A Pilot Feasibility Trial for an Intervention to Reduce Chronic Pain Following Cesarean Delivery

Informed Consent Form

NCT07090018

July 14, 2026

Please check all that are applicable:

☐ I am an adult participant in this study.

Print your name here:

_____

☐ I am the parent or guardian granting permission for a child in this study (the use of "you" refers to "your child" or "your ward.")

Print child's name here:

_____

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FOR QUESTIONS ABOUT THE STUDY, CONTACT: Pervez Sultan MD, 453 QUARRY RD, STANFORD, California 94305 , (650) 723-5439.

DESCRIPTION: You are invited to participate in a 6-week research study looking at a non-pharmacological pain relief option for women who have had cesarean deliveries. This research study seeks to understand if pain education can improve pain outcomes and quality of life. You were selected as a possible participant in this study because you gave birth via cesarean delivery 6 weeks ago and have moderate to severe pain (≥ 4 out of 10).

We have previous data showing that chronic postsurgical pain (CPSP) following cesarean delivery (CD) occurs in 17% of patients between 3 and 6 months after delivery. More than 50% of these patients have interference with all domains of life, with even mild pain affecting quality of life. There are few accessible non-pharmacological treatments for these patients, and none have been tested in the obstetric population.

The study will provide important information regarding the effectiveness of the pain education class, Empowered Relief (ER), for the obstetric population. The information learned in this study will allow us to determine how learning pain relief skills may impact related areas like pain, sleep, fatigue, physical function, depression, motherhood experience and anxiety.

Empowered Relief is a single, virtual, live session with a licensed practitioner who will guide you through mindfulness, cognitive behavioral skills and pain education. It is not recorded.

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Study Design

50% will be randomized to receive the intervention (Empowered Relief) alongside the normal standard of care and 50% will receive the normal standard of care.

No other changes to your postpartum care will occur. Patients should continue their own pain management plan, including medications as prescribed and directed by their provider.

The normal standard of care: Patients are transitioned back to their primary care physician after the 6 week postpartum visit and are not scheduled for additional follow up in the obstetric clinic unless active concerns arise at that visit and shorter interval obstetric follow up is needed.

- All participants will be asked to answer a survey at the beginning of the study and at the end of the study at 6 weeks.
- The questionnaires will be completed remotely on a smart device (such as a cell phone) or computer. You will be asked about pain and how it affects you in your daily life.
- All participants will be sent a check-in text every 3 days with 3 questions to assess symptoms and pain interference with daily activities.
- If you are selected to receive an Empowered Relief session, you will also complete an survey after the session as well as an additional survey at the end of the study You will also have access to a free app accessible from a smartphone to continue your practice.
- A medical records review will be conducted of your chart and your newborn to obtain relevant demographic, medical, obstetric and neonatal variables. A list is included on HIPAA authorization page.

We do not anticipate potential for physical harm by participating in this study.

Research results from surveys and interviews will not be disclosed to individual participants, unless they are concerning for psychological illness such as depression.

In the event of self-harm ideation reported on any survey, the site PI and obstetrician will immediately receive notification to contact the participant and assess risk of harm. Appropriate action will subsequently be taken depending on risk severity assessment and follow-up care will be arranged. The final findings from the study will be published and accessible to individual study participants

This research study is looking for women who have had a cesarean delivery and have moderate to severe pain (≥ 4 out of 10) to be enrolled. Enrollment will occur within the Stanford Healthcare System. Stanford University expects to enroll 60 research study participants (30 receiving the new treatment and 30 receiving routine care).

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Are you currently enrolled in other research studies?____ Yes ____ No

VOLUNTARY PARTICIPATION: Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on your medical care nor loss of benefits to which you are otherwise entitled. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled. If you decide to terminate your participation in this study, you should notify the Investigator listed on the first page of this form.

FUTURE USE OF PRIVATE INFORMATION: Research using private information is an important way to try to understand human disease. You are being given this information because the investigators want to save private information for future research.

Identifiers might be removed from identifiable private information and, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

CLINICALTRIALS.GOV: A description of this clinical trial (NCT07090018) 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 website will include a summary of the results. You can search this website at any time.

RISKS AND BENEFITS: There are no anticipated physical risks, discomforts, and inconveniences associated with this research study. You should talk with the Investigator if you have any questions. Some of the questions may be personal in nature.

If you feel uncomfortable answering any question, then please skip it. You do not need to answer all questions. You can withdraw from the study at any time.

Risk of accidental disclosure of your personal information: Agreement to participate in the study will result in questionnaires during this study. Data collected will be coded and de-identified so will not be recognizable and your identity will not be known. There may be risks that are unknown.

POTENTIAL BENEFITS: We cannot and do not guarantee or promise that you will receive any benefits from this study. However, your participation may help other women following cesarean delivery who experience pain. This research will be used as the foundation for further studies into Empowered Relief and its use as a pain relief tool in postpartum women. It may prompt health care services to utilize these tools at an earlier stage to improve women's postpartum recovery.

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ALTERNATIVES This study involves a non-pharmacological treatment, Empowered Relief. If you choose to be in the study you are accepting that you may or may not receive treatment. The only alternative is not to participate

Your decision whether or not to participate in this study will not affect your employment/medical care.

TIME INVOLVEMENT: If you choose to enroll in the study, the duration of your study participation is 6 weeks. You will be randomized to either receive the intervention (Empowered Relief) or to receive nurse-led care.

Your participation in this experiment will take approximately 1 hour if you are not receiving Empowered Relief, and 3.5 hours if you are receiving Empowered Relief.

PAYMENTS: You will be paid (in gift vouchers) for participating in the research study as a small appreciation of your time

If you are randomly selected to receive normal standard of care

completing baseline survey	Completing Post ER Survey
$20	$50

If you are randomly selected to receive the intervention, Empowered Relief (ER) :

Signing up for ER Session and completing baseline survey	Completing ER session and doing quick feedback	Completing Post ER Survey
$20	$30	$50

Costs: There is no cost to you for participating in this study, other than the personal time it will take for you to participate in the study

PARTICIPANT RESPONSIBILITIES: As a participant, your responsibilities include:

- Following the instructions of the Investigator and study staff.
- Completing the electronic questionnaires at the beginning of the study, immediately after attending the Empowered Relief session (if you are randomized to this group) and at 6 weeks (the end of the study) (through Research Electronic Data Capture, or REDCap).
- Participating in the Empowered Relief session if randomized
- Keeping your study appointments.
- Replying to the text messages about your pain every 3 days
- If it is necessary to miss an appointment, please contact the Investigator or research study staff to reschedule as soon as you know you will miss the appointment.

- Tell the Investigator or research study staff about any hospitalizations that you may have.
- Complete your questionnaires and attend your online session if instructed.
- Ask questions as you think of them.
- Tell the Investigator or study staff if you change your mind about staying in the study.

SPONSOR: The Division of Obstetric Anesthesia, Stanford Healthcare system and NIH is providing financial support and/or material for this study.

SMS AUTHORIZATION: This study would like to use your phone number to send you important messages related to your participation, such as survey links, study updates, appointment reminders, or other scheduled information. By providing your phone number, you agree to receive SMS messages and phone calls from the study team. Standard message and data rates may apply based on your mobile carrier plan.

You may opt out at any time by replying with "STOP" or "UNSUBSCRIBE," or by contacting the study team directly. Your phone number and message content will be handled securely and will not be permanently stored on Twilio's servers.

Do you consent to providing your phone number and receiving messages from the survey team?____ Yes ____ No

PARTICIPANT'S RIGHTS: If you have read this form and have decided to participate in this project, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

The results of this research study may be presented at scientific or professional meetings or published in scientific journals. However, your identity will not be disclosed**.**

You have the right to refuse to answer particular questions.

CERTIFICATE OF CONFIDENTIALITY: This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including

for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by NIH which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of for instance, child abuse or neglect, harm to self or others, and communicable diseases.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

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Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?
We aim to trial the intervention, Empowered Relief, in the postpartum period to see if we can improve pain outcomes following cesarean delivery and prevent the transition of acute pain to chronic pain. Some aspects related to your maternal delivery and recovery will be recorded to help determine important factors which contribute towards recovery. The information will also be submitted to the sponsor in some form.

Do I have to sign this authorization form?
You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?
If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Pervez sultan, psultan@stanford.edu

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What Personal Information Will Be Obtained, Used or Disclosed?

Your health information related to this study may be used or disclosed in connection with this research study, including, but not limited to, basic demographic information, brief medical history, current medication use, obstetric history and current pregnancy health information, delivery information including mode of delivery and postpartum health data, brief health report of newborn and blood results from the peripartum period and general recovery information. Demographics will include:

- Name
- Telephone numbers
- Electronic mail address
- Date of birth
- Admission dates
- Medical record numbers
- Race/ethnicity
- Marital status
- Highest level of education,
- Employment status
- Household income
- Medical history: Medication/drugs/alcohol history); Active or previous sleep disorder diagnosis, Body mass index, American Society of Anesthesiologists physical status, Cardio-respiratory, Gastrointestinal, Endocrine, Hematological, Musculoskeletal Neurological co-morbidity)
- Obstetric factors: Parity, Gestation, Gestational age, Multiple gestation, Delivery mode Desired delivery mode, Anesthesia mode, Indication for cesarean delivery (if relevant), Hypertension, Pre-eclampsia, Chorioamnionitis, Other complications, Length of hospital stay
- Psychiatric factors: Previous or active psychiatric diagnosis, Pharmacological (or other) therapy, Hospital admission for psychiatric illness, Family history of psychiatric illness;
- Social factors: Self-reported social support, Caregiver burden and Partner support (none/minimal/some/lots);
- Infant factors Length of hospital stay, Admission to Neonatal Intensive Care Unit, Need for neonatal investigation, Unplanned consultation, Feeding (breast/bottle) Maternal perception of infant health state.
- Survey data including pain metrics and global health may also be used or disclosed

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Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director: Dr Sultan
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff
- NIH

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections (OHRP) in the U.S. Department of Health and Human Services (DHHS)

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will end on December 31st 2050 or when the research project ends, whichever is earlier.

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_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

Signing your name below means you give authorization for the inclusion of your child's protected health information in this study as describe above.

_____ _____
Signature of Legally Authorized Representative (LAR) Date
(e.g., parent, guardian or conservator of infant)

_____
Print Name of LAR

_____
LAR's Authority to Act for Participant
(e.g., parent, guardian or conservator of infant)

WITHDRAWAL FROM STUDY: If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw your consent to participate in this study, you should notify the Investigator listed on the first page of this form. However, please note that information collected up to the point of your withdrawal may not be removed from the study

The Protocol Director may also withdraw you from the study and the study intervention (Empowered Relief) may be stopped without your consent for one or more of the following reasons

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

CONTACT INFORMATION:

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr Pervez Sultan. You may contact them now or later at (650) 723-5439.

Injury Notification: If you feel you have been hurt by being a part of this study, please contact the Protocol Director, Dr Sultan at (650) 723-5439 .

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at 650-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

Alternate Contact: If you cannot reach the Protocol Director, please contact Dr Aleesha Jethwa at 453 QUARRY RD, STANFORD, California 94305 (650) 723-5439.

May we contact you about future studies that may be of interest to you?
____ Yes ____ No

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Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent

Signing your name below means you give permission for the inclusion of your child's information in this study as described above in the consent information.

_____ _____
Signature of Legally Authorized Representative (LAR) Date
(e.g., parent, guardian or conservator)

_____
Print Name of LAR

_____
LAR's Authority to Act for Participant
(e.g., parent, guardian or conservator)

The IRB determined that the permission of one parent is sufficient in accordance with 45 CFR 46.408(b).