

Telehealth Cognitive Behavioral Therapy for Depression
in Parkinson's Disease (PD)

ClinicalTrials.gov ID: NCT02475954

Document Date: 6/9/17

VETERAN SUBJECT CONSENT INFORMATION

This is a type of research study called a randomized clinical trial. The study staff will explain the trial to you. You may want to talk with your family, friends, health care team, and study staff and ask their advice and what it means to you if you take part. When you have answers to all of your questions, please take your time to decide if you want to take part in the trial.

SECTION I. THE PURPOSE OF THE STUDY AND HOW LONG IT WILL LAST

You are being asked to take part in the research study because you are experiencing symptoms of depression and have a Parkinson's disease (PD) diagnosis.

The purpose of this research is to test a new treatment for depression in Veterans with Parkinson's disease. This treatment is called "Telehealth Cognitive Behavioral Therapy (TH-CBT)." Cognitive Behavioral Therapy teaches people to become more aware of their thoughts and feelings, and to change thinking patterns and behaviors that may be related to depressive symptoms. "Telehealth" means that the treatment will be delivered through your home computer, using videoconferencing so you do not have to travel to VA NJ. Telehealth treatment is being studied because many people with Parkinson's disease have a difficult time getting to doctor's appointments on a regular basis. The treatment can also provide a family member or friend that you choose (called your "Care-partner") with information and skills to help him/her best support and assist you in living with your medical condition.

To evaluate this treatment, 90 participants with depression and Parkinson's disease and their Care-partners, if a Care-partner participates, will take part in this study over a period of 4 years at the VA NJ Health Care System. Your participation in this study will last up to 9 months. If you decide to participate, you will be "randomized" into one of two study groups. This means you are put into a group by chance. Like flipping a coin, you will have a 1 in 2 chance of receiving either:

- The treatment you would usually receive at the VA (called the "Control Group"), or;
- Telehealth Cognitive Behavioral Therapy (TH-CBT), in addition to the treatment that you would usually receive at the VA (called the "Intervention Group").

Having these two groups allows the research team to compare the results of those who receive the study treatment and those who do not. This helps determine if the treatment is helpful.

If you are selected for the Intervention Group, you will receive 10 weekly individual sessions (60 minutes each) of TH-CBT, delivered via a secure telehealth connection. If a care partner participates with you, your Care-partner will also be offered 3 sessions, which are designed to provide him/her with skills to assist you with coping with your depression and Parkinson's disease.

If you are selected for the Control Group, you will continue to receive your standard care, including all mental health and Parkinson's disease care that you qualify for through the VA, but you will not be offered the additional TH-CBT treatment during the 9-month study period.

However, after completing the 9-month study period, you and your Care-partner, if a Care-partner participates with you, will be offered TH-CBT.

The US Veterans Administration is paying for the VA NJ Health Care System to do this study.

SECTION II. STUDY DESCRIPTION AND PROCEDURES TO BE USED

This is what will happen if you agree to take part:

1. If you decide to take part, you will be asked a series of assessment questions about your medical diagnosis and psychiatric history over the telephone, which will take approximately two to three hours. This screening appointment can be split into two sessions if necessary. Part of this assessment will also involve completing questionnaires that will be mailed to you, which you would return through the mail. In addition, a Movement Disorder specialist will review your VA medical record or the information about your Parkinson disease symptoms we collect during the research assessment.
2. After you have completed the first set of assessment questions, you will be “randomized” into one of two study groups. This means that you are put into a group by chance. Like flipping a coin, you will have a 1 in 2 chance of receiving either the treatment you would usually receive at the VA (called the “Control Group”), or Telehealth Cognitive Behavioral Therapy (TH-CBT), in addition to the treatment that you would usually receive at the VA (called the “Intervention Group”).
3. If you are assigned to the Intervention Group, you will receive 10 weekly individual sessions (60 minutes each) of CBT, delivered via telehealth. Treatment will teach you coping skills (such as relaxation training) to more effectively manage your depression. If a Care-partner (friend or family member) participates with you, he or she will also attend 3 separate educational sessions (30-60 minutes each), that are evenly spaced throughout your treatment. The Care-partner sessions are intended to provide your family member or friend with the skills needed to help you practice your new coping skills (i.e., exercise, socializing, reframing thoughts).
4. Participants assigned to the Intervention group will need access to a computer or tablet and a webcam to use telehealth videoconferencing. If you do not have a webcam, one will be provided to you. You will need to download the telehealth software and will be assisted with this process.
5. If you get randomly selected for the Intervention Group, you will also continue to receive all of your regular VA care.
6. No matter which group you are randomized into, we will conduct the first research assessment with you shortly after you sign up for the study as described above and we will ask you to participate in 4 more research follow-up assessments during the 9 months of the study, at approximately 5 weeks, 10 weeks, 4 months, and 9 months from the time you sign up. These assessments will be conducted over the telephone and through mailed surveys and will take approximately 1-2 hours to complete.
7. The study team will reimburse you for your time for completing these study assessments with a \$45 payment voucher. If you complete all five assessments, you will receive a total of \$225 ($\$45 \times 5 = \225). Also, twenty veterans will be selected to complete an additional interview about their experiences in the study about 10 weeks after signing up. If you

complete the “exit interview,” you will receive an additional \$20. These incentive payments are for completing the research assessments only. Payments are not made for the study treatment, if you are randomized into the group that receives the study treatment.

8. As part of your participation in this study, the study staff will contact you by telephone and/or letter to arrange for upcoming appointments related to the study.
9. If any of the questionnaires used in the study show significant symptom worsening, your study clinician will discuss this with you to determine your needs and/or will coordinate with your usual care clinicians so that treatment options can be considered.
10. If you are currently receiving mental health care, the study clinician may contact your usual VA mental health care clinician to coordinate treatment as necessary.
11. You will continue to receive all of your routine VA clinical care, regardless of which study group that you are assigned to.

SECTION III. EXPECTED RISKS, DISCOMFORTS, OR INCONVENIENCES OF TAKING PART IN STUDY

Taking part in this study may involve some added risks.

1. There is a risk that study information (data) could be connected to your name. This is called “loss of confidentiality.” We believe that the risk of this is small.
2. Because each assessment session involves completing questionnaires about your mental health, it is possible that you may find some of the questions uncomfortable. You can stop completing the questionnaires at any time if you feel uncomfortable answering the questions. Following each assessment session, you will be able to discuss with the interviewer any concerns that you may have about the procedures. Counseling and assistance will be provided if needed. You can also ask to take a break during the assessment interviews if needed. If your symptoms worsen at any time between study visits, or you experience unwanted effects, you should contact your doctor or Dr. Alejandro Interian at (908) 647-0180, ext. 4617.
3. The study staff will tell you about any new risks or new side effects that could happen to you from taking part in the study.
4. You can be withdrawn from the study without your consent if you fail to follow study procedures, or if your symptoms get worse and the Principal Investigator, Dr. Alejandro Interian, determines that it is in your best interest not to participate in the study.

SECTION IV. EXPECTED BENEFITS OF THE STUDY

Participating in this research program may provide you with direct benefits that include improved emotional (such as less depression and anxiety) and physical health. These benefits may be due to the study treatment or the treatment you are already receiving as part of your standard care. Participants in both treatment conditions will receive closer monitoring of depressive symptoms relative to standard care. This increased monitoring will help detect if your symptoms are getting worse or if you are having a mental health crisis, allowing for appropriate care to be provided and coordinated which is an additional benefit. In addition, the findings from this study

may help other Veterans like yourself who have depression and Parkinson's disease. Finding out whether this treatment is helpful to Veterans could not be discovered without conducting a study like this, in which we compare people who receive the treatment to those who do not.

SECTION V. OTHER TREATMENTS AVAILABLE

1. If you choose not to participate in this study, you will not receive the additional services included in the TH-CBT program. You will still receive the standard VA treatment for patients who have depression with Parkinson's disease.
2. You do not have to take part in this study if you do not want to. If you choose not to take part in this study, you and your doctor will decide on available treatment options.

SECTION VI. CONFIDENTIALITY: PROTECTING YOUR INFORMATION

1. The study information that is collected consists of questionnaires. These questionnaires contain questions about your mental and physical health, substance abuse history, family history, and history of suicidal thoughts and behaviors. In addition, the study team will use information from your medical record, including information about appointments, hospitalizations, medications, and diagnoses.
2. Only members of the research team have possession of and access to the study-related information and materials.
3. To protect your confidentiality, all of your sensitive study information will be stored separately from any information that identifies you, such as your name. Your sensitive study information will be given a confidential code number, which will help ensure that your sensitive study information cannot be associated with your identify or name. There is a link connecting your name and your confidential code, but will only be accessible by approved research staff and is kept separately from the study data.
4. The information you tell us in the questionnaires is identifiable only by research staff members with access to the password-protected computer files stored on the VA secure server that contains the link between your confidential code and your study information.
5. This link is maintained on the secure VA network in a password-protected database.
6. All study documents collected by you are maintained in a locked file cabinet in a locked room on the Lyons campus of the VA New Jersey Health Care System. All data obtained from the study that is entered into the secured database is associated with the subject's code. Study materials will be stored until no longer needed and then destroyed as per the VA's policy for destruction of study records.
7. Your study records that are kept at the VA, including the links, will be destroyed as allowed by the VA's policy for destruction of study records.

Your medical and study records may be reviewed by:

- VA Quality Assurance and VA Research Compliance personnel
- Federal regulatory officials (e.g., Office of Research Oversight, Office of Research and Development, and the Office for Human Research Protections)

- Institutional Review Board members
- Research and Development Committee members
- Collaborating Institutions
- VA Health Services Research and Development (HSR&D), the sponsor of this study
- Members of the Data Safety Monitoring Board (DSMB) for this study

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Your medical records will be kept according to VA NJ Health Care System policies.

If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent.

With your permission, study staff make audio-recordings of some of the assessment interviews as well as the exit interviews for those who received the study treatment. The purpose for recording these assessments is to ensure accurate ratings and to gain an understanding of your experiences with the study.

Study staff will also make and use audio-tapes of the treatment (TH-CBT) sessions with your permission. The purpose is to have experts listen to them to make sure that the therapist conducting the session is following the correct treatment procedures. Study staff will always ask for your permission before starting to record. The recordings will be kept on a secure server and will be disposed of per the VA's policy after the study is complete.

SECTION VII. SPECIAL INFORMATION

1. Taking part in this study is your voluntary decision. You may choose to take part or choose not to take part in the study. This choice will not affect the medical care you are receiving or will receive at the VA NJ Health Care System.
2. You can stop taking part in the study now or at any time after you give your consent. This choice will not affect the medical care you are receiving or will receive at the VA NJ Health Care System.
3. There will be no cost to you for the treatment or testing done specifically for this study. Tests and treatments that are considered the standard care for your condition will be charged according to your VA co-pay eligibility.
4. Important new findings found during this study which may change your willingness to continue in the study will be given to you.
5. We will let you and your doctor know of any important information found during this study that may affect you or your condition.

6. Research-related injuries:
 - a. If you think you have been injured by the research, you should contact Alejandro Interian, Ph.D. at 908-647-0180 x4617 during the day.
 - b. The VA NJ Health Care System will provide you with medical care if you are injured from taking part in this study.
 1. This does not apply if your injury was caused from not following study procedures. This is called non-compliance with study procedures.
 2. Except in limited circumstances, the necessary care will be provided in VA medical facilities.
 - c. If you are injured from taking part in this study, you may be able to take legal action under federal law to receive monetary compensation for your damages.
 - d. This study has not set money aside to compensate you for injuries caused by taking part in this study.
7. As described above, you will be paid up to \$225 in payment vouchers for completing the research assessments in this study. You will receive \$45 for the first assessment, \$45 for the second, \$45 for the third, \$45 for the fourth and \$45 for the fifth assessment. You will complete the first assessment shortly after you decide to participate in the study, and 4 more that will take place within the next 9 months. Also, some participants will be invited to complete an exit interview and will receive \$20 for this interview. Reimbursement will be mailed to you, following the completion of each study assessment. However, there are no incentive payments made for treatment sessions if you are randomized into the treatment condition.

SECTION VIII. AFFIRMATION FROM SUBJECT

RESEARCH SUBJECTS' RIGHTS: I have read or have had read to me all of the above. Study staff has explained the study to me and answered all of my questions.

I have been told these things.

1. The risks or discomforts and possible benefits of the study.
2. The choices of treatment available to me.
3. I do not have to take part in this study. My choice not to take part will involve no penalty or loss of benefits to which I am entitled.
4. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.
5. If results of this study are published, I will not be identified without my specific consent. My records will not be released unless required by law.
6. I should contact Dr. Alejandro Interian at 908-647-0180 ext. 4617 if I have any questions about the study.
7. I should contact Dr. Alejandro Interian at 908-647-0180 ext. 4617 or the Patient Representative at 973-676-1000 extension 2169 if I have any questions about my rights as a study participant.
8. I should contact the Patient Representative at (973) 676-1000 extension 2169 if I have concerns, questions, or complaints, or wish to talk to someone else about this study or to verify the validity of the study.