
# EMPOWER: A Multi-Site Pilot Trial to Reduce Distress in Surrogate Decision-Makers in the ICU

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# EMPOWER:

## A Multi-Site Pilot Trial to Reduce Distress in Surrogate Decision-Makers in the ICU

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**Abstract**

**Context:** Efforts to reduce the psychological distress of surrogate decision-makers of critically ill patients have had limited success, and some have even exacerbated distress.

**Objectives:** The aim of this study was to determine the feasibility, acceptability, and preliminary efficacy of EMPOWER (Enhancing and Mobilizing the POtential for Wellness and Resilience), an ultra-brief (~2-hour), 6-module manualized psychological intervention for surrogates.

**Methods:** Surrogates who reported significant anxiety and/or an emotionally close relationship with the patient (n=60) were randomized to receive EMPOWER or enhanced usual care (EUC) at one of three metropolitan hospitals. Participants completed an assessment of EMPOWER's acceptability, measures of psychological distress pre-intervention, immediately post-intervention, and at 1- and 3-month follow-up assessments.

**Results:** Delivery of EMPOWER appeared feasible, with 89% of participants completing all 6 modules, and acceptable, with high ratings of satisfaction (mean=4.5/5, SD=0.90). Compared to EUC, intent-to-treat analyses showed EMPOWER was superior at reducing peritraumatic distress (Cohen's *d*=–0.21, small effect) immediately post-intervention and grief intensity (*d*=–0.70, medium-large effect), posttraumatic stress (*d*=–0.74, medium-large effect), experiential avoidance (*d*=-0.46, medium effect), and depression (*d*=-0.34, small effect) 3 months post-intervention. Surrogate satisfaction with overall critical care (*d*=0.27, small effect) was higher among surrogates randomized to EMPOWER.

**Conclusions:** EMPOWER appeared feasible and acceptable, increased surrogates' satisfaction with critical care, and prevented escalation of posttraumatic stress, grief, and depression 3 months later.

**Key Message:** An ultra-brief psychological intervention, EMPOWER, appears feasible, acceptable, and promising for improving surrogate decision-makers' mental health and adjustment months after the patients' ICU stay.

**Key Words:** critical care; surrogate decision-making; psychological intervention; grief; trauma

**Running Title:** EMPOWER FOR SURROGATES OF CRITICALLY ILL PATIENTS

**Introduction**

The Intensive Care Unit (ICU) can be distressing for family members, who are often anxious, concerned, and confused. They may be in a state of shock and horrified by what they witness in the ICU. Compounding their acute traumatic distress, family members - defined as those "for whom it matters" (1) - are often thrust into the role of surrogate decision-maker. This responsibility for making life-and-death decisions on the patient's behalf places an additional burden on family surrogates. These circumstances heighten surrogates' risk of anxiety, depression, Posttraumatic Stress Disorder (PTSD), Prolonged Grief Disorder, and decisional regret about the care that the patient received (2-10). The growing body of research on Post Intensive Care Syndrome-Family (PICS-F) among family surrogate decision-makers acknowledges the long-lasting mental health challenges that result from this experience (3, 11), circumstances further exacerbated by the COVID-19 pandemic (8, 12).

Numerous efforts have sought to address family surrogates' distress, ranging from passive educational interventions to more active counseling approaches (13). However, prior research has shown these interventions not only have limited success but that some may even exacerbate surrogates' traumatic stress responses (14-20). This may be because most prior interventions, while targeting psychological outcomes, were not informed by psychological insights and proven psychotherapeutic approaches to promote adjustment to stress, grief, and trauma (21-24) delivered by trained mental health professionals. To address this limitation, we developed EMPOWER (Enhancing & Mobilizing the POtential for Wellness & Emotional Resilience), an ultra-brief (~2 hours; 25) psychological intervention (26, 27). Delivered by a mental health professional (e.g., social worker), EMPOWER aims to reduce experiential avoidance (i.e., the tendency to avoid unpleasant feelings). Reassurance-seeking, indecision,

pursuit of more aggressive care, ruminative worry, or more explicit avoidance of experiences are all reflections of the individual's drive to not feel negative emotional states. In the short term, experiential avoidance may provide respite from uncomfortable experiences. In the longer term, however, experiential avoidance can reinforce negative emotions, interfere with decisions aligned with value-concordant care, and undermine engagement in processes that promote adaptation following trauma and loss. Unsurprisingly, experiential avoidance can paradoxically maintain psychological distress (28, 29), including symptoms of PTSD and Prolonged Grief Disorder (30, 31) among surrogate decision-makers in ICU settings. Indeed, Curtis and Levy (32) highlighted the significant benefits of tolerating rather than avoiding feelings of grief, emotional pain, and uncertainty. EMPOWER offers tools to support surrogates in these uncomfortable psychological states. By offering surrogates coping strategies for tolerating distress and increasing psychological flexibility, we hypothesized EMPOWER would reduce psychological distress. This may in turn positively impact other key outcomes, such as decision-making (33). The aim of the current pilot randomized controlled trial was to examine the feasibility, acceptability, and preliminary effects of EMPOWER on psychological distress among family surrogates of patients in the ICU.

## Methods

### Study Design

The EMPOWER (Enhancing and Mobilizing the POtential for Wellness and Resilience) study was a multi-site, parallel randomized controlled trial (RCT) of an ultra-brief psychological intervention to reduce distress among family surrogate decision-makers. It represents Stage IB (feasibility and pilot testing) of the Stage Model of Behavioral Therapies (34). Family surrogates were recruited from ICU settings in 3 New York City sites (a university hospital, a tertiary

cancer center, and a community hospital) from March 2019 to June 2022, with a 3-month follow-up to August 2022. This study was approved by an Institutional Review Board (Weill Cornell Medicine IRB #1610017622), with the protocol published in 2019 (27). Clinicaltrials.gov registration for the EMPOWER intervention development research program was posted by September 8, 2017 (# NCT03276559). Randomization was amended to a single-arm design, and we transitioned from in-person to telehealth delivery of EMPOWER at the height of the COVID-19 pandemic on May 14, 2020 to address the acute needs of distressed surrogates in New York City and ensure all study participants received the support of this intervention. The protocol was amended again on August 19, 2021 to resume randomization.

**Participants**

Family members were identified through ICU records and vetted for approach through consultation with members of the critical care team. They were eligible if they were the healthcare proxy or surrogate of a critically ill adult (age $\geq$ 18) or pediatric patient (age < 18) who was admitted to an ICU or stepdown unit (used when the ICU was at capacity during the COVID-19 pandemic). There was no minimum amount of time from admission that an approach could be made. Eligible surrogate decision-makers were English-speaking and at higher risk for psychological distress (2) based on self-reported closeness to the patient (> 8 on two items from the Partner Dependence Scale) (35) and/or anxiety (> 5 on an anxiety item of the McGill Quality of Life Scale) (36), both of which have been associated with poor outcomes (e.g., prolonged grief (35) and PTSD (37)). Surrogates identified by clinical staff as distressed and likely to benefit from participation in this study were also eligible. Prior to May 14, 2020, surrogates were eligible if the patient lacked decisional capacity (e.g., on ventilator, non-communicative), were admitted to an ICU or stepdown unit, and the ICU attending or fellow indicated they would not

be surprised if patients did not survive more than 3 months (38). During the COVID-19 pandemic, we eliminated the decisional capacity and prognosis criteria so that more surrogates had the opportunity to participate.

Surrogates were excluded if they reported current suicidal ideation on the Columbia-Suicide Severity Rating Scale (39), as this might indicate more intense distress than an ultra-brief psychological intervention could address. Excluded and withdrawn surrogates were provided with referrals and resources. One surrogate per patient was enrolled.

**Interventions**

EMPOWER is an ultra-brief psychological intervention that packages evidence-based approaches (21, 22, 40-43) using a flexibly-administered, modular format to accommodate the multiple interruptions and crises common to ICU settings. Consisting of 6 discrete 15-20-minute modules, EMPOWER assesses the surrogates' most significant struggles (Module 1), teaches tools for addressing the physiological stress response and building distress tolerance (Module 2), provides psychoeducation on the cognitive-behavioral model and experiential avoidance (Module 3), reviews acceptance-based coping strategies (Module 4), invokes the patient's voice for emotional and decision-making support (Module 5), and engages in coping rehearsal to prepare for anticipated stressors (Module 6). These 6 modules were delivered in a single session or over multiple sessions based on the surrogates' needs and preferences. Two booster calls were conducted approximately 2 and 4 weeks after completion of the 6 modules to review the key principles of EMPOWER and to help the surrogate apply those principles in coping with current and anticipated stressors, including acute bereavement. Booster calls were included to reinforce the EMPOWER concepts and because they reflect the type of realistic follow-up in which an ICU mental health clinician might engage after administering the EMPOWER modules.

Additional details on EMPOWER, including how it was developed using stakeholder feedback, are described elsewhere (26).

EMPOWER interventionists received didactic training by WGL and were asked to listen to at least two cases prior to assignment. They received regular supervision to ensure treatment fidelity. Two independent raters evaluated a randomly selected 25% of cases and found 92% were adherent (rater agreement Kappa=0.89).

Enhanced Usual Care (EUC) included the standard emotional support care provided by staff (e.g., social workers, nurses, chaplains) to surrogates in and out of the ICU. This usual care was enhanced by providing surrogates with resources (e.g., caregiver support group information, social worker contact information) as well as an informative packet about caregiving (44). Surrogates of pediatric and adult patients received separate information packets and resource lists tailored to their respective patient populations. EUC resources and information packets were delivered to participants in-person, via mail or electronically based on their preferences.

**Outcomes and Measures**

The aims of this pilot study included assessment of the feasibility of the trial, acceptability of EMPOWER, and evaluation of the preliminary efficacy of EMPOWER on surrogate mental health in the short- and longer-term. Self-report assessments were conducted online or with research staff pre-intervention (Time 1 [T1]), immediately post-intervention (T2, which was approximately 2 to 3 weeks after T1 for those in EUC, or once all 6 EMPOWER modules were delivered for those randomized to the intervention arm), 1 month after T2 (T3), and 3 months after T2 (T4).

*Demographic and background information.* Self-reported demographic information was collected from surrogates at T1.

*Feasibility and Acceptability.* The feasibility of conducting a larger trial was assessed in terms of the proportions of surrogates approached who consented, declined participation, and were ineligible; the number of modules of EMPOWER completed by participants randomized to the intervention arm; and the proportion of participants in both arms who completed assessments at each timepoint. The feasibility target was completion of 4 of 6 modules for at least 60% of participants. Usefulness of the EMPOWER components were rated by participants on a post-intervention satisfaction questionnaire at T2 ranging from 1 (not useful at all) to 5 (very useful). All EMPOWER participants were asked to evaluate the treatment length (i.e., just right or too much), preferences for delivery schedule (i.e., single vs. multiple sessions), and general helpfulness and effectiveness of the intervention on a Likert-style scale ranging from 1 ("not at all") to 5 ("extremely"). The acceptability target was defined as an average score of 4 or greater on items in the post-intervention satisfaction questionnaire among at least 60% of EMPOWER participants.

*Psychological outcomes.* The primary psychological outcome was peritraumatic stress symptoms as measured by the Peritraumatic Distress Inventory (PDI; 45), administered only at T2 because peritraumatic stress is assessed during the potentially traumatic experience (i.e., the patient's ICU stay). Secondary psychological outcomes included posttraumatic stress symptoms (Impact of Event Scale-Revised [IES-R]; 46), pre-loss grief (Prolonged Grief-12 [PG-12]; 47, 48), experiential avoidance (Brief Experiential Avoidance Questionnaire [BEAQ]; 29), decisional regret (Decisional Regret Scale [DRS]; 49), anxiety (State-Trait Anxiety Inventory [STAI] State Subscale; 50), depression (Patient Health Questionnaire-9 [PHQ-9]; 51), caregiving self-efficacy (Caregiving Self-Efficacy Scale-8 [CSES-8]; 52), and family satisfaction with critical care (Critical Care Family Satisfaction Survey – ICU Version [CCFSS]; 53). See Table 1 for measure descriptions and the timepoint(s) at which they were assessed.

**Sample Size, Randomization, and Blinding**

This pilot RCT aimed to enroll 60 participants. As a pilot study, it was understood to be underpowered (54). Participants were randomized using computer-generated random numbers. Originally, randomization was 1:1, but due to the COVID-19 pandemic and intensified support needs of surrogates in ICUs in New York City, the design was altered to a single-arm trial for a 15-month period. As critical care settings stabilized, randomization resumed. The goal then was to achieve a 2:1 ratio of EMPOWER to EUC. Blinding was not possible because of the nature of the interventions.

**Statistical Analysis**

Descriptive statistics were used to characterize the feasibility and acceptability of EMPOWER by examining helpfulness/satisfaction ratings, rates of recruitment, attrition, and number of modules and booster calls completed. We conducted planned intention-to-treat (ITT) analyses, in which multiple imputation by chained equations was used to fill in missing data for study measures using classification and regression trees (CART) in the "mice" R package. Given the amount of missing data by T4 (46%), we followed the recommendation of Jakobsen et al. (55) and conducted per-protocol analyses, restricting our analytic sample to participants who completed all assessments (T1 through T4; see online supplement for tables and figures presenting per-protocol findings). To evaluate the preliminary effects of EMPOWER, we used descriptive statistics and Cohen's d within-subjects effect size estimates (56) at each timepoint relative to baseline. Two-sample *t*-tests were used to compare mean changes in quantitative measures across pre- and post-intervention timepoints between EMPOWER and EUC participants (difference-in-difference). A *p*-value of 0.05 was used as a threshold for determining statistical significance.

**Results**

**Participant Characteristics**

Eighty-one participants enrolled, and 63 participants completed T1 assessments (see Figure 1). Table 2 presents background information about the 63 surrogate participants who completed the T1 assessment. Most participants were female, married, under age 65, and college graduates. The sample was racially/ethnically diverse, with 55% of participants identifying as Black/African-American, Hispanic/Latine, or Asian. Participants were parents, adult children, and spouses or partners of patients. Sixteen patients died (27%) during the study period, although patient mortality rates did not significantly differ between the EMPOWER (29%) and EUC (26%) groups ($p > .10$).

**Feasibility and Acceptability**

Study staff obtained permission from their critical care team to approach 492 surrogates. Of these, 389 were approached (79%). Reasons for not approaching surrogates included changes in eligibility status, patient vital status, and the patient being discharged. Of those approached, 91 (23%) declined participation. Reasons for declining included lack of interest in research or support (52%), feeling too overwhelmed (9%), concerns about taking time away from the patient (8%), and reporting adequate support (3%). Reasons the remaining 222 surrogates did not enroll included the patient dying or being discharged before consenting or the surrogate not speaking English (though reasons were unknown for 181 surrogates). We ultimately consented 81 of the surrogates approached, 63 completed the T1 pre-intervention assessment, and 60 were randomized. Fifty-six percent of participants who completed the T1 assessments completed T4 assessments, demonstrating that data collection over time was moderately feasible in this population. Details about how enrollment varied during the RCT and single arms periods are presented in an online supplemental file.

Surpassing our feasibility target (>60%), we observed that 92% of participants who began EMPOWER completed 4 of 6 modules, and 89% completed all 6 modules. In addition, 75% of participants completed the first booster call, and 68% completed both booster calls. There was significant variability in the length of time surrogates took to complete the 6 modules because of the unpredictable circumstances they faced, including bereavement. For EMPOWER participants, T2 questionnaires were administered after all 6 modules were completed, which occurred on average 26.8 days (SD=28.1) after T1. For EUC participants, T2 was administered on average 13.8 days (SD=12.1) after T1. These group differences were not statistically significant ($p > .10$).

Acceptability of EMPOWER was evidenced by high ratings (greater than 4 on a 1-5 scale) that the intervention was helpful, clear, and understandable, and that the benefits of participating in EMPOWER outweighed the costs. Overall satisfaction was very high (mean=4.46 out of 5). We achieved our acceptability target (>60%), with 63% of EMPOWER participants reporting overall satisfaction scores of 4 or higher. Most participants rated the length of EMPOWER "just right" and preferred to receive EMPOWER in multiple sessions rather than a single session (79%). Table 3 details additional post-intervention satisfaction questionnaire ratings.

**Preliminary Efficacy**

Descriptive statistics and effect size estimates for the study outcomes are detailed in Table 4. We examined between-group differences with Cohen's d, applying conventional interpretation of effect sizes, whereby $d$=.2 reflects a small effect, $d$=.5 is a medium effect, and $d$=.8 is a large effect (57). At T2 (immediately post-intervention), which occurred on average 23 days (SD=25 days) from T1, EMPOWER demonstrated superiority relative to EUC, with small

effects on peritraumatic distress and anxiety and medium effects on posttraumatic stress symptoms, grief intensity, and caregiving self-efficacy. Between-group effects were generally sustained over time. EMPOWER demonstrated statistically significant, medium-sized effects on posttraumatic stress symptoms and pre-loss grief intensity at T3 and T4. EMPOWER also appeared to prevent increases in experiential avoidance and depression that were observed in the EUC arm, with small to medium effects at T3 and T4. See Figure 2.

Findings from per-protocol analyses, presented in an online supplemental file, demonstrated larger effects on psychological outcomes, with EMPOWER resulting in large effects on pre-loss grief intensity, experiential avoidance, and decisional regret at T3 and T4 and medium effects on posttraumatic stress symptoms at T3 and T4.

In addition to improvements in psychological outcomes, we also found that, compared to those who received EUC, surrogates who received EMPOWER also reported greater overall satisfaction with the critical care received ($d$=0.27, small effect). See Table 5.

**Discussion**

This pilot clinical trial examined the feasibility, acceptability, and preliminary efficacy of an ultra-brief psychological intervention, EMPOWER, on reducing distress and preventing its exacerbation among surrogate decision-makers of critically ill pediatric and adult patients admitted to the ICU. EMPOWER is ultra-brief (25) and modular, flexibly designed to deliver evidence-based approaches to reduce short-term traumatic stress, grief, decisional regret, depression, and anxiety and to prevent poor psychological outcomes in the longer-term. This pilot study demonstrated the feasibility of delivering the EMPOWER intervention, with most participants completing all 6 modules and 2 booster calls, surpassing our feasibility target. There were expected challenges to enrollment and retention given the ICU circumstances and onset of

the COVID-19 pandemic mid-study, but the 23% refusal rate was in fact lower than other surrogate and palliative care caregiver intervention trials (16, 17, 20). Still, given the challenges we observed with attrition, it is important to note feasibility difficulties inherent to conducting research in the ICU and plan future studies accordingly.

Acceptability of EMPOWER was strong, with high satisfaction and helpfulness ratings. This trial also suggested the promise of EMPOWER for reducing short-term psychological distress and preventing poor outcomes in surrogate decision makers. Through conservative ITT analyses, we observed decreases in the primary outcome of peritraumatic distress and several secondary outcomes, including pre-loss grief, posttraumatic stress symptoms, experiential avoidance, depression, and anxiety. Some effects increased in magnitude over time, reflecting not only improvements among those randomized to EMPOWER, but, importantly, the worsening of symptoms among those who received EUC. These effects, several of which were larger in the per-protocol analyses, are notable given that the main intervention is administered in only 1.5 to 2 hours of intervention over approximately 1 to 3 weeks. It is further notable that several surrogates in both randomized groups became bereaved during the follow-up period, which would be expected to intensify their distress given the effects of acute grief as well as the increased risk of mental health challenges among bereaved surrogates (2, 3). Still, EMPOWER appeared to improve surrogates' overall psychological functioning as compared to EUC.

EMPOWER does not aim to eliminate traumatic stress, grief, and anxiety symptoms, as these are normal and expected reactions to the immense challenges surrogates face. By empowering surrogates to tolerate and respond to challenging emotions and thoughts and increasing their sense of self-efficacy, the intervention mitigates the intensity of these reactions over time. Indeed, experiential avoidance is believed to play a role in the etiology of several

mental health challenges, including PTSD, Prolonged Grief Disorder, depression, and anxiety symptoms (30, 31, 58-60). We hypothesize that reducing experiential avoidance may drive the observed benefits across psychological outcomes.

The psychological benefits of EMPOWER may also explain the effects on surrogates' increased satisfaction with critical care. Surrogates who received EMPOWER provided higher ratings of critical care clinicians' ability to treat them with dignity, greater help with making medical decisions, lesser pressure to sign a DNR, and lower clinical insensitivity. The ability to cope better with the vast array of challenging emotions surrogates commonly experience may have improved their perceptions of the care the patients received.

EMPOWER has several design features that may have contributed to its likelihood of success. Importantly, it targets surrogates who are anxious and/or emotionally dependent on the patient, thus placing them at heightened risk of PTSD, Prolonged Grief Disorder, and other adverse longer-term psychological outcomes (21, 22, 48, 61), which the majority of prior trials of surrogate interventions did not do (14-20). Our focus on those who are most distressed by the ICU experience and loss of the patient is a key distinction. In addition, EMPOWER is theoretically-based, targeting experiential avoidance, a validated correlate of PTSD, Prolonged Grief Disorder, depression, and anxiety. It also uses evidence-based cognitive-behavioral and acceptance-based approaches delivered by mental health clinicians, distinguishing it from several interventions that have not observed strong effects on psychological outcomes (14-20). Its focus on grief (including pre-loss grief) and the intrapsychic plight of the surrogate distinguishes EMPOWER from another promising dyadic intervention that focuses on how patients with acute neurological injuries, who are likely to survive, can cope effectively with distress together with their caregivers post-ICU discharge (62). Another strength is that EMPOWER is flexibly-

delivered so that it can be adapted to surrogates' dynamic needs in the hectic ICU setting. Finally, EMPOWER was developed and refined using stakeholder feedback to optimize its acceptability and fit for surrogates' specific needs (26).

**Study Limitations**

There were several methodological limitations inherent to this pilot intervention research, including a small sample size, focus on a single metropolitan area, and disruption in randomization because of the COVID-19 pandemic. Due to the small sample size and limited number of interventionists who delivered EMPOWER, we opted against using hierarchical linear modeling as initially planned (27). Our use of effect sizes was, however, deemed appropriate for this pilot trial (55, 63). Jakobsen et al. (55) suggested considering these results hypothesis generating and noted the importance of highlighting the limitations of interpreting results when large proportions of data are missing, as we observed when randomized participants dropped out at successive post-intervention time points. The attrition observed prior to completion of T1 and over time was likely due to the challenges of completing the study assessments during such an unpredictable and stressful time rather than drop-out due to the EMPOWER intervention itself, as 89% of participants randomized to EMPOWER completed all 6 modules, and 68% completed both booster calls. Notably, however, there were no statistically significant differences in baseline psychological outcomes between those who completed T4 assessments and those who did not ($p > .10$). Still, those who enrolled and completed follow-up assessments may have been more responsive to intervention, biasing the results in EMPOWER's favor. We acknowledge missing data represents a meaningful limitation. While we feature ITT results to be conservative in our report, results should be interpreted with caution. Also, blinding was not possible, and assessments were self-report, which may have introduced response biases. Because of

unpredictable challenges inherent to the critical care setting, there was substantial variability in time between T1 to T2 assessments, with greater delays in completion of T2 among those randomized to EMPOWER as compared to EUC. Variability in the timing of patients' deaths limited our ability to examine EMPOWER's effects on Prolonged Grief Disorder symptoms in bereaved participants.

Additionally, those who enrolled in the study may have been self-selecting and more likely to benefit from support, especially during peaks of the COVID-19 pandemic when a single-arm design was used. Given that we were unable to determine the reasons that the majority of surrogates approached did not enroll, including when the patient died or was discharged prior to surrogate consent, our ability to uncover other biases impacting our findings is limited. Because of limited statistical power, we are unable to determine which components of EMPOWER were most effective, including the relative effects of the booster calls. Future research with proper designs will allow this. Finally, this study was undertaken in the United States, guided by American models of care that would allow for a professional with training in mental health to deliver EMPOWER in the ICU.

**Conclusions**

EMPOWER appears to be a feasible and acceptable intervention that showed promise in reducing surrogates' psychological distress in the short-term and preventing it in the longer-term. EMPOWER has the potential to be highly scalable in ICU settings, requiring brief training of staff mental health clinicians, such as critical care social workers. Findings from this pilot are considered hypothesis generating (55); future research should examine efficacy of EMPOWER in a well-powered RCT that focuses on minimizing attrition and missing data. Such efforts with improved retention strategies are currently underway. We plan on further examining experiential

avoidance as a mediator of intervention effects. We will also explore facilitators and barriers to dissemination and implementation of EMPOWER in critical care settings, considering how it may be integrated with ICU bereavement services (64). Cultural adaptations of EMPOWER should be developed, such as the adaptation for Spanish-speaking Latine caregivers that is currently being evaluated (65). Future studies may also examine the impact of EMPOWER on patient care, as addressing surrogate distress may not only offer support to caregivers, but it may also help "empower" the critical care team.

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**Table 1.** Measure Descriptions

| Measure | Timepoints | Description |
|---|---|---|
| Peritraumatic Distress Inventory (PDI) – ICU Version (45) | T1, T2 | 13-item instrument, scored from 0 to 5, measuring emotional, cognitive, and physical responses in the immediate aftermath of a trauma, modified to refer to the patient's ICU stay as the traumatic event and the past two days as the time frame. Scores range from 0 to 52, with higher scores indicating greater peritraumatic stress. |
| Caregiving Self-Efficacy Scale-8 (CSES-8) - ICU Version (52) | T1, T2 | 8-item instrument, with items scored on a 1-4 scale, measuring self-perceived caregiving confidence and coping ability. Total scores range from 8 to 32, with higher scores indicating greater self-perceived caregiving efficacy. |
| Impact of Events Scale – Revised (IES-R) (46) | T1, T2, T3, T4 | 22-item instrument, scored on a 0-4 Likert scale, measuring symptoms of Post-Traumatic Stress Disorder (PTSD), including intrusion and avoidance symptoms. Total scores range from 0 to 88, with higher scores indicating greater symptoms of PTSD. |
| Brief Experiential Avoidance Questionnaire (BEAQ) (29) | T1, T2, T3, T4 | 15-item instrument with items scored on a 1-4 Likert scale. Indexes the tendency to avoid unpleasant thoughts and emotions. Total scores can range from 15 to 90, with higher scores representing greater report of experiential avoidance. |
| Prolonged Grief-12 (PG-12) (47, 48) | T1; patient vital status-dependent at T2, T3, T4 | 14-item instrument measuring pre-loss grief intensity, with items scaled on a 1-5 Likert scale. Adapted from the Prolonged Grief-13 questionnaire (PG-13), a measure of Prolonged Grief Disorder symptoms. Total scores range from 14 to 70, with higher scores indicating greater pre-loss grief intensity. |
| Decision Regret Scale (DRS) (49) | T1, T2, T3, T4 | 5-item instrument, scored on a 1-5 Likert scale, measuring regret over treatment decisions made by caregivers. Total scores range from 5 to 25, with higher scores indicating greater regret. |
| State Trait Anxiety Inventory (STAI) (50) | T1, T2, T3, T4 | 20-item instrument measuring symptoms of generalized anxiety disorder, with items scored on a 1-4 scale. Total scores range from 20 to 80, with higher scores indicating greater anxiety. |
| Patient Health Questionnaire–9 (PHQ-9) (51) | T1, T3, T4 | 9-item instrument measuring depressive symptoms, with items scored from 0 to 3. Total scores range from 0 to 27, with higher scores indicating greater severity of depressive symptoms. |
| Critical Care Family Satisfaction Survey (CCFSS) – ICU Version (53) | T3 | 12-item instrument, with items scored on a 1-5 Likert scale, adapted for the ICU from a scale developed by Wasser and Matchett (53). Total scores range from 12 to 60, with higher scores indicating greater satisfaction. |

**NOTE:** T1 = pre-intervention for EMPOWER participants and baseline for EUC participants. T2 = immediately following completion of the 6 main modules for EMPOWER participants and 2-3 weeks after T1 for EUC participants. T3 = 1 month after completion of T2. T4 = 3 months after completion of T2.

**Table 2.** Background Characteristics of Surrogate Decision-Makers and Their Associated Patients and Comparisons by Trial Arm

| | All Participants [Valid N] | EMPOWER [Valid N] | Usual Care [Valid N] | *p-value* |
|---|---|---|---|---|
| Age - Mean (SD) | 45.3 (12.5) [58] | 42.8 (10.1) [41] | 51.4 (15.7) [17] | **0.015** |
| Patient Age - Mean (SD) | 41.3 (30.1) [53] | 40.3 (28.8) [40] | 44.5 (34.7) [13] | 0.662 |
| Surrogate Gender | | | | |
| Male % | 25.0% [15] | 25.6% [11] | 23.5% [4] | 0.869 |
| Female % | 75.0% [45] | 74.4% [32] | 76.5% [13] | |
| Patient Gender | | | | |
| Male % | 38.6% [22] | 30.2% [13] | 64.3% [9] | **0.023** |
| Female % | 61.4% [35] | 69.8% [30] | 35.7% [5] | |
| Surrogate Race/Ethnicity | | | | |
| White Non-Hispanic % | 45.2% [28] | 44.4% [20] | 47.1% [8] | 0.816 |
| Hispanic % | 25.8% [16] | 26.7% [12] | 23.5% [4] | |
| Black Non-Hispanic % | 16.1% [10] | 17.8% [8] | 11.8% [2] | |
| Asian % | 11.3% [7] | 8.9% [4] | 17.6% [3] | |
| Missing/Refused % | 1.5% [1] | 2.2% [1] | 0.0% [0] | |
| Patient Race/Ethnicity | | | | |
| White Non-Hispanic % | 36.5% [19] | 37.5% [15] | 33.3% [4] | 0.191 |
| Hispanic % | 19.2% [10] | 22.5% [9] | 8.3% [1] | |
| Black Non-Hispanic % | 13.5% [7] | 15.0% [6] | 8.3% [1] | |
| Asian % | 5.8% [3] | 7.5% [3] | 0.0% [0] | |
| Missing/Refused % | 25.0% [13] | 17.5% [7] | 50.0% [6] | |
| Surrogate Education | | | | |
| Less than High School % | 6.5% [4] | 6.7% [3] | 5.9% [1] | 0.266 |
| High School Graduate % | 16.1% [10] | 17.8% [8] | 11.8% [2] | |
| Some College % | 9.7% [6] | 4.4% [2] | 23.5% [4] | |
| College Graduate % | 21.0% [13] | 22.2% [10] | 17.6% [3] | |
| Graduate Degree % | 46.8% [29] | 48.9% [22] | 41.2% [7] | |
| Surrogate Religion | | | | |
| Christian % | 54.1% [33] | 44.4% [20] | 81.2% [13] | 0.061 |
| Jewish % | 16.4% [10] | 20.0% [9] | 6.2% [1] | |
| Muslim % | 4.9% [3] | 4.4% [2] | 6.2% [1] | |
| Other % | 24.6% [15] | 31.1% [14] | 6.2% [1] | |
| Surrogate Marital Status | | | | |
| Married | 67.8% [40] | 70.0% [28] | 80.0% [12] | 0.377 |
| Unmarried | 27.1% [16] | 31.8% [14] | 13.3% [2] | |
| Separated | 6.7% [1] | 4.5% [2] | 6.7% [1] | |
| Surrogate Relationship to Patient | | | | |
| Parent | 46.6% [27] | 43.9% [18] | 52.9% [9] | 0.200 |
| Adult Child | 27.6% [16] | 34.1% [14] | 11.8% [2] | |
| Spouse/Partner | 25.9% [15] | 22.0% [9] | 35.3% [6] | |
| Patient Place of Death | | | | |
| Hospital % | 40.5% [15] | 38.5% [10] | 45.5% [5] | 0.919 |
| Died Following Discharge % | 10.8% [4] | 11.5% [3] | 9.1% [1] | |

| | | | | |
|---|---|---|---|---|
| Still Alive Following T4 % | 48.6% [18] | 50.0% [13] | 45.5% [5] | |
| Patient ICU Length of Stay | | | | |
| Number of Days - Mean (SD) | 24.3 (21.0) [37] | 25.5 (21.0) [26] | 21.5 (21.8) [11] | **0.008** |
| Patient with Active Cancer | | | | |
| Yes % | 43.2% [16] | 46.2% [12] | 36.4% [4] | 0.583 |
| No % | 56.8% [21] | 53.8% [14] | 63.6% [7] | |
| Patient Receiving Chemotherapy[a] | | | | |
| Yes % | 62.5% [10] | 66.7% [8] | 50.0% [2] | 0.551 |
| No % | 37.5% [6] | 33.3% [4] | 50.0% [2] | |
| Patient Had Palliative Care Consult | | | | |
| Yes % | 28.6% [10] | 24.0% [6] | 40.0% [4] | 0.594 |
| No % | 71.4% [25] | 76.0% [19] | 60.0% [6] | |

**NOTE:** ICU = intensive care unit. SD = standard deviation. A small number of trial participants were missing information on demographic variables. While there were significant differences in surrogate age, patient gender, and ICU length of stay in the EMPOWER and EUC groups, these variables and receipt of palliative care consults were not significantly associated with psychological outcomes ($p > .05$) and thus were not adjusted for in subsequent analyses given limited statistical power. [a] Among active cancer patients.

**Table 3.** EMPOWER Program Evaluation Ratings Using an Intent-to-Treat Analytic Approach

| EMPOWER Program and Service Evaluation Items | EMPOWER Participants M (SD) [N] or % [N] |
|---|---|
| Average Service Evaluation Item Score (7 items; Range 1-5) | |
| I am glad I received EMPOWER | 4.33 (0.89) [43] |
| Participating in EMPOWER was burdensome * | 4.23 (1.21) [43] |
| EMPOWER was helpful | 4.12 (1.05) [43] |
| I felt confident I could engage in EMPOWER | 4.33 (0.84) [43] |
| Information from EMPOWER was clear/understandable | 4.58 (0.76) [43] |
| It was emotionally difficult to participate in EMPOWER* | 3.81 (1.16) [43] |
| The benefits of participating in EMPOWER outweighed the costs | 4.05 (1.40) [43] |
| Overall Program Satisfaction (range 1-5) | 4.53 (0.85) [43] |
| How would you rate the length of the EMPOWER intervention? (% Rating "Just Right") | 79.1% [34 of 43] |
| How would you have preferred to receive EMPOWER? (% Preferring "Multiple Sessions") | 79.1% [34 of 43] |

**NOTE:** * These items were reverse coded so that higher scores indicate higher service evaluation ratings; multiple imputation by chained equations was used to fill in missing values for EMPOWER participants without follow-up data.

**Table 4.** Comparisons of Study Outcomes by Study Arm and Time Point Using an Intent-to-Treat Analytic Approach

| Outcome | Pre-Intervention Time 1 M (95% CI) [N] | Post-Intervention Time 2 M (95% CI) [N] | T2-T1 Cohen's *d* | One Month Time 3 M (95% CI) [N] | T3-T1 Cohen's *d* | Three Months Time 4 M (95% CI) [N] | T4-T1 Cohen's *d* |
|---|---|---|---|---|---|---|---|
| PDI | | | | | | | |
| EMPOWER | 14.6 (12.4-16.8) [43] | 13.0 (9.9-16.0) [43] | -0.205[a] | | | | |
| Usual Care | 14.2 (10.2-18.3) [17] | 14.4 (9.2-19.5) [17] | | | | | |
| IES-R | | | | | | | |
| EMPOWER | 29.9 (25.2-34.5) [43] | 23.1 (17.7-28.5) [43] | -0.503 | 24.3 (18.3-30.2) [43] | -0.579 | 16.0 (12.1-19.8) [43] | -0.741 |
| Usual Care | 24.6 (15.5-33.8) [17] | 25.8 (16.7-34.9) [17] | | 29.8 (21.0-38.7) [17] | * | 22.1 (14.5-29.6) [17] | * |
| PG-12 | | | | | | | |
| EMPOWER | 29.1 (26.4-31.8) [43] | 25.7 (22.8-28.6) [43] | -0.523 | 24.2 (22.1-26.4) [43] | -0.722 | 20.3 (17.8-22.9) [43] | -0.700 |
| Usual Care | 24.8 (20.5-29.2) [17] | 25.4 (20.9-29.0) [17] | | 26.5 (21.9-31.2) [17] | * | 23.0 (19.3-26.7) [17] | * |
| BEAQ | | | | | | | |
| EMPOWER | 44.7 (40.3-49.1) [43] | 42.2 (38.2-46.3) [43] | 0.183 | 43.3 (39.0-47.7) [43] | -0.358 | 43.2 (39.0-47.4) [43] | -0.462 |
| Usual Care | 44.5 (40.2-48.9) [17] | 40.7 (34.7-46.7) [17] | | 48.2 (43.2-53.3) [17] | | 48.2 (41.1-55.3) [17] | |
| DRS | | | | | | | |
| EMPOWER | 17.2 (10.3-24.1) [43] | 20.5 (15.3-25.6) [43] | 0.270 | 24.3 (19.1-29.5) [43] | 0.315 | 19.1 (14.2-23.9) [43] | -0.070 |
| Usual Care | 19.4 (8.0-30.8) [17] | 15.3 (5.7-24.9) [17] | | 18.5 (8.7-28.4) [17] | | 22.6 (13.7-31.6) [17] | |
| PHQ-9 | | | | | | | |
| EMPOWER | 8.9 (6.7-10.4) [43] | | | 6.9 (5.9-12.5) [43] | -0.623 | 7.6 (5.6-9.6) [43] | -0.337 |
| Usual Care | 6.8 (4.3-9.2) [17] | | | 9.2 (5.9-12.5) [17] | * | 8.2 (5.4-11.1) [17] | |
| STAI (State) | | | | | | | |
| EMPOWER | 40.6 (38.3-42.9) [43] | 37.0 (34.5-39.6) [32] | -0.270 | 36.2 (32.9-38.5) [43] | -0.131 | 35.2 (32.3-38.1) [43] | 0.150 |
| Usual Care | 38.8 (35.4-42.3) [17] | 37.4 (33.4-41.3) [17] | | 35.4 (32.1-38.7) [17] | | 32.2 (28.1-36.4) [17] | |
| CSE | | | | | | | |
| EMPOWER | 28.2 (27.1-29.3) [43] | 26.8 (25.3-28.3) [43] | 0.578 | | | | |
| Usual Care | 28.8 (26.9-30.7) [17] | 25.4 (23.3-27.5) [17] | * | | | | |

**NOTE:** * statistically significant ($p<0.05$) difference-in-difference in group means across time points (two-sample *t* test). PDI=Peritraumatic Distress Inventory. [a] PDI only examined at T1 and T2 because peritraumatic symptoms are assessed during the potential traumatic experience rather than following the experience. IES-R=Impact of Event Scale-Revised. PG-12=Prolonged Grief-12. BEAQ=Brief Experiential Avoidance Questionnaire. DRS=Decision Regret Scale. PHQ-9=Patient Health Questionnaire-9. STAI State=State-Trait Anxiety Inventory State Subscale. CSE=Caregiving Self-Efficacy Scale. Calculations used an intent-to-treat approach using multiple imputation by chained equations to impute missing data for participants at follow-up time points.

**Table 5.** Comparison of Post-Intervention Critical Care Family Satisfaction Survey Items (Time 3; Intention-to-Treat)

| Critical Care Family Satisfaction Survey (CCFSS) Items | EMPOWER M (SD) [n] | Enhanced Usual Care M (SD) [n] | *p* [Cohen's *d*] |
|---|---|---|---|
| Family Satisfaction Overall Score (12 items; range 1-5) | 4.2 (0.7) [43] | 4.0 (0.7) [17] | 0.348 [**0.271**] |
| Support and encouragement given to me | 4.3 (1.1) [43] | 4.2 (0.8) [17] | 0.946 [0.020] |
| Help with making medical decisions for the patient | 4.1 (1.1) [43] | 3.7 (1.0) [17] | 0.346 [**0.233**] |
| Help with understanding pros and cons of treatment options | 4.1 (0.9) [43] | 3.9 (0.8) [17] | 0.400 [**0.244**] |
| Help in planning ahead | 3.6 (1.3) [43] | 3.6 (1.1) [17] | 0.932 [-0.025] |
| Unhelpful in answering my questions * | 4.1 (1.3) [43] | 3.9 (1.4) [17] | 0.614 [0.145] |
| Made me feel unwelcome * | 4.5 (1.0) [43] | 4.5 (0.7) [17] | 0.874 [0.046] |
| Pressuring me to sign a DNR order * | 4.0 (1.3) [43] | 3.6 (1.7) [17] | 0.259 [**0.327**] |
| Explained why they wanted me to sign a DNR order | 2.8 (1.3) [43] | 2.5 (1.5) [17] | 0.467 [**0.210**] |
| Seemed insensitive to me * | 4.4 (1.0) [43] | 4.0 (1.3) [17] | 0.229 [**0.349**] |
| Seemed insensitive to the patient's suffering * | 4.6 (0.8) [43] | 4.4 (0.7) [17] | 0.459 [**0.214**] |
| Treated me with dignity | 4.6 (0.8) [43] | 4.1 (1.3) [17] | 0.100 [**0.480**] |
| Treated the patient with dignity | 4.4 (0.9) [43] | 4.6 (0.6) [17] | 0.534 [-0.179] |

**NOTE:** The CCFSS was administered at T3. Classification and regression trees (CART) methods were used to impute missing responses for study participants with missing data; * items were reverse coded so that higher values indicate greater levels of satisfaction with critical care. Bolded Cohen's *d* statistics reflect at least small positive effects of EMPOWER.

**Figure 1.** Consolidated Standards of Reporting Trials (CONSORT) diagram of participant flow.

EMPOWER FOR SURROGATES OF CRITICALLY ILL PATIENTS

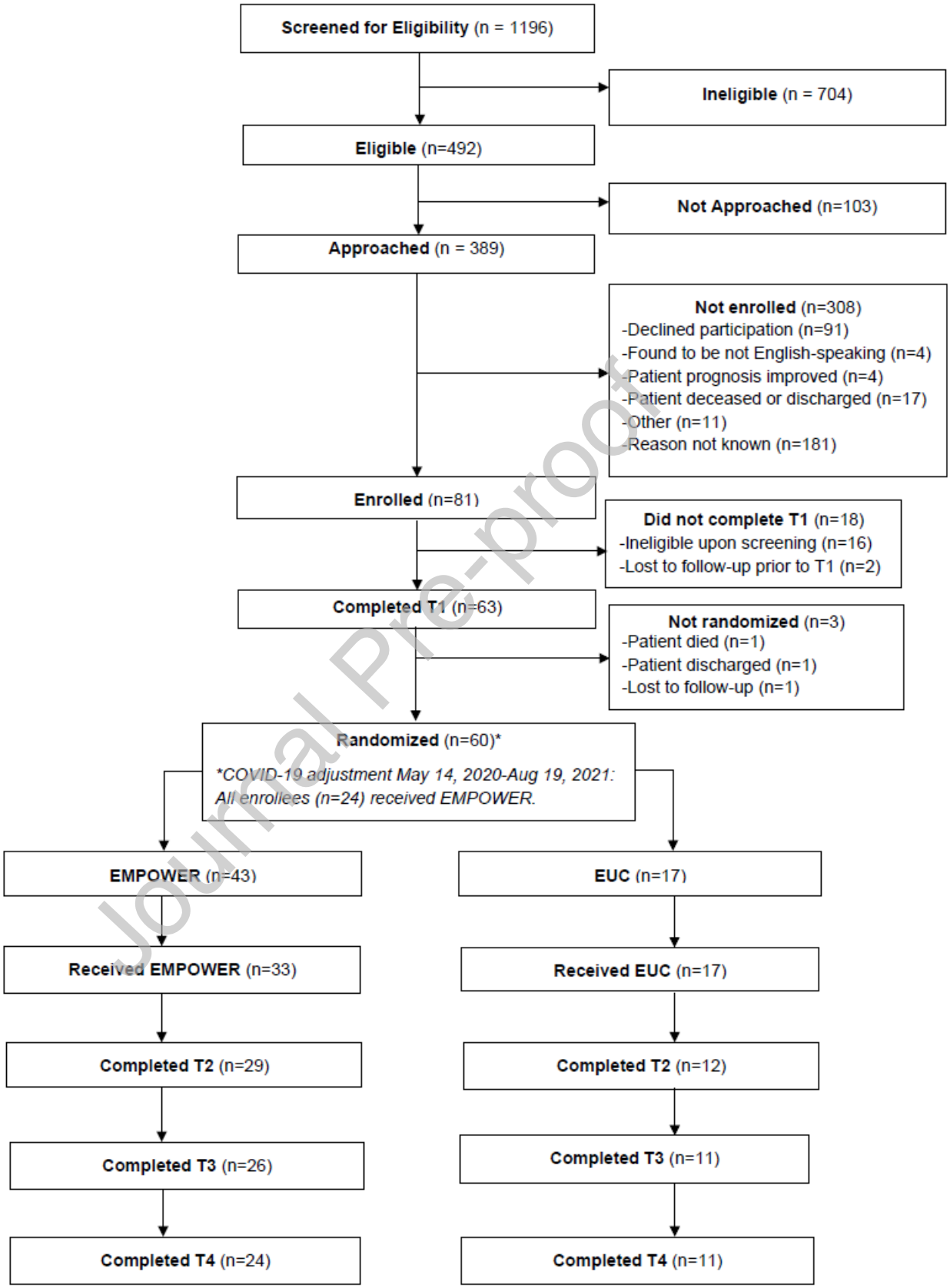
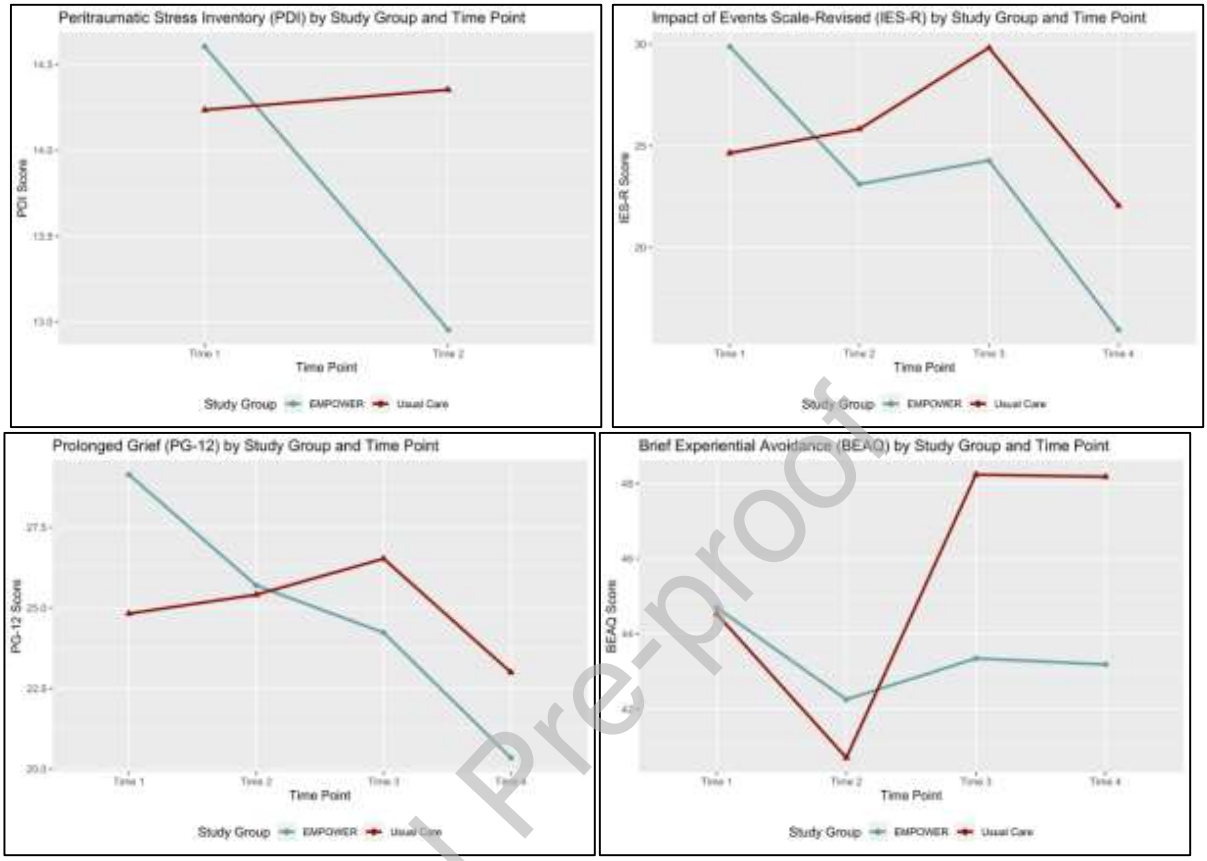
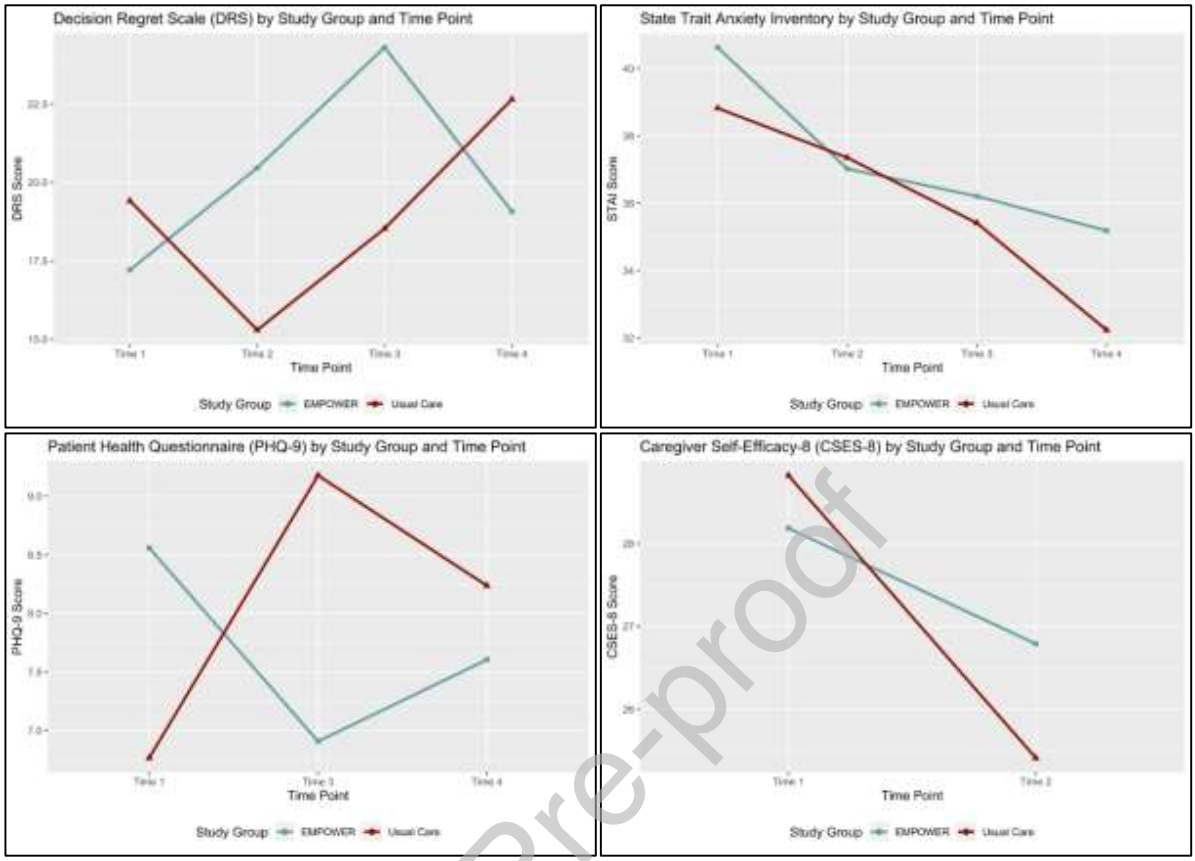


**Figure 2.** Plots of Mean Changes in Outcome Measures by Study Group Using an Intent-to-Treat Analytic Approach






**NOTE:** PDI=Peritraumatic Distress Inventory. IES-R=Impact of Event Scale-Revised. PG-12=Prolonged Grief-12. BEAQ=Brief Experiential Avoidance Questionnaire. DRS=Decision Regret Scale. PHQ-9=Patient Health Questionnaire-9. STAI State=State-Trait Anxiety Inventory State Subscale. CSE=Caregiving Self-Efficacy Scale. Calculations used an intent-to-treat approach using multiple imputation by chained equations to impute missing data for participants at follow-up time points.

## Supplemental Files

**Supplemental Table 1.** Enrollment According to Changes in Study Methods

| Enrollment Period | Number of Participants | Monthly Recruitment Rate |
|---|---|---|
| Pre-COVID RCT (March 2019 – May 2020) | 19 | 1.2 |
| Peri-COVID Single Arm Trial (May 2020 – August 2021) | 32 | 2.1 |
| Post-COVID RCT (August 2021- June 2022) | 30 | 3.0 |

**NOTE:** RCT = randomized controlled trial. Three phases are reported in the clinicaltrials.gov registration for this study: a pre-pilot trial phase, a manual refinement phase, and a pilot RCT phase. The first participant in the pre-pilot trial phase was enrolled on July 12, 2017. The first participant in pilot RCT phase reported in this paper was enrolled March 14, 2019 (thus, the date of enrollment of the first participant in the pilot RCT was after registration of the RCT in clinicaltrials.gov). The enrollment period reported in this table were all part of the pilot RCT phase.

**Supplemental Table 2.** EMPOWER Program Evaluation Ratings Using a Per-Protocol Analytic Approach

| EMPOWER Program and Service Evaluation Items | EMPOWER Participants M (SD) [N] or % [N] |
|---|---|
| Average Service Evaluation Item Score (7 items; Range 1-5) | 4.23 (0.63) [28] |
| I am glad I received EMPOWER | 4.43 (0.84) [28] |
| Participating in EMPOWER was burdensome * | 4.29 (1.18) [28] |
| EMPOWER was helpful | 4.18 (1.09) [28] |
| I felt confident I could engage in EMPOWER | 4.29 (0.98) [28] |
| Information from EMPOWER was clear/understandable | 4.54 (0.88) [28] |
| It was emotionally difficult to participate in EMPOWER* | 3.75 (1.21) [28] |
| The benefits of participating in EMPOWER outweighed the costs | 4.14 (1.27) [28] |
| Overall Program Satisfaction (range 1-5) | 4.46 (0.92) [28] |
| How would you rate the length of the EMPOWER intervention? (% Rating "Just Right") | 82.1% [23] |
| How would you have preferred to receive EMPOWER? (% Preferring "Multiple Sessions") | 75.0% [21] |

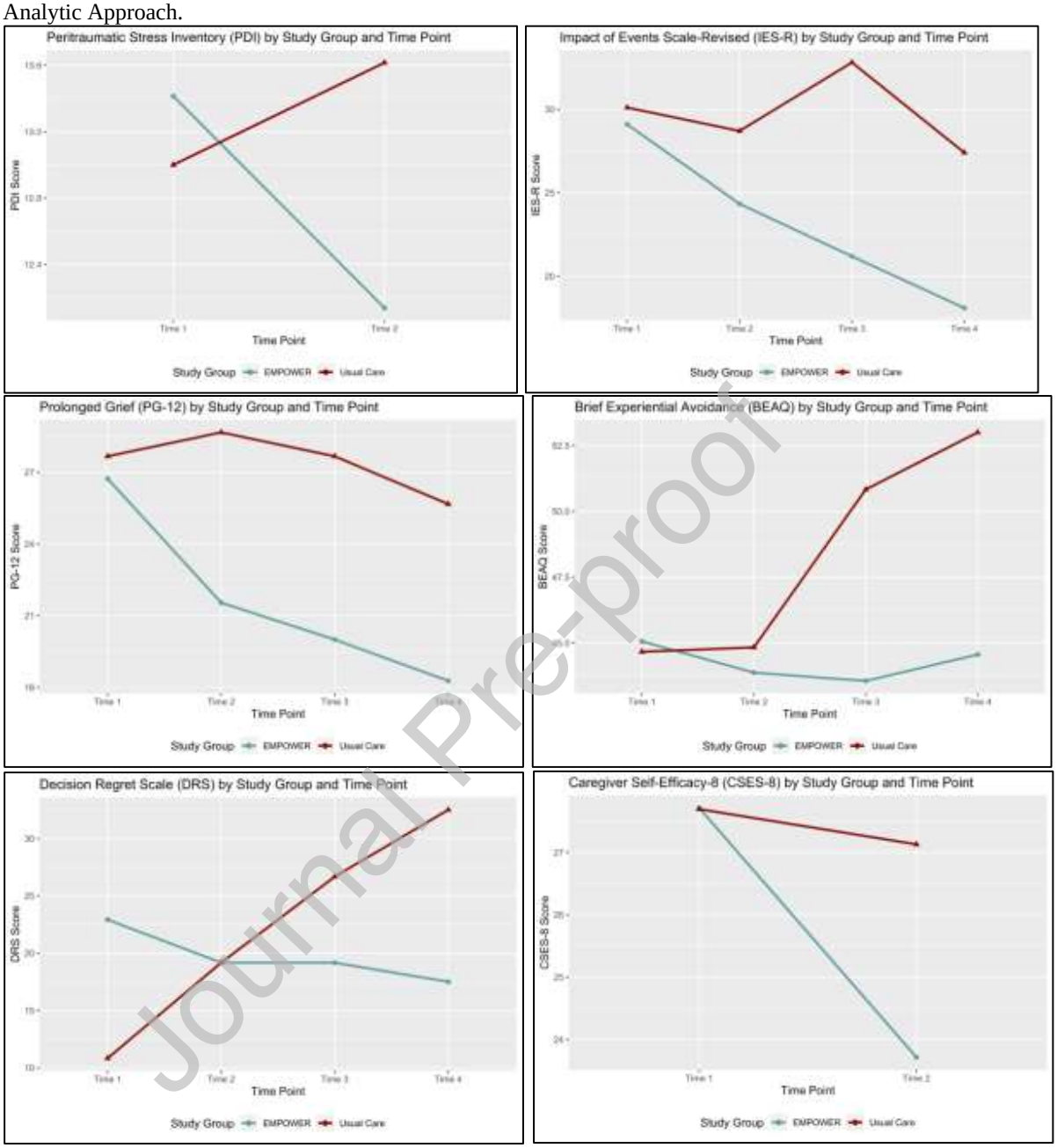
**NOTE:** * These items were reverse coded so that higher scores indicate higher service evaluation ratings. Multiple imputation by chained equations to impute values for a small number of missing responses to individual assessment items. The analytic sample included 28 study participants randomized to EMPOWER who completed both Time 1 and Time 2 assessments (per protocol).

**Supplemental Table 3.** Comparisons of Study Outcomes by Study Arm and Time Point Using a Per-Protocol Analytic Approach

| Outcome | Pre-Intervention Time 1 M (95% CI) [N] | Post-Intervention Time 2 M (95% CI) [N] | T2-T1 Cohen's *d* | One Month Time 3 M (95% CI) [N] | T3-T1 Cohen's *d* | Three Months Time 4 M (95% CI) [N] | T4-T1 Cohen's *d* |
|---|---|---|---|---|---|---|---|
| PDI | | | | | | | |
| EMPOWER | 13.4 (10.6-16.3) [29] | 12.1 (8.4-15.9) [13] | -0.258 | | | | |
| Usual Care | 13.0 (8.5-17.5) [13] | 13.6 (8.2-19.0) [13] | | | | | |
| IES-R | | | | | | | |
| EMPOWER | 29.1 (20.9-37.3) [21] | 24.3 (15.5-33.1) [21] | -0.235 | 21.2 (12.4-29.9) [21] | -0.615 | 18.1 (11.1-25.0) [21] | -0.478 |
| Usual Care | 30.1 (16.5-43.7) [10] | 28.7 (16.2-41.2) [10] | | 32.8 (19.7-45.9) [10] | | 27.4 (15.9-38.9) [10] | |
| PG-12 | | | | | | | |
| EMPOWER | 26.7 (20.7-32.8) [11] | 21.5 (15.3-27.8) [11] | -1.379 | 20.0 (17.0-38.3) [11] | -1.138 | 18.3 (12.8-23.7) [11] | -0.809 |
| Usual Care | 27.7 (19.4-35.9) [6] | 28.7 (20.2-37.1) [6] | * | 27.7 (17.1-38.3) [6] | * | 25.7 (15.5-35.9) [6] | |
| BEAQ | | | | | | | |
| EMPOWER | 45.1 (37.5-52.6) [16] | 43.9 (35.5-52.3) [16] | -0.169 | 43.6 (35.7-51.4) [16] | -1.004 | 44.6 (36.6-52.5) [16] | -0.974 |
| Usual Care | 44.7 (33.3-56.0) [6] | 44.8 (34.2-55.4) [6] | | 50.8 (41.5-60.2) [6] | * | 53.0 (42.8-63.2) [6] | |
| DRS | | | | | | | |
| EMPOWER | 22.9 (11.5-34.4) [12] | 19.2 (7.8-30.5) [12] | -0.801 | 19.2 (9.4-28.9) [12] | -1.258 | 17.5 (6.5-28.5) [12] | -2.063 |
| Usual Care | 10.8 (-1.3-23.0) [6] | 19.2 (-3.9-42.3) [6] | | 26.7 (1.0-52.3) [6] | * | 32.5 (12.9-52.1) [6] | * |
| PHQ-9 | | | | | | | |
| EMPOWER | 10.2 (7.1-13.2) [17] | | | 7.6 (4.1-11.0) [17] | -0.640 | 6.5 (3.5-9.6) [17] | -0.188 |
| Usual Care | 10.5 (5.7-15.3) [6] | | | 11.8 (4.5-19.2) [6] | | 8.0 (2.4-13.6) [6] | |
| STAI State | | | | | | | |
| EMPOWER | 40.6 (36.8-44.4) [21] | 37.0 (32.3-41.7) [21] | -0.136 | 35.4 (30.8-39.9) [21] | -0.156 | 34.3 (29.6-39.0) [21] | -0.160 |
| Usual Care | 40.2 (34.8-45.6) [10] | 37.7 (31.8-43.6) [10] | | 36.2 (30.8-41.5) [10] | | 35.3 (29.4-41.2) [10] | |
| CSES-8 | | | | | | | |
| EMPOWER | 27.7 (26.1-29.3) [23] | 27.1 (26.4-28.9) [23] | 1.356 | | | | |
| Usual Care | 27.7 (23.8-31.7) [7] | 23.7 (19.2-28.3) [7] | * | | | | |

**NOTE:** * significant ($p<0.05$) difference-in-difference in group means across time points (two-sample *t* test); the analytic sample was restricted to participants with complete data at all relevant time points for the reported measure. PDI=Peritraumatic Distress Inventory. [a] PDI only examined at T1 and T2 because peritraumatic symptoms are assessed during the potential traumatic experience rather than following the experience. IES-R=Impact of Event Scale-Revised. PG-12=Prolonged Grief-12. BEAQ=Brief Experiential Avoidance Questionnaire. DRS=Decision Regret Scale. PHQ-9=Patient Health Questionnaire-9. STAI State=State-Trait Anxiety Inventory State Subscale. CSE=Caregiving Self-Efficacy Scale. Multiple imputation by chained equations to impute values for a small number of missing responses to individual assessment items. The analytic sample included study participants who were randomized to either EMPOWER or usual care and completed assessments at Time 1 through Time 4 (per protocol).

**Supplemental Figure 1.** Plots of Mean Changes in Outcome Measures by Study Group Using a Per-protocol Analytic Approach.

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