# Consent to participate as a Research Subject in:

## Groups for **R**egaining **O**ur **W**ellbeing **("GROW")**

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:**
David J. Kearney, MD

**Research Staff:**
Tracy Simpson, PhD
Tiffanie Fennell, PhD
George Sayre, PsyD

**Study Title:**
A Randomized Clinical Trial of Group Interventions for Veterans with Chronic Multi-Symptom Illness

**For study-related questions.**

This study is being conducted by the VA Puget Sound Health Care System ("VA Puget Sound") through a grant from VA Human Subjects Research & Development (HSR&D).

### 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 study staff at (206) 277-1012. 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; and/or
- 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; or
- Have questions about your rights as a research subject.

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

The purpose of this study is to see if Mindfulness-Based Stress Reduction (MBSR) is an effective treatment option for veterans with chronic multi-symptom illness (or "CMI"), particularly among those who were deployed to the Persian Gulf War I in 1990-1991. CMI is a cluster of medically unexplained chronic symptoms that can include:

- Fatigue
- Headaches
- Joint pain
- Joint stiffness
- Muscle pain
- Skin rashes
- Indigestion
- Insomnia
- Dizziness
- Respiratory disorders
- Menstrual issues
- Memory problems
- Depression
- Moodiness
- Anxiety
- Psychological problems
- Cognitive problems

We want to determine whether there are unique elements about MBSR that contribute to its impact on CMI symptoms or if the benefits are due to group participation in general.

To do this, we will be randomly assigning participants to take part in either MBSR or an adapted version of the Chronic Disease Self-Management Program (aCDSMP) and comparing changes in CMI symptoms before and after participants have completed the 8-week Group Sessions. Both groups will be held remotely using the VA's Video Connect platform. Below is a brief outline of each group:

- **MBSR** is the "mindfulness group," which teaches techniques for enhancing a person's capacity for mindfulness, such as the breathing meditation, the body scan, walking meditation, and some gentle yoga. These exercises are designed to help learn skills that can help work with chronic symptoms such as pain, fatigue, or memory lapses. The focus is on learning self-care practices that other studies have shown to be helpful for chronic symptoms.

- **aCDSMP** is the "self-management group," which provides education about self-management for a variety of common conditions based on principles of cognitive behavioral therapy; you will develop an action plan to follow throughout the program.

To be eligible for this study, you must have at least two of the following symptoms:

- Chronic musculoskeletal pain involving two or more regions of the body
- Fatigue that limits usual activity
- Cognitive symptoms (memory, concentration, or mood disturbances)

We are planning to enroll 308 subjects from VA Puget Sound. Approximately half of these subjects will be veterans who were deployed to the Gulf War between

1990-1991 and meet criteria for CMI. The other half will be veterans from other periods of service who also meet criteria for CMI.

Completing the study procedures will take approximately 9 months and will include:

- Four research assessments by phone (about 1-2 hours each)
- A Midpoint Assessment by mail (about 30 minutes)
- An optional qualitative interview for Gulf War veterans (20-60 minutes)
- Over an 8-week period, attend 8 Video Group Sessions (2½ hours a week)

In total, completing these study procedures will require approximately 30 hours of your time for a period of 8-9 months. All study visits will be held remotely with staff of the VA Puget Sound Health Care System.

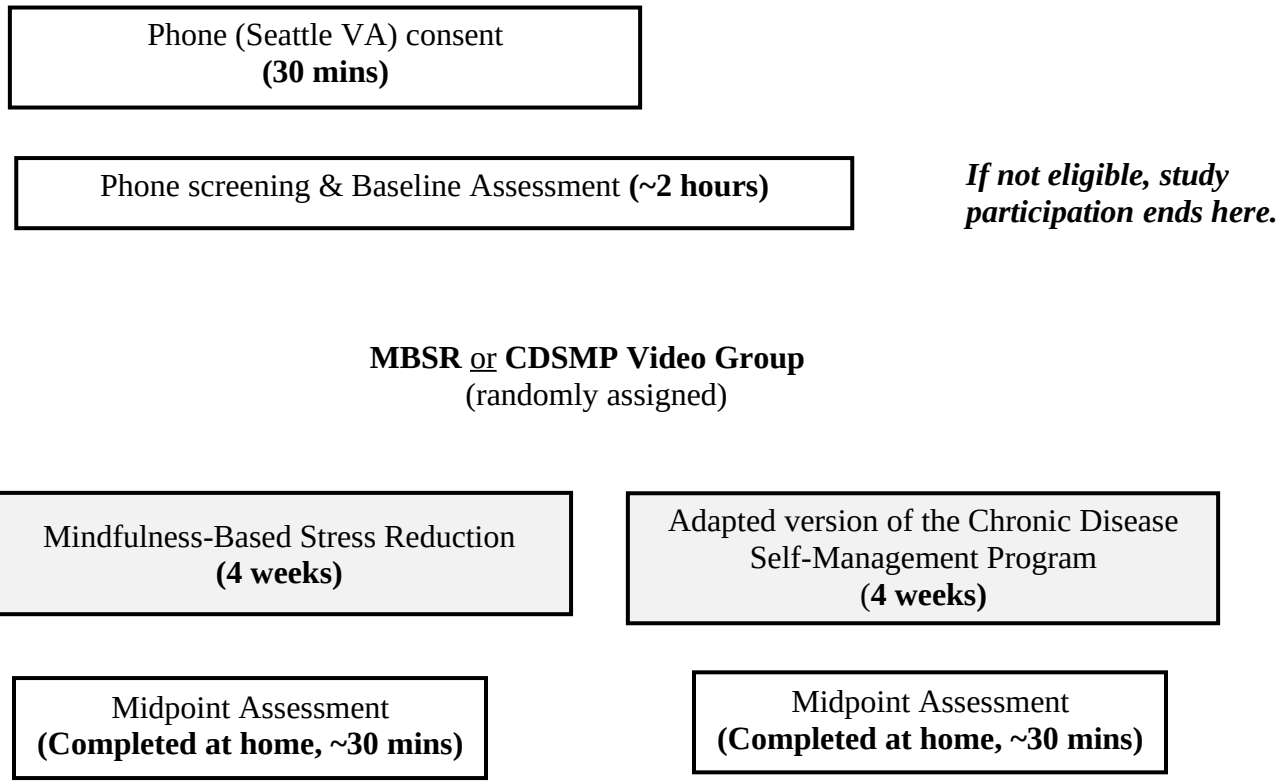
## 3. What will I be asked to do in this research study?

In this study, we will ask you to participate in two types of appointments—research assessments and Group Sessions:

- **Research assessments** will be scheduled with research staff for a mutually convenient time within a predetermined month-long time frame. At a research assessment appointment, you will need to complete a series of questionnaires over the phone with a member of our study team; this is when the researcher collects information about your symptoms and health status.

- **Group Sessions** are the MBSR and aCDSMP appointments, which take place between the first and second research assessments. There are eight Group Sessions for both MBSR and aCDSMP. For 8 weeks, you will need to attend a weekly Group Session by video, which will be 2½ hours long.

The order of these appointments is outlined in the following diagram:




We will audio-record the MBSR and aCDSMP Group Sessions. These recordings may include the use of first names within the group. The purpose of these recordings is to ensure that the group leaders are adhering to the appropriate treatment curriculum as closely as possible.

## Medication reviews

We will be tracking the medications that you take and the other treatment you receive while you are enrolled in the study so that we are aware of whether other factors, other than the study treatment, may contribute to fluctuations in the symptoms that we are measuring for this research. We will gather this medication and treatment information from your VA electronic medical record.

## Drug use reviews

We will be tracking non-prescribed drug and opioid use while you are enrolled in the study so that we are aware of whether other factors, other than the study treatment, may contribute to fluctuations in the symptoms that we are measuring for this research. We will gather this drug and opioid use information from you at all four assessment points (Baseline, Post-Assessment, 3-Month Assessment, and 6-Month Assessment).

The following chart provides a more detailed description of what occurs at each study appointment:

| Study Week | Study Visit | Total Time | Study Activities / Group Sessions |
|---|---|---|---|
| **Week 0** (up to 6 weeks prior to the start of the Group Sessions) | **1** | **30-45 minutes** | Provide informed consent |
| **Week 0** (up to 5 weeks prior to the start of the Group Sessions) | **2** | If eligible, up to **2 hours**<br><br>If not eligible, about **30 minutes** | **Screening**<br>• Complete screening procedures<br>Determine inclusion/exclusion criteria<br><br>**If eligible:**<br>• Continue visit with **Baseline Assessment**<br>• Randomization to MBSR or aCDSMP<br>Group Sessions schedule provided<br><br>**If not eligible:**<br>• Participation in study is completed; no additional appointments |
| **Week 0** (up to 5 weeks prior to the start of the Group Sessions) | **3** | About 30 minutes | Orientation to VA Video Connect Technology phone appointment |
| **Week 1** | **4** | 2½ hours | Group Session 1 |
| **Week 2** | **5** | 2½ hours | Group Session 2 |
| **Week 3** | **6** | 2½ hours | Group Session 3 |
| **Week 4** | **7** | 2½ hours<br>30 minutes | Group Session 4<br>Following Session 4, complete |

| | | | |
|---|---|---|---|
| | | | Midpoint Assessment at home and mail back prior to Group Session 5 |

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|---|---|---|---|
| **Week 5** | **8** | 2½ hours | Group Session 5 |
| **Week 6** | **9** | 2½ hours | Group Session 6 |
| **Week 7** | **10** | 2½ hours | Group Session 7 |
| **Week 8** | **11** | 2½ hours | Group Session 8 |
| **Weeks 9-12** | **12** | 2 hours<br><br>Up to 1 hour | Complete Post-Group Assessment<br><br>Complete audio-recorded interview with researcher (optional for Gulf War veterans) |
| **Weeks 21-24** | **13** | 2 hours | Complete 3-Month Follow-Up Assessment |
| **Weeks 33-36** | **14** | 2 hours | Complete 6-Month Follow-Up Assessment |

## Baseline Assessment

If you are eligible to continue participating in the study, we will ask you to begin the Baseline Assessment immediately following the screening procedures (during the same phone appointment). This will take about 1-2 more hours. The Baseline Assessment, as well as the remaining three research assessments for this study, will include several questionnaires that measure your physical and mental health, including pain, fatigue, cognitive problems, PTSD symptoms, depression, emotions, drug and alcohol use, and physical symptoms.

## Midpoint Assessment

Following Group Session 4, you will be mailed the Midpoint Assessment to complete at home and mail back to the researchers the following week before Group Session 5. The Midpoint Assessment is a packet of several questionnaires measuring physical and mental health as well as physical symptoms. The Midpoint Assessment is estimated to take approximately 30 minutes to complete.

## Optional Interview for Gulf War Veterans during Post Assessment

If you are a Gulf War veteran, as part of the second research assessment (the Post Assessment), you may be asked to participate in an interview with one of the researchers. This interview will include questions that focus on your overall impression and satisfaction with the MBSR or aCDSMP group (whichever one you were assigned). The interview will be audio-recorded.

## Computer questionnaires through Microsoft Access

We will administer questionnaires through Microsoft Access electronic forms; data collected will be saved directly to a database located in the password-protected VA computer system to which only VA study personnel have access.

When the study staff member fills out the questionnaires in the computer-based database (a Microsoft Access file), new health information will be created about you. This information will not be added to your medical record, and you will not be allowed to see it until after your study participation is complete. Once you have completed your participation in the study, you may request copies of your results from these questionnaires, which you may share with your providers or anyone else that you wish.

Some of the questionnaires deal with sensitive topics about exposure to possible toxins and trauma. Examples of potentially uncomfortable questions include:

- *In the past month, did you think about suicide*?
- *Please indicate if you have experienced the following traumas* (from a checklist).
- *Respond "Yes," "No," or "I don't know" for each statement about your exposure to nuclear, biological, and chemical agents during deployment*.

You may refuse to answer any question or item, but we reserve the right to exclude you from further participation if we are unable to get a complete picture of your health status and verify that you are eligible to participate.

After you have completed 8 weeks of Group Sessions, we will need to schedule you for the following three research assessments: a Post-Group Assessment, a 3-Month Follow-Up Assessment, and a 6-Month Follow-Up Assessment.

## OPTIONAL

- **Data Repository**

  We will ask your permission to include your study data in a data repository. We would like to use the data collected from this study and combine it with data from similar studies for future research. If you are interested in allowing your data to be used in this way, we will provide you with a separate Consent Form to sign.

### 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 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:

**Confidentiality.** There will be a risk that a breach of confidentiality could occur; however, every effort will be made to prevent this from happening. Your personal information will be kept secure and only accessed by authorized study staff as needed to conduct this study. Participating in a VA Video Connect group has some limitations in confidentiality. Because this is an internet- based platform, there are some potential risks to information security. We ask that all participants commit to maintaining group confidentiality, and we take steps to positively identify group participants and lock the video groups to prevent intrusions.

- **Audio-recordings.** Although your full name and other identifying information will not be mentioned during the recorded interview, there will be a chance that the transcriptionist listening to your interview could recognize your voice. However, please note that your voiceprint is considered a "personal identifier" according to the patient privacy rules. Therefore, even if you are identifiable by voice, your identity will never be disclosed without your authorization to anyone not listed outside the research team.

- **Questionnaires.** Answering questions during the research assessments may result in emotional discomfort, since it can be unpleasant to think about different mental and physical health symptoms and their impact on your life. During the questionnaires, you may feel uncomfortable answering questions or focusing your experience on past stressful or traumatic experiences. In addition, you may feel as if your privacy has been invaded. You should feel free to discuss any discomfort with the study procedures with any person on the study team.

If any of the risks included in this Consent Form change enough during this study that they may change your decision to be in this research study, we will let you know.

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

There may be no direct benefit to you by participating in this study. However, we will be monitoring you more closely and there is the possibility that your CMI may decrease – and your quality of life may increase – as a result of participating in either MBSR or aCDSMP. Regardless of whether you participate in the study or not, the results from this study may lead to new therapies for CMI, which could help other individuals who suffer from chronic pain, fatigue, and cognitive difficulties, and/or mood disturbances.

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

Although we anticipate that MBSR and aCDSMP will be beneficial, it is also possible some of the strategies or methods involved in these programs may not be effective or could result in symptom worsening.

If you do not wish to participate in this research, you may continue your usual treatment for CMI. If you are not currently receiving other treatment, we recommend that you speak to your primary care provider about the treatment options available to you.

## 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.

If we learn you intend to harm yourself or others, we must report this information to appropriate authorities.

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

- Research team members
- The Data Safety Monitoring Board (DSMB) who advise the sponsor or PI regarding the continuing safety of 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 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
- VA HIPAA-certified transcription service (Gulf War interview audio-recordings only)

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. If you are not a VA patient, we will create a VA medical record for you. The creation of a VA medical record for you for the purposes of this study does not entitle you to any services at the VA beyond those services to which you are otherwise entitled.

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 may include health insurance companies who are being billed for medical costs. This record will be kept forever.

## Study Code

If you agree to participate in our study, we will assign you a study code number. We will not include your name or other identifiers (such as your name or social security number) on any of the information that we collect from you. Only your study code number will be used. We will keep a master list that links study participants' names to code numbers separate from the study data in a secure VA database with restricted access.

## Safekeeping of Study Information

- **Study data (paper and electronic)**
  To protect the confidentiality of the information obtained about you during this research study, we take many preventative measures. Any paper study documents we have, received, or created will be secured in locked file cabinets accessible only to study staff. Any electronic study records will be kept in electronic folders on the secure VA network with access to the specific folders restricted to designated study staff.

- **Audio-files from Group Sessions**
  The audio-files will be listened to by a member of the research staff and then coded. The files will be stored along with all other study data on the secure VA network. The audio-recorder will be stored in a locked cabinet when not in use and accessible only to authorized study staff. Current VA regulations require us to keep audio-files indefinitely.

  Recordings which have not yet been uploaded into the password-protected VA network folder will be stored in a locked file cabinet in an office which will be locked when unoccupied.

- **Audio-files from Post-Assessment interview (optional for Gulf War veterans)**
  Audio-files will be accessible to members of the HIPAA-certified transcription service through the secure VA network. All transcription is conducted by VA employees. Recordings which have not yet been uploaded into the password-protected VA network folder will be stored in a locked file cabinet in an office which will be locked when unoccupied. We will store the transcripts with all other study data accordingly.

## Certificate of Confidentiality

We have been granted a Certificate of Confidentiality from the National Institutes of Health (NIH). 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 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 the VA Puget Sound office 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.

## Upon Study Completion

Once this study is completed, we will not use the study code linking you to your data (including audio-file transcripts) 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; we will keep your coded data indefinitely.

In the future, researchers may write about the information (study data which includes audio-file transcripts) collected from this research study. Any future publications or articles will not include any identifying information about you without your approval in writing.

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

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

## Research Assessments:

We will pay you accordingly:

- Phone screening / Baseline Assessment

(even if you are not eligible) . . . . . $40

- Midpoint Assessment. . . . . $20
- Post-group Assessment . . . . . $40
  - Optional interview for Gulf War veterans . . . . . $30
- 3-Month Follow-Up Assessment . . . . . $45
- 6-Month Follow-Up Assessment . . . . . $55

**TOTAL** for completing all research assessments . . . . . $**200**

**TOTAL** for Gulf War veterans completing all research assessments **plus** the optional interview . . . . . $**230**

Payments will be mailed within 6-8 weeks after you complete each research assessment. However, if you would rather receive payments as cash vouchers or by direct deposit, please let someone on the research team know.

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

## 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.

Your participation in the study may be terminated without your consent, if you become a threat to the safety of others in your treatment group or to the research team. Your termination can be initiated by any of the research team members, but the decision must be confirmed with the study's Principal Investigator before you are withdrawn from the study.

If you decide to withdraw from the study, no new information will be collected from you. Information already collected up to that point will continue to be used for the 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