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Feasibility and Acceptability of Pain Reprocessing Therapy in Racially/Ethnically Diverse Adults with Chronic Back Pain

You are being asked to participate in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

The purpose of this study is to understand the effect of mind-body treatments for chronic back pain. This entire study will be conducted virtually (i.e., online) through telehealth.

You have been invited to participate in this study because you have chronic back pain and meet other eligibility criteria. Up to 75 people will participate in the study.

What happens if I join this study?

First, we will ask you to complete several online surveys. Then you will be randomized (like a coin flip) to one of the study groups. If you are randomized to a treatment group, you will complete 9 telehealth treatment sessions with a clinician that will take place around twice a week over about 1 or 1.5 months. If you are randomized to a no-treatment group, we would ask you to simply continue whatever care you are already receiving for your back pain. At the end, we will ask you to complete another round of surveys.

More details about all these steps are below.

Eligibility Screening and Daily Surveys

If you join this study, you will be asked to complete a daily survey throughout the active portion of the study (approximately 1 month). The daily survey should last about 2 - 3 minutes per day. The link to this survey will be texted to you (on a daily basis) and can be done on a personal electronic device (laptop, desktop, tablet, smartphone, etc.)

In order to be eligible for this study, you must complete at least 85% of the first week's daily surveys (at least 6 of the 7 surveys). If you are unable to complete at least 85% of daily surveys during the first week, then you will not be able to continue participating in the study.

Baseline Assessment

Before randomization to a specific group, you will be asked to complete questionnaires online through a website link sent by the study team. Participants may use any personal electronic device to complete this questionnaire (laptop, desktop, tablet, smartphone, etc.) This assessment should take about 30 - 45 minutes to complete and must be complete before you can be randomized.

Official Kick-off Call with Study Staff

Once the baseline is complete, we will schedule another short 10-minute Zoom call with the participant to confirm their interest in the study and provide compensation for completing the baseline assessment. In this call, we will also remind you of study procedures and inform you of next steps.

Randomization

Once deemed eligible for the study, you will be randomized (like a coin-flip) to one of three conditions. You will be randomized to either one of two different psychological treatments for chronic pain or to a control group without any treatment. Both of the psychological treatments in this study have been tested in previous randomized clinical trials and have shown to be safe and improve pain-related outcomes in participants. In this present study, we want to further test the

efficacy of these two psychological treatments for chronic pain and gather information on how they affect participants' experiences with pain. Treatment sessions will be conducted through telehealth and these sessions will be videorecorded. Due to the nature of the study, participants must consent to having treatment sessions video-recorded in order to participate. Recordings will never be shared without your consent.

The control group that continues normal treatment will be asked to answer the survey questions throughout the study but will not participate in any study treatments.

Treatment

The active psychological treatment group will include 9 sessions over about 1 month, and sessions will take place biweekly. Each session will last around 45 minutes and will be conducted through telehealth. Treatments will focus on how thoughts and behaviors influence pain. Please know that if you are assigned to a treatment called Pain Reprocessing Therapy, you will participate in a short phone call with a PRT therapist, then attend one session with a physician, and then attend either sessions led by a therapist. You also may be assigned to a therapy that requires you to practice pain management skills between therapy sessions. Therefore, by signing up for this study, you are committing to completing 15-minute "homework assignments" on your own between therapy sessions, at least four days per week, while you are receiving therapy. Treatments may also ask you to engage in physical activity, which may cause a temporary increase in your pain. You will not need to do any physical activities that you don't want to do.

Mid-treatment Assessment, Post-treatment Assessment and Follow-up Assessments

Around the middle of your treatment (usually within about 3 weeks of starting treatment and around 4 treatment sessions completed), you will be asked to complete another set of questionnaires that should take approximately 30-45 minutes.

Once you complete the active treatment portion of the study (1.5 months and after 9 treatment sessions), you will be asked to complete another set of questionnaires that should take approximately 30 - 45 minutes.

Finally, you will also be asked to complete five more assessments at the following follow-up timepoints: 1-month, 2-month, 3-month, 6-month, and 1-year after treatment ends.

Participation in this study from start to finish should last 15 months, but the treatment phase and the daily surveys will only be about 1 or 1.5 months.

What are the possible discomforts or risks?

Some participants may experience psychological discomfort during the active treatment or during questionnaires because they may be asked to reflect upon sensitive issues or negative thoughts.

You may decide to stop participation in the active treatment at any time. If you decide to stop participation in the active treatment, you will still be eligible to complete the questionnaires and earn compensation.

There is also an additional risk that people outside of our research team will see your research information. We will do all in our power to protect your information, but it cannot be guaranteed.

At any time, you can also ask to speak to the Principal Investigator, Dr. Yoni Ashar, about any discomfort or questions that arise during the study: yoni.ashar@cuanschutz.edu.

What happens if I am injured or hurt during the study?

While it is possible that treatment could lead to temporary increases in pain, different levels of pain intensity are part of living with chronic pain. People living with chronic pain often experience fluctuations in their pain. We do not expect any part of this treatment or study to put people beyond their normal range of pain.

Because this study involves no more than minimal risk, the University of Colorado has no plan to pay for physical or psychological injury. If you are injured or hurt during this study, you may call Dr. Yoni Ashar at (303-724-2536).

What are the possible benefits of the study?

If you are assigned to one of the treatment groups, you may experience improved pain and functioning. If you are assigned to the no-treatment group, you may benefit from an increased awareness of your emotional state from

completing the questionnaires. We also anticipate results from this study may benefit future research that seeks to relieve chronic pain.

Who is paying for this study?

This research is being paid for by the National Institute of Aging, University of Colorado Anschutz Medical Campus, and Psychophysiological Disorders Association.

Will I be paid for being in the study? Will I have to pay for anything?

You will receive compensation for participating in this study, and it will not cost you anything to be in the study. You are only compensated for completing the questionnaires in this study. You will not be compensated for your time spent in telehealth sessions.

You will receive $25 for the first Baseline questionnaire and this will be provided to you during the "Official Kick-off Call" with the study team over Zoom. You will then receive $20 each for completing the Mid-treatment and Post-treatment assessments. This will be sent to you at the end of the active treatment period, totaling $40.

After the active treatment portion, you will also be asked to complete 5 additional follow-up questionnaires, which will be completed at 1-month, 2-months, 3-months, 6-months, and 12-months following treatment. You will be compensated $20 for completing each questionnaire.

Participants randomized to the treatment or control groups will receive the same compensation. Participants will be compensated through gift cards to a store of their choosing (Amazon, Walmart, or Target).

For completing the daily surveys, you will be entered into a lottery system. Each survey completion will function as a lottery ticket. Therefore, the more surveys completed, the more likely you will be selected to win the lottery. At the end of the study, we will select 12 people (10% of the study) from the lottery to win $100 in additional compensation.

If at any point, you decided to stop treatment, you will still be eligible to complete the questionnaires and daily surveys to earn compensation. If you decide to exit the study entirely at any time, you will still receive the payment you are entitled to.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled. If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

Certificate of Confidentiality:

This study has been issued a Certificate of Confidentiality from the federal government to help protect your privacy. The Certificate prohibits the researchers from disclosing your name, or any identifiable information, document or biospecimen from the research, with the exceptions listed below. A certificate provides protections against disclosing research information in federal, state, or local civil, criminal, administrative, legislative or other proceedings.

These protections apply only to your research records. The protections do not apply to your medical records.

The researchers may disclose your name or identifiable information, document or biospecimen, under the following circumstances:

- To those connected with the research,
- If required by Federal, State or local laws,
- If necessary for your medical treatment, with your consent,
- For other scientific research conducted in compliance with Federal regulations,
- To comply with mandated reporting, such as a possible threat to harm yourself or others, reports of child abuse, and required communicable disease reporting, or
- Under other circumstances with your consent.

A Certificate of Confidentiality does not protect information you or a member of your family voluntarily release.

Who do I call if I have questions?

The researcher carrying out this study is Dr. Yoni Ashar. You may ask any questions you have now. If you have questions later, you may call Dr. Yoni Ashar at 303-724-2536. You may also email him at Yoni.ashar@cuanschutz.edu

You may have questions about your rights as someone in this study. You can call Dr. Yoni Ashar with questions. You can also call the Multiple Institutional Review Board (IRB) at 303-724-1055.

Who will see my research information?

We will do everything we can to keep your records a secret, but it cannot be guaranteed.

Both the records that identify you and the consent form signed by you may be looked at by others including:

- Federal agencies that monitor human subject research
- The National Institutes of Health, the study sponsor
- Human Subject Research Committee
- The group doing the study
- Regulatory officials from the institution where the research is being conducted who want to make sure the research is safe

The data we collect will be used for this study but may also be important for future research. Your data may be used for future research or distributed to other researchers for future study without additional consent if information that identifies you is removed from the data.

Recorded treatment sessions will never be shared without your consent. Video recordings will be kept in a password protected survey only accessible to the study team. We will specifically ask you at the end of the study for explicit permission to share video recordings. Your video recordings will only be shared if you explicitly grant us permission to do so.

The results from the research may be shared at a meeting. The results from the research may be in published in articles. All data will be deidentified (e.g., your name and all other identifying information will be removed) when information is presented.

Some things we cannot keep private: If you tell us you are going to physically hurt yourself or someone else, we are obligated to report to your local authorities or other appropriate reporting agency. If you tell us that you know about any children or vulnerable adults who are currently being hurt, we have to report that as well. Also, if we get a court order to turn over your study records, we will have to do that.

Contact for future studies:

Thank you again for your interest in participating in research. We would like to contact you in the future to see if you would be interested in participating in another research study. Please indicate below if you are willing to be contacted about any future research studies. (At any time, Participants may withdraw consent to be contacted for future studies by emailing pain.science@cuanschutz.edu)

____ Yes, I agree to be contacted about future research studies.

____ No, I do not want to be contacted about future research studies.

HIPAA Authorization for Optional Additional Study Procedures:

In this form, you were given the option to agree to additional, optional research procedures. You must also give us your permission, under HIPAA rules, to use and disclose the information collected from these optional procedures, as described above.

If you decline to give us permission to use and disclose your information, you cannot take part in these optional procedures, but you can still participate in the main study. Please initial next to your choice:

_____ I give permission for my information, from the optional procedures I have agreed to above, to be used and disclosed as described in this section.

_____ I **do not** give permission for my information for any optional procedures to be used and disclosed; I understand that I will not participate in any optional procedures.

Agreement to be in this study

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I know that being in this study is voluntary. I choose to be in this study. (Additional text for E-consent: I agree to provide my consent electronically. I may download copy of this signed consent form during the E-consent process. To indicate that you agree to sign electronically and that you consent to participate in the study, please provide your signature and today's date below).

Signature: Date:

Print Name:

Consent form explained by: Date:
Print Name: