A Randomized Clinical Trial Comparing Brief and Standard Cognitive-Behavioral Therapies for Insomnia in Veterans

NCT05724498

January 19, 2023

Participant Name: _____ Date:_____

Title of Study: A Randomized Clinical Trial Comparing Brief and Standard Cognitive-Behavioral Therapies for Insomnia in Veterans

Principal Investigator: Wilfred Pigeon, Ph.D. VA Facility: VA Finger Lakes Health Care

Principal Investigators for Multisite Study: Henry Orff, Ph.D. and Wilfred Pigeon, Ph.D.

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by the VA Rehabilitation Research & Development Service. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

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

Drs. Henry Orff (San Diego, CA VA) and Wilfred Pigeon (Canandaigua, NY VA) are conducting a research study to determine if a brief (4 session) cognitive-behavioral treatment for insomnia can be as effective in improving sleep in Veterans as the more commonly used (6 session) intervention. You have been asked to participate because you are a Veteran with insomnia.

Your participation will take approximately 2 hours for an initial intake visit and approximately 1 hour for each treatment and follow-up assessment visit. Your assessment visits will be conducted in-person however your treatment visits can be conducted through remote (telemed) contacts if you choose.

By doing this study, we hope to learn whether a brief intervention for insomnia can provide equal benefits as the standard longer intervention in terms of sleep, functional, and psychiatric outcomes in Veterans with sleep problems.

Your participation in the study will be approximately 20 weeks. The study itself will take about 4 years to complete. There will be approximately 125 participants at each of the two VA sites.

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

There may or may not be a direct benefit to you from participation in the study. You will be assessed on measures of sleep and mental health. If any previously unknown conditions or sleep disorders are discovered as a result of these exams, we will discuss the results with you and make an appropriate referral for treatment. You will also receive treatment for your insomnia. Other than these items, you will not personally benefit from participation in this study, however, the investigators may learn more about the effectiveness of interventions used to treat insomnia in Veterans.

For a complete description of benefits, refer to the Detailed Information section of this consent.

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

Participation in this study may involve some discomforts. At intake, you will be asked to answer interview questions on a iPad tablet addressing your sleep, mental and physical health, and quality of life and provide responses on the sleep diaries. Risks associated with completing the screening and questionnaires may include frustration, boredom and/or fatigue.

There may also be risks associated with the treatment interventions which may include initial worsening of nighttime sleep difficulties and/or a temporary increase in daytime sleepiness.

Other potential risks of this study include loss of confidentiality. As a result of participation in this project, there is a very small risk that sensitive information (e.g., psychiatric information which you have provided) could become known outside the research setting. To minimize this risk, your name will not be on any of your data; instead, your name will be replaced with a code number. All of your data will be kept in locked cabinets and electronic data will be stored on secured VA databases that are password protected and will only be available through the investigators at the VA San Diego and Canandaigua research sites.

Because this is an investigational study there may be some unknown risks that are currently unforeseeable. You will be informed if the researchers learn of any change in the amount of risk to you. The alternative to participation in this study is to not participate.

For a complete description of risks, refer to the Detailed Consent and/or Appendix.

DO YOU HAVE TO TAKE PART IN THE STUDY?

Participation in this study is voluntary. 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 persons in charge of the study at VA Finger Lakes Heath Care is Dr. Wilfred Pigeon at the Canandaigua VA. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study you may contact Dr. Pigeon at (585) 393-7918.

Participant Name: _____ Date:_____

Title of Study: A Randomized Clinical Trial Comparing Brief and Standard Cognitive-Behavioral Therapies for Insomnia in Veterans

Principal Investigator: Wilfred Pigeon, Ph.D. VA Facility: VA Finger Lakes Health Care

Principal Investigators for Multisite Study: Henry Orff, Ph.D. and Wilfred Pigeon, Ph.D.

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

By conducting this research project we hope to compare a 4-session brief Cognitive-Behavioral Therapy for Insomnia (CBT-I) to VA standard 6-session CBT-I to evaluate whether a brief intervention can provide comparable benefits to sleep, functional, and psychiatric outcomes in Veterans with insomnia.

HOW LONG WILL I BE IN THE STUDY?

Your individual participation in the project will take approximately 20 weeks (5 months). The overall study will take about 4 years to complete. There will be approximately 125 participants at each of the two VA sites.

ENROLLMENT CRITERIA

To be eligible for participation in the study you **must** meet the following criteria:

1. Have a diagnosis of insomnia which includes: trouble falling asleep, staying asleep, and/or waking too early in the morning, with accompanied impairment in daytime functioning, for at least 3 months and occurring at least 3 nights per week.
2. Your sleep disturbance needs to be sufficiently severe as defined by an Insomnia Severity Index score >7 at intake.
3. You must meet criteria for having at least one other mental health disorder (e.g., depression, anxiety) as verified by clinical assessment.
4. You must be stable on any sleep or psychiatric medications for at least 4 weeks prior to enrollment in the study.

To be eligible for participation in the study you **must not** meet any of the following criteria:

1. Have a history of neurological disorders or dementia.
2. Have a current or past diagnosis of schizophrenia and/or bipolar disorder.
3. Show evidence of risk for suicide as determined by clinical assessment.
4. Have significant or untreated sleep disturbances other than insomnia (e.g., untreated obstructive sleep apnea).
5. Meet criteria for alcohol and/or substance use disorder within 90 days prior to enrollment in the study as determined by clinical assessment.

6. Have had formal therapist guided treatment with Cognitive-Behavioral Therapy for Insomnia within the past 2 years.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

A. At your first visit you will meet with study staff to receive information regarding the research study and be given an opportunity to ask questions about study participation. If you consent to participate, the staff will conduct a comprehensive interview in which we will ask you questions about your sleep and current mental health status. We will also administer additional questionnaires addressing your life circumstances, your daily functioning and quality of life, any medical symptoms you are experiencing, medications you may be taking, and current sleep patterns. You will be free to decline responding to any questions that you prefer not to answer without this affecting your participation in the study. This visit will take about 2 hours.

B. You will then be provided with a sleep diary to complete for 7 days. The sleep diary will be filled out each morning and will ask you reflect on how you slept the night before. You will be required to record the time you went to bed and when you woke up for the day, how long it took for you to fall asleep and how long you were awake during the night, and will have sections for you to rate the quality of your sleep and note if there were any special reasons why you slept well or poorly on the previous night. This log typically takes less than 5 minutes to complete.

C. Following completion of the 7-day sleep monitoring period, you will email your sleep diary back to your VA site coordinator at which time you will be randomly assigned (e.g., by chance or like the flip of a coin) to one of the two treatment conditions. Treatment will last for either 4 or 6 weeks depending on your assignment. During treatment you will have the option to either come into the VA for your sessions or meet with the study therapist virtually. Sessions will be conducted individually once a week for 30-60 minutes. These sessions will be audiotaped so that they can be independently reviewed by VA study staff to ensure that the treatment is being administered correctly. As evaluation of the treatments used in this investigation is an important component of the research, you will have to agree to audiotaping of sessions to be able to participate in the study. The audiotaped sessions will be labeled with your subject code number to help protect your privacy and no audiotaped sessions will be disclosed outside the VA or to other individuals not on the study team.

D. After treatment is completed, you will participate in a 1-week post-treatment evaluation of your sleep. For this assessment you will be emailed a sleep diary to complete for 1 week. At the end of this week you will bring your diary to the study coordinator and at this time you will be provided with an iPad tablet on which you will answer questions regarding your sleep, mental and physical health, and quality of life in the same manner as the initial assessment visit. This session should only take about an hour to complete.

E. Approximately 3 months after you complete the post-treatment evaluation, we will be asked to return to the study site to perform a follow-up assessment. Prior to this session you will be emailed a sleep diary to complete for one week. You will then bring your diary to the study coordinator and at this time you will be asked to complete the questionnaires assessing your overall functioning on the iPad tablet just as you did for the intake and post-treatment visits. Following this assessment your participation in the study will be completed.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

- 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 diaries as instructed.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Notify the investigator or research team if you experience any sudden onset of medical or psychological concerns.
- Keep the study staff informed as to any changes in medications or dosages of medications you are taking while in treatment.
- While participating in this research study, do not take part in any other research project without approval from 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.

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

Participation in this study may involve some discomforts. At intake, you will be asked to answer interview questions and provide responses on the sleep diaries and self-report questionnaires. Risks associated with completing the screening and questionnaires may include frustration, boredom, and/or fatigue.

There may also be risks associated with the treatment interventions which may include initial worsening of nighttime sleep difficulties and/or a temporary increase in daytime sleepiness which occur to some extent in most patients. The study therapist will discuss possible risks and provide recommendations for minimizing risks during the initial treatment sessions. If you notice any severe side effects to treatment you will be able to pause treatment until you can discuss your symptoms with the study therapist.

Other potential risks of this study include loss of confidentiality. As a result of participation in this project, there is a very small risk that sensitive information (e.g., psychiatric information which you have provided) could become known outside the research setting. To minimize this risk, your name will not be associated with any of your data and will be kept in a separate secured location; instead, your name will be replaced with a numerical code. All of your data will be kept in locked cabinets and electronic data will be stored on secured VA databases that are password protected and will only be available to the investigators.

The treatments employed in this investigation are standard interventions commonly used in treating insomnia and primarily focus on changing behaviors, thoughts, and habits related to sleep. There are no significant health risks associated with these treatments nor are there any known concerns to pregnant women or the fetus from receiving cognitive-behavioral treatments for insomnia.

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.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

You will receive a comprehensive sleep and mental health evaluation as well as treatment for your insomnia. Otherwise, there are no direct/personal benefits to you from taking part in this research study. However, the information the investigators obtain from this study may help other Veterans with insomnia.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

This study will be testing two versions of a standard therapy for insomnia. Since CBT-I is a commonly administered treatment you could receive this intervention from providers not affiliated with the study if you desire. Please feel free to discuss this option with the study staff and/or your health care provider.

No other treatment options will be available through participation in this study. Therefore, the only other alternative to participation in the procedures in this study would be to not participate.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

We will take multiple steps to protect your privacy and confidentiality. All data will be labeled with a code number that is unique to each Veteran in the study. We will NOT include any protected health information (PHI) in the data files. All hard copy data will be stored in locked filing cabinets in locked rooms, while all electronic data will be stored in password-protected files on the secure VA network drive. Only Dr. Orff and Dr. Pigeon and approved study personnel will have access to data files or informed consent forms. We will analyze and report summary findings from the study such that no individual personal information will be entered into these analyses or reports. Note that after removal of all identifiers associated with your private information, non-identifiable information obtained in this study could be used for future research studies or distributed to another investigator for future research studies without additional informed consent by you. We will include information about your study participation in your medical record.

There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central Institutional Review Board (IRB), local Research and Development Committees, and other study monitors may look at or copy portions of records that identify you.

Additionally, by law, the investigators and study staff are mandated reporters and therefore will be required to disclosure to local authorities reports of child or elder abuse or neglect, or harm to self or others.

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.

Health Information Portability and Accountability Act (HIPPA)

There are rules to protect your private information. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. The study team may also collect other information including your name, address, date of birth, and information from your medical records such as HIV status, drug, alcohol or STD treatment, genetic test results or mental health treatment.

The research team may also need to disclose the information to others as part of the study progress. Others may include the following: the VA Office of Research Oversight (ORO), the VA Central IRB, and the local VA medical facility Human Research Protections Program.

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

While this study is being conducted you will not have access to your research related health records. This will not affect your VA healthcare, including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility, or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when

the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, Dr. Pigeon and/or the research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time

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 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. If you receive a bill for services that you think could be related to your participation in this study, you should contact Dr. Pigeon and/or the study coordinator(s).

For this study participants will receive compensation based on the following schedule:

Baseline Assessment	$25
Post-treatment Assessment	$25
20-week follow-up assessment	$50

Total reimbursement for completion of the study will be $100, however we will prorate payments to reimburse you for your participation if you elect to leave the study early. Payments will be made through electronic transfer from the VA Financial Services Center to your bank account. You will therefore need to provide your account information to the study staff to process your reimbursement. This information will only be used to process the payment and will not be stored in your patient file.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with

study procedures or if the research is conducted for VA under contract with an individual or non-VA institution. If you should have a medical concern or get hurt or sick as a result of taking part in this study, call Dr. Pigeon at (585) 393-7918 or a Patient Advocate at (585) 393-7612.

DO I HAVE TO TAKE PART IN THE STUDY?

Participation is voluntary. Refusal to take part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you are a VA employee or student, refusal to take part in the study will in no way influence your employment, ratings, subsequent recommendations, or academic progress as applicable. If you decide to leave the study, we may attempt to contact you to assess your reasons for withdrawal and to ensure that your health and welfare will not be negatively impacted by stopping treatment. However, given the nature of the interventions employed in this study we do not expect any negative consequences to your health and welfare from discontinuing treatment. If you withdraw from the study the investigators may continue to review the data already collected from you for the study but cannot collect further information, except from public records, such as survival data.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

To further minimize risks to your participation in the study, study personnel may choose to discontinue your participation if we feel that the assessments or treatments are inappropriate for you. Examples may include your inability to comply adequately with study procedures, a sudden onset or exacerbation of a medical or mental health condition, or if you experience negative side-effects to treatment. If this determination is made we will provide and facilitate referrals to you as needed for continued care.

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

If you have questions about this research, you can call Dr. Pigeon at (585) 393-7918 or a Patient Advocate at (585) 393-7612.

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 VA Central Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Central IRB toll free at 1-877-254-3130 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date:	**11/02/2022**
LSI Approval Date:	**01/19/2023**
LSI Verification Date:	**N/A**

Participant Name: _____ Date:_____

Title of Study: A Randomized Clinical Trial Comparing Brief and Standard Cognitive-Behavioral Therapies for Insomnia in Veterans

Principal Investigator: Wilfred Pigeon, Ph.D. VA Facility: VA Finger Lakes Health Care

Principal Investigators for Multisite Study: Henry Orff, Ph.D. and Wilfred Pigeon, Ph.D.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

Sometimes during the course of a research study, new information becomes available about the treatment that is being studied that might change a person's decision to stay in the study. If this happens, the study staff will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw from the study, we will arrange for your medical care to continue. If you decide to continue in the study, you might be asked to sign an updated informed consent form. Other than in these circumstances clinical results of the study will not be disclosed to you.

FUTURE USE OF DATA AND RE-CONTACT (Include if Applicable)

We will retain de-identified data from this study for analysis and future presentations and publication of the results. All hard copy data will be stored in locked filing cabinets in locked rooms, while all electronic data will be stored in password-protected files on the secure VA network drive. Only authorized study staff will have access to this data.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms_____ _____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.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date:	**11/02/2022**
LSI Approval Date:	**01/19/2023**
LSI Verification Date:	**N/A**