Informed Consent Form

Comparative Mechanisms (Moderators, Mediators) of Psychosocial Treatments of Chronic Pain

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RUSH

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

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Protocol Title: Comparative mechanisms (moderators/mediators) of psychosocial treatments of chronic pain
ORA#: 22010705

Sponsor(s): National Institutes of Health

Name of Participant: _____

Key Information:

You are being invited to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Taking part in this research study is voluntary. You do not have to participate in this study and may choose to leave the study at any time. If you decide not to participate in this study or leave the study at a later time, your health care, benefits, or relationship with Rush University Medical Center will not change or be affected.

The purpose of this study is to compare the processes and outcomes of Cognitive-Behavioral Therapy (CBT), Acceptance and Commitment Therapy (ACT), and Emotional Awareness and Expression Therapy (EAET) for the treatment of chronic pain. CBT, ACT and EAET are behavioral treatments that are known to help people better manage their chronic pain.

If you agree to participate in this study, your participation will last about 9 months. You will be asked to complete an initial assessment, 7 weekly assessments during treatment, a post-treatment assessment, and a follow-up assessment 6 months later. These assessments consist of self-report surveys that ask about demographic information, pain-related symptoms, mental health symptoms, trauma-related experiences, and attitudes and beliefs. All assessments will be conducted entirely remotely.

After the initial assessment, you will be assigned randomly (by chance, like flipping a coin) to receive CBT, ACT, EAET, or to receive only your usual care but no extra treatment. If you are assigned to one of the three treatments, you will meet by secure telehealth (Zoom), one hour per week for eight weeks, with a psychologist. You will be paid up to $325 for completing all of the assessments. The treatments are provided for free. For a detailed description of study procedures, please see the "What are the activities you will be doing if you participate in this study?" section of this consent form.

There are risks to you for participating in this study. CBT, ACT, and EAET have been shown to be both effective and safe, but there is a risk of feeling temporarily distressed (upset or anxious) during sessions. Any increased distress is expected to be temporary. For a detailed list of risks, you should know about, please see the "What are the risks and discomforts of participating in this study?" section of this consent form.

Although unlikely, there is a risk of loss of confidentiality if your medical information or identity is obtained by someone other than the investigators. To prevent this risk, all study staff will work very hard to ensure that all data are stored securely so that only members of the study staff will have access to data that could identify you. No data that could identify you will ever be revealed to any outside parties without your consent. Your identity will not be revealed in any report, publication, or at scientific meetings. You may benefit from taking part in this study. Based on past research, you may experience reduced pain and improved mood and function if you are assigned to the CBT, ACT, or EAET treatments. If you are assigned to the usual treatment condition, you are not expected to get any health benefits from participating in this study.

You have the option to not participate in this study and may discontinue at any time. Your only other option to participating in this study is to not participate.

Detailed Information: Please review the rest of this document for details about the above topics and additional information you should know before making a decision about whether or not you will participate in this study.

Why are you being invited to participate in this study?

You are being asked to participate in this study because you are an adult with pain in your back or neck for at least 3 months that is at least mildly severe and interferes with some daily activities. You also are interested in having a behavioral treatment for your pain.

How many participants will take part in this study?

Approximately 460 participants are expected to take part in this study.

What are the activities you will be doing if you participate in this study?

If you provide your consent to be in this study by signing this informed consent form, you will have a baseline (pre-treatment) assessment during which you will be asked about your pain, activity level, various physical and mental health symptoms, sleep, substance use, traumatic events, and various attitudes and beliefs. You will complete these questionnaires on-line. This baseline assessment session will require up to 1.5 hours (90 minutes).

After the baseline assessment, you will be randomly assigned (by chance, like flipping a coin) to 1 of 4 different conditions or experiences: You will receive either one of three different behavioral treatments, or you will continue your usual health care and not receive an additional behavioral treatment.

If you are assigned to one of the three behavioral treatments, you will be asked to meet privately, for 1 hour per week, for 8 weeks (total of 8 sessions) by telehealth (remotely) with a psychologist who is skilled providing the assigned treatment. You will be asked to learn the techniques that you are taught during these sessions and to practice exercises at home between sessions. These sessions will be recorded for supervision purposes and later analysis of the treatments.

If you are assigned to Cognitive Behavioral Therapy (CBT): CBT is based on the idea that chronic pain leads to learned, negative patterns of thinking, behaving, and feeling that worsen pain intensity, mood, and activity. During the 8 CBT sessions, you will learn ways to manage your chronic pain through self-regulation skills including relaxation, learning different ways to respond to pain, and how to pace your physical activities.

If you are assigned to Acceptance and Commitment Therapy (ACT): ACT is based on the idea that chronic pain leads to avoiding activities that you find valuable and, thus, leads you to have more and more restrictions on what you can and want to do. During the 8 ACT sessions, you will identify thoughts, feelings, and actions that have been affected by your pain, learn techniques including mindfulness to help you live in the moment to decrease avoidance and establish and practice plans to engage in valued activities.

If you are assigned to Emotional Awareness and Expression Therapy (EAET): EAET is based on the idea that stress and fear, including fear of your pain and injury as well as stressful experiences and relationships throughout a person's life, can trigger or worsen chronic pain. During the 8 EAET sessions, you will engage in exercises to help you reduce those fears, including talking about stressors and conflicts, identifying and expressing important feelings, and engaging in feared activities such as healthy communication in relationships. Skills training will include techniques to improve communication and relationships in real life.

If you are assigned to your usual care: You will not receive any additional behavioral treatment. You will continue with any ongoing treatments for pain or mood, as you and your health care providers determine is best for you.

In addition, you will be asked to complete a set of questionnaires on-line once per week for 7

consecutive weeks. You will complete questionnaires regardless of which treatment condition (CBT, ACT, EAET or usual treatment) you are assigned. These questionnaires will ask about your pain, functioning, mood, and beliefs. Completing the questionnaires will take about 30 minutes each week. After the 8th week, you will complete a larger set of questionnaires, which should require about 1 hour.

You will be contacted by study staff about 6 months after the start of the study (3 months after treatments end) for a brief assessment. Then, 9 months after the start of the study (6 months after treatments end), you will complete most of the same questionnaires that you completed at the start of the study. This should require about 45 minutes.

Will your information be used for research in the future?

Information collected from you for this study may be used for future research or shared with other researchers. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, you will not be asked for additional consent.

What are the risks and discomforts of participating in this study?

There are risks to you for participating in this study.

If you receive CBT, ACT or EAET, one potential risk is that you may experience some emotional upset when sharing personal information during the interviews and during sessions. Any emotional upset from these behavioral treatments can be expected to decrease over time. If you experience an emergency or a life-threatening medical situation during a remote video assessment or treatment session, you will be asked to call 911 or go to your nearest emergency room immediately.

There is a risk of loss of confidentiality. To minimize risk of loss of confidentiality, all participants will be assigned a participant study number that will be used to identify them. Only study team members will have access to the study data.

There may be other risks that may happen that we cannot predict.

What if there is new information that may affect your decision to participate in this study?

During this study, you will be told about important findings (either good or bad), such as changes in the risks or benefits of participation in the study or new choices to participation that might cause you to change your mind about being in the study. If new information is shared with you, you may be asked to sign a revised consent form in order to continue participating in this study.

Can you leave or be removed from this study?

You have the right to leave a study at any time without penalty. If you leave this study before the final study visit, the study staff may ask you to complete some final questionnaires. You are able to ask that your study-related information be removed from the study at any time. However, it may not be possible to withdraw or delete your information in cases when it has already been shared with other researchers. The removal of any study-related data does not include any information that may be stored on the secure Rush network server. Upon leaving the study, you will be given appropriate referrals to Rush University Medical Center or other community resources as needed. If you become actively suicidal with intent, the study clinician will refer you to a higher level of care (i.e., psychiatric, medical, or emergency services). You will no longer be able to continue in this study but may be able to enroll at a later time after reaching stability per eligibility requirements.

The researchers and Sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests;
- You do not follow the instructions;
- The study is cancelled for any reason.

What about confidentiality of your medical information?

This authorization is voluntary. Rush University Medical Center and its affiliates ("Rush") will not withhold or refuse your treatment, payment, enrollment, or eligibility for benefits if you do not sign this authorization. You do not have to sign this authorization, but that means that you cannot be in the study.

By signing this document, you voluntarily authorize (give permission to) Dr. John Burns, his study team, and other Rush personnel involved with the conduct and review of this study (which may include off-site personnel) to use or disclose (release) health information that identifies you for the study described in this document.

During the study, Dr. Burns and his study team will collect Protected Health Information (PHI) about you for the purposes of this research. PHI is your health information that includes your medical history and new information obtained as a result of this study. The health information that Rush may use or disclose for this research includes:

- Name
- Dates related to study visits and length of study participation
- Email address
- Telephone number
- Responses to self-report assessments
- Audio and video recordings of sessions and copies of session materials

The study team will use this information about you to complete this research. Dr. Burns and his study team may share your health information and the results of your study-related procedures and tests with people outside of Rush who assist with the conduct and review of this study. The persons who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, but only if permitted by the laws governing them. Your health information described above may be used or disclosed to:

- De-identified video recordings will be sent to approved external collaborators for analysis
- Scientific databases in de-identified form
- Monitoring agencies such as the Food and Drug Administration (FDA), The National Institutes of Health, and the Rush Institutional Review Board (IRB).

While you participate in the study you will have access to your medical record, but Dr. Burns is not required to release to you study information that is not part of your medical record. Rush is required by law to protect your health information, and study records that identify you will be kept confidential. Any study information in your medical record will be kept indefinitely. Your identity will not be revealed on any report, publication, or at scientific meetings. As part of this study, all treatment sessions will be recorded. All audio and video recordings collected for research will be uploaded to the secure Rush University Medical Center server within one business day and will be deleted from the recording device immediately upon upload. Transcriptions of interview recordings will be stored on the secure server as well and will only be accessed by members of the study staff. Electronic copies of treatment session worksheets will be stored in a secure folder and will be accessed only by you and members of the study staff. After your final visit, the worksheets stored in this folder will be deleted and copies will be uploaded to the secure Rush University Medical Center server.

You have a right to inspect and copy the information to be disclosed with this authorization and you may obtain a copy of the information by contacting the office listed below.

If you no longer want to be in the study and do not want your future health information to be used, you may change your mind and revoke (take back) this authorization at any time by writing to Dr. John Burns at 1645 W. Jackson Blvd, Suite 400, Chicago, IL 60612 or phone 312-942-0379. If the authorization is revoked, you will no longer be allowed to participate in the study and previously authorized individuals/entities may still use or disclose health information that they have already obtained about you as necessary to maintain the integrity or reliability of the current study.

This authorization is valid for the entirety of this research study. It will expire upon completion of the study or if you revoke (take back) the authorization.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Records of participation in this study will be maintained and kept confidential as required by law. All information and data collected in the study will be stored on the RUMC secure server or in a secure, locked cabinet in the Department of Psychiatry and Behavioral Sciences. Only members of the study staff will have access to identifiable data. No identifiable data will ever be disclosed to outside parties. De-identified data may be reported in aggregate (with other participants' data) for internal clinical use, publications, or other presentations. In order to conduct the study, the study investigators will use and may share personal health information. This includes information already in your medical record, as well as information created or collected during the study. Any data shared will have all identifying information removed and will be assigned a unique study code. When identifying data cannot be removed (as in the case with audio and video files), they will be provided with a unique study code and stored in a separate and secure network location.

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human participants.

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.

All information collected about you during the course of this study will be kept confidential to the extent permitted by law. You will be identified in the research records by a code name or number. Information that identifies you personally will not be released without your written permission. However, the study sponsor (National Institutes of Health), the Institutional Review Board (IRB) at Rush University Medical Center, the IRB at Wayne State University, and federal agencies with appropriate regulatory oversight may review your records.

What are the costs to participate in this study?

All costs for the required study surveys and costs associated with clinic time and supplies will be paid by the National Institutes of Health.

Will you be paid for your participation in this study?

You will be compensated up to $325 in gift cards for your time and effort to participate in all of the assessment sessions. This compensation will be allocated according to this schedule: $50 for completion of the initial baseline session; $25 upon completion of each of the 7 weekly assessment sessions; $50 upon completion of the post-treatment (week 8) assessment, and $50 upon completion of 6–month follow-up assessment. We will email these gift cards after each of the three time points (baseline session, post-treatment session, and 6-month assessment). The 8 treatment sessions you receive (if you are assigned to receive a treatment) will be provided for free.

What if you are injured as a result of your participation in this study?

If you get ill or injured from being in the study, Rush University Medical Center will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Burns at telephone number 312-942-0379.

You should let any health care provider who treats you know that you are in this study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact your study doctor.

Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. Costs not covered by insurance could be substantial.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

In the event that this research related activity results in an injury, treatment will be made available including first aid, emergency treatment, and follow-up care as needed. Cost for such care will be billed in the ordinary manner to you or your insurance company. No reimbursement, compensation, or free medical care is offered by Wayne State University or by Rush University Medical Center.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

Who can you contact for more information about this study?

Questions are encouraged. If you have further questions about this study, you may call Dr. Burns at 312-942 0379 or email at john_burns@rush.edu.

Who can you contact if you have concerns about your rights as a study participant?

Questions about the rights of research participants may be addressed to the Rush University Medical Center Office of Research Affairs at 1-800-876-0772.

What are your rights as a study participant?

Taking part in this study is voluntary. If you choose not to participate in this study or to leave the study at any time, your health care, benefits or relationship at Rush University Medical Center will not change or be affected.

If you choose to leave this study and you do not want any of your information to be used, you must inform Dr. Burns in writing at the address on the first page. Dr. Burns may still use your information that was collected prior to your written notice.

Attachment: Study Consent Form.docx

SIGNATURE BY THE PARTICIPANT:

Please type your full legal name (participant) in the box below:

Please enter today's date below (mm/dd/yyyy)

Please select one of the options below:

By clicking on this text box, you are **CONSENTING TO PARTICIPATE** in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily by the study staff. You do not waive any of your legal rights by signing this consent form.

☐ I **agree** to participate

By clicking here, you **DO NOT AGREE** to participate

☐ I **do not agree** to participate

Will you be contacted about participating in future research?

If you agree, we may contact you after your participation in this study about participating in future research. Please initial and date one of the following options:

_____ _____Yes, I agree to be contacted about future research.
Initials Date

_____ _____No, I do NOT agree to be contacted about future research.
Initials Date