Virtual Empowered Relief for People With Chronic Pain Who Take Methadone or Buprenorphine

NCT05057988

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1. PURPOSE OF THE STUDY

a. Brief Summary

Pain catastrophizing is a psychological response to pain that serves to make pain worse. In order to reduce suffering in people with chronic pain, it is important to treat pain catastrophizing. The purpose of the study is to test a single-session pain education class for treating pain catastrophizing in people with chronic pain on long-term opioid therapy. Class participants learn skills and develop a personalized plan to use the skills every day. The study will follow participants for 3 months by administering 5 follow-up surveys at 2 weeks and 1 month, 2 months, and 3 months post-treatment to determine whether the class confers long-term benefits across various aspects of health.

b. Objectives

The study will provide important information regarding the effectiveness of the pain education class and how well it reduces pain catastrophizing in patients on long-term opioid therapy for chronic pain. The information learned in this study will allow us to determine how reductions in pain catastrophizing may impact related health factors, such as pain, sleep, function, depression, and anxiety.

c. Rationale for Research in Humans

This research necessitates human participants because there is no equivalent animal model or non-human model to answer the study questions. The "Virtual Empowered Relief" (vER) class is designed for human participants only.

2. STUDY PROCEDURES

a. Procedures

I. Recruitment: Participants with chronic pain and opioid use disorder will be recruited by posting a flyer at methadone or buprenorphine clinics. Potential participants will be screened for interest and eligibility via the attached phone script. Participants will be informed that participation in the study is optional and not required as part of their care at methadone or buprenorphine clinics. They will also be informed that their information will not be shared with medical providers and staff at methadone or buprenorphine

clinics. During or after this call, all eligible participants will be invited to participate in the 2-hour Virtual Empowered Relief (vER) class.

Researchers at RTI International will be involved in recruiting study sites, check-in with each study site for posting a flyer, and resolve any recruitment issues at each site-contact. However, researchers at RTI will not have a direct contact with patients. Researchers at RTI may also analyze de-identified data and write a paper together.

II. Pre-Class Procedures: All interested and eligible participants will receive study information and informed consent will be obtained over the phone from each eligible participant prior to attending the vER class. Informed consent will be obtained on the phone with a research coordinator. All participants will have the informed consent presented to them through REDCap, emailed, or mailed to them.

Participants will complete the questionnaire using a secure, HIPAA-compliant, online system (via REDCap) or phone. Additionally, the questionnaire may be administered in hard copy form.

III. Intervention Pain Education Class "Virtual Empowered Relief" The participants will attend the class offered by pain psychologists at Stanford Pain Management Center or the Stanford Pain Relief Innovations Lab. This class will be held online via Zoom. The class will NOT be recorded. Zoom video function will be disabled so participants will NOT see other participants' faces. Participants will also be recommended to display only their first name. Class participants will learn skills and develop a personalized plan to use the skills every day. At the end of class, participants will be given a survey about the class. Treatment participants will receive a relaxation audio file via email or a CD/USB post-class via mail. We aim to give all patients rapid access to low-risk care that empowers them to self-manage their pain and reduce reliance on opioids. If participants cannot download the app, they will receive an audio file of the relaxation resource.

IV. Post-Class follow-up: Participants will be followed for approximately 3 months after completing the class. Participants will be asked to complete questionnaires at 2 weeks and 1, 2, and 3 months after the class. All participants will be provided a link to an online secure system (REDCap), paper, or phone to complete follow-up questionnaires.

All questionnaires to be administered by the research staff are attached under section 16 of the protocol.

Time line for questionnaire administration is as follows:

BEFORE CLASS:
- Demographics
- Treatment expectation
- Medication Use
- PROMIS clinical questions
- Non-PROMIS clinical questions

IMMEDIATELY AFTER CLASS:
- Post-class questionnaire

WEEKS 2 and MONTH 1, 2, and 3 POST-CLASS:
- Medication Use
- PROMIS clinical questions
- Non-PROMIS clinical questions
- Global Impression of Change
- Treatment change and adverse events

Participants may also be mailed a thank you note.

b. Procedure Risks

All members of the study team have been trained to conduct the research procedures in the safest manner possible. There are no known risks to completing the questionnaires or undergoing the vER class. Participants will be informed that they have the right to refuse to answer questions and they can withdraw from the study at any time. All the responses will not be shared with their medical providers and staff at their methadone or buprenorphine clinics.

c. Use of Deception in the Study

No deception will be used.

d. Use of Audio and Video Recordings

The class will NOT be recorded.

e. Alternative Procedures or Courses of Treatment

No standard treatment is being withheld. Participants are encouraged to continue with their current course of treatment for their pain under the care of their regular physician. Participant's alternative is to not participate.

f. Will it be possible to continue the more (most) appropriate therapy for the participant(s) after the conclusion of the study?

Participants are free to pursue the treatment of their choice at any time during and/or after the study

g. Study Endpoint(s)

Each participant will meet the study endpoint once he/she completes the last set of questionnaires at the final time point. The study will end once the target enrollment is reached.

3. BACKGROUND

a. Past Experimental and/or Clinical Findings

At Stanford Pain Management Center, we have routinely delivered the Empowered Relief class as pain psychology treatment and have received very high indices of satisfaction from class participants. Our previous NIH-funded study on patients with chronic low back pain has also shown reductions of pain, pain catastrophizing, and pain interference and increase in pain self-efficacy after taking the class. However, we do not know if vER is effective in patients with opioid use disorder and chronic pain. The current study will allow us to understand whether vER is effective in this patient population who usually has a limited access to pain psychology services. Based on the findings from the current study, we plan to apply for a NIH funding and do a large scale study.

Darnall BD, Sturgeon JA, Kao MC, Hah JM, Mackey SC. From catastrophizing to recovery: a pilot study of a single-session treatment for pain catastrophizing. Journal of pain research. 2014;7:219.

Darnall BD, Ziadni MS, Krishnamurthy P, Flood P, Heathcote LC, Mackey IG, Taub CJ, Wheeler A. "My surgical success": effect of a digital behavioral pain medicine Intervention on time to opioid cessation after breast cancer surgery—a pilot randomized controlled clinical trial. Pain Medicine. 2019 Nov 1;20(11):2228-37.

Darnall et al., Comparison of a Single session Pain Management Skills intervention to a Single session Health Education Intervention to Eight sessions of Cognitive Behavioral Therapy in Patients with Chronic Low Back Pain: A Randomized Clinical Trial (Submitted to JAMA
open)

b. Findings from Past Animal Experiments

NA

4. PARTICIPANT POPULATION

a. Planned Enrollment

i-iii) A total of up to 100 participants with chronic pain are expected to enroll.

b. Age, Gender, and Ethnic Background

Men and women, ages 18 and older of any race or ethnicity will be recruited.

c. Vulnerable Populations

NA

d. Rationale for Exclusion of Certain Populations

The pain catastrophizing protocols (Taub et al, 2016, Roditi et al, 2009) have been validated only for adults with chronic pain. This study will be the first to use this protocol

in patients taking opioid pain medications for chronic pain management. If this study finds no safety concerns in adult patients with chronic pain and chronic opioid therapy, a future study can include children.

e. Stanford Populations

All participants will be recruited at methadone and buprenorphine clinics in the US. Laboratory personnel and employees at Stanford will not be recruited for this study.

f. Healthy Volunteers

Healthy volunteers are not being recruited for this study

g. Recruitment Details

We will recruit patients from the methadone or buprenorphine clinics via a flyer (attached). Participants with chronic pain and opioid use disorder will be identified by a prescreening survey by a research staff at Stanford. We will also recruit patients from the Stanford Pain Clinic using the Stanford Pain Registry (https://choir.stanford.edu/). We will partner with the Research Participant Engagement Program (RPEP) team for Honest Broker outreach. Potential participants are identified via STARR and invited by RPEP team (honest broker) on behalf of study team. See Section 16 for Honest Broker study invitation letters. We will be using Postal Mail Honest Broker outreach. For Postal Mail, study team may support the process by sticking pre-printed address labels (created by RPEP, the honest broker) on the envelopes.

h. Eligibility Criteria

i. Inclusion Criteria

1)Age 18+
2)Chronic pain at least 3 month
3)Taking Methadone or buprenorphine

ii. Exclusion Criteria

1) Cognitive impairment
2) Pregnant
3) non-English speaking.

i. Screening Procedures

Contact information of potential participants will be collected from the Stanford Pain Clinic or via REDCap survey linked to the study website. Potential participants will be screened using the attached phone script (section 13) to determine eligibility prior to consent. We are obtaining a limited waiver of authorization to collect eligibility information in the phone screen as well as to access the patient's Medical Record and Clinic Registry (clinical questionnaire database) to assess eligibility.

j. Participation in Multiple Protocols

Participants will be asked whether they are enrolled in any other research studies. If another study's procedures interferes with our own or places the subject at increased risk, he/she will not be enrolled in our study.

k. Payments to Participants

Participants will be compensated with Amazon gift card for completing assessments at prescreening ($10), baseline and post-intervention ($20 & $25), 2-week ($20), 1-month ($30), 2-month ($20), and 3-month ($20) after the class ($145 total). Participants will be compensated with $20 gift card for completion of optional lifetime OUD survey.

l. Costs to Participants

No costs will be charged to the participant.

m. Planned Duration of the Study

We estimate the study to take less than 1 year to complete.
i)1-3 months for recruitment and screening of participants
ii)approximately 3 months of active participation, including 2.5 hours for the class, 15-20 minutes for completing each round of questionnaires, and a 15-30 minutes post class phone call by a Stanford Research Coordinator.
iii)3 months of analysis.

5. RISKS

a. Potential Risks

i. Investigational devices

NA

ii. Investigational drugs

NA

iii. Commercially available drugs, biologics, reagents or chemicals

NA

iv. Procedures

NA.

v. Radioisotopes/radiation-producing machines

NA

vi. Physical well-being

NA

vii. Psychological well-being

viii. Economic well-being

NA

ix. Social well-being

There is the risk that PHI will be accidentally be disclosed to people outside of the study staff.

x. Overall evaluation of risk

Minimum

b. International Research Risk Procedures

NA

c. Procedures to Minimize Risk

Risks of discomfort due to the questionnaires will be minimized by allowing the participant to refuse to answer particular questions.

All participant information will be stored in a locked cabinet and on an encrypted, password-protected computer.

Patients exhibiting signs of depression may be encouraged to speak to their medical providers at methadone or buprenorphine clinic.

d. Study Conclusion

The experiment will terminate when all participants have completed participation. If an individual participant chooses to withdraw, or the researcher determines it is unsafe or scientifically invalid for him/her to continue, his/her participation will end. We do not anticipate the study will directly result in adverse effects to the participants. However, we will encourage them to speak to their medical provider at methadone or buprenorphine clinic for any necessary medical intervention in the event of an adverse event.

e. Data Safety Monitoring Plan (DSMC)

i. Data and/or events subject to review

Self-reported adverse events were collected at each data point (monthly) for 3 months (the study endpoint). Adverse events were reviewed as soon as participants reported any events on the REDCap, which sent automatic email notification to Dr. You, PI.

ii. Person(s) responsible for Data and Safety Monitoring

Dokyoung Sophia You, PhD

iii. Frequency of DSMB meetings

N/A

iv. Specific triggers or stopping rules

Any SAEs that are probably or possibly related to this study

v. DSMB Reporting

No DSMB

vi. Will the Protocol Director be the only monitoring entity? (Y/N)

Y

vii. Will a board, committee, or safety monitor be responsible for study monitoring? (Y/N)

N

f. Risks to Special Populations

NA

6. BENEFITS

Participants may or may not experience benefits from the "Virtual Empowered Relief" (vER) class. The vER class is designed to help patients learn new skills to better cope with chronic pain. Knowledge gained from this study may inform future research studies and clinical treatments aimed at reducing catastrophizing in patients with opioid use disorder and chronic pain. Furthermore, the patient may also benefit from lowering opioid dose.

7. PRIVACY AND CONFIDENTIALITY

All participant information and specimens are handled in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and privacy policies of Stanford University, Stanford Health Care, and Stanford Children's Health.