Interventions for Parent Caregivers of Injured Military/Veteran Personnel

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Title of Study: Interventions for Parent Caregivers of Injured Military/Veteran Personnel

Principal Investigator: Linda Nichols, PhD **VAMC:** Memphis TN (614)

Subject Name:_____ **Date:** _____

1. Research Statement.

You are being asked to take part in a research study. Such studies include only participants who choose to take part. Take your time to make a decision and ask the person obtaining your consent any questions you have regarding the study. You may discuss this with your family and friends.

This 6-month study is for parents of post 9/11 service members who have returned with injuries (including traumatic brain injury (TBI), post-traumatic stress disorder (PTSD), or any other physical or mental injuries). This study will determine if Caregivers in the REACH Parents caregiving intervention arm will be significantly more effective in improving Caregiver outcomes including depression, anxiety, and burden than the Caregivers in the online educational webinar arm. There will be 160 parents recruited for this study. This study is funded by the U.S. Army Medical Research and Material Command (USAMRMC). If agreeable, all of your participation is by telephone, email, or through the mail, so there will be no travel involved.

Description of the Study, including Procedures to be Used.

If you join the study, you will be asked questions about your health and well-being. These questions will take 30 to 45 minutes and will be conducted by telephone at a time that is convenient for you. If you get tired during this time, you may ask for a break or you may ask to end the session if you are too tired to continue. If you are too tired to continue, we will finish the questions at another time. You will be asked questions again at 3 and 6 months; this interview will be similar to the first interview.

You will be assigned, by chance (like flipping a coin), to one of two arms. If assigned to Arm A, you can participate in the REACH (**R**esources for **E**nhancing **A**ll **C**aregivers **H**ealth) Parents individual sessions with a trained program coach. Because the sessions are conducted by telephone, there will be no travel; you will participate from home. Arm A will complete 6 sessions during 3 months and provide education, training in coping skills, and support. The purpose is to reduce Caregiver stress and burden while increasing coping skills and support.

If assigned to Arm B, you can participate in online education webinar sessions. Arm B will meet 6 times during 3 months and provide education about such topics as safety, social support, problem behaviors, your emotional well-being, and your health.

Reasonably Foreseeable Risks or Discomforts.

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You may experience discomfort or fatigue in answering questions. Some questions may be upsetting to respond to. In the intervention, some of the discussion topics may be upsetting to you. A trained program coach will be able to help you should this occur. Also, you can stop at any point.

Reasonably Expected Benefits to Subjects or Others.

You may not benefit directly from your participation in this study. However, there may be a benefit to society, in general, from the knowledge gained in connection with your participation in this study. Taking part in this study may help participants better understand the problems they may be having caring for injured Veterans including TBI, PTSD, and any other physical or mental injuries. Any information obtained from this research study that may be important to your health will be shared with you.

Appropriate Alternatives.

The alternative is not to participate in this study. Education materials and support on the topic of caregiving concerns are available from the Department of Veterans Affairs, and health care and community organizations by mail or online. There may be family support groups that meet in your community.

Extent of Confidentiality.

Your information used for this study will be kept confidential. The results of your participation in this study may be used for publication or for scientific purposes, but the results will not include any information that could identify you.

Project staff will have access to your information. Although we will attempt to keep all information confidential, there is a minimal risk of inadvertent release of personal information. Care will be taken to preserve the confidentiality of all information you provide. Your research record will be labeled with a code number. The master key that links your name and the code number will be maintained in a separate and secure location in the data analyst's office. Only the project staff will have access to this information. Records will be maintained and/or destroyed in accordance with the VA Records Control Schedule (RCS 10-1).

The research team may also need to disclose information to others including the study sponsor, the U.S. Army Medical Research and Material Command (USAMRMC), and the Memphis VAMC Institutional Review Board (IRB), Research Compliance Officers (RCO), and the Human Research Protection Office (HRPO) that will monitor this study as part of the study process. The USAMRMC will have access to the study data to monitor and oversee the conduct of the study in the event of a for-cause audit of research records.

Compensation or Treatment for Injuries.

Every reasonable safety measure will be used to protect your well-being. If any medical problems occur in connection with this study, the Memphis VA medical facility shall provide

necessary medical treatment to you as a research subject injured as a result of participation in a research project approved by the Memphis VA R&D Committee and conducted under the supervision of one or more Memphis VA employees in accordance with Federal regulations.

Participation is Voluntary.

Participation is voluntary, refusal to participate involves no penalty or loss of benefits to which you are otherwise entitled, and you may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. You have the right to withdraw from the study at any time.

Investigator-Initiated Termination of Participation.

Your participation in this project may be terminated at any time during the project if the Veteran becomes upset at your participation and no longer wishes for you to talk to the research staff. You may also be terminated if you decide you no longer wish to participate or if the research staff decides that your participation is too upsetting for you to continue.

Additional Costs.

You will not be required to pay for treatment required by the research study.

Subject Payment.

Each person who joins the study will be paid $25.00 when information is collected at baseline, 3, and 6 months. As long as you stay in the study, you will be paid $25.00 at these three times. If you complete all interviews, and the program evaluation, after the 3 month interview, you will receive an additional $25.00 up to a total of $100.00 at the completion of the program.

Disclosure of Results.

The results of this study may be published, but your records will not be revealed unless required by law. No specific information that could identify you will be in this document.

A description of this clinical trial will be available on http://www.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.

Future Use of Data.

If you choose to participate in this study, your data will be saved in a secure repository for future analysis and publications. All data collected during the study will be kept in the repository. Data will be stored only on a computer system operating within the VA's network, which is protected by secure firewalls. Only research staff will have access to this secure repository.

Whom to Contact in the Event of Injury or Research-Related Questions:

In case there are problems or questions, you can call: Dr. Linda Nichols or Dr. Jennifer Martindale-Adams at (901) 523-8990 Ext. 5082 during the day or the Emergency Room at the Memphis VA Medical Center (901) 523-8990, ext. 7948 after hours.

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If you would like to discuss problems, concerns, or questions with someone who is not directly associated with this project, you may contact the Memphis VA Institutional Review Board Office at (901) 577 7267 to obtain information or offer input.

RESEARCH SUBJECT'S RIGHTS:

I have read or have had read to me all of the above. The study has been explained to me and all of my questions have been answered. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled. I voluntarily consent to participate in this study. I understand what the study is about and how and why it is being done.

Subject's Signature	Date
Signature of Person Obtaining Consent	Date
Printed name of Person Obtaining Consent	

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