

Empowered Relief for Osteoarthritis (OA)
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Cedars-Sinai

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Collaborating Institutions and Researchers	Not applicable.



**Empowered Relief for Osteoarthritis (OA)
CONSENT FORM FOR RESEARCH
For Cedars-Sinai and Participating Affiliates¹**

Study title: Empowered Relief for Osteoarthritis (OA)

Study support provided by: Cedars-Sinai

Cedars-Sinai Principal Investigator: Caryn Lindsey, PhD

Cedars-Sinai study contact: caryn.lindsey@cshs.org

To help guide your review of this form, the main sections include:

- 1. Key Information**
- 2. Purpose of the Study**
- 3. Study Procedures**
- 4. Possible Benefits From Taking Part in the Study**
- 5. Possible Risks and Discomforts of the Main Research Procedures**
- 6. Common Medical Procedures Performed for Research Purposes and Risks**
- 7. Reasons Participation May Be Stopped by the Researchers or Sponsor**
- 8. Voluntary Participation and Other Options**
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- Flowchart of Visits, Tests and Procedures**
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1. Key Information

¹ The **Cedars-Sinai Affiliated Covered Entity (“ACE”)** is comprised of covered entities under the common ownership or control of Cedars-Sinai Health System, including Cedars-Sinai Medical Center (CSMC); Cedars-Sinai Medical Care Foundation; Cedars-Sinai Marina Del Rey Hospital (MDRH); Torrance Memorial Medical Center (TMMC); Torrance Health Association, Inc., d/b/a Torrance Memorial Physician Network; Huntington Hospital (HH), and Huntington Medical Foundation.

Thank you for considering research participation. Research helps make medical and scientific advancements possible. In this form, we are asking for your consent to take part in this research study. Taking part in this research study is voluntary.

This section provides key information about the study. Please take your time to read this entire form. Also, please ask questions before deciding whether to take part in this research study. You are welcome to talk with family, friends and other healthcare providers before you decide.

- **Purpose:** The purpose of this study is to provide scientific evidence to demonstrate the efficacy of Empowered Relief (ER), and also to provide a comparison of the success of ER against the standard of care – group pain-cognitive behavioral therapy (CBT). Treatment allocation is randomized to minimize confounder effects, meaning groups of patients who either receive or do not receive the ER will be decided at random. Statisticians performing analyses will be blinded. Section 2 includes more details.
- **Duration:** Taking part in this study will last about 12 weeks.
- **Procedures:** The main things that will happen in this study are: 2-hour empowered relief session and questionnaire assessments at weeks 2, 4, 8, and 12. Section 3 includes more details.
- **Benefits:** The possible benefits of taking part in this study are better pain management as a result of the empowered relief course. Section 4 includes more details.
- **Risks:** All research studies involve some risks. Risks or discomforts from this study may be: discomfort while performing the empowered relief tools.
 - If you have problems during the study, contact the study team using the contact information on the first page of this consent form.
- **Alternatives:** You can choose not to be in the study. There may be other choices for you. These are described in Section 8 of this form.
- **New Information:** During the study, we may find out new information about this study. We will tell you about any important changes or new findings that may impact your decision to continue taking part in the study.

2. Purpose of the Study

We are doing this study 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. The primary objective of this study is to evaluate the efficacy of Empowered Relief (a novel, single-session (2-hour), evidence-based online pain management class) on reducing pain burden and improving quality of life in patients with advanced osteoarthritis. Empowered Relief is designed to compress key cognitive behavioral therapy

(CBT) skills, mindfulness principles, and pain neuroscience education into a brief, scalable format.

You are being asked to take part in this research study because you meet the following inclusion criteria and could help us evaluate the efficacy of ER on pain management in patients with advanced osteoarthritis:

- Axial low back pain without radicular symptoms³
- Pain duration ≥ 6 months (per recent NIH Task Force on Research Standards for Chronic Low Back Pain [44] (Dr. Mackey was a committee member and guideline coauthor) based on participant self-report
- Average pain intensity $\geq 4/10$ for the past month at screening visit
- English fluency
- Males and females 18-70 years of age
- PCS score ≥ 20 [14]⁴

The study will include up to 100 people total.

3. Study Procedures

This section talks about what will happen in this study.

When you read this section, also read the table of procedures. The table is given with this consent form. The flowchart of procedures shows a timeline of the study.

The table of procedures shows:

- When study procedures will occur,
- Whether they will be covered by the study or billed to you and/or your insurance, and
- Which study procedures are research-related and which are standard of care (routine).

Research-related procedures are procedures done only for the research study. They would not be performed for your routine care outside of the study. **Standard of care (routine) procedures** are routine care generally given to people with your condition. They would be performed even if you did not take part in this study. The researchers will schedule the visits and procedures at the listed timepoints.

The procedures in this study are often part of routine care for a person with your condition. They are not experimental procedures. The procedures and their risks are research-related. This means they are being done only for research purposes. These common procedures and their risks should be the same as when performed outside this study.

Description of research procedures:

- **Empowered relief session:** You will partake in a single-session 2 hour evidence-based online pain management class.

- **Questionnaires:** You will be asked to complete a questionnaire. We will ask you questions to find out about your pain and general wellbeing. We think it should take about 30 minutes to complete the questionnaires.

How long will you be in the study?

We think you will be in this study for/until about 12 weeks. This includes one 2-hour empowered relief course, followed by questionnaire submission at time points 2, 4, 8, and 12 weeks.

4. Possible Benefits From Taking Part in the Study

Being in this research study may or may not have direct medical benefit to you. The possible benefits of taking part in the research study are better pain management knowledge. However, no benefit is guaranteed. It is possible that your condition may stay the same or even get worse.

We hope the information learned from this research study will further advance our understanding of the efficacy of ER.

5. Possible Risks and Discomforts of the Research Procedures

This section talks about the possible risks and discomforts of the study procedures.

- **Questionnaires:** Some questions may make you feel uncomfortable or embarrassed. The questionnaire will be labeled with a unique study number. This will link your identity so that only the research team can recognize you.

6. Reasons Participation May Be Stopped by the Researcher or Sponsor

Your participation in this study may be stopped at any time. The researcher or the sponsor can stop your participation without your consent for any reason. If your participation is stopped early, the researcher will discuss next steps with you. Some reasons for stopping your participation include:

- The study is stopped or suspended.
- Funding for the study is reduced, stopped or withdrawn.
- It is in your best interest.
- You do not follow the study procedures.

7. Voluntary Participation and Other Options

Taking part in research is voluntary. You have the right to choose not to take part. You can stop taking part in this research study at any time. You can do this without any penalty or loss of benefits to which you would be entitled outside of the study. Your choice not to take part or to stop taking part will not affect the care you get at Cedars-Sinai.

If you decide to stop taking part, we will keep any data collected on you up to the time you choose to stop. Also, if you stop taking part, the study team may ask you whether you want to give further data from your routine medical care.

8. Confidentiality Protections

General Confidentiality

We will do our best to keep your personal information collected as part of this study private. But we cannot guarantee total privacy. We may put a copy of your research consent and authorization forms in your electronic medical record at Cedars-Sinai. Your personal information may be given out if required by law. Publications or presentations about this study at scientific meetings will not use your name and other identifiable personal information.

Organizations that may look at and/or copy your medical records for research oversight, quality assurance and data analysis include:

- Accrediting agencies (agencies that grant official certifications to educational institutions)
- Government and regulatory groups, such as the Food and Drug Administration (FDA) and Office for Human Research Protections (OHRP)
- The Institutional Review Board (IRB), which reviews research to protect people taking part in studies
- Safety monitors, which monitor the safety of individual participants and the overall safety of the study
- Companies that sponsor the study and authorized representatives of the sponsor

Attached to this consent form is an Authorization Form. It outlines with whom your information may be shared for this research and under what circumstances.

Clinical Trials Website

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

Sharing Information or Samples

We might share your information and/or research samples collected in this study. The information shared may include genomic data and health data or samples that could be used in future genomic research. It might be shared with other researchers at Cedars-Sinai, other researchers outside of Cedars-Sinai, or third-party commercial entities for future research without additional informed consent from you. In some cases, your information and/or specimens may be submitted to a database or repository for future research. These databases and repositories have safeguards to prevent inappropriate access to and use of the information and specimens. Information that identifies you will be removed and will not be shared with other researchers or anyone outside of Cedars-Sinai. However, there is a remote possibility that someone could identify you.

9. Research-Related Illness or Injury

Contact in Case of Illness or Injury

We do not expect you will have any illness or injury from this research study. If you believe that you are ill or have been injured from this study, please contact the study team at the phone number listed on page 1 of this consent form.

10. Financial Considerations

Costs of Participation

You and your insurance company will not be charged for your participation in this research study.

Payment

You will be paid for your participation in this study. The total amount for completing the whole study is \$50. You will be paid via Visa gift card. You will only be paid for those visits and procedures you complete.

You may have to fill out a W-9 form to get paid. Our accounting department at Cedars-Sinai will keep the W-9 form. Any amount of payment may be reportable to the IRS. If you receive \$600 or more from Cedars-Sinai in a calendar year, a 1099 form will be filed with the IRS in accordance with federal tax law. Check with a tax professional if you have questions.

If you are a Cedars-Sinai employee, you should provide your employee identification number to the research team. This allows your payment to be processed through Payroll. For your own protection and to comply with tax laws, your payment for taking part will be reported to the IRS together with other payment you get from Cedars-Sinai.

Financial Interest in the Research

The principal investigator and institution have no potential financial conflict of interest with this study.

11. Contact for Questions or Problems

Please contact the investigator for questions, problems or concerns about the research. Their contact information is on page 1 of this form.

You might have feedback, questions, problems, concerns or want to obtain more information about this study. If so, you can talk with someone who is not part of this study by contacting:

Cedars-Sinai Human Research Protection Program (HRPP)

Phone: 310-423-3783

Email: ResearchConcerns@cshs.org

Website: cedars-sinai.org/research/administration/office-of-research-compliance/review-board.html

The Cedars-Sinai HRPB protects the rights and welfare of research participants.



**AUTHORIZATION FOR USE AND DISCLOSURE OF
IDENTIFIABLE HEALTH INFORMATION FOR RESEARCH
FOR CEDARS-SINAI AFFILIATED COVERED ENTITIES²**

1. USE AND DISCLOSURE OF HEALTH INFORMATION

If you agree to this Authorization, you give permission to the Sponsor, Principal Investigator, other investigators and their research team described in the Consent Form for Research (“Research Team”) to use or disclose your identifiable health information (“private information”) for the research study titled “Empowered Relief for OA” which is described in the Consent Form for Research (“Consent Form”) to which this Authorization is attached. In particular, you authorize the research team acting under the direction of the Principal Investigator to review your medical records and collect your private information from the following sources:

- | | |
|--|--|
| <input type="checkbox"/> Laboratory tests | <input checked="" type="checkbox"/> Doctor/clinic records |
| <input type="checkbox"/> Pathology reports | <input checked="" type="checkbox"/> Hospital/medical records |
| <input type="checkbox"/> Imaging reports (e.g., x-rays or scans) | <input type="checkbox"/> Billing records |
| <input type="checkbox"/> Photographs or videos of your image | |
| <input checked="" type="checkbox"/> Demographics, which may include, but is not limited to, age, gender identity, race, ethnicity, and/or sexual orientation | |
| <input type="checkbox"/> Mental health records | |
| <input type="checkbox"/> Substance abuse records | |
| <input type="checkbox"/> HIV test results | |
| <input checked="" type="checkbox"/> Other tests or other types of medical information: Questionnaires | |

2. WHO WILL HAVE ACCESS TO YOUR PRIVATE INFORMATION?

Your private information will be used by and/or shared with the Research Team.

² The **Cedars-Sinai Affiliated Covered Entity (“ACE”)** is comprised of covered entities under the common ownership or control of Cedars-Sinai Health System, including Cedars-Sinai Medical Center (CSMC); Cedars-Sinai Medical Care Foundation; Cedars-Sinai Marina Del Rey Hospital (MDRH); Torrance Memorial Medical Center (TMMC); Torrance Health Association, Inc., d/b/a Torrance Memorial Physician Network; Huntington Hospital (HH), and Huntington Medical Foundation.

In addition to the research team, if applicable, the following parties may receive your private information and inspect your records:

- The reviewing Institutional Review Boards and Cedars-Sinai offices with authority to oversee research compliance.
- U.S. government agencies, such as the Food and Drug Administration and the Department of Health and Human Services.
- Researchers at other organizations who are participating in this research study.
- The Study Sponsor, its business partners, and Cedars-Sinai's business partners for matters related to research study oversight, conduct of the research, data analysis, use of research results in product development, and payment or reimbursement.
- Representatives from regulatory agencies in other countries may join in the review of your research records, including research-related medical reports and information, with the Sponsor and/or the FDA.

Cedars-Sinai takes steps to protect your private information when sharing it with the recipients described above. Though these steps and applicable law are meant to protect your private information, there is a risk that a recipient could share your private information without your permission.

3. WHEN WILL MY AUTHORIZATION EXPIRE?

By signing this document, you authorize the use and sharing of your private information until the end of the research study and any related optional sub-study you choose to participate in.

4. REVOKING AUTHORIZATION

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, the research team may still use or disclose private information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must write to the Principal Investigator of the research study by writing to the Office of Research Compliance and Quality Improvement, 6500 Wilshire Blvd, Suite 1800, Los Angeles, Calif. 90048 and/or emailing to ResearchConcerns@cshs.org.

5. NOTICE OF RIGHTS AND OTHER INFORMATION

You do not have to agree to this Authorization, but if you do not agree, you may not participate in the research study. Cedars-Sinai may not condition (withhold or refuse) the provision of standard of care treatment for you on whether you agree to this Authorization.

If you agree to this Authorization, please sign on the appropriate signature line on the Signature Page. You will receive a copy of this Authorization.

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

Footnotes:

Signature Page

Consent Form for Research and Authorization for Use and Disclosure of Identifiable Health Information (Research)

If you agree to take part in this study, you should sign and date on the signature lines below. You will be given a signed and dated copy of this form. This includes the “Experimental Subject’s Bill of Rights,” “Authorization for Use and Disclosure of Identifiable Health Information (Research)” and any optional sub-study descriptions, when applicable.

Signature by the Participant

Main Research Study: *I agree to take part in the research study described to me during the informed consent process and described in this informed consent form. My questions have been answered to my satisfaction.*

You will be given a signed and dated copy of this form.

Participant name (please print)	Signature	Date
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Authorization for Use and Disclosure of Identifiable Health Information (Research): *I hereby agree that my identifiable health information may be used and/or disclosed in accordance with the “Authorization for Use and Disclosure of Identifiable Health Information (Research).”*

Participant name (please print)	Signature	Date
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Signature by the Investigator

I attest that all the elements of informed consent described in this form have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.

Investigator name (please print)	Signature	Date
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Signature by the Interpreter/Witness

(Signature of an interpreter is only required when enrolling a non-English-speaking subject with the assistance of an interpreter and IRB-approved “short form” consent processes. The witness may be any person who is conversant in both English and the language of the non-English-speaking subject, such as a certified hospital interpreter, study staff, a family member or other person. The witness signs the consent forms to confirm that the oral interpretation occurred.

Signature of a witness is required when an English-speaking subject who has been determined to have capacity to consent is unable to read or physically sign the consent form but chooses to indicate via a “mark” or verbally that he/she agrees to participate. The witness signs the consent form to confirm that an oral consent process occurred and that the individual verbally consented to participate in the research.)

Interpreter/Witness name (please print)	Signature	Date of signature
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