Empowered Relief for Osteoarthritis (OA)
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Table of Contents

1.0 Protocol Summary

Study Purpose	• "Empowered Relief" (ER) Intervention was developed by Beth Darnall, PhD at what is now the Stanford Pain Relief Innovations Lab. Our design is a randomized 3-arm study with test treatment, active control, and placebo arms. Our goals are to provide scientific evidence to demonstrate the efficacy of ER, and also provide a comparison of said efficacy against the standard of care – group pain-CBT. Treatment allocation is randomized to minimize confounder effects. Statisticians performing analyses will be blinded.
Research Procedures	**The primary research procedures are:** • One 2-hour ER session • Questionnaires and Patient Evaluations
Subject Population	• The study will enroll all eligible and interested individuals who go through the consent process and enroll into the study
Duration of Subject's Participation	• The study includes 1 visit, during which they will engage in the 2-hour ER course and answer all necessary questionnaires • Participants will complete online assessments at 2, 4, 8 , and 12 weeks

2.0 Background, Rationale

"Empowered Relief" (ER) Intervention was developed by Beth Darnall, PhD at what is now the Stanford Pain Relief Innovations Lab (2014, *J Pain Res*) [7]. ER has 2 main components: education and skills acquisition. First, participants learn mind-body science as it relates to pain and PC. They learn to identify PC and how to self-treat it. Self-treatment involves applying skills to decrease physiological hyperarousal-- diaphragmatic breathing and progressive muscle relaxation-- within the context of PC. Self-treatment also involves applying skills that improve cognitive and emotional regulation, including PC reframing and thought restructuring. Participants identify their typical PC thoughts and practice writing out personal reframes. Finally, self-treatment includes enacting behaviors that modulate attention and counteract helplessness. Participants self-tailor the information by developing a comprehensive plan to stop and prevent PC (See Appendix 7). Participants leave the class with the following tangibles: (1) their own written, self-crafted, personalized plan for relief; (2) a 20- minute relaxation response audio CD; and (3) a printed copy of the ER didactic content to access as needed in their PC cessation plan.

3.0 Study Purpose and Objectives

The primary objectives of this study are to provide scientific evidence to demonstrate the efficacy of ER, and also provide a comparison of said efficacy against the standard of care – group pain-CBT. Treatment allocation is randomized to minimize confounder effects. Statisticians performing analyses will be blinded.

4.0 Study Population

4.1 Inclusion Criteria

- Adults age 18 or older who are eligible and interest in enrolling

4.2 Exclusion Criteria

- Any records flagged “break the glass” or “research opt out.”

4.3 Subject Identification, Recruitment, and Consent

Recruitment will take place in person in the clinic setting. At this visit, they will go through Step 1 of the Consenting Procedure detailed in the section 6.2.1. If eligible, they will go through Step 2 of the consenting process and will be enrolled as participants and randomized after consent.
Participants will also receive an electronic tablet if they do not have an appropriate electronic handheld device to complete their daily questions on. Participant compliance will be monitored remotely during the baseline period, and they will also be issued reminders. During this period if participants indicate that they have developed an illness, have travel plans, or may not be able to complete baseline and treatment visits on the schedule discussed, their participation will be deferred and they will be invited to participate again after resolution of the issue(s). At the end of the deferral period (up to 6 months), their updated baseline data may be collected. To establish an accurate pre-treatment baseline for participants, the period between baseline data and start of treatment should be within one month.

Subjects will be initially identified in the following ways:

- Subjects with eligibility for the study will be identified and recruited at their standard of care clinic visit. At this visit, subjects will be briefed on the study and consented. Should they agree to participate, they will be randomized and provided with the control education material or information on the ER class. This is also where baseline data collection will take place.

4.3.1 Consent Description

Informed consent will take place prior to collecting any in-person screening or research information. Designated and trained Clinical Core staff will review the participant’s IRB-

approved Consent Form with him/her in a private area, answer any questions, witness the participant sign the informed consent and write the date consent was obtained, and verify by signing as the research team member that obtained consent. Each participant will receive a signed and dated copy of their Consent Form documents. The consenting process will be divided into two steps:

STEP 1: The participant will first sign a consent form for the study team to collect basic screening information. After they have signed and dated the Screening Consent Form and are eligible to participate in the study (based on details in the Screening section below), they will go to Step 2 of the consenting process.
STEP 2: At this step, participants will sign the Study Consent Form and will learn in detail about the study procedures. Research staff will answer all study-related questions and make sure that the participant fully understands all procedures, tests, and visits for the study.

5.0 Study Design and Procedures

5.1 Schedule of Events

Legend

- **R** = Research item/procedure done only for research purposes and their costs are covered by the study. You are not responsible for the costs of these procedures.

Procedures	Screening Visit	Visit #1	Visit #2	Visit #3	Visit #4	Visit #5
Informed Consent	R					
Medical History	R					
Questionnaires		R	R	R	R	R

5.2 Study Design and Duration

The duration of the study is a single empowered relief session lasting approximately two hours. The single-session may be delivered online. ER has two main components: didactics and skills acquisition. Didactic content includes mind– body science as it relates to pain and PC. Participants learn how to identify unhelpful thought patterns in the moment, and how to self-treat it. During the class, participants acquire skills and develop a plan to apply the learned skills to decrease physiological hyperarousal – diaphragmatic breathing and progressive muscle relaxation – within the context of unhelpful thought patterns (pain catastrophizing). Participants also acquire skills that improve the regulation of cognition and emotion, including thought reframing and thought restructuring, and develop a plan for implementing these skills in daily life. During the class participants identify their typical unhelpful thoughts and practice writing out their reframes. Finally, participants develop a plan to use behaviors that modulate attention and counteract helplessness. During the class, participants create personalized lists of self- soothing behaviors; lists are customized to various settings. Participants self-tailor the

information relayed during the class by developing their own comprehensive self-treatment plan to stop and prevent catastrophizing. Participants leave the class with the following tangibles: 1) their self- written, self-crafted plan for pain relief; 2) a 20-minute relaxation response audiofile; and 3) a printed copy of the Empowered Relief slides to access as needed.

The study will be conducted at one site only, Cedars-Sinai (including online participation by research patients).

5.3 Description of Study Procedures

The study involves participation at a single timepoint only. The study procedures to be done are listed below.

The study involves one ER class to be done at 1 visit, either in person or online.

Questionnaires/surveys:
This study involves the administration of questionnaires. The questionnaire(s) will be administered once at baseline, then at weeks 2, 4, 8, and 12. The questionnaire will be administered electronically. The study will not collect sensitive information. This information is routinely collected as part of clinical care.]

We will be doing the following questionnaires:

- Pain Catastrophizing Scale (PCS)
    - This questionnaire is validated
- NIH PROMIS measures
    - This questionnaire is validated
- Pain Self-Efficacy Questionnaire
    - This questionnaire is validated

6.0 Data Collection and Management

6.1 Data Procurement

- **Identification/Access/Abstraction**

  ☒ Members of the study team will require access to the clinical data source (e.g., electronic medical record) to identify eligible data/specimens and to conduct data abstraction or gain access to specimens.[1]

[1] Clinical records can only be accessed by study team members who are listed on the CS-IRB application and are IRB Certified.

☐ Electronic Information Systems (EIS) Department will identify and/or abstract applicable data or specimens (e.g., RISCC website, request query of Deep6 through EIS).

☐ Separate registry or repository will identify, abstract, and/or provide specimens and/or data to the study team.

☐ Other:

- **Source(s) of Data/Specimens**:
  The source(s) of the data/specimens to be analyzed is from patient reported outcomes in the form of questionnaires.

6.2 Time Period of Data under Review

- Information will be kept for indefinitely.

6.3 Data Elements

- The following data points will be collected:
  - Medical Record Number
  - Age
  - Birth date
  - Sex
  - Diagnosis
  - Date of treatment
  - Date of admission
  - Medications
  - Surgical complications
  - Questionnaires (PCS, PROMIS, PSEQ)

The information to be accessed and reviewed is that which is minimally necessary to achieve the goals of this research.

HIPAA Identifiers
☐ **No HIPAA Identifiers will be collected for this study (or select the identifiers from the following list).** *The investigators will not attempt to re-identify subjects from the collected data.*
☒ Medical Record Number
☒ Name
☒ Address (all geographic sub-divisions smaller than state, including street address, city county, and zip code)

☒ All elements (except years) of dates (including birthdate, admission date, discharge date, date of death, and exact age if over 89)
☐ Telephone Numbers
☐ Fax Numbers
☐ Email Address
☐ Social Security Number
☐ Health plan beneficiary number
☐ Account Number
☐ Certificate or license number
☐ Vehicle identifiers and serial numbers, including license plate numbers
☐ Device identifiers and serial numbers
☐ Web URL
☐ Internet Protocol (IP) Address
☐ Finger or Voice Print
☐ Photographic Image (photographic images are not limited to the face)
☐ Any other characteristic that could uniquely identify the individual

6.4 Confidentiality and Security of Data

- **Secure Storage**: Data will be housed in a HIPAA-compliant secure storage system, like REDCap or Box, within the Cedars-Sinai network with access restricted to approved members of the research team.
- **Limited Access:** Private identifiable information will be accessible only to IRB approved study team members with current IRB training.
- Any data, specimens, forms, reports, video recordings, and other records that leave the site will be identified only by a participant identification number (Participant ID, PID) to maintain confidentiality. All records will be kept in a locked file cabinet. All computer entry and networking programs will be done using PIDs only. Information will not be released without written permission of the participant, except as necessary for monitoring by IRB, the FDA, the NCCIH, and the OHRP.
- **Retention/Destruction of Study Materials:** Study data/materials will be kept and/or destroyed according to applicable policy.

7.0 Data and Safety Monitoring

7.1 Data and Safety Monitoring Plan

The study will be monitored by the PI to ensure appropriate study conduct, including obtaining proper access to data/specimens, compliance with the HIPAA Privacy Rule, compliance with Cedars-Sinai policy, and adhering to the plans outlined in the protocol for all study procedures, abstracting and recording data, data and/or specimen security and maintenance, and data accuracy and integrity. Any adverse events, deviations, protocol exception requests, potential

unanticipated problems involving risks to subjects or others, or other events will be submitted to the IRB in accordance with IRB reporting policy.

7.2 Quality Control and Quality Assurance

- Data will be evaluated for adherence with the protocol and for accuracy in relation to source documents.

8.0 Sample Size and Statistical Considerations

8.1 Sample Size

This is a single-site study at Cedars-Sinai. The sample size of the study is 100 subjects.

8.2 Statistical Sample Size Justification

A statistical sample size is not required because this study involves:

- Procedures that are limited to medical record reviews, interviews/focus groups and/or surveys/questionnaires with no more than minimal risk,

8.3 Statistical Analysis Methodologies

No statistical methods description is required given that the study does not require a sample size justification.

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