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

Statistical Analysis Plan

NCT07090018

July 14, 2026

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ClinicalTrials.gov ID: NCT07090018

Planned analyses

This pilot feasibility trial was not powered to test efficacy. All analyses are descriptive.

Outcome	How it is measured	How it is reported
Primary (feasibility)		
1. Registration for Empowered Relief session	Number of intervention-arm participants who register, within 1 week of baseline	n (%)
2. Attendance at Empowered Relief session	Number of intervention-arm participants who attend, within 2 weeks	n (%)
3. Participant satisfaction	7-item satisfaction scale (0- 42), 1 - 2 weeks after session	Mean (SD), median (IQR)
4. Treatment skills use	5-item skills use scale (0 - 25), 4 - 6 weeks after session	Mean (SD), median (IQR)
Secondary (clinical)		
5. Pain interference	PROMIS Pain Interference 8a (8 - 40), baseline and 12 weeks postpartum	Mean (SD) change by arm
6. Pain intensity	PROMIS Pain Intensity 3a (3 - 15), baseline and 12 weeks postpartum	Mean (SD) change by arm
7. Pain catastrophizing	Pain Catastrophizing Scale (0 - 52), baseline and 12 weeks postpartum	Mean (SD) change by arm
8. PEG composite	PEG via text message (0–30), enrollment to 12 weeks postpartum	Mean (SD) change by arm
9. PEG pain interference	PEG interference items via text message (0 - 20), enrollment to 12 weeks postpartum	Mean (SD) change by arm
10. PEG pain intensity	PEG intensity item via text message (0 - 10), enrollment to 12 weeks postpartum	Mean (SD) change by arm
11. PEG response rate	Items answered out of items sent, enrollment to 12 weeks postpartum	% of items answered, by arm

Analyses will use available data, with no imputation.