Targeting Barriers to Pain Self-Management in Women Veterans: Refinement and Feasibility of a Novel Peer Support Intervention (Project CONNECT) (CDA 18-005)

NCT04229134

February 13, 2020

Department of Veterans Affairs

Authorization for Use and Release of Individually Identifiable Health Information Collected for VHA Research

Subject Name (Last, First, Middle Initial):	**Subject SSN** (last 4 only):	**Date of Birth:**

VA Facility (Name and Address):
VA Connecticut Healthcare System (VACHS)
Research
950 Campbell Avenue
West Haven, CT 06516

VA Principal Investigator (PI):	**PI Contact Information:**
Mary Driscoll, PhD	(203) 932-5711 x3953

Study Title:
Targeting Barriers to Pain Self-Management in Women Veterans: Refinement and Feasibility of a Novel Peer Support Intervention (Project CONNECT)

Purpose of Study:

This study will examine the best way to provide a peer support pain self-management intervention (designed to increase your ability to use pain self-management skills either in place of or in addition to medication) for Women Veterans who have chronic pain and obtain feedback regarding overall helpfulness of the intervention. The best way to do this is to instruct patients on how to complete the self-management manual, provide/obtain support from peers, and practice the learned skills. Afterwards, we want to get feedback about whether they think the interventions helped them, and what they liked or would change about the program to make future improvements. We'll also want to get information about preferences for future treatment.

USE OF YOUR INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION (IIHI):

Your individually identifiable health information is information about you that contains your health information and information that would identify you such as your name, date of birth, or other individual identifiers. VHA is asking you to allow the VA Principal Investigator (PI) and/or the VA research team members to access and use your past or present health information in addition to new health information they may collect for the study named above. The investigators of this study are committed to protecting your privacy and the confidentiality of information related to your health care.

Signing this authorization is completely voluntary. However, your authorization (permission) is necessary to participate in this study. Your treatment, payment, enrollment, or eligibility for VA benefits will not be affected, whether or not you sign this authorization.

Your individually identifiable health information used for this VA study includes the information marked below:

☐ Information from your VA Health Records such as diagnoses, progress notes, medications, lab or radiology findings

☒ Specific information concerning:

☒ alcohol abuse ☒ drug abuse ☐ sickle cell anemia ☐ HIV

☒ Demographic Information such as name, age, race

☐ Billing or Financial Records

☒ Photographs, Digital Images, Video, or Audio Recordings

☒ Questionnaire, Survey, and/or Subject Diary

☒ Other as described: Information shared during the interviews.

Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research

Subject Name (Last, First, Middle Initial)**:**	**Subject SSN** (last 4 only)**:**	**Date of Birth:**

USE OF YOUR DATA OR SPECIMENS FOR OTHER RESEARCH: (Instruction: When banking or further analysis is an **optional** research activity, complete page 5 and leave this section blank. If banking is a required research activity to store "Data" and/or "Specimen" for future use or if "Not Applicable" is selected, remove page 5 in its entirety.)

☒ Not Applicable - No Data or Specimen Banking for Other Research

An important part of this research is to save your

☐ Data

☐ Specimen

in a secure repository/bank for other research studies in the future. If you do not agree to allow this use of your data and/or specimen for future studies approved by the required committees, such as the Institutional Review Board, you will not be able to participate in this study.

DISCLOSURE: The VA research team may need to disclose the information listed above to other people or institutions that are not part of VA. VA/VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Privacy Act of 1974 and all other applicable federal laws and regulations that protect your privacy. The VHA Notice of Privacy Practices (a separate document) provides more information on how we protect your information. If you do not have a copy of the Notice, the research team will provide one to you.

Giving your permission by signing this authorization allows us to disclose your information to other institutions or persons as noted below. Once your information has been disclosed outside VA/VHA, it may no longer be protected by federal laws and regulations and might be re-disclosed by the persons or institutions receiving the information.

☐ Non-VA Institutional Review Board (IRB) at _____
who will monitor the study

☒ Study Sponsor/Funding Source: VA Health Services Research & Development; PRIME Center
VA or non-VA person or entity who takes responsibility for; initiates, or funds this study

☒ Academic Affiliate (institution/name/employee/department): Yale University
A relationship with VA in the performance of this study

☐ Compliance and Safety Monitors: _____
Advises the Sponsor or PI regarding the continuing safety of this study

☐ Other Federal agencies required to monitor or oversee research (such as FDA, OHRP, GAO):

☐ A Non-Profit Corporation (name and specific purpose):

☒ Other (e.g. name of contractor and specific purpose):
Veteran's mobile phone number will be stored on Yale REDCap to deliver link to mobile surveys during study.
Digital copies of interviews will be securely transferred to VA Salt Lake City for transcription.

Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research

Subject Name (Last, First, Middle Initial)**:**	**Subject SSN** (last 4 only)**:**	**Date of Birth:**

Note: *Offices within VA/VHA that are responsible for oversight of VA research such as the Office of Research Oversight (ORO), the Office of Research and Development (ORD), the VA Office of Inspector General, the VA Office of General Counsel, the VA IRB and Research and Development Committee may also have access to your information in the performance of their VA/VHA job duties.*

Access to your Individually Identifiable Health Information created or obtained in the course of this research: While this study is being conducted, you

☐ will have access to your research related health records

☒ will not have access to your research related health records

This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

REVOCATION: If you sign this authorization you may change your mind and revoke or take back your permission at any time. You must do this in writing and must send your written request to the Principal Investigator for this study at the following address:

Mary Driscoll, PhD
VA Connecticut Healthcare System
950 Campbell Avenue (11ACSLG)
West Haven, CT 06516

If you revoke (take back) your permission, you will no longer be able to participate in this study but the benefits to which you are entitled will NOT be affected. If you revoke (take back) your permission, the research team may continue to use or disclose the information that it has already collected before you revoked (took back) your permission which the research team has relied upon for the research. Your written revocation is effective as soon as it is received by the study's Principal Investigator.

EXPIRATION: Unless you revoke (take back) your permission, your authorization to allow us to use and/or disclose your information will:

☒ Expire at the end of this research study

☐ Data use and collection will expire at the end of this research study. Any study information that has been placed into a repository to be used for future research will not expire.

☐ Expire on the following date or event:

☐ Not expire

Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research

Subject Name (Last, First, Middle Initial)**:**	**Subject SSN** (last 4 only)**:**	**Date of Birth:**

TO BE FILLED OUT BY THE SUBJECT

Research Subject Signature. This permission (authorization) has been explained to me and I have been given the opportunity to ask questions. If I believe that my privacy rights have been compromised, I may contact the VHA facility Privacy Officer to file a verbal or written complaint.

I give my authorization (permission) for the use and disclosure of my individually identifiable health information as described in this form. I will be given a signed copy of this form for my records.

_____ _____

Signature of Research Subject Date

_____ _____

Signature of Legal Representative (if applicable) Date

To Sign for Research Subject (Attach authority to sign: Health Care Power of Attorney, Legal Guardian appointment, or Next of Kin if authorized by State Law)

_____

Name of Legal Representative (please print)

connect
women joining forces to combat pain.

INFORMATION SHEET:

RESEARCH SUMMARY

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

We are asking you to choose whether or not to volunteer for a research study about an intervention (Project CONNECT) where women Veterans learn to better manage their pain with the support of another woman Veteran. We are trying to learn whether it is feasible to continue to offer this care option and whether women find it to be beneficial. This initial summary is to give you key information to help you decide whether to participate. We have included detailed information after this brief summary. Ask the research team questions. Taking part in this study is completely voluntary.

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

Women Veterans may experience difficulty accessing programs or treatments to help them manage their pain. The current study was designed to address the difficulties and challenges that women Veterans face when trying to access and use pain self-management programs. Participation in this study will consist of a series of activities that will occur over a 22-week period.

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

If you enroll in this program, you may experience improvements in pain, the degree to which it interferes in your life and/or affects your mood. You may also benefit from connecting with another woman Veteran. These are possible benefits and are not guaranteed. Additionally, the information we obtain from you and the other women who enroll can help us to improve CONNECT and other pain programs that may benefit other Veterans, particularly women Veterans.

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

There are some reasons you might not choose to volunteer for this study. The study involves several activities that occur over a 28-week period. If you do not have the time, this might affect your decision to volunteer. This study requires you to use your personal smartphone to respond to assessments and to interact with your peer partner. If you have limits on cell phone utilization or are uncomfortable using your cell phone to do so, this might influence your decision to volunteer. If you have concerns about being matched with another woman Veteran, this study might not be right for you. Finally, if you have difficulty walking or concerns about learning pain self-management skills at home, this study might not be appropriate for you.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

RESEARCH DETAILS

WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

Women Veterans may experience difficulty accessing programs or treatments to help them manage their pain. The current study was designed to address the difficulties and challenges that women Veterans face when trying to access and use pain self-management programs.

With this research we hope to learn more about the feasibility of CONNECT, your perceptions of it and the best ways to evaluate it in the future.

HOW LONG WILL YOU BE IN THE STUDY?

This research study is expected to take approximately 3 years. Your participation in this research will follow the schedule described above and will occur over a 28-week period.

WILL OTHERS BE IN THE STUDY?

We expect to enroll a total of 45 women Veterans from VA Connecticut and VA Central Western Massachusetts into this study.

WHAT WILL HAPPEN IF YOU TAKE PART IN THE STUDY?

The figure, below, details the timeline of activities that you will be asked to participate in. A description of each activity follows on the next page:

	Prospective Preference Assessment	Behavioral Run-in	CONNECT	Follow-Up Assessments
Time	1 Hour	1 Week	8 Weeks	1 week after CONNECT 12 Weeks after CONNECT
Activities	Phone Interview with Staff One-time Phone Survey	Phone Call with staff (20 minutes) Brief Nightly Survey (7x; 3-5 min each) Web Survey (30 min)	Pain Coping Skills Practice (15 min/day) Brief Nightly Survey (3-5 min each) Peer-to-Peer 15-Minute Calls (1/week) Individual Phone Call with Staff (2 total, 15 min each)	Telephone Interview with Staff (1-hour) Brief Nightly Survey (7x; 3-5 min each) Web Survey (30 min)

It is important to understand that participation in the home-based pain self-management intervention (CONNECT portion) is contingent on successful completion of at least 6 pre-intervention nightly assessments, the pre-intervention call and the pre-intervention assessment. If you do not successfully complete the week-long pre-intervention activities, we will briefly ask you what made it difficult to complete them. You will still be asked to participate in the post-intervention assessments unless you indicate you are no longer interested

WHAT IS EXPECTED IF YOU TAKE PART IN THIS STUDY?

If you decide to participate in this study, you will participate in several activities that are detailed below and occur in chronological order:

Preference Assessment:
The preference assessment is a *one-hour* interview that can be conducted in-person or via home. Information from this interview will help us to understand preferences for self-management treatment and how we can best evaluate CONNECT in the future. This interview will be conducted by a study investigator or research coordinator. During this interview you will be:

- Asked to respond to questions from standard assessments to understand more about you
- Asked to listen to a description of self-management treatments for future research trial and to respond to a series of questions to better understand your preferences and willingness to participate
- Following this interview, you will be sent a pedometer, and a CONNECT treatment manual via mail. The interviewer will then schedule your weeklong pre-intervention activities.

Pre-Intervention Run-In Week
Because the intervention pairs you with another woman Veteran and her participation is, in part, reliant on yours, the pre-intervention run-in period includes a series of activities similar to those that are required during the intervention and allows us to understand more about your pain. This *week-long* period requires:

- Completion of brief (3-5 minute) nightly pre-intervention smartphone assessments to assess daily pain, pain coping, stress, mood, activity level, etc.
- Completion of one 30-minute pre-intervention baseline smartphone assessment to learn more about your pain, functioning, social support, and quality of life.
- Participation in one 20-minute call with CONNECT staff (investigator or coordinator)

If you are able to complete 6 of the 7 brief nightly pre-intervention assessments, the pre-intervention baseline assessment and the staff call, you will be eligible to participate in the intervention itself. If you do not complete all of these, you will not be eligible for the intervention, but we will ask what made it difficult to complete them; we will also ask you to complete the follow-up activities, below.

CONNECT Intervention
The CONNECT Intervention is an 8-week home-based pain self-management program. Together with a peer partner, you will work through the CONNECT manual to:

- learn a new pain coping skill each week
- participate in a walking program

- set goals
- support each other via nightly text messages and one 15-20-minute weekly phone call.

Post-Intervention Activities:
Whether you participate in the CONNECT intervention or not, you will be asked to complete a series of assessments:

- At 9 and 21 weeks after the baseline, you will complete another week of brief (3-5 minutes) nightly smartphone assessments
- At 10 and 22 weeks after the baseline, you will complete another 30-minute smartphone assessment.

If you participated in CONNECT, you will be asked to complete a one-hour post-treatment telephone interview with an investigator or research coordinator to learn more about your perceptions of the program.

Please understand that you may decline to complete any assessment or individual question for any reason, without penalty. All study activities will be overseen by the Principal Investigator, Mary Driscoll, PhD, who will be responsible for reviewing and addressing any safety issues or other concerns that come up. She can be reached on 203.932.5711 X3953.

Should you decide that you wish to participate, we ask that you adhere to the following:

- Keep all appointments made with study staff whether they are in-person or by phone. If you need to miss an appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment.
- Schedule and keep your peer check-in calls. If you cannot make one, please make sure you let your peer partner know.
- Fill out your nightly assessments as instructed.
- Complete your pre and post-intervention assessments as instructed, even if you don't like the program or feel it hasn't helped. Receiving assessments only from those who liked it may prompt investigators to conclude that CONNECT was more beneficial than it really was.
- Complete the self-management program as instructed.
- Ask questions as you think of them.
- Report any new symptoms or other changes in your health that you experience.
- Report any difficulties you are having with the assessments, the pain coping strategies, the walking program, or with your peer to study staff so we can assist you.
- Be honest with your feedback in study interviews/appointments with research staff.
- While participating in this research study, do not take part in any other research project without approval from the investigators. This is to protect you from possible injury from things such as extra blood drawing, extra X-rays, or potential drug interactions. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

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

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

Below, the risks and/or discomforts are described for each aspect of the study.

Preference Assessment:
The interview and/or certain questions may be boring, confusing or cause distress. You are not under any obligation to answer any question you don't want to, and you may end the interview at any time. The interview will be audio recorded and maintained behind the VA firewall. This recording will not be used publicly. The audio recording is to allow staff to identify themes and draw conclusions across all individuals who participate. Interviews will be de-identified and transcribed by the VA transcription office in Salt Lake City.

Pre-Intervention Run-In
The pre-intervention run-in involves several components (assessments/staff call) and may be annoying or time-consuming. Some of the questions may cause distress. You are under no obligation to answer any question or assessment you don't want to and you can discontinue participation at any-time. Additionally, the self-assessments are administered using a web-based program called REDCAP. In order to receive these assessments, we will enter your phone number into this program, but we will not include any other identifying information and your data will be assigned a unique identifier to maintain your confidentiality.

CONNECT Intervention:
The CONNECT intervention pairs you with another woman Veteran. Your peer is not bound by confidentiality rules, so anything you say can be repeated. It is recommended that you not share anything you would like to remain private. In any peer relationship there is the possibility of interpersonal conflict or disconnection; this can be distressing. Study staff are available to assist with any interpersonal difficulties. Should you decide to terminate the peer relationship for any reason, study staff will facilitate this. It is always possible that your peer partner may experience an elevation in psychological distress – this can be stressful. Should this happen, you are under no obligation to provide care for your partner – you may reach out to study staff for assistance if there are concerns. Every effort has been made to ensure that participants are able to fully participate before enrolling. There is the possibility of confusion around the pain coping skills; monthly staff calls are available to address this and check in calls with staff are built in at weeks 2 and 5. Additionally, you may reach out to staff for clarification during business hours. The CONNECT intervention also involves participation in a walking program which may lead to soreness or physical discomfort. Beginning to exercise, especially if you do not regularly do so, could lead to physical discomforts such as muscle tightness, muscle soreness, or blisters. In the event that you experience a significant increase in pain or sustain an injury, please alert study staff and contact your primary care provider before continuing to engage in the exercise portion.

Post-Intervention Assessments:
The post-intervention assessments and interview may be annoying or time-consuming. Some of the questions may cause distress. You are under no obligation to answer any question or assessment you don't want to and you can discontinue participation at any-time. Additionally, the self-assessments are administered using REDCAP. As noted above,in order to receive

these assessments, we will enter your phone number into this program, but we will not include any other identifying information and your data will be assigned a unique identifier to maintain your confidentiality. Following the intervention, you will be asked to participate in an interview that will be audio recorded and stored on a server behind the VA firewall. This recording will not be used publicly. The audio recording is to allow staff to identify themes across all individuals who participate in the intervention. Interviews will be de-identified and transcribed by the VA transcription office in Salt Lake City.

Though every effort will be made to maintain privacy and confidentiality, there is always a risk that this may be breached. With the exception of the phone number which will be entered into REDCAP, all personally identifying information will be kept behind the VA firewall. All data will be assigned a unique identifier.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of your usual care.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. However, possible benefits may include improvements in pain, mood, or functioning and the opportunity to connect with another woman Veteran. Additionally, the information we get from this study might help other women with chronic pain.

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

You may choose not to participate in this study. If this is your decision, there are other choices that might be more appealing to you. In-person pain-self management interventions are available through the health psychology program and/or the mental health service line. Depending on your location and preferences, there are several ways to access similar interventions. These include: Pain Rehab School (West Haven), Pain University (Newington), cognitive behavioral therapy for chronic pain (health psychology and/or mental health service lines (all locations).

You may discuss these options with your doctor.

HOW WILL YOUR PRIVATE INFORMATION BE PROTECTED?

All personally identifiable information, with the exception of your phone number, will be kept in locked filing cabinets at the VA Connecticut Healthcare System in the Principal Investigators office and/or behind the electronic VA firewall. Only your phone number will be entered into Yale's REDCAP system to allow for electronic distribution of assessments. A unique identifier will be assigned to your data and the master key linking your data to you will be kept in a password protected electronic worksheet behind the VA firewall. Only authorized research staff will have access to your information.

Storage and Future Use of Data:

Your information collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

UNDER WHAT CIRCUMSTANCES MIGHT CONFIDENTIALITY BE BREACHED?

If we discover that you are experiencing depression, worsening depression, or suicidal thoughts, we will immediately share this with your primary physician and, if you have one, with your mental health provider. Participants considered to be a danger to themselves or to others, including children or vulnerable adults, may be reported to the authorities and potentially hospitalized against their will.

MEDICAL RECORD

We will include information about your study participation in your medical record.

CLINICAL TRIAL

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

WHAT ARE THE COSTS TO YOU IF YOU TAKE PART IN THIS STUDY?

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

IS THERE PAYMENT TO YOU IF YOU TAKE PART IN THIS STUDY?

You are eligible to be paid for the time you spend completing assessments for the study. These assessments involve considerable time to complete and include self-report questionnaires, as well as daily electronic logs during and after the intervention. In sum, you can be compensated up to $240 which includes $25 for the prospective preference assessment, and $20 for the Baseline Assessment, plus up to $10 for the nightly logs ($1.00/day, $3 for completing all 7) that you complete during the run-in period. During the intervention, you may earn up to $100 for completing the daily logs. Specifically, you will earn $1.00 for each daily log and an additional $3.00/week for completing all 7 daily logs in a given week This includes the 8 intervention weeks, and 2 follow-up weeks (weeks 9 and 21). You can earn $25 for the Week 10 follow-up, $25 for the post-treatment interview and $35 for the Week 22 follow-up. See the table, below for a breakdown of possible compensation broken out by study activities.

Prospective Preference Assessment	**$25**
Behavioral Run-In	
Baseline Assessment	**$20**
Daily EMA ($1.00/day*7 days)	**$7**
****BONUS EMA $3****	**$3**

Intervention	
Daily EMA ($1.00/day*56 days)	$56
BONUS EMA $3/week*8 weeks	$24
Post Intervention	
Week 9 & 21 EMA ($1.00/day*14 days)	$14
BONUS EMA $3/week *2 weeks	$6
Week 10 Interview	$25
Week 10 Assessment	$25
Week 22 Assessment	$35
Total Possible Remuneration	$240

Payments will be disbursed by the VA Financial Management System. In order to process payment, your social security number must be disclosed to the finance department. In the event you have direct deposit, funds will be electronically sent. Otherwise, a check will be mailed to the address the VA Financial Management System has on file. Payments are processed within 4-6 weeks. You should know that, due to limitations in the Financial Management System, payments made to subjects through Austin Financial Services Center generate Internal Revenue Service Form 1099 regardless of amount. Should you owe the Federal Government any money, your compensation may be garnished.

WHAT WILL HAPPEN IF YOU ARE INJURED BECAUSE OF YOUR BEING IN THE STUDY?

If you are injured as a direct result of your participation in this research study, VA will provide necessary medical treatment at no cost to you (in accordance with applicable federal regulations (38 CFR 17.85). Except in very limited circumstances, this medical treatment will be provided in a VA Medical facility. There are no plans to provide compensation for disability or other losses occurring over the long term or if an injury becomes apparent after your participation in the study has ended. However, by agreeing to participate in this research study, you are not waiving or giving up any legal rights to seek compensation.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY:

The VA Connecticut Research Coordinator at 203-937-3830, OR

Dr. Mary Driscoll at 203.932.5711 X3953 and

AFTER HOURS:

The VA CT Emergency Room at 203-932-5711 x4777

Emergency and ongoing medical treatment will be provided as needed.

WHO ELSE MAY YOU CONTACT IF YOU HAVE QUESTIONS?

If you have questions about your rights as a study subject, or you want to make sure this is a valid VA study, you may contact the Chairman of the Human Studies Subcommittee at 203-

932-5711 x3350.If you have questions, complaints or concerns about the study or if you would like to obtain information or offer input you may call the Principal Investigator, Dr. Mary Driscoll at 203.932.5711 X3953. If you have any complaints, concerns or pertinent questions regarding the conduct of this study, or if you have any questions about compensation for injury, you may contact the Human Studies Coordinator in the Research Office at 203-937-3830.

DO YOU HAVE TO TAKE PART IN THE STUDY?

Participation this study is completely voluntary. Refusal to take part in the study, or withdrawing from the study, will involve no penalty or loss of benefits to which you are otherwise entitled.

If you are VA employee or student, refusal to take part in the study will in no way influence your employment, ratings, subsequent recommendations, or academic progress as applicable. You may discontinue taking part at any time without any penalty or loss of benefits. Should you withdraw from the study, you will still receive the same standard of care that you are otherwise entitled to.

Should you withdraw from the study, any data collected prior to your withdrawal will be used but no further information will be collected from you except from public records, such as survival data.

RIGHT OF INVESTIGATOR TO TERMINATE YOUR PARTICIPATION

If the principal investigator decides that you are not appropriate for the study, you could be withdrawn even if you want to continue. This could happen if you do not meet the requirements for the study, if you are not able to do things required by the study (like nightly text messages or weekly phone calls), if it becomes medically unsafe for you to continue, or if approval to conduct the study is withdrawn. Should this happen, study staff can provide information regarding similar pain self-management programs available at your local facility.

WILL YOU BE TOLD NEW INFORMATION ABOUT THIS STUDY?

You and your personal physician will be informed of any important discoveries made during this study that may affect you, your condition, or your willingness to participate in this study.

If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means.

RE-CONTACT

Although there is no current plan for follow-up beyond what is described above, you may be contacted for further follow-up with regard to this study. If findings from the current study require us to make changes to CONNECT, we may re-contact you to solicit your opinion about these changes.

Upon completion of the study a newsletter summarizing the findings from the current study will be sent to everyone who enrolled. No identifying information will be included; findings will be reported on aggregate.