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

Study Protocol

NCT07090018

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A pilot feasibility trial for an outpatient intervention to reduce chronic pain following cesarean delivery

Background

Data shows that chronic postsurgical pain (CPSP) following cesarean delivery (CD) occurs in 16.7% of patients between the 3 month to 6 month post delivery window. >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 behavioral pain treatments for this subtype of patients, and none have been tested in the obstetric population. The purpose of this study is to conduct a feasibility and preliminary efficacy test using an evidence-based single-session pain relief skills class (Empowered Relief) at 6 weeks postpartum to determine impact on chronic pain incidence at 12 weeks postpartum.

The study will provide important information regarding the effectiveness of the pain education class for the obstetric population. The information learned in this study will allow us to determine how learning pain relief skills may impact related multidimensional postpartum health domains, (e.g., pain, sleep, fatigue, physical function, depression, motherhood experience and anxiety).

Results from 4 randomized controlled trials demonstrate multidimensional efficacy of Empowered Relief across different patient populations and settings, including mixed etiology chronic pain when received in a group online format. The aim of this study is to evaluate Empowered Relief in the obstetric postpartum population. The primary outcome for this study is the feasibility of delivering Empowered relief in the outpatient postpartum setting. The primary clinical outcome is pain interference at 3 months. Secondary clinical outcomes are chronic pain incidence, pain severity, and global recovery at 3 months

Definitions

- Acute pain - An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage.

- Chronic postsurgical pain - constant or intermittent pain that persists for 3 months or more.

- Empowered relief is a 120 min session given over zoom/in person by a healthcare professional. Following the session, participants are given access to an app with continual guidance (e.g. breathing exercises, mindfulness etc) and sent a daily supportive text message.

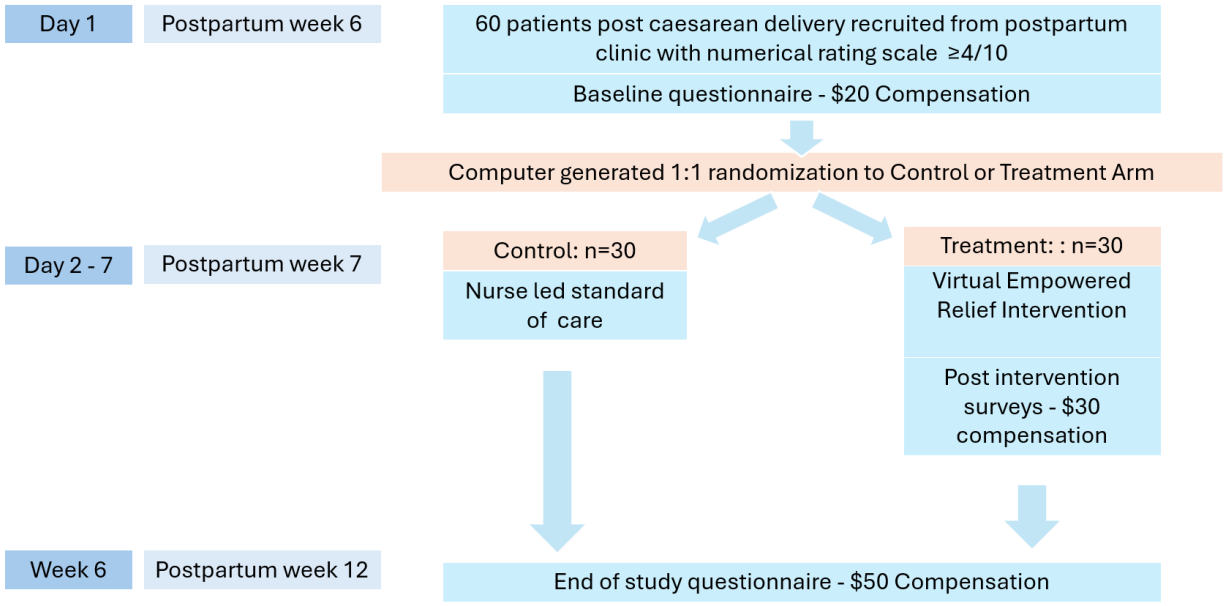
Hypothesis:

The Empowered Relief program will be feasible and acceptable for individuals with acute pain, and participation in the program will lead to meaningful improvements in average pain-related outcomes (e.g., severity, interference) compared to those not receiving the intervention

Methods

Overview:

Figure 1: Study Design and Methods



1) Patients recruited from 770 Welch Roach outpatient Postpartum clinic
    a. 30 patients in control arm
    b. 30 patients in treatment arm
2) Eligibility will be determined based on presence of moderate/severe pain (numerical pain scale; pain score ≥4/10) at the 6-week postpartum clinic from any source since delivery.
3) Obtain informed consent and request completion of baseline questionnaires
4) Randomize patients to either receive Empowered relief treatment or standard care (nursing led follow up with no empowered relief) using computer generated stratified randomization.
5) For patients completing Empowered Relief:

a. Complete a single 120 min session given over zoom with a healthcare professional within 7 days of the 6 week clinic visit
b. Following the session, participants are given
    i. Unlimited access to an app with continual guidance (e.g. breathing exercises, mindfulness etc)
    ii. Daily supportive text messages that can be stopped by the patient at any time
        1. This will include a daily question asking them to rate their pain on a score of 0 – 10
c. Completion of post intervention feedback

6) At 12 weeks postpartum (6 weeks post start of study), patients on both arms will be asked to complete a final questionnaire pack assessing pain and global recovery

Table of Questionnaires and outcomes

	Questionnaire (no of questions)	Baseline (6 weeks post CD)	Post ER session (6 - 8 week post CD)	End of study (week 12 post CD)
Approximate time		20 - 25 mins	10 min (+ 2 hr session)	45 mins
	PROMIS Pain interference 8a (8)	x		x
	PCS - pain catastrophizing score (13)	x		x
	PROMIS Pain Intensity (3)	x		x
	Post intervention Survey - ER appraisal (12)		x	
	Treatment skills use (5)			x
	Treatment changes (3)			x
	Adverse events - new medical (3)			x
	Study Satisfaction (1)			x
	Feedback (1)			x
	Every 3 days PEG question: Sent a text message with 3 questions every 3 days asking them about current pain, pain interference and enjoyment of life.			

BASELINE AT 6 WEEKS POSTPARTUM (Day 1)
All participants
- PROMIS Pain interference 8a (research only)
- PCS - pain catastrophizing score (research only)
- PROMIS Pain Intensity (research only)
- Baseline Feedback (research only)

IMMEDIATELY AFTER Empowered Relief
Intervention group only (Day 2-7)
- Post intervention Treatment Appraisal (research only)

12 WEEKS POSTPARTUM (Week 6)
All Participants
- PROMIS Pain interference 8a (research only)
- PCS - pain catastrophizing score (research only)
- PROMIS Pain Intensity (research only)
- Adverse events - new medical (research only)
- Treatment Changes (research only)
- Study Satisfaction and feedback (research only)

Intervention group only
- Treatment skills use (research only)

All Participants
Sent a text message with 3 questions every 3 days asking them about current pain, pain interference and enjoyment of life.

Compensation Table

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

Inclusion criteria:

- Age 18 or above
- Any postpartum woman who has had a cesarean delivery in the Stanford Healthcare system
- has had a viable birth
- single / multiple gestation

- maternal demographics and complications: parity, medical conditions (pre-eclampsia, gestational diabetes etc), post-surgical complications (hysterectomy, admission to ICU, extended hospital stay etc)
- Neonatal complications: admission to NICU, extended hospital stay etc
- at the postpartum clinic
- has moderate/severe pain, scoring ≥ 4/10 on the visual analog scale
- English fluency + ability to read and write
- Ability to adhere to and complete study protocols
- Access to smart device for zoom / video meetings

Exclusion criteria:

- Cognitive impairment, non-English speaking, or psychological factors that would preclude comprehension of material and/or full participation in the study.
- Participants unable to or refuse to give informed consent
- Participants that do not understand English or are hearing impaired
- <18yrs
- chronic pain prior to pregnancy

Outcome Measures:

Primary Outcome: Feasibility, as indexed by (1) engagement and (2) patient appraisal/satisfaction metrics.

Priority Secondary Outcomes: clinical outcomes (pain intensity, pain interference and pain catastrophizing).

Other Secondary Outcomes:
Treatment Experience measures, Treatment skills use and changes,
patient enrollment, participation in the class, successful delivery of the group intervention across cohort, collection of pre–post treatment data, collection of longitudinal outcomes using an electronic system

Registered on CT.gov: NCT07090018

Expected Outcomes:

- patient enrollment
- participation in the class

- successful delivery of the group intervention across cohort
- collection of pre–post treatment data
- collection of longitudinal outcomes using an electronic system

Conclusion

30% of live births in the US are via CD, and as this continues to increase we need to be aware of future implications for women and the impact on quality of life. Not enough is known about the transition from acute to chronic pain post CD. This study has the potential to impact the way we deliver postpartum care.

Supporting information

Ciechanowicz S, Joy RR, Kasmirski J, Blake L, Carvalho B, Sultan P. Incidence, Severity, and Interference of Chronic Postsurgical Pain After Cesarean Delivery: A Systematic Review and Meta-analysis. J Clin Anesth. 2025 Jun;104:111832. doi: 10.1016/j.jclinane.2025.111832. Epub 2025 Apr 24. PMID: 40279839. - https://pubmed.ncbi.nlm.nih.gov/40279839/

Acute pain definition - https://pmc.ncbi.nlm.nih.gov/articles/PMC7680716/

Empowered Relief - https://empoweredrelief.stanford.edu/