate. Refusal to participate will involve no penalty or loss of rights to which individuals are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits. You will receive a copy of this signed consent form.

In case there are medical problems or questions, Dr. Virginia Daggett can be called at 317-988-3155 during the day. If any medical problems occur in connection with this study, the VA will provide emergency care.

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Please direct questions about the consent process and the rights of research subjects to the VA Customer Service Office at (317) 988-2602. For questions about your rights as a research participant or complaints about a research study, contact the IU Human Subjects Office at (317) 278-3458 or (800) 696-2949. If you have any questions about the research study or want to check the validity, discuss problems, concerns or obtain information or offer input, please call the Research Office at (317) 988-3032.

The study has been explained to me and all of my questions have been answered. The risks or discomforts and possible benefits of the study have been described. Other choices of available treatment have been explained.

_____	_____	_____
Subject's Signature	Printed Name of Subject	Date
_____	_____	_____
Signature of Person Obtaining Consent	Printed Name of Person Obtaining Consent	Date