Mechanisms of Psychosocial Treatments for Chronic Pain

Participant Information Statement

IRB Approval Date: June 1, 2020

***IRB Title*: Back on Track to Healthy Living Study**
***Short Title*: Back on Track (BOT) Study**
***NCT Number*: NCT03687762**

Mechanisms of Psychosocial Treatments for Chronic Pain

A randomized, 3-group parallel design, 240-subject clinical trial to test the mechanisms of cognitive therapy, mindfulness meditation, and activation skills on individuals with chronic pain.

Study Chairman or Principal Investigator:

Mark P. Jensen, Ph.D., Professor and Vice Chair for Research, University of Washington Department of Rehabilitation Medicine

Melissa A. Day, Ph.D., Senior Lecturer, University of Queensland School of Psychology

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University of Washington

UNIVERSITY OF WASHINGTON
INFORMATION STATEMENT
Back on Track to Healthy Living Study

Mark P. Jensen, Ph.D.	Professor, Rehabilitation Medicine	206-543-3185
Joy Chan, B.S.	Research Coordinator, Rehabilitation Medicine	206-744-3626
Sydney Drever, B.A.	Research Study Coordinator, Rehabilitation Medicine	206-616-7671
Emily Stensland, B.S.	Research Study Coordinator, Rehabilitation Medicine	206-616-8744
Madison Sherwood, B.A.	Research Assistant, Rehabilitation Medicine	206-616-9242

General Study Phone Numbers: 206-221-7224 or toll-free 1-800-570-5576

Researchers' Statement

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

What is the purpose of the study?

Chronic pain is a significant problem affecting millions of Americans. Research has shown that psychological treatments can help people with chronic pain manage their pain and improve their quality of life. Three common psychological treatments for chronic pain are Cognitive Therapy (CT), Mindfulness Meditation (MM), and Activation Skills (AS). While research has shown these treatments are helpful for people with chronic pain, there is little research explaining *why* these treatments are helpful. The purpose of this study is to understand the specific ways these treatments work. Increasing our understanding of how these treatments work will help researchers and clinicians improve treatments for people with chronic pain in the future.

What does my participation in the study involve?

After we go over this form, and we have answered any questions you have about the study, we will ask for your verbal agreement to participate. After you provide your verbal consent to participate, we will collect your contact information, including emergency contact information and contact information for people we may contact if we are unable to get a hold of you after multiple attempts. We will also be asking for the locations from which you plan to normally attend the group treatment sessions.

This study involves participating in eight videoconference group treatment sessions and telephone interviews over the course of approximately eight to nine months. We will ask you to wear an activity monitor daily and also to complete brief online surveys twice daily (once in the morning and once in the evening) for about two and a half months starting two weeks before

treatment begins. These surveys will be completed on your computer, tablet, or smartphone. These procedures are explained in more detail below. At the end of this form, there is a table that lists study procedures to help you understand the time commitment. You should only agree to participate if you think you can finish the study.

If you agree to participate in the study, we will schedule a time for a research staff member to ask you some basic questions about you and your pain problem over the phone. During this call, we will ask questions about your age, biological sex, gender, education, race and ethnicity, marital status, drug and alcohol use, height, weight, income, household size, and disability compensation and lawsuit status. We will also ask about your pain and past treatments you may have used for your pain. This Baseline Assessment will take about 20-30 minutes to complete. You may refuse to answer any question(s) you do not wish to answer.

During the study, you would complete four extended interviews. The first interview is completed before treatment begins, the second is completed after treatment ends, the third is completed three months after treatment ends, and the fourth and final is completed six months after treatment ends. The first two of these interviews will be done over the telephone with a research staff member, while the last two may be done either over telephone or independently online (pending sponsor approval for online administration). Research staff will schedule at least the first two telephone interviews for a specific time that is convenient for you. You will be provided and required to use a response key during the telephone interviews. If completing the third and fourth interviews online, you will be responsible for using your own device and Internet service. Regardless of modality, these interviews will take about 45-60 minutes to complete.

During these interviews, we will ask you a variety of questions about your pain, how your pain has interfered with different types of activities, thoughts and feelings you have both when you are in pain and about your pain problem in general, how much you have been bothered by other problems besides your pain, mood, activity level, sleep, quality of life, healthcare use, medication use, and/or cannabis use. There will also be several questions about COVID-19's effects on your mental health and well-being. After treatment ends, you will be asked how often you practiced the skills learned during treatment, how satisfied you are with the treatment, as well as any changes you noticed since beginning the study. Additionally, we will ask you about your experiences in the treatment groups and how COVID-19 has impacted treatment; these open-ended questions will take approximately 15-30 additional minutes to complete. This open-ended interview will be audio recorded in order to have an accurate record of your responses; the interviewer will let you know if the interview will be recorded before s/he starts recording. You may refuse to answer any question(s) you do not wish to answer or decline participation in any study components.

Some examples of the questions/requests asked include, (1) "Please rate the intensity of your usual pain by choosing the one number that best describes your usual pain on average in the past 7 days, where 0 is 'no pain' and 10 is 'pain as bad as you can imagine'."; (2) "In the past 7 days, how much did pain interfere with your day to day activities?"; (3) "Thinking about yourself and how you normally feel, to what extent in the past 7 days did you feel determined?"; (4) "Please read the labels from all antidepressant, sedative/hypnotic, anticonvulsant, NSAID, or opioid medications you took during the past week."; and (5) "Have you taken any cannabis or cannabis products in the past 7 days? Please note that the term cannabis is being used to refer to marijuana, cannabis concentrates, and cannabis-infused edibles."

A research staff member will also schedule a time to do a one-on-one technology training session with you. Staff will send you an invitation to join a test meeting where s/he will give a brief overview on how to use the basic features of the videoconference platform used to deliver the group treatment. We will also review the online survey and activity monitor technologies with you during this training session. This training is required to make sure you are able to use the videoconferencing platform with your video and audio devices, and to answer any questions you may have about using the study technology; we may ask participants to demonstrate proficiency of basic computer skills as part of the tech training. At the end of the training, we will ask you if you feel comfortable using all study-required software and with participating in group sessions using the software. Written instructions on using the study software will also be provided.

We will also re-assess pain chronicity, frequency, and interference by asking you several questions from the same screening interview you initially completed to determine eligibility for this study. If you no longer meet study eligibility criteria, you will be withdrawn from the study. If you still meet study eligibility criteria, you will be asked additional pain interference questions to help us determine how to randomly assign you to one of the three treatment interventions.

About three weeks before you begin treatment, you will be mailed an activity monitor to wear. You will be required to wear the activity monitor all day and night, including while you sleep. You will wear this activity monitor starting approximately two weeks before you begin treatment and through four weeks after the completion of treatment, and return the activity monitor to us at the end of the 2.5-month Monitoring Period. At the end of study participation, you may request a copy of summary data from your activity monitor.

About two weeks before you begin treatment, you will also be asked to complete brief online surveys twice a day. The online surveys can be completed on a smartphone, tablet, laptop, or desktop computer. You will be sent automated notifications in the morning and in the evening reminding you to complete the brief survey twice a day. These surveys will take about 5 minutes to complete and will include questions about your pain and your thoughts surrounding pain, how your pain has interfered with your activities, your mood, what time you went to bed and what time you woke up, how often you wore your activity monitor, the activities that you engaged in and overall activity level, and how often you practiced the skills you learned during treatment (asked after treatment begins). Some of the surveys will ask questions about your expectations for the treatment, experiences during the sessions, and your thoughts about the group clinician.

You will be provided verbal and written instructions on how to access and complete the daily surveys, as well as general care instructions for the activity monitor.

You will complete all of the following baseline procedures:

1) provide demographic and baseline information;
2) complete the pre-treatment telephone interview;
3) participate in the technology training session and verbally agree you are comfortable with all study software and with participating in group sessions using the videoconferencing software;
4) complete re-assessment of study eligibility; and
5) complete at least 7 of 14 online surveys in the first week of the Monitoring Phase.

If you do not complete all the required baseline procedures described above, you will be withdrawn from the study. If you are withdrawn from the study, we will ask you to return all activity monitors still in your possession and to stop completion of the online surveys. We may also exclude people who demonstrate extreme difficulty executing the computer skills necessary to participate in the study.

If you complete the pre-treatment telephone interview and/or start the Monitoring Period but defer to a future cohort before starting treatment, you will need to redo the pre-treatment telephone interview, the technology training session, and all online surveys at the time of the future cohort, as well as wear the activity monitor again. You may also need to re-provide demographic and baseline information.

If you complete the baseline procedures and are still eligible for the study, you will be randomly assigned (by chance, like flipping a coin) to one of the three treatment interventions. All three treatment interventions will involve educating you about pain, discussing the impact of pain, and discussing different ways to manage it in hopes of decreasing your pain and its impact on your life.

- **Mindfulness Meditation.** This treatment will help you learn how to focus your attention on an object, such as the breath or body.
- **Cognitive Therapy.** This treatment will teach you how your thoughts affect your pain, and help you learn ways to change your thoughts from less helpful (distressing and alarming) to more helpful (reassuring) ones.
- **Activation Skills.** This treatment will help you increase your activity level, set realistic goals, and reinforce healthy, pleasurable activities.

We anticipate that all three treatments will result in increases in your ability to cope with your pain and improve your overall quality of life, although it is possible that some people will benefit and some people will not.

There will be eight total group treatment sessions. Each treatment session will take place over the internet on your computer, tablet, or smartphone using a videoconference application. There will be, on average, two sessions per week, and each session will take up to 90 minutes. You will be required to use a video camera and audio through either a microphone or phone for each group treatment session. At the beginning of each treatment session, the study clinician may ask all participants in attendance if they are attending the session from one of the addresses on file for them. This is done to ensure your safety if you indicate self-harm or harm to others. If you are not at one of your locations on file, then a staff member may follow up privately to ask your current location.

Each treatment intervention will have home practice activities to complete between sessions. Home practice activities may include, but are not limited to, creating thought records, listening to pre-recorded guided practices, and keeping track of activities and goals. You will be asked to record your home practice on a Google Drive document that will be available to your clinician prior to each session. You will also receive a treatment workbook with materials to refer to and discuss during the group sessions as well as additional materials to read between sessions.

The group treatment sessions will be audio-recorded to make sure the study clinician is following study procedures. The recordings may also be used for training purposes. If you do not agree to have the group treatment sessions audio-recorded, you should not participate in the study. If you change your mind about audio-recording after treatment starts, we will withdraw you from treatment, but you may be allowed to complete all remaining non-treatment related study procedures.

What are the risks?

Some people may find discussing their pain problem and other issues regarding pain, depression, and mood uncomfortable. In addition, some people may focus on their pain problem as a result of discussions with a study clinician, which may lead to a temporary increase in pain intensity. Some people may find sitting for the entire treatment session uncomfortable. Additionally, some participants may find it uncomfortable to share or hear personal information in a group setting or knowing the sessions are being audio-recorded.

Some individuals who learn how to change their thoughts and beliefs or practice mindfulness meditation may remember past experiences that are uncomfortable and/or cause distress, even after the session has ended. For the mindfulness meditation intervention, some people may find it difficult or uncomfortable to focus their attention for a period of time. In addition, some individuals practicing mindfulness meditation may also experience mild disorientation or grogginess during or after the session has ended due to the occasionally relaxing nature of this practice.

Although there is little chance of physical injury from the treatment procedures described above, there is a possible risk that you could hurt yourself when completing physical activities involved in the activation skills intervention. The physical activities you engage in are self-chosen, and self-directed. However, if you have concerns about whether the activation skills intervention is appropriate for you, please consult a medical provider before agreeing to participate in the study.

Participants may experience fatigue and/or boredom while completing the extended assessments, online surveys, and/or the treatment sessions. Some people may find some of the questions we ask during the assessments and online surveys personal or sensitive, which may cause mild stress or discomfort. Some people may focus more on their pain problem as a result of answering questions about their pain, which may lead to a temporary increase in pain intensity. You do not have to answer any question that you do not wish to answer, and may stop any interview or survey at any time.

This study asks questions on cannabis. For participants under the age of 21, or for those who live in areas where cannabis is not legal, there is a risk of legal harm if there was an accidental breach of confidentiality. The study has a federal Certificate of Confidentiality granted by the National Institutes of Health that is used to protect the confidentiality of your information. See section "How is my information kept confidential?" below for specific details on our data security protections and this Certificate.

Participants may find it uncomfortable or inconvenient in general to wear an activity monitor both during the day and while sleeping. There is no risk of electrical shock while wearing the activity monitor and it cannot track where participants are or what they are doing. Participants

may experience sweating or skin irritation while wearing the activity monitor if they have sensitive skin.

Although we make every effort to keep your information confidential, no system for protecting your confidentiality can be completely secure. It is still possible that someone could find out you were in this study and could find out information about you. Given that this is a group intervention, participants within each group will know the first names and some information about other participants. However, participants will be encouraged to share only their first names, and to disclose only information that they are comfortable sharing and that pertains to pain and treatment.

We expect that any uncomfortable or negative effects from the assessments or treatment sessions are highly unlikely. If they do happen, you can talk about these issues with the Principal Investigator, Dr. Jensen, a licensed clinical psychologist. Dr. Jensen will then give you information about people you should call if needed. You may stop an assessment, interview, treatment session, or procedure at any time.

Please note we cannot guarantee the confidentiality of email communication or the use of cloud-based sharing services (e.g., Google Drive). There is a risk of loss of confidentiality for any information transmitted over email or entered into a cloud-based sharing service.

Are there alternatives to participating in the study?

There may be other treatments or procedures available to help you manage your pain if you choose not to participate in this study. We recommend that you speak to your doctor about the different options for pain management that may be available to you.

If you would like any additional information on national resources for disability, pain, mental health, and other resources, you may request a clinical resource list be mailed or emailed to you.

Are there any benefits to participating in this study?

If the treatment you receive works for you, your pain may decrease. You might not experience any benefit from being in the study. The information from the study may help us treat chronic pain better.

Who is funding this study?

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

How is my information kept confidential?

All of the information you provide will be confidential. However, if we learn that you intend to harm yourself or others, we must report that to the authorities. Your name and other identifying information will be linked to a unique study ID. Your study ID will not include any information that can identify you. All of the data we collect from you will be coded with your study ID and stored securely, in a password-protected computer database, and/or on a secure and encrypted internet database. The master list linking your identifying information to your study data will be kept in a separate, secure location.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

A description of this clinical trial is 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.

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

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

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

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

The Certificate expires when the NIH funding for this study ends. Currently this is July 31, 2022. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

If a research staff member finds out you have plans or intent to harm yourself or others, s/he may refer you to or contact an appropriate individual or institution. You may be withdrawn from the study without your consent if the researchers believe it is in your best interest or if you are not able to fulfill the study requirements.

Will my study data be shared?

Study data may be shared in de-identified form (i.e., not with your name or other identifying information) with outside researchers and collaborators as requested and deemed acceptable by study investigators. In addition, direct identifiers such as first and last name and contact information may be shared with other study researchers within the UW Department of Rehabilitation Medicine if you indicate you would like to be enrolled in the department participant pool and contacted regarding future opportunities to participate in research. You may change your mind about participating in the participant pool and request not to be contacted for

future studies. Study data cannot be withdrawn following data collection or retrieved after they are released.

Will I be paid for taking part in this study?

You will not be charged for any study-related procedures. We will pay you for the following:

- $25 for each extended assessment you complete (up to $100).
- $1 for each online survey you complete. You will receive a bonus of $6 for every week you complete 12 or more surveys in that week.
- $70 for returning the activity monitor.

Is there any cost to participate?

You may incur costs associated with receiving text messages with study reminders or survey notifications, and/or the usage of Internet data required to complete surveys, extended assessments, or participate in the treatment sessions. We will not reimburse you for any messaging or data charges incurred as part of participation in this study.

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

If you think you have an injury or illness related to this study, contact Dr. Jensen at (206) 543-3185 right away. He will treat you or refer you for treatment. No money has been set aside to pay for things like lost wages, lost time, or pain. However, you do not waive any rights by enrolling in this study.

Participant's Statement

This study has been explained to me. I volunteer to take part in this research. I also agree to be audio recorded during the treatment sessions. I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed above. If I have questions about my rights as a research participant, I can call the Human Subjects Division at (206) 543-0098. I will receive a copy of this information statement.

Back on Track to Healthy Living Study Procedures

Procedure	Number of Assessments	How Often / When	Time Required for Participants	Compensation
Re-Assessment of Study Eligibility	One telephone assessment	Once, following informed consent process; before 2-Week Baseline Monitoring Period	About 1 minute	$0
Randomization Stratification	One telephone assessment	Once, following informed consent process; before 2-Week Baseline Monitoring Period	About 5 minutes	$0
Baseline Data and Demographics Collection	One telephone assessment	Once, following informed consent; before treatment begins	About 20-30 minutes	$0
Pre-Treatment Extended Assessment	One telephone assessment	Once, following informed consent process; before 2-Week Baseline Monitoring Period	About 45-60 minutes	$25
Technology Training	One videoconference training session	Once, following informed consent process; before 2-Week Baseline Monitoring Period	About 30-45 minutes	$0
Baseline Monitoring Period*	At least twenty-eight (28) EMA assessments	Twice daily EMA assessments for approximately 2 weeks prior to first treatment session	About 5 minutes per assessment	$1 per completed EMA assessment; $6 bonus for every week with ≥12 completed
Treatment	Eight (8) videoconference group treatment sessions	Average of twice per week for approximately 4 weeks	90 minutes per session	$0
Treatment Monitoring Period*	Twice daily EMA assessments for duration of treatment	Twice daily EMA assessments, commencing on day of first treatment session, ending on day of last session	About 5 minutes per assessment	$1 per completed EMA assessment; $6 bonus for every week with ≥12 completed
Post-Treatment Extended Assessment	One telephone assessment	Once following end of treatment	About 45-60 minutes	$25

Post-Treatment Qualitative Assessment	One telephone assessment	Once following end of treatment	About 15-30 minutes	$0
Post-Treatment Monitoring Period*	Fifty-six (56) EMA assessments	Twice daily EMA assessments for 4 weeks following end of treatment	About 5 minutes per assessment	$1 per completed EMA assessment; $6 bonus for every week with ≥12 completed
Return Activity Monitor	N/A	Once, following end of Post-Treatment Monitoring Period	N/A	$70
3-Month Extended Assessment	One online or telephone assessment	Once, approximately three months following end of treatment	About 45-60 minutes	$25
6-Month Extended Assessment	One online or telephone assessment	Once, approximately six months following end of treatment	About 45-60 minutes	$25

* Participants will wear activity monitor for the duration of monitoring periods