Document: Consent Form, Main Phase
Official Study Title:
Hypnosis and Meditation for Pain Management in Veterans: Efficacy and Mechanisms
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| **SUBJECT NAME** | |
| **TITLE OF STUDY** | **Chronic Pain Skills Study** |
| **PRINCIPAL INVESTIGATOR** | **Rhonda M. Williams, PhD** |

**LAY TITLE: Chronic Pain Skills Study – Main Study**

**Research Team:**

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| Rhonda Williams, PhD | Principal Investigator | (206) 277-6290 |
| Mark Jensen, PhD | Principal Investigator | |
| Aaron Turner, PhD | Co-Investigator | (206) 277-6134 |
| Dawn Ehde, PhD | Co-Investigator | |

**CPSS Study toll-free number: 1-800-329-8387; then dial 1-65167**

**24-hour emergency contact:**

- In case of medical emergency, you are advised to call 911. If you feel like harming yourself or others, you are advised to go to the nearest Emergency Room or call the Veteran's Hotline at 1-800-273-8255.
- For any other psychiatric emergency, please call the VA operator at (206) 762-1010 and press "0" for the operator. Both during and outside of business hours, there is an on-call provider. The operator will take your name and number, contact the on-call provider, and have the provider call you back. You are also welcome to come to the Emergency Room at VA Puget Sound.

You are invited to be in a research study. The purpose of this Consent Form is to give you the information you will need to help you decide whether to be in the study. Please read this form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide whether you want to be in the study. You are free to discuss this with friends or family. This process is called "informed consent."

## 1. Purpose of research study and how long it will last:

Chronic pain is a significant problem for many Veterans. Individuals with chronic pain also experience a number of other problems, such as mood and sleep problems. All of these can have negative effects on the quality of life of Veterans.

Three different types of treatment that have been used to treat chronic pain in the general population include self-hypnosis, education about chronic pain, and teaching individuals how to be more mindful. The purpose of this study is to see if these three treatments can help decrease pain in Veterans. Additionally, the researchers want to determine if each of these treatments can help reduce the negative consequences associated with pain, such as changes in mood, sleep, and enjoyment of life.

You are being asked to participate in this study because:

- You are a Veteran.
- You have reported that you experience moderate-to-severe chronic pain on a regular basis.

This study is a joint effort between VA Puget Sound Health Care System ("VA Puget Sound") and the University of Washington (UW). The sponsor of this study is the National Center for Complementary and Integrative Health (NCCIH), part of the National Institutes of Health. All of the participants in this study will be Veterans recruited from VA Puget Sound. The study will enroll up to 355 subjects.

The overall study will last for 5 years, but each person's involvement in the study will take 9-12 months. The study activities will take 9 months once you start treatment, but it can take up to 3 months for each treatment group to start.

## 2. Description of the study including procedures to be used:

### Length of Study

If you participate in this study, we will need approximately 20-23 hours of your time over a 9-month period. Some study activities can be completed by telephone. The cognitive assessment and the relaxation and hypnotic exercise at the beginning of the study will be completed at VA Puget Sound. You will also need to attend group classes at VA Puget Sound.

This study is time intensive, so you should enroll only if you think you can finish the study. A flowchart of study procedures is at the end of this Consent Form to help you decide if you can make the time commitment.

### Overview of Study Activities

- Informed consent process
- Assessments:
  - One in-person cognitive assessment (20-30 minutes)
  - Relaxation and hypnotic exercise (15-20 minutes)
  - One baseline assessment that can be done in person or by telephone (20-30 minutes)
  - Seven telephone assessment periods (45-60 minutes total)
- Eight in-person treatment sessions (90 minutes each)

### Research vs. Standard Care

For **research** purposes, you will need to complete:

- A cognitive assessment
- Relaxation and hypnotic exercise
- Telephone assessments

These research procedures are outlined in "Assessments" below.

The treatment sessions you will need to attend at VA Puget Sound will be considered **standard care,** since you would receive the same treatment with your usual care. However, if you enroll in the study, you will not get to choose which of the three treatments you will participate in. The treatment that you will be receiving would then be considered as **research.**

After completing the final assessment period, we will offer to mail you the treatment materials for one or both of the treatment interventions you did not participate in the first time. The treatment materials would include a workbook and audio recordings.

## Informed Consent Process

This form and this informed consent process is for all procedures at VA Puget Sound. This informed consent for all VA study activities will take place at the VA Seattle Campus or the VA American Lake Campus. A research staff member will review the details of the study with you and answer any questions you may have to see if you are interested in participating.

This informed consent process does not cover the optional brain activity assessments that take place at the University of Washington (UW). There is a separate UW Consent Form for that part of the study.

## Assessments

The research assessments you will need to complete are described below. None of the findings from these assessments will affect the treatment group assignment, study eligibility, or any aspect of your clinical care.

- **Cognitive Assessment.** The first assessment is a short series of tests of your memory, ability to think quickly, and reasoning skills. This assessment needs to be completed in person. You can complete the cognitive assessment immediately following the informed consent process, or you can schedule them for a time that is more convenient for you.

- **Relaxation and Hypnotic Exercise.** A research staff member will see how well you respond to a relaxation and hypnotic exercise. During this exercise, the research staff member will ask you if you are willing to describe a part of this experience. However, you will only be asked to describe as much of this experience as you want. You do not have to describe any of it if you do not want to. This exercise needs to be completed in person. You can complete the hypnotic exercise immediately following the informed consent process, in combination with the cognitive assessment, or schedule it for a time that is more convenient for you.

- **Baseline Assessment.** A research staff member will ask you a number of standard questions. The most straightforward of these questions will ask about your age, gender, race, ethnicity, education level, employment status, and military service. You will also be asked question about your pain problem(s) and any other health problems you may experience. You will also be asked two questions about whether or not you ever experienced military sexual trauma, as well as questions about potentially stressful military experiences. Some examples of the questions that will be asked during the evaluation include:

- *When you were in the military, did anyone ever use force or the threat of force to have sex with you against your will?*
- *How often did you see someone hit by incoming or outgoing rounds?*

You are free not to answer any questions you do not wish to answer.

- **Brain Activity Assessments (optional).** There is a brain activity assessment portion of the study that takes place at the University of Washington Integrated Brain Imaging Center (IBIC). This portion includes completing one brain activity assessment before treatment begins and one assessment after treatment ends. Signing this Consent Form does not mean that you are consenting to participate in the brain activity assessments. If you choose to participate in the brain activity assessments at the UW, you will be asked to review and sign a separate UW Consent Form at the UW before participating in any assessments there.

- **Telephone Assessment Periods.** Throughout your participation in the study, you will be asked to complete seven telephone assessment periods. Each of the seven telephone assessment periods includes a set of **four telephone calls on different days, all within the same week.** This is a total of 28 telephone calls over the 9-month study period.

  During **each telephone call,** research staff will ask you to rate your pain intensity. These questions will take about 2 minutes to complete.

  Researchers may ask you to answer these questions more than four times within an assessment period if you do not complete the four telephone calls within 1 week.

  Within **each assessment period,** we will ask you additional questions relating to:
  - How pain has interfered with your life.
  - How you have been feeling recently.
  - Thoughts or feelings you have had about your pain.
  - Medications you use.
  - Personal habits.
  - History including alcohol and drug use.
  - Any problems you may experience related to stressful military experiences.
  - How logical the treatment seems to you.
  - How successful you think the treatment will be in reducing your pain.
  - How your relationship is with your group leader(s) during treatment.
  - Whether you were satisfied with the treatment (once the treatment is over).

  You are free not to answer any questions you do not wish to answer.

  To make each of the 1-week telephone assessment periods more convenient to your schedule, you may choose to:
  - Complete the extra set of questions all at once in any one of the four telephone interviews.
  - Spread the extra set of questions across four telephone interviews so that each call is about 10 minutes long.

Research staff may ask you to complete additional short assessments per assessment period if you are unable to complete all four assessments within a span of 7 days. There will be seven telephone assessment periods, each including four phone interviews, which will occur at the following stages of the study:

- **Pre-Treatment Assessment Period** must be completed before the first group treatment session. These questions can be completed only over the phone. You may be asked to complete this assessment period again if you do not begin treatment within four weeks of completing the assessment period the first time.

- **During Treatment / 2-Week Assessment Period** will occur between the second and third treatment session (about 2 weeks after you start treatment). Even if you have missed treatment sessions, we will still ask you to do the assessment period at that time.

- **During Treatment / 4-Week Assessment Period** will occur between the fourth and fifth treatment session (about 4 weeks after you start treatment). Even if you have missed treatment sessions, we will still ask you to do the assessment period at that time.

- **During Treatment / 6-Week Assessment Period** will occur between the sixth and seventh treatment session (about 6 weeks after you start treatment). Even if you have missed treatment sessions, we will still ask you to do the assessment period at that time.

- **Post-Treatment Assessment Period** will occur at the end of your treatment (if you complete treatment). If you don't complete the treatment, we will still conduct this assessment period about 8 weeks after you started the treatment.

- **3-Month Follow-Up Assessment Period** will occur about 3 months after you complete the post-treatment assessment period regardless of how many treatment sessions you complete.

- **6-Month Follow-Up Assessment Period** will occur about 6 months after you complete the post-treatment assessment period regardless of how many treatment sessions you complete.

After the completion of the 3- and 6-month telephone assessment periods, research staff will invite you to participate in an additional optional telephone assessment. This optional assessment should take approximately 10-15 minutes to complete and will include questions about how you manage your activities, thoughts you might have about yourself, and your sense of humor.

This optional assessment is completely voluntary. You may refuse to complete the optional assessment with no effect on your medical care, your study involvement, or your compensation for completing each assessment period. You will not be compensated for completing the optional assessment.

## Medications for Pain/Pain Treatments during Study Participation

In order to know if the study treatments have any effect on your well-being we will ask you not to make changes to the amount or type of medications you currently take for pain. Additionally, we will ask that you not begin any additional types of pain therapy during the study, including during the follow up assessment period. If you and your health care provider decide that your medication needs adjustment or change, or additional therapies are needed, you are free to make these changes. Please notify study staff members of any changes you make to the medication you are taking or pain therapies being used.

## Use of Telephone Headsets for Assessments

Some telephones have the ability to be used with a headset. If you are able to use a headset with your phone and would like to use one during the study assessments, please let a member of the research staff know and you will be provided with one.

The purpose of the telephone headset is to reduce physical discomfort that you may experience while speaking on the telephone to research staff during the study assessment periods. You may keep the headset after your participation in the study has ended.

## Group Treatment Sessions

You will attend eight treatment group sessions conducted at VA Puget Sound at either the Seattle Campus or the American Lake Campus, whichever location is more convenient for you.

The group treatment sessions will be audio-recorded to make sure the group leaders are following study procedures. Prior to the first treatment session, each study participant will sign a consent giving permission to do so. The group leaders will remind the group at the start of the session before recording begins.

You will be randomly assigned (not chosen in any particular order) to one of three treatment groups. All three treatment groups involve:

- Educating you about pain.
- Discussing the impact of pain.
- Discussing different ways to manage it in hopes of decreasing your pain and its impact on your life.

One treatment focuses on educating you about chronic pain and its impact on your life. People find that with this greater knowledge, they are able better manage their pain.

One treatment involves self-hypnosis training. People in this group learn how to enter a state of focused attention in order to help you change how you experience pain.

The third group involves self-management. People in this group learn how to focus your attention on an object, such as a thought or sensation, in a manner that might help them cope with or manage your pain.

Importantly, evidence indicates that ALL three of these treatments result in improvements (e.g., less pain, more ability to function).

You will be encouraged to use what you learned in the group sessions outside of treatment to help you with your pain. You will be asked by the group leaders whether you completed the tasks or "homework" assigned during the previous session. You will also be asked to answer questions about your pain intensity and comfort level before and after each session. You will be asked to answer these questions using paper and pencil worksheets as part of the group classes. The group leaders will collect these worksheets and store electronic copies of them on a secure computer drive that group leaders and select research team members on this project can access. Research study staff will extract data from these forms into a larger study database. This database will not contain any identifying information about you; only your study identification number will be included in this database.

You will be given a treatment workbook with materials to refer to and discuss during the group sessions as well as additional materials to read between sessions. In addition, you will receive pre-recorded audio-recordings that you will listen to between sessions and talk about in treatment.

The sessions will be conducted by licensed, credentialed VA Puget Sound providers who have undergone a formal training process with study investigators. The group leaders will not have access to the link between your identity and your responses to the questions you answer during the study telephone assessments.

The treatment sessions will be considered part of your VA clinical care. As a result, the treatment sessions will be scheduled as VA medical appointments and there will be progress notes written in your medical chart after each class.

The research staff members who will conduct the assessments with you will not know which treatment group you have been assigned to nor will they have access to any information covered during the group treatment sessions with your group leaders. Any questions about the treatment you are receiving should be directed towards your group leaders.

**3. <u>Description of any procedures that may result in discomfort or inconvenience</u>:**

If any uncomfortable or negative effects from the assessments or treatment sessions do happen, you can talk about these issues with Dr. Williams, a licensed clinical psychologist.

Dr. Williams will then give you information about people you should call if needed. You may stop a treatment session or assessment at any time.

**Cognitive Assessment.** During the memory testing, it may be hard for you not to have the answer to a question that you think you should be able to answer. In addition, you may become tired during the testing sessions. You will be able to take breaks if you want. We will make these interviews and testing periods as stress-free as possible.

**Relaxation and Hypnotic Exercise.** During or after the hypnosis session has ended, you may remember things which cause discomfort or distress or experience mild disorientation or grogginess.

**Baseline Assessment / Telephone Assessment Periods.** You may find some of the questions we ask during the assessments to be personal or sensitive. As a result of answering questions about pain, you may focus more on your pain, which may lead to a temporary increase in pain intensity. You can skip any questions that you do not feel comfortable answering.

**Group Treatment Sessions.** You may find it uncomfortable to discuss your pain and other issues in a group setting. You may also find it uncomfortable or distressing to hear other Veterans discuss their pain or other problems in a group setting. Group treatment discussions or exercises may result in you remembering past experiences that are uncomfortable and/or cause distress, even after the session has ended. In addition, as a result of these discussions or exercises, you may focus more on your pain, which may lead to a temporary increase in pain intensity and/or distress regarding your pain problem. Some people may find sitting for the entire treatment session uncomfortable.

Some people may learn self-hypnosis techniques during treatment depending on the treatment intervention in which they are assigned.

Some people may find the state of deep relaxation or hypnosis uncomfortable. Some people under hypnosis may remember past experiences that are uncomfortable and/or cause distress, even after the session has ended.

Some people under hypnosis may also experience mild disorientation or grogginess during or after the session has ended. Although rare, some people may experience a temporary loss of sensation in their arms or legs while under hypnosis.

Group leaders will take steps to ensure groups are as comfortable as possible by doing things like facilitating relevant discussion, limiting side conversations, and addressing concerns that are raised. Group leaders may ask some people to talk more or less to ensure that everyone has an opportunity to participate and the conversation is productive and positive. You are free to move around if you need to stretch or re-position during group. If you have any concerns or questions about any group materials, processes, or experiences, you are encouraged to talk with your group leader.

## 4. Potential risks of the study:

The procedures in this study may involve risks that are currently unknown. We may need to contact you if we learn of a new study risk, even if you have completed the study. You may be asked to sign a new (updated) Consent Form to document that this new information has been explained to you. Below are study-related risks that are known at this time.

**Privacy and Confidentiality.** There is a possible risk of loss of privacy. We will make every effort to stress the importance of confidentiality during the group treatment sessions, but we cannot guarantee that comments will not be made outside of the group at some time in the future.

Therefore, we encourage you to be as honest and open as you can but remain aware of our limits in protecting your privacy.

Information that identifies you will be used in this study and shared with research staff. Although the research team will make every effort to protect your private health information and guard against any loss of privacy, accidental breaches in confidentiality do sometimes occur. Although extremely unlikely to occur, a breach in confidentiality and a resulting loss of privacy could have significant effects (such as monetary loss due to identity theft, some type of discrimination resulting in loss of health and/or life insurance coverage, or loss of job).

The steps we take to protect your confidentiality to the best of our ability are further detailed in Section 7. The Principal Investigator and all researchers associated with this study will make every reasonable effort not to disclose any of this information, but it is important for you to understand that the possibility of this information being disclosed exists despite every reasonable effort. If you have any questions, please ask Dr. Rhonda Williams at (206) 277-6290.

**Audio-Recordings.** The group treatment sessions will be audio-recorded ensure they were delivered as intended. Although your full name and other identifying information will not be mentioned during the recorded sessions, please note that your voice is technically identifiable according to patient privacy rules.

Our methods of securing your privacy and confidentiality are described in Section 7. You will also have the right to review and mark for deletion any portions of the audio-recording without jeopardizing your continued participation in the study.

**Worsening or Discovery of Problems.** As a result of participation in this study, you may learn information that could be upsetting to you. If this happens and it becomes upsetting to you, please let someone on the research team know and one of the investigators will talk with you and, if appropriate, refer you to a counselor. Further, just like with any type of treatment, you may not feel like the type of treatment being offered in this study is helping you get much better.

It is even possible that your symptoms will get worse over time. Again, you are free to discontinue with the study at any time. If, at any point during the study you or research staff feels like your symptoms are getting worse, please call Dr. Rhonda Williams at (206) 277-6290. She will work with you and your group leaders to figure out additional or alternative treatment options. This is to make sure that you are receiving the best possible care at all times.

**Depressive and Suicidal Thoughts.** You will be asked questions about symptoms of depression as part of this study. Our study survey is not intended to diagnose depression. If you feel depressed and would like more information, we encourage you to follow up with your mental health provider. If you do not already have a provider, you may contact the Principal Investigator (Dr. Williams) for referral information.

If you are having thoughts of harming yourself in some way, or indicate to us that you may be in some danger of hurting yourself, the group leaders and/or investigators (who are clinical psychologists) will assist you in getting additional help. This may include talking with you and/or

your mental health provider in order to further evaluate these risks. Another alternative is to call the VA Suicide Prevention Hotline at 1-800-273-TALK (1-800-273-8255) if you are having thoughts of harming yourself.

**5. Potential benefits of study:**

There may not be any direct benefit to you by participating in this study. However, if the treatment you receive is effective for you, you may experience a decrease in your daily pain or an improvement in how you manage your pain. As a result, pain may interfere less with your daily activities. The investigators expect the information gathered during the study will help them to better understand and design treatment for individuals with chronic pain in the future. If the treatments we are testing in this study are shown to be effective, then they will be made available for other Veterans.

**6. Other treatment available:**

If you choose not to participate in this study, you will receive the same standard care for chronic pain at VA Puget Sound. If you choose not to participate in this study, you may speak to your health care provider about the different options for pain management that may be available to you.

If you would like any additional information on national resources for disability, pain, mental health, and other resources at any time, you may request assistance from study staff in obtaining up-to-date information.

Your choice about being in this study is entirely up to you. Participation is voluntary. Your medical care and any VA-related benefits will not be affected in any way whatsoever by your choice about study participation.

**7. Use of research results / Confidentiality:**

The information obtained about you will be kept confidential. However, for purposes of this study, the following list of people or groups may know that you are in this study. They will have access to your records, which may include your medical records:

- Research team members at VA Puget Sound and the University of Washington
- The National Center for Complementary and Integrative Health (NCCIH), the study sponsor
- Seattle Institute for Biomedical and Clinical Research (the nonprofit institute that works with the VA to conduct research) will be provided with your full name, address, phone number, and social security number in order to authorize payment for your participation in this study
- Federal agencies including, but not limited to, the Food and Drug Administration (FDA), the Office for Human Research Protection (OHRP), the VA Office of Research Oversight (ORO), the VA Office of the Inspector General (OIG), and the Government Accountability Office (GAO)
- The VA committees that oversee research, including the Institutional Review Board that oversees the safety and ethics of VA studies
- The UW committees that oversee research, including the Institutional Review Board that oversees the safety and ethics of UW studies

The access to your records, including your medical records, could be either for study-related purposes or to make sure that your records meet all legal, compliance, and administrative requirements. The reviewers will protect your privacy.

The identifiers that will be used in this research study include your name, medical record number, social security number, address, and contact information. These identifiers will be used to obtain personal information about you or your health from VA records, interviews, surveys, and tests.

All information obtained about you will be held in the strictest confidence by taking several precautions.

The researchers will make sure that your identifying information (such as your name, address, and social security number) is kept separate (both electronically and in hard copy) from your personal information. “Personal information” would include your answers to the interview questions and information from your medical records.

We will create and use a study code to link your personal information and identifying information. This study code will be accessible only to the investigators and research staff listed within this Consent Form.

The “crosswalk” that will link your identifying information to your research data will be stored in a password-protected file on a secure server at the VA. The master list linking study participant names to code numbers will be kept separately from other research records at VA Puget Sound in Seattle.

Part of your research records will be stored in paper form in a locked file cabinet at VA Puget Sound (Seattle Campus and American Lake Campus) and part will be stored electronically. The file cabinets and computers will be locked and are housed in rooms that are locked when unoccupied. All electronic data will be stored in encrypted, password-protected files on the VA secure research server. Data will not be stored on any laptops or computers outside VA Puget Sound.

Any data that needs to be transmitted will be done so electronically through a shared server or by secure, VA-encrypted email. The UW investigators associated with this project have appointments at VA Puget Sound and have access to study data through the VA secure server. This means that data will not have to be transported electronically. Access to the identifiable information within the crosswalk will be limited to staff members.

We will ask you for your permission to include your data from this study in a larger data repository. If you agree, we will provide you with a separate Consent Form specifically for the repository.

Once this study is completed, we will not use the study code linking you to your data for any additional research. We will store the code linking you to your data in a secure database or in a locked filing cabinet until the VA receives authorization to destroy it in accordance with federal records regulations, which could be several years. We will keep your coded, de-identified data indefinitely.

We will use the information that we collect for this study only for research purposes, not for profit. However, researchers may use this research information in the future for the development of new ways to ways to treat pain. Neither you nor your family will gain financially from discoveries made using the information that you provide.

In the future, researchers may write publications using the information collected from this research study. Any future publications will not include any identifying information about you without your approval in writing.

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.

## Certificate of Confidentiality & Mandatory Reporting

We have been given a Certificate of Confidentiality from the National Center for Complementary and Integrative Health (NCCIH). The researchers will use the Certificate to resist any demands, even by a court of law, for information that would identify you. You may still share information about yourself or your part in this research as you see fit.

The Certificate of Confidentiality does not protect us from:

- Disclosing information to the National Center for Complementary and Integrative Health (NCCIH), the study sponsor, involved in auditing or compliance of research, risk management, patient safety, and financial controls.
- Disclosing information to state or federal public health authorities to whom certain contagious diseases (tuberculosis, HIV, anthrax, syphilis) are reported (if we observe such diseases in any subjects).
- Disclosing information to law enforcement authorities if we get any information that suggests the occurrence of child abuse, elder abuse, or your intent to immediately and substantially harm yourself or others.
- Putting any specific information as described elsewhere in this form in your VA medical record.
- Giving the VA Research Administration Office database your name, the fact you are participating in this study (including the study name), and contact information for the researcher.
- Giving the Seattle Institute for Biomedical and Clinical Research that manages payment to subjects your name, social security number, address, and the name of this study.
- Giving your name to state, federal, and institutional offices involved in auditing or compliance of research, risk management, patient safety, and financial controls (which include the Food and Drug Administration).

## Audio-Recordings

The group leaders will use an audio recorder to record the group treatment sessions. The audio recordings will be stored on a secure server at the VA. The audio recorders will be stored in locked file cabinets inside of locked offices until the recordings are uploaded to the secure server and removed from the recorder. Current VA regulations require us to keep audio-recordings indefinitely.

Audio-recordings will only be reviewed by study personnel and used for assessing consistency between group leaders. The audio-recordings will not be labeled with any of your identifying information.

## Medical Record

We will put information about your attendance in the treatment program into your medical record, including your presence or absence at each session, the basic content of each treatment session, and any comments you may report during a treatment session. All authorized users of the national VA medical records system can have access to your medical record. This may include health insurance companies who are being billed for medical costs. This record will be kept forever.

**Please note:** No information collected during the telephone assessments will be entered into your medical record.

## Access to Research Data

During this research study, you will not be able to see the research data collected about you. After the study is complete and the study results are determined or published, you may request your personal health information from Dr. Williams at (206) 277-6290.

## 8. Special circumstances:

The VA requires some Veterans to pay co-payments for medical care and services. If you normally have to pay co-payments for your clinical appointments, you will have to pay these co-payments for the classes, because they are considered regular clinic appointments. These co-payments could be as much as $50.00 per class.

I understand that I may be required to pay a co-pay for treatment visits. ☐

You will not be compensated for participating in the group treatment classes. However, you will be compensated for each component of the study as you complete them, as described here:

- Cognitive assessment $ 10
- Relaxation and hypnotic exercise $ 5
- Baseline assessment $ 10
- Telephone assessment periods:
  - Before treatment $ 25
  - During treatment
    - 2-week assessment period $ 25
    - 4-week assessment period $ 25
    - 6-week assessment period $ 25
  - Immediately following treatment $ 25
  - 3 months after treatment $ 25
  - 6 months after treatment $ 25

- **Bonus** for completing all 7 sets of telephone assessments $ 50

**POSSIBLE TOTAL** **$250**

In sum, you may be reimbursed up to $250 if you complete all VA research-related study procedures.

Compensation will be by check, which will be mailed to you approximately 2-4 weeks after completing each component. You may receive an Internal Revenue Service Form 1099. If so, your social security number will be used for this purpose.

Details of payments are outlined in the attached flowchart for your convenience.

**Travel reimbursement**

You will be provided $10 travel reimbursement per trip for all **in-person research-related study procedures.** Please note this does not include the eight treatment sessions. You may be able to receive travel reimbursement from the VA for the **treatment procedures** based on your eligibility.

## 9. Withdrawal from the study:

You do not have to take part in this study. If you are in this study, you can withdraw at any time. You will not be penalized for your decision not to participate or withdraw nor will you lose your VA or other benefits if you decide to do so.

If you decide to withdraw from the study, no new information will be collected from you; however, data already collected will continue to be part of the analyses. If you decide you no longer want to participate in the study before you finish the group treatment sessions, you will be asked to complete the follow-up assessment periods. You do not have to answer any questions you do not want and, if you prefer, you may request not to be contacted for further assessments and withdraw from the study completely. If you withdraw from the study for any reason, we will place a note in your medical record indicating that you are no longer participating.

You may be withdrawn from the study without your consent if the researchers feel you are not able to fulfill the study requirements. Sample reasons that you may be withdrawn from the study include:

- The researchers cannot reach you to coordinate appointments
- You become incarcerated during the course of this study
- The researchers feel that this study is not in your best interest

You may withdraw permission to use your personal health information for research purposes at any time. To withdraw your permission, you can write to:

Dr. Rhonda Williams
VA Puget Sound Health Care System
1660 S. Columbian Way (RCS-117)
Seattle, WA 98108

Or, you can ask a member of the research team to give you a form to withdraw your authorization. If you withdraw your authorization, you may not be able to continue to participate in the study.

## 10. Questions or concerns related to the study:

The study researchers (listed below) *must* be contacted immediately if:

- You think you may have been harmed or injured as a direct result of this research; and/or
- You have any questions regarding your medical care issues.

| | |
|---|---|
| **During business hours (8:00 a.m. – 4:30 p.m.)** | Call Dr. Rhonda Williams at (206) 277-6290. |
| **After business hours (nights and weekends)** | Call (206) 762-1010 and ask the operator to page the on-call Psychiatrist. |

*In the event of a life-threatening emergency, call 911 or go to the Emergency Room.*

You may contact the Institutional Review Board (IRB) – VA Office at (206) 277-1715 if you:

- Would like to speak with a neutral party who is not involved with this study;
- Have questions, concerns, or complaints about the research;
- Would like to verify the validity of the study; or
- Have questions about your rights as a research subject.

An IRB is an independent body made up of medical, scientific, and non-scientific members, who ensures the protection of the rights, safety, and well-being of subjects involved in research.

## 11. Research-related injury:

Medical treatment will be provided, if necessary, by the VA if you are injured by being in this study. You will not be charged for this treatment. Veterans who are injured because of being in this study may receive payment under Title 38, United States Code, Section 1151. Veterans or non-Veterans who are injured may receive payment under the Federal Tort Claims Act.

You do not waive any legal rights by signing this Consent Form.

## 12. Research subject's rights:

I have read or have had read to me all of the above. The study has been explained to me, including a description of what the study is about and how and why it is being done. All of my questions have been answered. I have been told of the risks and/or discomforts, possible benefits of the study, and other choices of treatment available to me. My rights as a research subject have been explained to me and I voluntarily consent to participate in this study. I will receive a signed copy of this Consent Form.

I agree to participate in this research study as you have explained it in this document.

| | |
|---|---|
| **Subject Signature** | **Date** |
| **Print Name of Subject** | |
| **Signature of Person Obtaining Consent** | **Date** |
| **Print Name of Person Obtaining Consent** | |

| Procedure | Number of Visits or Assessments | How Often / When | Time Required | Compensation |
|---|---|---|---|---|
| **Cognitive Assessment** | One in-person session at VA Puget Sound (Seattle or American Lake) | **Once** (after informed consent process; before treatment begins) | 20-30 minutes | $10 |
| **Relaxation and Hypnotic Exercise** | | **Once** (after informed consent process; before treatment begins) | 15-20 minutes | $5 |
| **Baseline Assessment** | One session at VA Puget Sound (Seattle or American Lake) **OR** over the phone | **Once** (after informed consent process; before treatment begins) | 20-30 minutes | $10 |
| **Treatment** | Eight 90-minute group treatment sessions at VA Puget Sound (Seattle or American Lake) | Average of **once per week for 8 weeks** | Up to 12 hours total | $0 |
| **Phone Assessment Periods** | | | | |
| **Pre-Treatment** | Four phone assessments conducted within a 1-week period | **Once** (after informed consent process; before treatment begins) | 45-60 minutes total | $25 |
| **During Treatment** | Four phone assessments conducted within a 1-week period | **Following sessions 2, 4, and 6** | 45-60 minutes per assessment period (2¼ – 3 hours total) | $25 per assessment period ($75 total) |
| **Post-Treatment** | Four phone assessments conducted within a 1-week period | **Once** (following end of treatment) | 45-60 minutes total | $25 |

| Procedure | Number of Visits or Assessments | How Often / When | Time Required | Compensation |
|---|---|---|---|---|
| **3-Month Follow-Up Assessment Period** | Four phone assessments conducted within a 1-week period | **3 months** (following end of treatment) | 45-60 minutes total | $25 |
| **6-Month Follow-Up Assessment Period** | Four phone assessments conducted within a 1-week period | **6 months** (following end of treatment) | 45-60 minutes total | $25 |
| **Bonus Payment:** **All phone assessments completed** | All seven phone assessment periods are completed | **Over 9-month period** (see timeline listed above) | 5-7 hours total over a 9-month period (see time listed above) | $50 |

Document: Consent Form, EEG Assessment
Official Study Title:
Hypnosis and Meditation for Pain Management in Veterans: Efficacy and Mechanisms
NCT Number: NCT02653664
Document Date (Date Approved): 1/19/2018

**UNIVERSITY OF WASHINGTON**
**Consent Form**
**Chronic Pain Skills Study – Brain Activity or EEG Assessments**



Research Team:

| | | |
|---|---|---|
| Rhonda Williams, PhD | Principal Investigator | (206) 277-6290 |
| Mark Jensen, PhD | Principal Investigator | |
| Aaron Turner, PhD | Co-Investigator | (206) 277-6134 |
| Dawn Ehde, PhD | Co-Investigator | |

CPSS Study toll-free number: 1-800-329-8387; then dial 1-65167

**Researchers' Statement**

We are asking you to participate in an optional part of a research study you enrolled in earlier. The purpose of this consent form is to give you the information you will need to help you decide whether to participate in this part of the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in this part of the study or not. This process is called "informed consent."

## What is the purpose of the study?

Chronic pain is a significant problem for many Veterans. Individuals with chronic pain also experience a number of other problems, such as mood and sleep problems. All of these can have negative effects on the quality of life of Veterans.

Three different types of treatment that have been used to treat chronic pain in the general population include self-hypnosis, education about chronic pain, and teaching individuals how to be more mindful. The purpose of this part of the study is to see how different patterns of brain activity may predict the effectiveness of the three treatments being studied. We also want to see if these treatments may change brain activity and, if they do, how these changes affect your chronic pain and other problems including mood and sleep.

## What does my participation in this part of the study involve?

We will record your brain activity by using an electroencephalogram (EEG) up to two times during your participation in the study: once before treatment begins, and once after treatment ends.

Before each brain activity of EEG assessment begins, a research staff member will ask some questions, such as:

- *How much pain are you currently experiencing?*
- *How well did you sleep the last night?*
- *When was the last time you ate?*
- *Which medications do you take regularly?* (if not recorded beforehand)
- *Are you still having menstrual cycles?* (if applicable)



We may decide to reschedule the EEG assessment if we decide it might not be a good time to do the procedure based on your answers.

As mentioned above, we will record your brain activity by using an electroencephalogram (EEG), a device that measures the electrical activity in the brain through electrodes put on the scalp. We will be using an electrode net (a little like a moist shower cap with chin straps) to record your EEG.

We will measure the size of your head to find an EEG net that fits you well.

We will ask you to stay as still as possible with your eyes closed during the assessment.
We will also ask you about your pain during and immediately following the end of the assessment.

The second EEG assessment that may take place after treatment ends will be very similar to the first assessment described above, except you will also be asked to think about the skills you have learned to manage your pain while brain activity is being recorded.

**What are the risks?**

Although we will make every effort to keep your information confidential, no system for protecting your confidentiality can be completely secure. It is still possible that someone could find out you were in this part of the study and could find out information about you.

You may find sitting still for up to one hour may cause a temporary increase in your overall pain and discomfort. You may experience some discomfort or pain while wearing the electrode net on your head. Although the net should fit snugly, please let someone know if it is uncomfortably tight. Also, your hair may become wet and disturbed when the damp electrode net is placed on your head. You will be offered a towel or hair dryer to dry your hair after the assessment has been completed. The EEG assessment, including questions asked during the EEG, may cause a temporary increase in your PTSD symptoms. You are free to discontinue the EEG at any time and it will not affect your participation in the study.

**Is participating in this part of this study voluntary?**

Both EEG assessments are optional. You may choose not to participate in these assessments and still participate in the other parts of the study. You may choose not to participate or to discontinue participation without penalty or loss of benefits to which you are otherwise entitled.

**Are there any benefits to participating in this study?**

There are no benefits from participating in the EEG assessments.

**Who is funding this study?**

The study team and/or the University of Washington are receiving financial support from the National Center for Complementary and Integrative Health (NCCIH).

**How is my information kept confidential?**

The information obtained about you will be kept confidential. However, for purposes of this study, the following list of people or groups may know that you are in this part of the study. They will have access to your records:

- Research team members at VA Puget Sound and the University of Washington
- The National Center for Complementary and Integrative Health (NCCIH), the study sponsor
- Seattle Institute for Biomedical and Clinical Research (the nonprofit institute that works with the VA to conduct research) will be provided with your full name, address, phone number, and social security number in order to authorize payment for your participation in this part of the study
- Federal agencies including, but not limited to, the Food and Drug Administration (FDA), the Office for Human Research Protection (OHRP), the VA Office of Research Oversight (ORO), the VA Office of the Inspector General (OIG), and the Government Accountability Office (GAO)
- The VA committees that oversee research, including the Institutional Review Board that oversees the safety and ethics of VA studies

- The UW committees that oversee research, including the Institutional Review Board that oversees the safety and ethics of UW studies

The access to your records could be either for study-related purposes or to make sure that your records meet all legal, compliance, and administrative requirements. The reviewers will protect your privacy.

The identifiers that will be used in this part of the research study include your name, address, social security number and contact information. All information obtained about you will be held in the strictest confidence by taking several precautions.

The researchers will make sure that your identifying information (such as your name and contact information) is kept separate (both electronically and in hard copy) from your personal information. "Personal information" would include your answers to the in-person questions during the EEG assessment and the electronic EEG data.

We will create and use a study code to link your personal information and identifying information. This study code will be accessible only to the investigators and research staff. The "crosswalk" that will link your identifying information to your research data will be stored in a password-protected file on a secure server at the VA. The master list linking study participant names to code numbers will be kept separately from other research records.

Part of your research records will be stored in paper form in a locked file cabinet at the VA Puget Sound (Seattle Campus and American Lake Campus), and part will be stored electronically. The file cabinets and computers will be locked and are housed in rooms that are locked when unoccupied. Electronic data entered from those paper forms will be stored in encrypted, password-protected files on the VA secure research server. The brain activity data collected during the optional brain activity assessments will be stored with no identifying information on a secure server at the UW. The data collected as part of this study will be linked to the data collected as part of the larger study through your study code.

We asked you for your permission to include your data from this study in a larger data repository. If you agreed, all data collected as part of the EEG assessments will be included in the repository.

Once this study is completed, we will not use the study code linking you to your data for any additional research. We will store the code linking you to your data in a secure database or in a locked filing cabinet until the VA receives authorization to destroy it in accordance with federal records regulations, which could be several years. We will keep your coded, de-identified data indefinitely. Your signed consent form will be kept at the University of Washington in a locked filing cabinet.

We will use the information that we collect for this study only for research purposes, not for profit. However, researchers may use this research information in the future for the development of new ways to ways to treat pain. Neither you nor your family will gain financially from discoveries made using the information that you provide. In the future, researchers may write publications using the information collected from this research study. Any future publications will not include any identifying information about you without your approval in writing.

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.

Certificate of Confidentiality & Mandatory Reporting

We have a Certificate of Confidentiality from the National Center for Complementary and Integrative Health (NCCIH). This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the University of Washington, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- state or local authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

**Will I be paid for taking part in this study?**

You will not be charged for any study-related procedures. We will pay you $100 for each EEG assessment you complete (up to $200).

**Who can I call for research-related illness or injury?**

If you think you have an injury or illness related to this part of the study, contact Dr. Williams at (206) 277-6290 right away. She will treat you or refer you for treatment. No money has been set aside to pay for things like lost wages, lost time, or pain. However, you do not waive any rights by enrolling in this part of the study. The UW will pay up to $10,000 to reimburse for treatment of injury or illness resulting from this part of the study.

**Subject's statement**

This part of the study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098. I will receive a copy of this consent form.

_____ _____

Subject Signature Date

_____

Print Name of Subject

_____ _____

Signature of Person Obtaining Consent Date

_____

Print Name of Person Obtaining Consent

Document: Consent Form, Sleep Sub-Study
Official Study Title:
Hypnosis and Meditation for Pain Management in Veterans: Efficacy and Mechanisms
NCT Number: NCT02653664
Document Date (Date Approved): 03/22/2019

## Consent to participate as a Research Subject in:

# CHRONIC PAIN SKILLS STUDY:
# Sleep and Pain in Veterans Sub-study

**Principal Investigator:**
Rhonda M. Williams, PhD

**Study Title:**
Chronic Pain Skills Study

We are inviting you to be in a sub-study of the Chronic Pain Skills Study entitled "Sleep and Pain in Veterans." The purpose of this Consent Form is to give you the information you will need to help you decide whether to be in the sub-study. Please read this form carefully.

You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear.

Your participation in this sub-study is entirely voluntary. Please take as much time as you need to discuss the sub-study with your doctors, family, and friends. The decision to participate or not is yours. If you choose to participate, you have the right to withdraw from the sub-study at any time.

This study is a joint effort between the VA Puget Sound Health Care System ("VA Puget Sound"), the University of Washington ("UW"), and Washington State University ("WSU") through a grant from the National Center for Complementary and Integrative Health (NCCIH), part of the National Institutes of Health.

### 1. Who can I contact with questions while I am in this research study?

During business hours (8:00 a.m. – 4:30 p.m.), please call the Principal Investigator at (206) 277-6290. After business hours (nights and weekends), please call (206) 762-1010 and ask the operator to page the on-call psychiatrist.

The study researcher(s) listed above must be contacted immediately if:

- You think you may have been harmed or injured as a direct result of this research.
- You have any questions regarding your medical care issues.

You may also contact the Institutional Review Board (IRB) at (206) 277-1715 if you:

- Would like to speak with a neutral party who is not involved with this study.
- Have questions, concerns, or complaints about the research.
- Would like to verify the validity of the study.
- Have questions about your rights as a research subject.

### 2. What is the purpose of this research study?

Chronic pain and sleep problems are common among Veterans. Study researchers believe the treatment interventions provided as part of the main phase of the study will help improve pain and sleep. However, the main phase of the study does not include a "real time" measurement of sleep nor does it include any specific strategies for examining the relationship between sleep and pain.

Previous research has shown that adequate sleep has been linked to improvements in pain reports. Adversely, sleep deprivation has been found to increase pain perception since it decreases a person's ability to disengage from pain. Therefore, the purpose of this sub-study is to measure sleep in order to learn more about how it interacts with chronic pain.

All of the subjects in this sub-study will be Veterans recruited from VA Puget Sound who experience moderate-to-severe chronic pain on a regular basis and who have enrolled in the main study. We will enroll up to 195 subjects.

If you agree to join this sub-study, we will need about 7 hours of your time over 5-6 months beginning shortly after you enroll in the main study. Some study activities can be completed by telephone.

**3. What will I be asked to do in this research study?**

Before you begin study activities, we will review the details of the sub-study and answer any questions you may have to see if you are still interested in participating. This can be done at any of the following locations:

- VA Seattle Campus
- VA American Lake Campus
- Integrated Brain Imaging Center (IBIC) at the UW

If you are still interested in joining the study, you will need to participate in the following activities:

| OVERVIEW OF STUDY ACTIVITIES | | |
|---|---|---|
| **Activity** | **Description** | **Number of occasions** |
| Call 1-800-329-8387; then dial 1-65167 | You will need to call a toll-free number (also provided in your Sleep Diary) twice a day for a 7-day period to report when you woke up and when you are going to bed. | 3 |
| Sleep Diary | You will need to answer basic sleep-related questions in a Sleep Diary twice a day for a 7-day period. | 3 |
| Telephone assessments | We will call you to ask you sleep-related questions, which should take 5-10 minutes each time. | 4 |
| Actigraph sleep monitor | You will need to wear an Actigraph sleep monitor for a 7-day period. | 3 |
| Mail items back to WSU | You will need to mail back the Actigraph sleep monitor and the Sleep Diary to the WSU after every 7-day period. | 3 |

**Call 1-800-329-8387 (then dial 1-65167)**

You will need to call a toll-free number twice a day for a 7-day period to report when you woke up and when you are going to bed. You will need to do this on three separate occasions.

**Sleep Diary**

You will need to answer basic sleep-related questions in a Sleep Diary twice a day for a 7-day period. You will need to do this on three separate occasions.

In the morning, you will need to answer questions in the Sleep Diary about your sleep experience during the previous night, such as:

- What time do you think you fell asleep last night?
- How many times did you awaken during the night?
- Did you feel you woke up too early this morning?

In the evening, you will need to answer questions in the Sleep Diary regarding things that could affect your quality of sleep, such as:

- Did you sleep or nap today during the morning, afternoon, or evening?
- How many caffeine drinks did you drink today?
- Did you take your regularly scheduled medications today?

You will also need to check whether you experienced a number of discomforts (such as upset stomach, headache, and joint aches) and emotions (such as sadness, irritability, and feeling confused) that you experienced during the day and evening. If you checked "Yes," you will need to rate its intensity and give an estimated amount of time that you experienced it.

**Telephone Assessments**

We will call you on four separate occasions to ask you sleep-related questions, which should take 5-10 minutes each time.

We will ask you two questions about how much you agree with certain statements about your sleep and another two questions about how confident you are about carrying out certain sleep behaviors. For instance, we will ask you:

- How much do you agree with the statement, "When I have insomnia, I know it is because of something I have done, such as not having enough time to relax or because of worrying about things that I can't control"?

- How confident are you that you can lie in bed, feeling mentally relaxed?

**Actigraph Sleep Monitor**

You will need to wear an Actigraph sleep monitor, which measures the duration and quality of sleep, for a 7-day period. You will need to do this on three separate occasions.

The Actigraph looks like a watch and is to be worn on your non-dominant wrist. You should wear it continually during each 7-day period. However, it is important to keep the Actigraph dry, so you will need to remove it when showering, bathing, and swimming.

**Mail items back to WSU**

You will need to mail back the Actigraph and the Sleep Diary to the WSU after each 7-day period. You will need to do this on three separate occasions.

We will provide you with three self-addressed, stamped envelopes for your convenience. The Actigraph and the Sleep Diary should be mailed together in one envelope.

You may be asked to complete the Pre-Treatment assessment period again if you do not begin treatment within 4 weeks of completing the Pre-Treatment assessment period the first time.

**Data Repository (optional)**

We have a database, called a repository, where we will include data from this sub-study together with data from the main study. We will use the data in the repository to answer new research questions in the future. The data will not include any information that could identify you, such as your name or social security number. If you agree, we will ask you to sign a separate Consent Form to include your sub-study data in the repository.

**4. What are some risks of joining this research study?**

The procedures in this study may involve risks that are currently unknown. We may need to contact you if we learn of a new study risk, even if you have completed the study. You may be asked to sign an updated Consent Form to document that this new information has been explained to you. Below are study-related risks that are known at this time:

- **Telephone Assessments and Sleep Diary.** You will be asked to respond to sleep-related questions during the telephone assessments and when completing the Sleep Diary. As a result, you may find yourself focusing more on your sleep, which may lead to a temporary increase in sleep problems. You can skip any questions that you do not feel comfortable answering.

  If you do find an increase in sleep problems and it becomes upsetting to you, please let us know and, if appropriate, we will refer you to a counselor or appropriate medical care. You also have the option of calling Dr. Williams at (206) 277-6290. We want to make sure that you are receiving the best possible care at all times.

- **Actigraph.** There is no risk of electrical shock while wearing the Actigraph and it cannot track where you are or what you are doing. However, you may find it uncomfortable or inconvenient to wear the Actigraph during the day and while sleeping. If you have sensitive skin, you may experience sweating or skin irritation while wearing the Actigraph. The actigraph contains metals (titanium in the band clasp, stainless steel in the marker button). Common symptoms of metal hypersensitivity are red, swollen, and/or itchy skin. Hives and blistering of skin may also develop.

- **Privacy and Confidentiality.** There is a risk that a breach of confidentiality could occur; however, we will make every effort to prevent this from happening. We will keep your personal information in a secure location; only authorized study staff will have access as needed to conduct this study. As described in Section 7, the researchers have taken a number of steps to prevent this from happening.

If any of the risks included in this Consent Form become significantly updated during this study, we will let you know.

**5. What are some benefits of joining this research study?**

You may not directly benefit from participating in this study. However, by participating, you will be making a meaningful contribution in helping researchers have a better understanding in ways to design treatments for Veterans with chronic pain and sleep issues.

**6. Are there other ways I could receive these benefits?**

If you choose not to participate in this sub-study, you would receive the same standard care for chronic pain and sleep issues at VA Puget Sound. Please feel free to speak to your health care provider about the different options for pain and sleep management that may be available to you. If you would like any additional information on national resources for disability, pain, mental health, and other resources at any time, you may request assistance from study staff in obtaining up-to-date information.

**7. Who will see my information and where will it be stored?**

Your research information will be kept confidential. However, some data will be shared, communicated, or stored during or after this research study.

The following list of people or groups may know that you are in this study. They may have access to your research records, which may include your medical records:

- Research team members
- The National Center for Complementary and Integrative Health, the Sponsor of the study
- Seattle Institute for Biomedical and Clinical Research (the nonprofit institute that works with VA Puget Sound to conduct research) will be provided with your full name, address, phone number, and social security number in order to authorize payment for your participation in this study
- Other federal agencies including, but not limited to, the Food and Drug Administration (FDA), the Office for Human Research Protection (OHRP), the VA Office of Research Oversight (ORO), the VA Office of the Inspector General (OIG), and the Government Accountability Office (GAO)
- The VA committees that oversee research
- The UW committees that oversee research, including the UW Institutional Review Board and supporting staff, will have access to your study records but not your medical records
- The WSU committees that oversee research, including the WSU Institutional Review Board and supporting staff, will have access to your study records but not your medical records

The access to your records, including your medical records, could be either for study-related purposes or to make sure your study record meets all legal, compliance, and administrative requirements. The reviewers will protect your privacy.

## Medical Record

We will write a progress note in your medical record. The progress note will simply state when you joined the study and when your participation was complete. The progress note will also include the name of the study. We will not put any results from the telephone assessments, Sleep Diary, or Actigraph into your medical records.

## Access to Research Data

During this research sub-study, you will not be able to see the research data collected about you. After the main study is complete and the study results are determined or published, you may request your personal health information from Dr. Williams at (206) 277-6290.

## Certificate of Confidentiality

We have been given a Certificate of Confidentiality from the National Center for Complementary and Integrative Health. The researchers will use the Certificate to resist any demands, even by a court of law, for information that would identify you. You may still share information about yourself or your part in this research as you see fit.

The Certificate of Confidentiality does not protect us from:

- Disclosing information to the National Center for Complementary and Integrative Health, the Sponsor of the study,
- Disclosing information to state or federal public health authorities to whom certain contagious diseases (tuberculosis, HIV, anthrax, syphilis) are reported (if we observe such diseases in any subjects).
- Disclosing information to law enforcement authorities if we get any information that suggests the occurrence of child abuse, elder abuse, or your intent to immediately and substantially harm yourself or others.
- Giving Seattle Institute for Biomedical and Clinical Research that manages payments to subjects your name, social security number, address, and the name of this study.
- Giving your name to state, federal, and institutional offices involved in auditing or compliance of research, risk management, patient safety, and financial controls

The identifiers that will be used in this sub-study include your name, medical record number, social security number, address, and contact information. These identifiers will be used to contact you to complete the telephone assessments, sleep diary reports, and Actigraph recordings, and compensate you for completing sub-study procedures.

All information obtained about you will be held in the strictest confidence by taking several precautions. The researchers will make sure that your identifying information (such as your name, address, and social security number) is kept separate (both electronically and in hard copy) from your personal information. "Personal information" includes the information you provide during the telephone assessments, sleep diary reports, and Actigraph recordings.

We will create and use a study code to link your personal information and identifying information. This study code will be accessible only to authorized study members.

The "crosswalk" that will link your identifying information to your coded research data will be stored in a password-protected file on a secure server at the VA. The master list of the crosswalk will be kept separately from other research records at VA Puget Sound in Seattle.

Part of your research records will be stored in paper form in a locked file cabinet at VA Puget Sound and part will be stored electronically. The file cabinets and computers will be locked and are housed in rooms that are locked when unoccupied. All electronic data will be stored in encrypted, password-protected files on the VA secure research server.

Data will not be stored on any laptops or computers outside VA Puget Sound with the exception of the sleep data collected while you are wearing the Actigraph. These data will not contain any of your personal identifiers (such as your name and social security number) and will be stored on a secure server at WSU Sleep and Performance Research Center in Spokane, WA.

Any data that needs to be transmitted will be done so electronically as de-identified datasets in a secure manner. Access to the identifiable information within the crosswalk will be limited to authorized study members at VA Puget Sound.

Once this sub-study is completed, we will not use the study code linking you to your data for any additional research. We will store the code linking you to your data in a secure database or in a locked filing cabinet in accordance with the VA records retention policy (which will be a minimum of 6 years after the study has been completed). We will keep your coded data indefinitely.

We will use the information that we collect for this sub-study only for research purposes, not for profit. However, researchers may use this research information in the future for the development of new ways to treat pain and/or sleep problems. Neither you nor your family will gain financially from discoveries made using the information that you provide.

In the future, researchers may write publications using the information collected from this sub-study. Any future publications will not include any identifying information about you without your approval in writing.

## 8. What are some other things to think about before I decide to join this research study?

The VA requires some Veterans to pay co-payments for medical care and services. You will still have to pay these co-payments as long as they are not related to this research study. You or your insurer will be responsible for any costs related to treatment of pre-existing medical conditions.

To show our appreciation for your continued participation in agreeing to participate in this sub-study, we will compensate you as follows:

| AMOUNT OF COMPENSATION & POSSIBLE BONUS | POSSIBLE TOTALS |
|---|---|
| $40 each time you mail back the Actigraph and Sleep Diary after completing a 7-day period (on three separate occasions). | **$120** |
| **$30 Bonus:** If you have returned the Actigraph and completed Sleep Diary after all three 7-day periods in a timely manner. | **$150** |
| **$15 Bonus:** If you completed less than 100% of your Sleep Diary or if you wore the Actigraph less than 100% of your required time. | **$135** |

Within 2 weeks of completing each 7-day period (on three separate occasions), we will mail you a $40 check. Any bonus payment will be determined once your participation in the sub-study is complete. If you are eligible for a full bonus of $30 or a partial bonus of $15, we will mail you a check accordingly within 2 weeks from your last study visit.

To comply with Internal Revenue Service (IRS) guidelines, we will collect your social security number. You may receive an IRS Form 1099.

**Travel reimbursement**

For any in-person visit to VA Puget Sound that relates to this sub-study, we will reimburse you $10 for travel expenses. We will reimburse you a total of $10 for travel expenses per visit if you participate in both main study and sub-study procedures during the visit.

**9. What will happen if I decide I don't want to be in this research study later?**

You do not have to take part in this sub-study. If you are in this sub-study, you can withdraw at any time. If you decide to withdraw from the study, no new information will be collected from you; however, data already collected will continue to be part of the analyses. If you decide not to participate or to withdraw, no action will be taken against you; for instance, you will not lose your VA benefits. You can decide not to participate in the sub-study but still participate in the main study.

We may withdraw you from the sub-study if we feel that you are not able to fulfill the sub-study requirements. This withdrawal would not need your consent. The following are examples of several reasons why we would withdraw you:

- The researchers cannot reach you to coordinate appointments or mailings of study materials.
- You become incarcerated during the course of this sub-study.
- The researchers feel that this sub-study is not in your best interest.
- You withdraw or are withdrawn from the main study.

You may withdraw permission to use your personal health information for research purposes at any time.

To withdraw your permission, you can write to:

Dr. Rhonda Williams
VA Puget Sound Health Care System
1660 S. Columbian Way (RCS-117)
Seattle, WA 98108

Or you can ask a member of the research team to give you a form to withdraw your authorization. If you withdraw your authorization, you may not be able to continue to participate in the main study or sub-study. If you decide to withdraw, or if you are terminated from the study, a person from the study team may need to meet with you to discuss the steps that are necessary to end your participation in the study.

**10. What will happen if I am hurt in this research study?**

If you are injured as a result of participation in a VA-approved research study, the VA will provide you with the necessary medical treatment. You will not be charged for this treatment. Veterans who are injured because of being in this study may receive payment under Title 38, United States Code, Section 1151. Veterans or non-Veterans who are injured may receive payment under the Federal Tort Claims Act.

You do not waive any legal rights by signing this Consent Form.

**11. What am I agreeing to by signing this form?**

I have read or have had read to me all of the above. The study has been explained to me, including a description of what the study is about and how and why it is being done. All of my questions have been answered. I have been told of the risks and/or discomforts I may encounter in the study, of the possible benefits of the study, and of the other choices of treatment that are available to me.

My rights as a research subject have been explained to me and I voluntarily consent to participate in this study. I will receive a copy of this Consent Form.

I agree to participate in this research study as described in this document.

_____ _____
Subject Signature Date

_____
Print Name of Subject

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent

Document: Consent Form, Open Label Phase
Official Study Title:
Hypnosis and Meditation for Pain Management in Veterans: Efficacy and Mechanisms
NCT Number: NCT02653664
Document Date (Date Approved): 03/22/2019

| | |
|---|---|
| **SUBJECT NAME** | |
| **TITLE OF STUDY** | **Chronic Pain Skills Study** |
| **PRINCIPAL INVESTIGATOR** | **Rhonda M. Williams, PhD** |

**LAY TITLE: Chronic Pain Skills Study – Open-Label Phase**

**Research Team:**

| | | |
|---|---|---|
| Rhonda Williams, PhD | Principal Investigator | (206) 277-6290 |
| Mark Jensen, PhD | Principal Investigator | |
| Aaron Turner, PhD | Co-Investigator | (206) 277-6134 |
| Dawn Ehde, PhD | Co-Investigator | |

**CPSS Study toll-free number: 1-800-329-8387; then dial 1-65167**

**24-hour emergency contact:**

- In case of medical emergency, you are advised to call 911. If you feel like harming yourself or others, you are advised to go to the nearest Emergency Room or call the Veteran's Hotline at 1-800-273-8255.
- For any other psychiatric emergency, please call the VA operator at 206-762-1010 and press "0" for the operator. Both during and outside of business hours, there is an on-call provider. The operator will take your name and number, contact the on-call provider, and have the provider call you back. You are also welcome to come to the Emergency Room at the VA Puget Sound.

You are invited to be in the open-label phase of a research study. The purpose of this Consent Form is to give you the information you will need to help you decide whether to be in this phase of the study. Please read this form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide whether you want to be in the study. You are free to discuss this with friends or family. This process is called "informed consent."

## 1. Purpose of research study and how long it will last:

Chronic pain is a significant problem for many Veterans. Individuals with chronic pain also experience a number of other problems, such as mood and sleep problems. All of these can have negative effects on the quality of life of Veterans.

Three different types of treatment that have been used to treat chronic pain in the general population include self-hypnosis, education about chronic pain, and teaching individuals how to be more mindful. The purpose of this study is to see if these three treatments can help decrease pain in Veterans.

Additionally, the researchers want to determine if each of these treatments can help reduce the negative consequences associated with pain, such as changes in mood, sleep, and enjoyment of life.

You are being asked to participate in the optional open label phase of this study because:

- You are a Veteran.
- You have reported that you experience moderate-to-severe chronic pain on a regular basis.
- You participated in the main part of the Chronic Pain Skills Study.

This study is a joint effort between the VA Puget Sound Health Care System ("VA Puget Sound") and the University of Washington (UW). The sponsor of this study is the National Center for Complementary and Integrative Health, part of the National Institutes of Health. All of the participants in this study will be Veterans recruited from the VA Puget Sound. The study will enroll up to 355 subjects.

## 2. Description of the study including procedures to be used:

### Length of Study

If you participate in this optional phase of the study, we will need approximately 13 hours over a 3-month period of your time. You will be invited to attend a group treatment you have not participated in at the time of consent.

A flowchart of the open-label phase procedures is at the end of this Consent Form to help you decide if you can make the time commitment.

### Overview of Study Activities

- Informed consent process
- Assessments:
  - One brief pre-treatment assessment (20-30 minutes)
  - One brief post-treatment assessment (20-30 minutes)
- Eight In-person treatment sessions (90 minutes each)

### Research vs. Standard Care

The assessments you will need to complete will be considered **research**. The treatment sessions you will need to attend will be considered **standard care** (normal treatment) you would receive at the VA Puget Sound.

After completing the final post-treatment assessment, we will offer to mail you the treatment materials for any treatment group that you did not participate in while enrolled in the study. The treatment materials would include a workbook and audio-recordings.

## Informed Consent Process

This process will take place via telephone. A research staff member will review the details of the open-label phase of the study with you and answer any questions you may have to see if you are interested in participating.

## Assessments

The research assessments you will need to complete are described below:

- **Pre-Treatment Telephone Assessment.** A research staff will call you to ask you questions relating to:
  - Your current, average, worst, and least pain intensity over the past 24 hours.
  - How pain has interfered with your life.
  - How you have been feeling recently (thoughts or feelings you have had about your pain).
  - Current medications you are using.
- **Post-Treatment Telephone Assessment.** You will be asked the same questions over the phone as the pre-treatment assessment described above. You will also be asked questions about your satisfaction with treatment.

You are free not to answer any questions you do not wish to answer.

## Medications for Pain/Pain Treatments during Study Participation

In order to know if the study treatments have any effect on your well-being we will ask you not to make changes to the amount or type of medications you currently take for pain. Additionally, we will ask that you not begin any additional types of pain therapy during the study, including during the follow up assessment period.

If you and your health care provider decide that your medication needs adjustment or change, or additional therapies are needed, you are free to make these changes. Please notify study staff members of any changes you make to the medication you are taking or pain therapies being used.

## Use of Telephone Headsets for Assessments

Some telephones have the ability to be used with a headset. If you are able to use a headset with your phone and would like to use one during the study assessments, please let a member of the research staff know and you will be provided with one. You may keep the headset after your participation in the study has ended.

## Group Treatment Sessions

You will attend eight treatment group sessions conducted at the VA Puget Sound at either the Seattle Campus or the American Lake Campus, whichever location is more convenient for you.

The group treatment sessions will be audio-recorded to make sure the group leaders are following study procedures. Prior to the first treatment session, each study participant will sign a consent giving permission to do so. The group leaders will remind the group at the start of the session before recording begins.

You will get to choose any group treatment you have not participated in yet. Study researchers define participation as attending four or more treatment sessions with that particular group. All treatment groups involve:

- Educating you about pain.
- Discussing the impact of pain.
- Discussing different ways to manage it in hopes of decreasing your pain and its impact on your life.

One treatment focuses on educating you about chronic pain and its impact on your life. People find that with this greater knowledge, they are able better manage their pain.

One treatment involves self-hypnosis training. People in this group learn how to enter a state of focused attention in order to help you change how you experience pain.

The third group involves meditation. People in this group learn how to focus your attention on an object, such as a thought or sensation, in a manner that might help them cope with or manage your pain.

Importantly, evidence indicates that ALL three of these treatments result in improvements (e.g., less pain, more ability to function).

You will be encouraged to use what you learned in the group sessions outside of treatment to help you with your pain.

You will be asked by the group leaders whether you completed the tasks or “homework” assigned during the previous session. You will also be asked to answer questions about your pain intensity and comfort level before and after each session. You will be asked to answer these questions using paper and pencil worksheets as part of the group classes.

The group leaders will collect these worksheets and store electronic copies of them on a secure computer drive that group leaders and select research team members on this project can access. Research study staff will extract data from these forms into a larger study database. This database will not contain any identifying information about you; only your study identification number will be included in this database.

You will be given a treatment workbook with materials to refer to and discuss during the group sessions as well as additional materials to read between sessions. In addition, you will receive pre-recorded audio-recordings that you will listen to between sessions and talk about in treatment.

The sessions will be conducted by licensed, credentialed VA Puget Sound providers who have undergone a formal training process with study investigators. The group leaders will not have access to the link between your identity and your responses to the questions you answered during the study telephone assessments.

The treatment sessions will be considered part of your VA standard care. As a result, the treatment sessions will be scheduled as VA medical appointments.

You will receive a reminder call prior to each of your scheduled sessions.

The research staff members who will conduct the assessments with you will not know which treatment group you have chosen nor will they have access to any information covered during the group treatment sessions with your group leaders. Any questions about the treatment you are receiving should be directed towards your group leaders.

**3. Description of any procedures that may result in discomfort or inconvenience:**

If any uncomfortable or negative effects from the assessments or treatment sessions happen, you can talk about these issues with Dr. Williams, a licensed clinical psychologist. Dr. Williams will then give you information about people you should call if needed. You may stop a treatment session or assessment at any time.

**Pre-Treatment / Post-Treatment Telephone Assessments.** You may find some of the questions we ask during the assessments to be personal or sensitive. As a result of answering questions about pain, you may focus more on your pain, which may lead to a temporary increase in pain intensity. You can skip any questions that you do not feel comfortable answering.

**Group Treatment Sessions.** You may find it uncomfortable to discuss your pain and other issues in a group setting. You may also find it uncomfortable or distressing to hear other Veterans discuss their pain or other problems in a group setting.

Group treatment discussions or exercises may result in you remembering past experiences that are uncomfortable and/or cause distress, even after the session has ended. In addition, as a result of these discussions or exercises, you may focus more on your pain, which may lead to a temporary increase in pain intensity and/or distress regarding your pain problem. Some people may find sitting for the entire treatment session uncomfortable.

Some people may learn self-hypnosis techniques during treatment depending on the treatment intervention in which they are assigned. Some people may find the state of deep relaxation or hypnosis uncomfortable.

Some people under hypnosis may remember past experiences that are uncomfortable and/or cause distress, even after the session has ended. Some people under hypnosis may also experience mild disorientation or grogginess during or after the session has ended. Although rare, some people may experience a temporary loss of sensation in their arms or legs while under hypnosis.

Group leaders will take steps to ensure groups are as comfortable as possible by doing things like facilitating relevant discussion, limiting side conversations, and addressing concerns that are raised. Group leaders may ask some people to talk more or less to ensure that everyone has an opportunity to participate and the conversation is productive and positive. You are free to move around if you need to stretch or re-position during group. If you have any concerns or questions about any group materials, processes, or experiences, you are encouraged to talk with your group leader.

## 4. Potential risks of the study:

The procedures in this study may involve risks that are currently unknown. We may need to contact you if we learn of a new study risk, even if you have completed the study. You may be asked to sign a new (updated) Consent Form to document that this new information has been explained to you. Below are study-related risks that are known at this time:

**Privacy and Confidentiality.** There is a possible risk of loss of privacy. We will make every effort to stress the importance of confidentiality during the group treatment sessions, but we cannot guarantee that comments will not be made outside of the group at some time in the future. Therefore, we encourage you to be as honest and open as you can but remain aware of our limits in protecting your privacy.

Information that identifies you will be used in this study and shared with research staff. Although the research team will make every effort to protect your private health information and guard against any loss of privacy, accidental breaches in confidentiality do sometimes occur. Although extremely unlikely to occur, a breach in confidentiality and a resulting loss of privacy could have significant effects (such as monetary loss due to identity theft, some type of discrimination resulting in loss of health and/or life insurance coverage, or loss of job).

The steps we take to protect your confidentiality to the best of our ability are further detailed in Section 7.

The Principal Investigator and all researchers associated with this study will make every reasonable effort not to disclose any of this information, but it is important for you to understand that the possibility of this information being disclosed exists despite every reasonable effort. If you have any questions, please ask Dr. Rhonda Williams at 206-277-6290.

**Audio-Recordings.** The group treatment sessions will be audio-recorded ensure they were delivered as intended. Although your full name and other identifying information will not be mentioned during the recorded sessions, please note that your voice is technically identifiable according to patient privacy rules.

Our methods of securing your privacy and confidentiality are described in Section 7. You will also have the right to review and mark for deletion any portions of the audio-recording without jeopardizing your continued participation in the study.

**Worsening or Discovery of Problems.** As a result of participation in this study, you may learn information that could be upsetting to you. If this happens and it becomes upsetting to you, please let someone on the research team know and one of the investigators will talk with you and, if appropriate, refer you to a counselor. Further, just like with any type of treatment, you may not feel like the type of treatment being offered in this study is helping you get much better.

It is even possible that your symptoms will get worse over time. Again, you are free to discontinue with the study at any time. If, at any point during the study you or research staff feels like your symptoms are getting worse, please call Dr. Rhonda Williams at 206-277-6290. She will work with you and your group leaders to figure out additional or alternative treatment options. This is to make sure that you are receiving the best possible care at all times.

**Depressive and Suicidal Thoughts.** You will be asked questions about symptoms of depression as part of this study. Our study survey is not intended to diagnose depression. If you feel depressed and would like more information, we encourage you to follow up with your mental health provider. If you do not already have a provider, you may contact the Principal Investigator (Dr. Williams) for referral information.

If you are having thoughts of harming yourself in some way or indicate to us that you may be in some danger of hurting yourself, the group leaders and/or investigators (who are clinical psychologists) will assist you in getting additional help. This may include talking with you and/or your mental health provider in order to further evaluate these risks. Another alternative is to call the VA Suicide Prevention Hotline at 1-800-273-TALK (1-800-273-8255) if you are having thoughts of harming yourself.

## 5. Potential benefits of study:

There may not be any direct benefit to you by participating in this study. However, if the treatment you receive is effective for you, you may experience a decrease in your daily pain or an improvement in how you manage your pain. As a result, pain may interfere less with your daily activities. The investigators expect the information gathered during the study will help them to better understand and design treatment for individuals with chronic pain in the future.

If the treatments we are testing in this study are shown to be effective, then they will be made available for other Veterans.

## 6. Other treatment available:

If you choose not to participate in this study, you will receive the same standard care for chronic pain at the VA Puget Sound if you are a Veteran. If you choose not to participate in this study, you may speak to your health care provider about the different options for pain management that may be available to you. If you would like any additional information on national resources for disability, pain, mental health, and other resources at any time, you may request assistance from study staff in obtaining up-to-date information.

Your choice about being in this study is entirely up to you. Participation is voluntary.

Your medical care and any VA-related benefits will not be affected in any way whatsoever by your choice about study participation.

## 7. Use of research results / Confidentiality:

The information obtained about you will be kept confidential. However, for purposes of this study, the following list of people or groups may know that you are in this study. They will have access to your records, which may include your medical records:

- Research team members at VA Puget Sound and the University of Washington
- The National Center for Complementary and Integrative Health (NCCIH), the study sponsor
- Seattle Institute for Biomedical and Clinical Research (the nonprofit institute that works with the VA to conduct research) will be provided with your full name, address, phone number, and social security number in order to authorize payment for your participation in this study
- Federal agencies including, but not limited to, the Food and Drug Administration (FDA), the Office for Human Research Protection (OHRP), the VA Office of Research Oversight (ORO), the VA Office of the Inspector General (OIG), and the Government Accountability Office (GAO)
- The VA committees that oversee research, including the Institutional Review Board that oversees the safety and ethics of VA studies
- The UW committees that oversee research, including the Institutional Review Board that oversees the safety and ethics of UW studies

The access to your records, including your medical records, could be either for study-related purposes or to make sure that your records meet all legal, compliance, and administrative requirements. The reviewers will protect your privacy.

The identifiers that will be used in this research study include your name, medical record number, social security number, address, and contact information. These identifiers will be used to obtain personal information about you or your health from VA records, interviews, surveys, and tests.

All information obtained about you will be held in the strictest confidence by taking several precautions. The researchers will make sure that your identifying information (such as your name, address, and social security number) is kept separate (both electronically and in hard copy) from your personal information.

"Personal information" would include your answers to the interview questions and information from your medical records.

We will continue to use the same study code to link your personal information and identifying information. This study code will be accessible only to the investigators and research staff listed within this Consent Form. The "crosswalk" that will link your identifying information to your research data will be stored in a password-protected file on a secure server at the VA. The master list linking study participant names to code numbers will be kept separately from other research records at the VA Puget Sound in Seattle.

Part of your research records will be stored in paper form in a locked file cabinet at the VA Puget Sound (Seattle Campus and American Lake Campus) and part will be stored electronically. The file cabinets and computers will be locked and are housed in rooms that are locked when unoccupied. All electronic data will be stored in encrypted, password-protected files on the VA secure research server.

Data will not be stored on any laptops or computers outside the VA Puget Sound. These data will be stored with no identifying information on a secure server at the UW.

Any data that needs to be transmitted will be done so electronically through a shared server or by secure, VA-encrypted email. The UW investigators associated with this project have appointments at VA Puget Sound and have access to study data through the VA secure server. This means that data will not have to be transported electronically. Access to the identifiable information within the crosswalk will be limited to staff members.

The data we collect from you as part of the open label phase of the study will be placed in a larger data repository if you have signed a repository consent form giving us permission to include your data from this study in the repository.

Once this study is completed, we will not use the study code linking you to your data for any additional research. We will store the code linking you to your data in a secure database or in a locked filing cabinet until the VA receives authorization to destroy it in accordance with federal records regulations, which could be several years. We will keep your coded, de-identified data indefinitely.

We will use the information that we collect for this study only for research purposes, not for profit. However, researchers may use this research information in the future for the development of new ways to ways to treat pain. Neither you nor your family will gain financially from discoveries made using the information that you provide.

In the future, researchers may write publications using the information collected from this research study. Any future publications will not include any identifying information about you without your approval in writing.

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.

## Certificate of Confidentiality & Mandatory Reporting

We have been given a Certificate of Confidentiality from the National Center for Complementary and Integrative Health (NCCIH). The researchers will use the Certificate to resist any demands, even by a court of law, for information that would identify you. You may still share information about yourself or your part in this research as you see fit.

The Certificate of Confidentiality does not protect us from:

- Disclosing information to the National Center for Complementary and Integrative Health, the study sponsor, involved in auditing or compliance of research, risk management, patient safety, and financial controls.
- Disclosing information to state or federal public health authorities to whom certain contagious diseases (tuberculosis, HIV, anthrax, syphilis) are reported (if we observe such diseases in any subjects).
- Disclosing information to law enforcement authorities if we get any information that suggests the occurrence of child abuse, elder abuse, or your intent to immediately and substantially harm yourself or others.
- Putting any specific information as described elsewhere in this form in your VA medical record.
- Giving the VA Research Administration Office database your name, the fact you are participating in this study (including the study name), and contact information for the researcher.
- Giving the Seattle Institute for Biomedical and Clinical Research that manages payment to subjects your name, social security number, address, and the name of this study.
- Giving your name to state, federal, and institutional offices involved in auditing or compliance of research, risk management, patient safety, and financial controls (which include the Food and Drug Administration).

## Audio-Recordings

The group leaders will use an audio recorder to record the group treatment sessions. The audio recordings will be stored on a secure server at the VA. The audio recorders will be stored in locked file cabinets inside of locked offices until the recordings are uploaded to the secure server and removed from the recorder. Current VA regulations require us to keep audio-recordings indefinitely.

Audio-recordings will only be reviewed by study personnel and used for assessing consistency between group leaders. The audio-recordings will not be labeled with any of your identifying information.

**Medical Record**

We will put information about your attendance in the treatment program into your medical record, including your presence or absence at each session, the basic content of each treatment session, and any comments you may report during a treatment session. All authorized users of the national VA medical records system can have access to your medical record. This may include health insurance companies who are being billed for medical costs. This record will be kept forever.

**Please note:** No information collected during the telephone assessments will be entered into your medical record.

**Access to Research Data**

During this research study, you will not be able to see the research data collected about you. After the study is complete and the study results are determined or published, you may request your personal health information from Dr. Williams at 206-277-6290.

**8. Special circumstances:**

The VA requires some Veterans to pay co-payments for medical care and services. If you normally have to pay co-payments for your clinical appointments, you will have to pay these co-payments for the classes, because they are considered regular clinic appointments. These co-payments could be as much as $50 per class.

I understand that I may be required to pay a co-pay for treatment visits ☐

You will be compensated for completing the pre-treatment and post-treatment telephone assessments ($10 each). Compensation will be by check, which will be mailed to you approximately 2-4 weeks after completing each component.

Details of payments are outlined in the attached flowchart for your convenience. You may receive an Internal Revenue Service Form 1099. If so, your social security number will be used for this purpose.

**Travel reimbursement.** You will be provided $10 travel reimbursement for the **consent session.** You may be able to receive travel reimbursement from the VA for the **treatment procedures** based on your eligibility

**9. Withdrawal from the study:**

You do not have to take part in this study. If you are in this study, you can withdraw at any time. You will not be penalized for your decision not to participate or withdraw nor will you lose your VA or other benefits if you decide to do so.

If you decide to withdraw from the study, no new information will be collected from you; however, data already collected will continue to be part of the analyses. If you decide you no longer want to participate in the study before you finish the group treatment sessions, you will be asked to complete the follow-up assessment period.

You do not have to answer any questions you do not want and, if you prefer, you may request not to be contacted for further assessments and withdraw from the study completely. If you withdraw from the study for any reason, we will place a note in your medical record indicating that you are no longer participating.

You may be withdrawn from the study without your consent if the researchers feel you are not able to fulfill the study requirements. Sample reasons that you may be withdrawn from the study include:

- The researchers cannot reach you to coordinate appointments
- You become incarcerated during the course of this study
- The researchers feel that this study is not in your best interest

You may withdraw permission to use your personal health information for research purposes at any time. To withdraw your permission, you can write to:

Dr. Rhonda Williams
VA Puget Sound Health Care System
1660 S. Columbian Way (RCS-117)
Seattle, WA 98108

Or, you can ask a member of the research team to give you a form to withdraw your authorization. If you withdraw your authorization, you may not be able to continue to participate in the study.

**10. <u>Questions or concerns related to the study</u>:**

The study researchers (listed below) *must* be contacted immediately if:

- You think you may have been harmed or injured as a direct result of this research; and/or
- You have any questions regarding your medical care issues.

| | |
|---|---|
| **During business hours (8:00 a.m. – 4:30 p.m.)** | Call Dr. Rhonda Williams at (206) 277-6290. |
| **After business hours (nights and weekends)** | Call 206-762-1010 and ask the operator to page the on-call Psychiatrist. |

*In the event of a life-threatening emergency, call 911 or go to the Emergency Room.*

You may contact the Institutional Review Board (IRB) – VA Office at (206) 277-1715 if you:

- Would like to speak with a neutral party who is not involved with this study;
- Have questions, concerns, or complaints about the research;
- Would like to verify the validity of the study; or
- Have questions about your rights as a research subject.

An IRB is an independent body made up of medical, scientific, and non-scientific members, who ensures the protection of the rights, safety, and well-being of subjects involved in research.

**11. Research-related injury:**

Medical treatment will be provided, if necessary, by the VA if you are injured by being in this study. You will not be charged for this treatment. Veterans who are injured because of being in this study may receive payment under Title 38, United States Code, Section 1151. Veterans or non-Veterans who are injured may receive payment under the Federal Tort Claims Act.

You do not waive any legal rights by signing this Consent Form.

**12. Research subject's rights:**

I have read or have had read to me all of the above. The open label phase of the study has been explained to me, including a description of what the study is about and how and why it is being done. All of my questions have been answered. I have been told of the risks and/or discomforts, possible benefits of this phase of the study, and other choices of treatment available to me. My rights as a research subject have been explained to me and I voluntarily consent to participate in this phase of the study. I will receive a signed copy of this Consent Form.

I agree to participate in this research study as you have explained it in this document.

_____ _____

**Subject Signature** **Date**

_____

**Print Name of Subject**

_____ _____

**Signature of Person Obtaining Consent** **Date**

_____

**Print Name of Person Obtaining Consent**

| Procedure | Number of Visits or Assessments | How Often / When | Time Required | Compensation |
|---|---|---|---|---|
| **Pre-Treatment Assessment** | One telephone assessment conducted prior to starting treatment | **Once** (before treatment begins) | 20-30 minutes | $10 |
| **Treatment** | 90-minute group treatment sessions that take place at the VA Puget Sound (Seattle or American Lake) | Average of **once per week** for 8 weeks | 12 hours total | $0 |
| **Post-Treatment Assessment** | One telephone assessment conducted after completing treatment | **Once** (following end of treatment) | 20-30 minutes | $10 |