Spanish Online & Telephone Intervention for Caregivers of Veterans with Stroke

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Title of Study: Spanish Online & Telephone Intervention for Caregivers of Veterans with Stroke
Principal Investigator: Keryl Motta Valencia, MD
Sponsor: VA HSR&D
Subject ID:

BACKGROUND AND PURPOSES

You are being asked to participate in this study because you are the caregiver of a veteran who has had a stroke. This is an educational and support study to help caregivers and does not involve any medical care. Two hundred forty-five caregivers of veterans with a diagnosis of stroke will be invited to participate in this study. This study is being conducted by a team of Department of Veterans Affairs (VA) researchers in the North Florida/South Georgia VHS, Gainesville, FL, and the VA Caribbean Healthcare System, San Juan, Puerto Rico, under the direction of Dr. Keryl Motta Valencia. This study is being funded by the VA's Health Services Research & Development.

With this research we hope to learn if a problem-solving telephone intervention that utilizes online educational resources from the "RESCUE" website helps to reduce depressive symptoms and burden, and increases their self-efficacy, ability to problem-solve, and health-related quality of life of caregivers of Veterans affected by a stroke.

Some participants will be asked permission to record the intervention sessions for quality assurance and training purposes. We will not record any telephone sessions without prior authorization. You are free to decline this permission. If you do not authorize the recording, we will only take notes of the conversation. Upon authorizing the recording, we will begin recording the session. At any time after you authorize the recording, you can ask us to pause or turn off the recorder.

Participant answered: ____ Yes ___ No

DURATION OF THE RESEARCH

This research study is expected to take approximately 7 years. Your individual participation in the project will take approximately 5 months.

STUDY PROCEDURES

If you decide to take part in this study, this is what will happen: All study participants will complete 3 data collection sessions expected to last 45-60 minutes each. Once we have discussed this written statement and answer any questions you may have, we will schedule a time to call you via telephone to collect baseline data. You'll be asked to answer several questionnaires including some basic demographic questions and questions related to your Veteran's ability to perform self-care activities and questions about stress, burden, problem-solving, etc. We estimate this call will take 45-60 minutes. After the initial data collection call, we will assign you to either the intervention group or the standard of

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care group (i.e., the care you would normally receive at the VA as a caregiver of a Veteran who had suffered a stroke). Participants assigned to the intervention group will received 8 weekly-scheduled telephone sessions with an interventionist who will discuss caregiving challenges. With participants' permission, some of these sessions will be digitally recorded for quality assurance purposes. Once the 8 telephone sessions are completed, we will schedule the two additional data collection telephone calls. These calls will take place between 1 and 12 weeks after the intervention is completed. In addition, eight to ten participants who completed the intervention will be invited to participate in a short telephone interview, approximately 30 - 45 min, to share their thoughts and opinions about the intervention. Study participants assigned to the standard of care group will not receive the intervention and will only complete the two additional 45 - 60-minute-long data collection calls.

The digital recordings of the sessions will be uploaded to the secured VA server and the interview will be deleted from the digital recorder. The recordings will be transcribed verbatim for analysis purposes. Dr. Keryl Motta Valencia is the study's Principal Investigator and is responsible for overseeing all research procedures and members of the study team. She will be responsible for making sure that as a study participant, you understand the potential risks and benefits of participating in the intervention, ensure the intervention is conducted properly, monitor all research procedures, identify whether there have been any adverse events as a result of the study. She will also be responsible for notifying you if there is a problem with the study.

All study related activities will take place over the phone from the comfort of your home or a location selected by you.

This study includes surveys, questionnaires and/or interviews covering questions from basic demographic information (i.e., age, gender) to questions about your perception of stress, burden, ability to perform caregiving tasks, feelings or symptoms of depression, to thoughts and opinions about the intervention.

If at any point during the study you do not feel comfortable with any of the questions or would prefer to skip any questions, you are free to do so. You are not obligated to answer any questions you do not wish to answer.

POSSIBLE RISKS OR DISCOMFORTS
This is an educational intervention that will be conducted over the phone. Study risks are minimal. You may become tired during the telephone intervention sessions. Breaks will be provided as needed. Also, some participants may feel

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uncomfortable or become stressed while discussing stroke-related issues that are affecting them. The interventionist(s) conducting the telephone intervention will be monitoring for signs of stress or discomfort.

If it determines that the participant feels stress, fatigue, or feels uncomfortable in any way, the interventionist will offer a break or stop the session. In the rare event that a participant exhibits sign of malaise, the interventionist will notify the Principal Investigator (PI) and the clinical co-investigators of the study to determine the best course of action.

If it is determined that participating in the study is too burdensome (i.e., caregiver is having a hard time keeping scheduled sessions, or if he/she is experiencing distress), the PI may decide to withdraw the participant from the study.

POTENTIAL BENEFITS
We cannot promise that you will get any benefits from taking part in this research study. However, possible benefits may include benefitting from learning problem-solving techniques to those participants assigned to the study intervention. These problem-solving techniques may help them adjust to their roles as caregivers. Also, participants may benefit from using the information, tools, and resource lists on the RESCUE stroke caregiver website. Possible future benefits are identification of best practices for improving transitional care for informal caregivers of Veterans post-stroke.

ALTERNATIVE PROCEDURES TO PARTICIPATE IN THIS RESEARCH
This study is not related to the medical care of your veteran or yours. Therefore, the only alternative to participating on this study is not to participate.

CONFIDENTIALITY
The United States Government has issued a privacy rule to protect the privacy rights of subjects. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The privacy rule is designed to protect the confidentiality of your health information.

We ask for your social security number for reimbursement purposes only.

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Your identity will not be disclosed to the public. The information collected for this study will be kept strictly confidential.

COST TO PARTICIPANTS AND PAYMENT
You nor your veteran will not be charged for any procedures that are part of this research. It is not expected that you will incur in any costs due to your participation on this study.

PAYMENT OFFERED FOR PARTICIPATION*:*
You will receive $15 for every data collection that you complete. You will receive payment at the end of the study. If you withdraw from the study prior to completing the 8 weeks, you will receive reimbursement for the data collection sessions that you completed.

The US Treasury requires that all participants in this study receive their study related compensation as an electronic transfer of money directly to their bank accounts. If caregivers are already set up to receive VA benefit payments electronically, then there is nothing that they need to do. If they are not already set up to receive VA benefit payments directly to their bank accounts then they will need to set up an account to receive an electronic funds transfer from the VA. Study staff will provide information on this process, if needed.

RESEARCH RELATED INJURY
If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:
Dr. Keryl Motta Valencia, PI (787) 641-7582 ext. 111335 or 787-641-7582 ask for the Physiatrist on call if it is after hours.

The VA Caribbean Healthcare System will cover any necessary medical treatment (i.e., not just emergency treatment) if you are injured as a result of your participation in this approved research study.

RIGHT OF INVESTIGATOR TO TERMINATE PARTICIPATION (if applicable)
If it is determined that participating in the study is too burdensome (i.e., caregiver is having a hard time keeping scheduled sessions, or if he/she is experiencing distress), the PI may decide to withdraw the participant from the study.

PERSONS TO CONTACT ABOUT THIS RESEARCH

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In case there are medical problems, questions, concerns or complaints, you can call Dr. Keryl Motta Valencia and/or her delegates at (787) 641-7582 extension 111335. If any medical problems occur in connection with this study, the VA Caribbean Healthcare System will provide emergency care.

If I have questions about my research rights in the study and validity of the research, you should contact Maria Anglada or her designee at (787) 641-7582 extension 111790.

If you have any concerns or complaints about this study or the research team; or if you wish to talk to someone who is not part of the research team, you may contact Maria Anglada or her designee at (787) 641-7582 extension 111790. **All calls will be confidential and if I choose, anonymous.**

WITHDRAWAL OR REFUSAL TO PARTICIPATE WILL NOT RESULT IN LOSS OF BENEFITS
Your participation in this research is voluntary. If you choose to refuse participation or to stop participating at any time during the research, the medical care of your Veteran will not be affected, and will not lose any of the benefits to which the Veteran is entitled.

INVESTIGATORS' CONFLICT OF INTEREST DISCLOSURE
None of the research team investigators associated with this study report any conflict of interest with this study.

PHOTOGRAPHY, VIDEO AND/OR AUDIO RECORDING FOR RESEARCH PURPOSES.
Some study sessions will be recorded to ensure the fidelity of the intervention. This is to ensure the interventionist is following study protocol and it is not meant to be an evaluation of your participation or responses. As soon as the session is over, we will upload the recording to a secure and password protected folder in the VA server and delete the recording from the recorder. Audio recordings will then be transcribed verbatim for analysis purposes. All electronic and paper records of the interviews will be kept locked in a private office in a locked cabinet or in a password protected VA computer. We will never disclose your personal information with anyone outside the VA.