Consent to participate as a Research Subject in:

Resilience and Well-Being Pilot Study

We are inviting you 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.

Your participation in this study is entirely voluntary. Please take as much time as you need to discuss the 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 study at any time.

Principal Investigator:
Rhonda Williams, Ph.D.

Research Staff:
Aaron Turner, Ph.D.
Ann Marie Roepke, Ph.D.
Joy Chan, B.S.

Study Title:
Intervention to Improve Resilience and Mental Health in Veterans with Injury, Illness, and/or Disability

This study is being conducted by researchers in VA Puget Sound Health Care System (VAPSHCS) Rehabilitation Care Service through a grant from the VAPSHCS Office of Research and Development.

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 Research Coordinator at **(206) 744-3626** or 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.

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 participants involved in research.

2. What is the purpose of this research study?

It is common for Veterans with injuries, illnesses, or physical disabilities to experience depression, post-traumatic stress disorder (PTSD), chronic pain, and other concerns. They may also have goals like becoming happier or better able to cope with challenges that life brings. The purpose of this research study is to learn whether Veterans like and benefit from a 5-week, group-based positive psychology program aimed at improving mental health, resilience, well-being, and quality of life. This study is considered research because Veterans will be asked to complete several assessments (surveys/interviews) over the course of the study that are not considered part of usual care. Additionally, Veterans will be asked to participate in a focus group at the end of the study to provide feedback about their experiences in the group.

You are being asked to participate in this study because:

- You are a Veteran,
- Are 18 years of age or older,
- Are eligible for services through Veteran Health Affairs,
- Have experienced an injury, illness, disability, or related health challenge
- Reported experiencing depression, PTSD, and/or chronic pain, and
- Are able to read, speak, and understand English.

This study will approach approximately 300 individuals for participation.

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

If you are interested in participating and eligible to do so, we will need about 4-5 hours of your time over 3-4 months. This includes two study visits at VA Puget Sound and three assessments over the phone. You will also need to attend weekly group sessions for 5 weeks, which will be held at VA Puget Sound as part of your standard care.

This study is time intensive, so you should enroll only if you think you can finish the study. A table 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 (1) baseline assessment in person at VA Puget Sound (20-30 minutes)
  - Three (3) telephone assessments (30-40 minutes each)
  - One (1) post-group satisfaction survey, in writing (10-15 minutes)
- One (1) in-person focus group (60-90 minutes) (optional)

These research procedures are outlined in “Assessments” and “Focus Group” below.

The group sessions you will need to attend at the VA Puget Sound will be considered standard care since you would receive the same treatment with your usual care. You will not receive compensation for the group sessions, and they are subject to standard co-pays as described below.

Informed Consent Process

This process will take place at the VA Puget Sound. 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.

Assessments

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

- **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, marital status, and military service. You will be asked questions about your medical and mental health treatment use, and any other health problems you may experience. You will also be asked questions about potentially stressful life experiences. Some examples of the questions that will be asked during the evaluation include:
  - *Have you ever experienced serious injury/harm, or caused death to someone else?*
  - *Which major illness, injury, or physical problem has been the most challenging for you?*

  If you are unable to complete your Baseline Assessment in-person during the Initial Intake, a research staff member will call you over the phone to complete the assessment.

- **Post-Group Satisfaction Survey.** This survey will happen following the completion of the 5-week group as long as you attended at least one session. You will be asked to complete this survey in-person at the end of Session 5, which is a shorter session compared to Sessions 1-4. If you are unable to attend Session 5, research staff will contact you to complete this survey over the phone. In this survey, we will ask you questions about how satisfying, engaging, and helpful you thought the program was; what you thought about the program, and whether you experienced any negative effects from participating in the program.

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

- **Telephone Assessments.** Throughout your participation in the study, you will be asked to complete three telephone assessments. Within each assessment, we will ask you questions relating to:
  - How you are feeling
  - Satisfaction with life and well-being
  - Positive and negative emotions
  - Participation and satisfaction with social activities
  - Problems related to very stressful experiences
  - Physical pain and how it is affecting your life
  - Current and past mental health treatment use
  - How likely you are to seek mental health treatment
  - Changes in medications, psychological treatment, or new major life events

- How illness/injury has impacted your life
- Whether you noticed any changes in your life after the group (once the group is over)

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

There will be three telephone assessments, which will occur at the following stages of the study:

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

  If you do not complete this assessment before the first group session, you will not be allowed to start the group and will be invited to a future group. You also have the option of withdrawing from the study and completing the group as part of standard care. If you choose to complete the group as part of standard care, you will not complete any research procedures such as telephone assessments or the focus group.

- Post-Group Assessment will occur at the end of the 5-week group period (if you complete the group). If you do not complete the group, we will still conduct this assessment about five weeks after the start of the group.

- 5-Week Follow-Up Assessment will occur about 5 weeks after the end of the 5-week group period, regardless of how many group sessions you complete.

Focus Group (Optional)

You will be invited to complete a focus group that will last about 60-90 minutes six to eight weeks after the completion of the group to talk about your experiences and satisfaction with the program. Completing the focus group is optional, but encouraged, as we would like to receive your feedback through open discussion to better improve this program for other Veterans. The focus group will be led by trained clinicians who have not been present to facilitate the group sessions. The focus group leaders will use prepared questions to help guide the flow of discussion. Examples of focus group questions include:

- *What will you take away from this program for the future?*
- *How would you describe this program to other Veterans who haven't heard of it?*

The focus group will be audio-recorded so we have complete and accurate feedback about the program so we can further refine and improve the program for other Veterans. Prior to the first group session, each study participant will sign a consent form giving permission for us to audio-record. The group leaders will remind the group at the start of the focus group before recording begins.

If you are unable to attend the focus group, research staff will contact you to answer the focus group questions over the phone. Depending on your responses to the open-ended questions, the call could take between 20-40 minutes. Because the focus group will be audio-recorded, if

you complete the focus group questions over the phone, this interview will also be audio-recorded so researchers 1) have an accurate record of your responses to the focus group's open-ended questions, and 2) ensure the staff member asking the focus group questions is following study procedure.

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 assessments. You may keep the headset after your participation in the study has ended.

Group Sessions

You will attend five (5) group sessions conducted at the VA Puget Sound at either the Seattle Campus or the American Lake Campus based on your schedule, preference, and available group schedule options.

You will be given a participant workbook with materials to refer to and discuss during the group sessions as well as additional materials to read between sessions. At the end of each session, you will also be asked to fill out a brief rating sheet with questions about the session (e.g., how helpful it was), whether you completed any home practice activities, and any feedback to improve that session. While these rating sheets are not research materials, researchers will extract data from these sheets into the larger study database. This database will not contain any identifying information about you; only your study identification number will be included in this database.

The group sessions will be considered part of your VA clinical care. As a result, the sessions will be scheduled as VA medical appointments and there will be progress notes written in your medical chart after each session. As with other standard VA clinical care, other members of your healthcare team may read these progress notes.

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:

Worsening or Discovery of Problems

As a result of participation in this study, you may think about or 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 program, you may not feel like the type of skills, techniques, or information being offered in this study make any improvements in your life.

It is even possible that your symptoms/problems 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/problems 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 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 or advanced trainees in clinical psychology) 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.

Loss of 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 sessions and focus group, but we cannot guarantee that the other group members will not make comments about your group participation 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 contact Dr. Rhonda Williams at 206-277-6290.

Audio-Recordings. The group sessions and focus group (or focus group questions, if asked through individual phone interview) will be audio-recorded to ensure 1) they were delivered as intended, and 2) we have complete and accurate feedback about the program. Although your full name and other identifying information will not be mentioned during the recordings, please note that your voice is technically identifiable, as noted in patient privacy rules.

Distressing or Uncomfortable Thoughts, Anxiety, and Frustration

You may experience fatigue and/or boredom while completing study assessments or forms. You may also experience mild anxiety, frustration, and/or stress while answering questions about depression, pain, stressful life events, PTSD symptoms, and your medical or mental health conditions. You are free not to answer any questions you do not wish to answer, and you may stop any assessment, interview, or procedure at any time.

The group sessions you are scheduled to attend are not considered research, and are considered standard care since you would receive the same treatment in your usual VA care. As usual, you should review any risks associated with skills-based group sessions with your regular health care providers.

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?

There may not be any direct benefit to you by participating in this study. The investigators will use the results from this study to determine how feasible, acceptable, and effective this program is for Veterans in rehabilitation-related settings. If the program is found to be very effective, Veterans in rehabilitation settings will have another good treatment option for helping them better improve their mental health and well-being during difficult times.

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

You do not need to participate in the research study to be involved in some of the activities the hosting clinic provides. Please speak with your care provider or study staff for other available options.

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. 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.

Reporting Risk of Harm or Abuse

If we learn you intend to harm yourself or others, we may be required by law and/or VA policy to report this information to appropriate authorities. If we learn about abuse of children, elders, or vulnerable adults, we may be required by law and/or VA policy to report this information to appropriate authorities. This includes learning about child abuse that happened many years ago, if the abuser may still be alive. The purpose of these laws and rules is in order to keep everyone safe.

People/Groups Who May Know You are in the 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
- 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 VA Puget Sound Fiscal Department and U.S. Department of the Treasury 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

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

If you are a VA patient, you already have a VA medical record. We will put information about you from this study into your medical record. All approved users of the national VA medical records system can have access to your medical record. This record will be kept forever.

We will put information about your attendance in the program into your medical record, including your presence or absence at each session, the basic content of each session, and any comments you may report during a group 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.

Safekeeping of Personal Identifiers

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 in our research data. “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 specific 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 at the VA Puget Sound in Seattle.

Safekeeping and Storage of Study Data

Part of your research records will be stored in paper form in a locked file cabinet at the VA Puget Sound Seattle 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 Health Care System. All data storage and access will be conducted in accordance with VHA guidelines for information privacy.

Any data that needs to be transmitted will be done so electronically through a shared server or by secure, VA-encrypted email. Access to the identifiable information within the crosswalk will be limited to staff members. If paper research records are transferred from one site to another (such as from American Lake to Seattle), they will only be transferred by research staff via secure lockbox which only staff have keys.

Audio Recordings

The group leaders will use an audio recorder to record the group sessions and focus group (or focus group questions, if asked through individual phone interview). 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.

Group session audio-recordings will only be reviewed by study personnel and used for assessing consistency between group leaders. The focus group audio-recording or any individual participant recordings will also be reviewed by study personnel and will be used to provide feedback about the program to investigators so we can further refine and improve the program for other Veterans. No audio-recordings will be labeled with any of your identifying information.

After Study Completion

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 file cabinet until the VA receives authorization to destroy it in accordance with federal records regulations (which will be a minimum of 6 years after the study has been completed). 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 mental health therapies. Neither you nor your family will gain financially from discoveries made using the information that you provide.

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.

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

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. 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. If you normally have to pay co-payments for your clinical appointments, you will have to pay these co-payments for the group sessions, because they are considered regular clinic appointments and not research appointments. These co-payments could be as much as $50.00 per session. Please initial the statement below to indicate that this is understandable and acceptable to you:

_____ I understand that I may be required to pay a co-payment for group sessions.
Please Initial

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

Component	**Payment**
Baseline Assessment	$20
Telephone Assessments	
• Pre-Group	$20
• Post-Group	$20
• 5-Week Post-Group	$20
Focus Group	$30
POSSIBLE TOTAL	**$110**

In sum, you may be reimbursed up to $110 if you complete all research-related study procedures.

Compensation will be by check, which will be mailed to you by the VA Puget Sound Fiscal Department after completing each component. The investigators are unable to directly control when the Fiscal Department processes participant payments, and it may take 30 or more days for you to receive your check.

If for whatever reason you prefer to receive compensation in the form of a cash voucher, please inform a member of the research staff and s/he will work with you to make this accommodation when it is possible. Please note that not all components of the study can use cash vouchers as a means of compensation; the default method is through check.

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

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

Travel Reimbursement

You may be able to receive travel reimbursement from the VA for the **clinical care procedures** (the 5 group sessions) based on your normal eligibility.

You or your insurer will be responsible for any costs related to treatment of pre-existing medical or mental health conditions.

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 study. If you are in this study, you can withdraw at any time. 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.

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 group sessions before you finish them, you will be asked to complete the follow-up assessments. 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.

You may still continue to attend sessions as part of regular clinical care if you withdraw from the study. As a result, you will not be contacted for further assessments, nor will you be invited to participate in the focus group.

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. 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

Resilience and Well-Being Pilot Study – Flow Chart

Procedure	Number of Visits or Assessments	How Often / When	Time Required	Compensation
Baseline Assessment	One session at VA Puget Sound OR over the phone, if needed	Once after informed consent process, before group begins	20-30 minutes	$20
Group Sessions	Five 75 to 120-minute group sessions at VA Puget Sound	Average of once per week for 5 weeks	Up to 10 hours total	$0
Post-Group Satisfaction Survey	In-person during Session 5 at VA Puget Sound OR over the phone, if needed	Once following end of Session 5	10-15 minutes	$0
Phone Assessments				
Pre-Group	One phone assessment	Once after informed consent process, before group begins	30-40 minutes	$20
Post-Group	One phone assessment	Once following end of Session 5	30-40 minutes	$20
5-Week Follow-Up	One phone assessment	About 5 weeks following end of Session 5	30-40 minutes	$20
Focus Group	One 60 to 90-minute focus group at VA Puget Sound	Once 6-8 weeks following end of Session 5	60-90 minutes	$30