Caregiver SOS: An Intervention for Employed Caregivers

NCT04337021

May 10, 2023

Title of Study: Caregiver SOS: An Intervention for Employed Caregivers

Principal Investigator's Name: _Amy Helstrom, Ph.D.

SUMMARY OF STUDY

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

We are asking you to choose whether or not to volunteer for a research study being funded by VA Health Services Research and Development about *a telephone-based counseling program for employed caregivers (CGs) of Veterans, entitled Caregiver Self-Management of Stress, or Caregiver SOS.* This initial material is to give you key information to help you decide whether to participate. We have included detailed information about this study. Ask the research team questions. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

This study is examining the effectiveness of a telephone-based counseling program for employed CGs of Veterans.

By doing this study, we hope to learn if this program is helpful to employed caregivers and the Veterans they assist. Your participation in this research will last about *9 months.*

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

If you decide to participate in this study, you may benefit from the counseling provided by the care manager.* For a complete description of benefits, refer to the *Research Details section of this document.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

If you decide to participate in this study, you may not benefit from the counseling provided by the care manager.* For a complete description of risks, refer to the *Research Details section of this document.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Dr. Shahrzad Mavandadi of the Corporal Michael J. Crescenz VA Medical Center. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is:
Amy Helstrom, Ph.D.
Corporal Michael J. Crescenz VA Medical Center
3900 Woodland Avenue

Philadelphia, PA 19104
215-823-4164

If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

APPROVED by CMCVAMC IRB on 05/10/2023

Terri Laufer, MD, IRB Chair

Title of Study: Caregiver SOS: An Intervention for Employed Caregivers

Principal Investigator's Name: _Amy Helstrom, Ph.D.

RESEARCH DETAILS

WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

The purpose of this research study is to see whether a telephone-based counseling program is effective in improving your wellbeing and ability to function effectively both at work and as a caregiver. With this research we hope to learn if this program, Caregiver SOS, can be helpful to employed caregivers of Veterans. You are being invited to participate because you have been identified as an employed caregiver of a Veteran with a diagnosis or clinically significant symptoms of depression, anxiety, PTSD, and/or traumatic brain injury (TBI).

HOW LONG WILL I BE IN THE STUDY? HOW MANY PEOPLE WILL BE IN THE STUDY?

Your individual participation in this this study will take 9 months. This research study is expected to take approximately four years.

We plan to enroll 220 caregivers of Veterans from CMCVAMC. This study will also take place at the VA Western New York Health System and we plan to enroll 80 individuals.

WHAT IS EXPECTED IF I TAKE PART IN THIS STUDY?

- **If you are interested in participating, we will first determine if you are eligible to take part in the study. This will involve answering a few questions about yourself and about the Veteran's diagnoses. This will take no more than 5-10 minutes to complete.To be eligible, you must meet certain criteria; these include being employed and assisting the Veteran with two or more instrumental activities of daily living (e.g., housework, arranging appointments, managing finances, etc.).**
- **If you are eligible, following your baseline research assessment,using a process like flipping a coin, we will assign you to one of two groups: usual care or care management. You have an equal chance of being assigned to either of these groups.**
  - **If you are randomized to the usual care (UC) arm, you will be called once by a Care Manager (CM). After a brief needs assessment, the CM will provide contact information for appropriate VA (e.g., local CSP clinicians) and non-VA community resources/services. You will also be sent brochures for the national VA Caregiver Support Program (CSP). Information on both the program's website (which includes links to training, education, resources, and outreach programs for CGs) and the national CG hotline number will be included in the mailed packet.**
  - **If you are randomized to the care management arm, you will participate via phone in the Caregiver SOS program. This will involve 6 one-hour sessions over 3-4 months addressing both work and caregiver stress. Any needs you**

or the Veteran might have for VA and community resources will also be addressed.

- **Regardless of which arm of the study you are assigned to, you will be asked to complete 3 research assessments. We will ask you questions about the care you provide the Veteran. We will also ask you questions about your background, mood, functioning at work, and your general experience as a caregiver. This interview will take approximately 1 hour and can be completed either over the phone, by mail, or through an online survey. The first interview would take place at your earliest convenience, and then repeated 4 and 9 months from the date of your first interview. If you are randomized to the intervention arm, you may also be randomly selected and invited to participate in a brief (10 minute) interview designed to learn more about your experience in the intervention.**

- **During the course of the study, you will have contact with multiple members of the study staff. The research coordinator will contact you to let you know which group you are in, to schedule and conduct assessments with you, and connect you with the care managerThe care manager will contact you after you complete the first research assessment.**
- **All study procedures will take place over the phone, or if you prefer to complete the questionnaires on your own, at home via mail or online survey.Any information sent/received electronically will be unlabeled or labeled with an ID number (i.e., no personal information, such as your name, will be on the study material). Do you consent to the use of your email for research purposes? YES/NO**
- **When completing the questionnaires, you are free to skip any question that makes you feel uncomfortable.**
- **Responsibilities and Expectations of Participants:**
  - **Keep your study appointments. If you miss an appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment.**
  - **Complete your questionnaires as instructed.**
  - **Ask questions as you think of them.**
  - **While participating in this research study, do not take part in any other research project without informing the investigators. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.**
- **Payment: If you are eligible for the study, you will receive up to $100 for participating. You will receive $40 for completing the first research assessment, either $25 or $35 for completing the 4-month research assessment (depending on a random assignment to complete either a shorter or longer assessment), and $25 for completing the 9 month assessment. You will be sent a check within 5 days of**

completing the interview. These will be disbursed by the Austin Financial Services Center. Due to this fact, an Internal Revenue Service Form 1099 will be generated for these payments. Because of this, we must use the Veteran's Social Security number for the payment.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

- **Questionnaires**
  Some people become uncomfortable when asked questions about the caregiving experience or psychological concerns. If, for any reason, you wish not to answer specific questions or you wish to terminate the session, you will be able to do so.

- **Audiotaping.**
  The study team has explained that by agreeing to be in this study, you voluntarily and without separate compensation, authorize voice recording(s) to be made of you by the care manager and research coordinator while you are participating in this study. You also authorize disclosure of the voice recording to other members of the study staff. The said voice recording is intended for the following purposes: quality control and evaluation of responses to the longer 4-month research assessment (if randomized).

  The study team has also explained that you will not receive any royalty, fee, or other compensation for such use. If you refuse to grant consent, there will be no effect on any VA benefits to which you may be entitled. You may at any time exercise the right to cease being recorded and may rescind your consent for up to a reasonable time before the voice recording is used.

  The recording is an optional part of the study; thus, you could refuse to be recorded but still be an active participant in the study. Do you refuse?

The main risk associated with participating in this study is potential breach of confidentiality. Every effort will be taken by study staff to ensure participants' privacy

and confidentiality. Please see the below section on "How will my private information be protected" for details of the plan to avoid breaching your confidentiality.

WHAT ARE THE POSSIBLE BENEFITS OF THE STUDY?
You may not benefit from participating in this research study.

If you are assigned to contact with the care manager, you may benefit from the counseling that the care manager will provide you. While no benefit is guaranteed, the information you provide may help us learn about whether the individual care management program is helpful to Veterans with behavioral health conditions and their employed caregivers.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?
One of the choices is to not participate in this research study. Participation is voluntary and you do not have to participate if you do not want to.

Your refusal to participate will involve no penalty or loss of rights to which you or the Veteran are entitled.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?
Information that will be used: During the course of this study, we will collect personal information such as your name, home address, email address (if you provide consent), phone number, and date of birth.

Your name will be used only as necessary within the CMCVA Medical Center. But other collected private information may be disclosed to the study sponsor (VA HSR&D).

Internal monitors from the CMCVAMC Institutional Review Board (IRB), a research oversight committee, also may inspect study records for quality assurance.

The results of this study may be published; however, you will not be identified by name or other personal identifiers.

Every attempt will be made by the research staff to keep all information you provide strictly confidential. Research forms will be coded with an ID number, de-identified from any personally identifiable information, and will be accessible to study staff only. All participant data will be stored and secured within locked filing cabinets in the research staff's office at the CMCVAMC (CHERP, Annex, Suite 202) or VAWNYHS (CIH research suite, Bldg 20, first floor, Room 128). All electronic data will be stored on CMCVAMC servers.

All research records, including the investigator's research records, must be retained according to the National Archives and Records Administration VHA's Records Control Schedule.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any treatments or procedures that are part of this study. If you receive care at the VA and usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?
It is important that you tell your study doctor, Shahrzad Mavandadi, PhD, if you feel that you have been injured because of taking part in this study. You can tell the study doctor in person or call her at (215) 823-5211.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY:

Dr. Amy Helstrom at (215) 823-4164 and

AFTER HOURS:

The VA Operator at 215-823-5800.

Emergency and ongoing medical treatment will be provided as needed.

DO I HAVE TO TAKE PART IN THE STUDY?
You understand that you do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you or the Veteran are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you or the Veteran are entitled.

You also may discontinue taking part at any time without any penalty or loss of benefits.

You should withdraw in writing in order to withdraw your permission for us to continue to use the protected health information we have already collected about you. Even if you withdraw, we can continue to use information about you that has been collected up to

that point. No information will be collected after you formally withdraw in writing and send the note to the address listed on the first page of this consent.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

This study may be stopped at any time without your consent because:

- **You have not followed study instructions, such as completing the first research assessment.**
- **The Sponsor or the study Principal Investigator has decided to stop the study.**

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You should contact the Research Compliance Officer at 215-823-7847 or the Patient Representative at 215-823-5803 from 8:00 AM to 4:30 PM, Monday through Friday if you have questions, complaints, or concerns about the study or if you would like to obtain information or offer input.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

Significant new findings developed during the course of the research which may relate to your willingness to continue participation will be provided to you.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

A member of the study staff has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers. You also confirm that you have read this consent, or it has been read to you. A copy of this consent will be given to you or sent to you via postal mail or already has been sent via mail.

SOS Oral Consent Script for Philadelphia

This is {Interviewer Name} and I am calling you about a research project sponsored by VA Health Services Research & Development at Corporal Michael J Crescenz VA Medical Center called Caregiver Self-Management of Stress, or Caregiver SOS.

Before we go over the information about the study, I would first like to ask you if you are in a location where you would feel comfortable speaking about this study and the Veteran you care for. *If no, schedule a time to call again.* Now I would like to go over the information with you, make sure that you understand it, answer any questions you may have, and see if you would consent to take part in the study. Please do not wait until I am done speaking to ask any questions. Feel free to interrupt me at any time. Your questions are important and I want to make sure that you have a chance to discuss any concerns. Depending on any questions you may have, the consent should take around 15-20 minutes, and then after the consent, if you are still interested, we can go over the 5–10-minute screening to make sure that the study is a good fit for you. We can stop at any time and take a break if you would like, and again you can choose to end this call at any time. Are currently enrolled in any other research studies? *If yes, ask what the research study is and what it's about. Let the CG know that you'll need to ask the PIs of this study if it's okay before continuing. Schedule a time to call back for the consent call.*

To begin, the purpose of this research study is to see whether a telephone-based counseling program is effective in improving your wellbeing and ability to function effectively both at work and as a caregiver. With this research we hope to learn if this program, Caregiver SOS, can be helpful to employed caregivers of Veterans.You are being invited to participate because you have been identified as an employed caregiver of a Veteran with a diagnosis or clinically significant symptoms of depression, anxiety, PTSD, and/or traumatic brain injury.

Your individual participation in this study will take place over the course of 9 months. This research study is expected to take approximately four years in full.

Approximately 220 people will participate in this research study at the CMCVAMC.

Additionally, about 80 people will participate at one other site in Buffalo, NY, for a total enrollment of 300 people at all sites.

You never need to come to the VA for this study; all parts of the study will take place over the phone, by mail or email.

Do you have any questions about the purpose of this study, where it is taking place, or why you're being asked to participate?

If you choose take part in the study, the following will take place:

- We will first determine if you are eligible to take part in the study through a brief (5-10 minute) screening.
    - To be eligible you must currently be at least 18 years or older, employed and work at least 10 hours per week, care for a Veteran who has a diagnosis

of depression, anxiety, PTSD and/or Traumatic Brain Injury (TBI); and help the Veteran you care for with day-to-day activities, like coordinating care or assisting in coping with symptoms

- You will complete a research assessment interview (approximately 1 hour), which can be done either by phone, through mail, or email.
    - You will repeat the research assessment interview after 4 months and then again after 9 months from the date of your first research interview.
    - You will be compensated for your time for completing each of the research assessment interviews by receiving a check in the mail after each completed assessment. You will receive $40 for completing the first research assessment interview, $25 or $35 for the 4-month follow-up research assessment interview (based on a random assignment to a slightly shorter or longer interview), and $25 for the 9 month follow-up research assessment interview.
- The completion of the 9 month follow-up research assessment interview will conclude your participation in the study.
- Shortly after the first research interview, you will be randomized into the usual care group OR the Caregiver SOS intervention group.
    - You will be informed of the group you are in with a call from the research coordinator.
- After you are randomized, you will be contacted by a care manager.
    - If you are in the usual care group, your care manager will provide some resources to you in a one-time (no more than 15 minute) phone call.
    - If you are in the intervention, you will be called by a care manager to begin taking part in the Caregiver SOS intervention. You will speak with this care manager for about an hour 7 times over the course of 4 months.
        - You will also receive a workbook to go along with the topics discussed with the care manager if you are in this group.
- Over course of the study, you will have contact with multiple members of the study staff. The research coordinator will contact you to let you know which arm of the research study you are in, to schedule and conduct the study assessments with you, and to connect you with the care manager. The care manager will contact you after you complete the first research assessment.
- All study procedures will take place over the phone, or if you prefer to complete the questionnaires on your own, you have the option of completing them at home via mail or email.Any information sent/received by email will be unlabeled or labeled with an ID number,sono personal information, such as your name, will be connected to the data we collect from you. Would you like for us to contact you via email throughout the study? *If yes, collect email address. Read back the spelling to be sure the e-mail address is correct*
- When completing the questionnaires, you are free to skip any question that makes you feel uncomfortable.
- Responsibilities and Expectations of Participants:
    - Keep your study appointments. If you miss an appointment, please contact research staff to reschedule as soon as you know you will miss the appointment.

    - Complete your questionnaires as instructed.
    - Ask questions as you think of them.
    - While participating in this research study, do not take part in any other research project without informing the investigators. Taking part in other research studies may not only invalidate the results of this study, but also the other studies as well.
- Payment: If you are eligible for the study, you will receive up to $100 for participating. You will receive $40 for completing the first research assessment, either $25 or $35 for completing the 4-month research assessment (depending on a random assignment to complete either a shorter or longer assessment), and $25 for completing the 9 month assessment. You will be sent a check within 5 days of completing each of the interviews. Those will be disbursed by the Austin Financial Services Center. Due to this fact, an Internal Revenue Service Form 1099 will be generated for these payments. Because of this, we must use the Veteran's Social Security number for the payment.

I have more information to go over with you, but I want to stop briefly to ask if you have any questions about the study procedures?

The likelihood that this study will cause you significant discomfort or inconvenience is small. There is a chance, however, that being asked questions about psychological concerns and/or your experiences as a caregiver may lead to some uncomfortable feelings. You do not have to respond to any questions that make you feel uncomfortable and a study counselor is available to speak withyou if you do experience discomfort as a result of your participation. All care management calls will be recorded. About 15% of these recordings will be reviewed by the lead investigators for quality control purposes only, basically, making sure the care manager is doing what they are supposed to. In addition, if you are randomly selected and agree to participate in a brief, qualitative interview at the 4-month research assessment, we will ask for your permission to record the interview. The recording is an optional part of the study, thus, you could refuse to be recorded but still be an active participant in the study. Do you refuse to be recorded?

The main risk associated with participating in this study is potential breach of confidentiality. This risk is also small. Every attempt will be made by the research staff to keep all information you provide strictly confidential. Research forms will be coded with an ID number, de-identified from any personal identifiable information, and will be accessible to study staff only. All participant data will be stored and secured in locked filing cabinets in the research staff's office at the CMCVAMC (CHERP, Annex, Suite 202) or VA Western New York (CIH research suite, Bldg 20, first floor, Room 128). All electronic data will be stored on CMCVAMC servers. Your name will be used only as necessary within the CMCVAMC. But other collected private information may be disclosed to the study sponsor (VA HSR&D).

Internal monitors from the CMCVAMC in Philadelphia Institutional Review Board (IRB), a research oversight committee, also may inspect study records for quality assurance.

The results of this study may be published; however, you will not be identified by name or other personal identifiers.

In terms of benefits, if you are assigned to contact with the care manager, you may benefit from the counseling that the care manager will provide you. While no benefit is guaranteed, the information you provide may help us learn about whether the individual care management program is helpful to Veterans with behavioral health conditions and their employed caregivers.

Again, you certainly do not have to participate if you don't want to; participation is completely voluntary and choosing not to participate involves no penalty or loss of rights to which you or the Veteran is entitled.

Do you have any questions about the risks and benefits associated with your participation?

Some Other information listed on your Information Sheet

- We will let you and the Veteran's doctor know of any important discoveries made while you are in this study that might affect you, the Veteran, or your willingness to take part.If during the study we find any major information related to the Veteran's health, we will notify the Veteran's doctor.

- If results of this study are published, there wouldn't be anything that would identify you; it would just be a summary of all the results of all the CGs put together. When the findings of this study are reported in medical journals or at meetings, you and the Veteran will not be identified by name, be recognizable by photograph, or in any other way without your specific consent.

- Again, you are not required to be in this study. Your participation is voluntary. If you want to make sure this is a VA-approved study you may contact the VA Research Office and that number will be on the copy of the consent information you will receive via mail or email.

- You can refuse to be in the study now. You can also leave the study whenever you wish after giving your consent, so a month into it, two months into it, and you decide it's not for you, that's certainly fine. This will not affect the Veteran's medical treatment, or your regular medical treatment if you are a patient at the VA.

- There will be no costs to you for any treatment or testing done as part of this study.

Eligibility for medical care is based on the usual VA eligibility policy, so basically, whatever copays the Veteran currently has will continue.

- If you have a medical record at this facility a copy of this consent information may be placed in that record.

- All research records will be maintained according to this Medical Center's requirements.

- A description of this clinical trial will be available on www.ClinicalTrials.gov, but again, that wouldn't have any information about you, it would just be at most a summary of the results as required by U.S. Law.

It is important that you tell the study investigator, Amy Helstrom, PhD, if you feel that you have been injured because of taking part in this study. She can be reached by phone at (215) 823-4164.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY:

Dr. Amy Helstrom at (215) 823-4164 and

AFTER HOURS:

The VA Operator at (215) 823-5800.

Financial compensation for research-related injuries is not available. However, by giving oral consent, you do not give up your legal rights to seek such compensation through the courts.

- You are not giving up any legal rights that you would otherwise have as a participant in a research study.

- Participation in this study is voluntarily, and means agreement to the use of personal identifiable information.

If you have questions, complaints or concerns about this study, you can contact the principal investigator for this study, Amy Heltrom, PhD., during the day at (215) 823-4164. If you have questions about your rights as a study participant, and you want to make sure this is a valid VA study, you may contact the Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. If you have a question, concern, or complaint and would like to speak to someone not on the study team, you should contact the Research Compliance Officer at (215) 823-7847 or the Patient Representative at (215) 823-5803 from 8:00 AM to 4:30 PM, Monday through Friday.

Significant new findings developed over the course of the research which may relate to your willingness to continue participation will be provided to you.

Anyone who has access to the VA Computerized Patient Record System (CPRS) could find out you are in this study. By giving oral consent, you understand that this information is available.

Okay, so I know that was a lot of information. Do you have any questions at this time? (If no): Okay, so Mr./Ms./Mrs X, are you interested in participating in the study?

Please say yes if you fully understand the information I have gone over and consent to be part of the study, if you have any questions at this time please make sure I have answered them to your satisfaction before responding yes. Do you consent to be enrolled in this study?

If Yes: Great, thanks! If you have any (other) questions as we progress through the study, please don't hesitate to reach out to the study coordinator. (Give number for study coordinator if you haven't already).The next step is to go through the screening, we can do that now or we can set up another time; it'll take about 5-10 minutes.

If they are not available to complete the screening now, schedule a time for fifteen minutes in the future. Let them know if you are working from home and that, if they need to contact you, they can reach your voicemail at your desk phone. You will call them back as soon as you receive their voicemail and they should tell you when the best time/what the best number to reach them at is if they need to reschedule or have any questions.