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Care partner problem solving training (CP-PST) for care partners of adults with traumatic brain injury during inpatient rehabilitation: Study protocol for a multisite, randomized, single-blind clinical feasibility trial

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A B S T R A C T

Traumatic brain injury (TBI) often leads to immediate and chronic functional impairments that affect care partners, or those providing physical and/or emotional support to individuals with TBI. The many challenges associated with being a care partner often lead to caregiver burden and can compromise the well-being and quality of life of care partners and individuals with TBI under their care. Equipping care partners with problem-solving skills could facilitate and sustain their transition into this supportive role. Problem-solving training (PST) has demonstrated efficacy for providing such skills to care partners of individuals with TBI after discharge from inpatient rehabilitation. We propose that PST delivered to care partners during inpatient rehabilitation of individuals with TBI will provide care partners with the skills to manage their caregiving roles across the transition from hospital to home. Herein, we describe the methodology of a current randomized controlled trial that examines the feasibility and efficacy of PST plus TBI education compared to TBI education alone to improve care partner burden, emotional distress, and adaptive coping when delivered during the inpatient rehabilitation stay of individuals with moderate-severe TBI.

1. Introduction

Individuals with traumatic brain injury (TBI) often require long term support, due to chronic impairments in mobility, cognition, and emotion [1–7]. This support generally falls to care partners [1], or the unpaid individuals (spouses, family members, friends) responsible for assisting others with activities of daily living and/or medical tasks [8] or for the emotional well-being of others. Most care partners live with and provide support to their care recipient with limited or no formal care-related training [9]. Independently managing mental health, challenging behaviors, and other issues experienced by their care recipients leads to a high prevalence and degree of perceived burden, emotional distress (e.g. depression, anxiety), and/or substance abuse, negatively affecting quality of life [9–22].

Care partner burden is largely predicted by the extent to which care partners' perceived needs are met [12,23], but one study suggests that only 55% of these care partner needs are perceived as being met [24]. Interventions should address not only current needs, but also needs that may arise over time, particularly as individuals transition out of formal care settings to community living [25]. Hence, it is especially important to focus on care partner issues that arise during gaps or transitions in services [26,27]. This can be done by providing information on long-term management of TBI [28,29] and training care partners in adaptive coping skills, such as effective problem-solving [30–32]. Though care partners often report receiving sufficient education, there is limited opportunity to provide any kind of comprehensive problem-solving intervention to care partners, especially as the length of inpatient stays after TBI shorten, leaving care partners feeling largely unprepared at the time of inpatient rehabilitation discharge.

There is emerging evidence for the effectiveness of self-management interventions to improve care partner outcomes across many clinical populations, including a growing body of evidence supporting Problem

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Solving Training (PST), a self-management intervention, based in Self-Regulation Theory [33], for care partners of individuals with traumatic injuries [29–31,34–37]. During PST, individuals learn a simple and systematic method for evaluating problems, generating and selecting solutions, developing specific goals and action plans, and evaluating and revising plans, as needed. As individuals learn to set achievable goals under the coaching of a therapist, they see that problems that may have overwhelmed them are indeed solvable when approached in a stepwise, rational fashion. In one trial of PST, care partners who were provided only 3 intervention sessions of PST post-discharge, with brief telephone contact over the first year of caregiving, reported fewer depressive symptoms and more constructive problem-solving after intervention [36]. Neither the number of hours devoted to PST nor time to follow-up assessment have been associated with treatment effect sizes [34]. This suggests that individuals can incorporate the PST metacognitive strategy rapidly into daily life and that the benefits do not diminish over time. However, no studies to date have examined the feasibility or efficacy of delivery PST to care partners *prior to* discharge of the patient from inpatient rehabilitation.

We propose that PST for care partners during inpatient rehabilitation of individuals with TBI will provide care partners with the skills to manage their caregiving roles across the transition from hospital to home. To that end, the purpose of this paper is to describe the methodology of a randomized controlled trial testing the feasibility and efficacy of PST plus TBI care partner education versus TBI care partner education alone delivered during the inpatient rehabilitation stay for improving care partner burden, emotional distress, and adaptive coping.

2. Design and methods

2.1. Overview and design

The study described herein is a multi-site, block-randomized, single-blind clinical trial of PST + Education compared to Education only for care partners of adults with TBI delivered during the individual with TBI's inpatient rehabilitation stay. Our primary aim is to assess the feasibility of delivering PST during inpatient rehabilitation, characterized by feasibility of recruitment, number of sessions completed during the inpatient rehabilitation stay (primary feasibility measure), care partner satisfaction and confidence with PST (primary feasibility measure), factors associated with refusal to participate and non-compliance with the intervention, high fidelity in intervention delivery. Our secondary aim is to evaluate the efficacy of PST + Education compared to Education alone for improving care partners' caregiver burden, depressive symptoms, and coping skills at 1-month after inpatient rehabilitation discharge. We will also explore maintenance of treatment effects at 6-months post-discharge. We hypothesize that:

1. Care partners will complete at least three intervention sessions (in person or via telephone) prior to discharge from inpatient rehabilitation and will report high satisfaction and confidence with the PST Intervention.
2. PST will result in less care partner burden and fewer depressive symptoms (primary) and more adaptive coping (secondary) at one-month post-discharge, compared to Education only.
3. Effects of the PST intervention on care partner burden, depression symptoms, and coping will be maintained at 6 months post-intervention.

2.2. Overview of interventions

Education is central to supporting care partners of adults with TBI; however, education alone may be insufficient for sustained behavior modification. Self-management skills are necessary for translating knowledge into action. The core tenets of self-management, as described by Lorig and Holman, include autonomy and control; ability and responsibility; a problem solving approach that revolves around perceived needs; tailoring to readiness to learn/change and beliefs about health; and the realization that self-management always occurs whether through active management or through chosen “non-management” [38,39]. Self-management works through enhancing self-efficacy, improving an internal locus of control, and improving knowledge. Problem-solving theories, especially D'Zurilla's social problem solving model, emphasize that problem-solving is critical for effective self-management [40,41]. As individuals learn to set achievable goals under the coaching of an interventionist, they see that problems that may have overwhelmed them are indeed solvable when approached in a stepwise, rational fashion. Therefore, formal training in a simple and systematic problem-solving approach would provide the requisite skills for care partners to translate the TBI-related health education they receive into realistic and effective action after hospital discharge.

PST is a self-management technique in which individuals learn a simple and systematic method for evaluating problems, generating and selecting solutions, developing specific goals and action plans, and evaluating and revising plans, as needed [42]. Though it follows a standardized protocol, PST offers the flexibility to individualize sessions to the unique needs and goals of the participant and teaches a global strategy that can be applied to any problem the participant may select during the sessions or face in the future. All goals are self-selected by participants, maximizing the likelihood that participants will be engaged, motivated, and ready to address the chosen goals. To serve as an attentional control condition, including the same number of points of contact and reflecting intervention that is more consistent with standard of care, we developed and manualized a brief Education-only intervention. Care partners in the PST (active intervention) group receive PST training in addition to TBI care partner specific education. Participants in the Education-only (attention control) group receive TBI care partner specific education alone. Trained members of the research team with master's level education or equivalent experience provide both interventions using a specific curriculum validated in our previous research studies [9,29,31,42–44] and summarized below (see Table 1). All intervention sessions occur in-person whenever possible or over the telephone when meeting in person is not feasible. PST has been successfully delivered via both modalities, with similar effects.

The first session, to provide education and orientation to study materials, will occur in person. During this session, participants will receive a Care Partner Workbook (education) and a participant folder with materials relevant to their assigned intervention group. We deliver up to six sessions, with a target of 2–3 sessions per week, maximizing the likelihood of completing all sessions before inpatient rehabilitation discharge of the care recipient. This timeframe will also enable care partners to put their plans into action between sessions. Sessions will conclude at discharge, with the exception of completing the final session via telephone within 1 week of discharge if not completed prior to discharge (see Table 1).

2.3. CP-PST intervention (active intervention)

The PST intervention consists of six sessions (~30 min each) that follow a structured format based on the PST manual derived from the CONTACT study [42] (see Table 1). In these sessions, the interventionist will first provide the same TBI-specific care partner education (Care Partner Workbook) as the Education Group receives, introduce the participant to the PST steps and structured PST Worksheets included in the participant folder, then help the care partner generate and select a problem to address first. The interventionist then facilitates the care partner's use of the ABCDEF steps of PST (Fig. 1), using the PST Worksheets, to develop a specific action plan to solve the problem. This sequence allows for maximal individual choice within a structure that is easy to remember. As problems are attempted or solved, the care partner will learn how to perform the steps on his/her own, thus

Table 1
PST Intervention Protocol.

PST session	Content
Session 1	Education and PST Overview: Provide the Care Partner Workbook and PST folder to care partners, including a brief orientation to the contents of the workbook and folder. Introduce the care partner to the PST steps (ABCDEF – see Fig. 1) and PST Worksheet 1: Sorting out problems for CP-PST.
Session 2	Problem-generation and selection: Select the first problem to address from the generated list of potential caregiving-related problems from PST Worksheet 1: Sorting out problems for CP-PST. Apply PST steps to selected problem (ABC) using PST Worksheet 2. Determine steps to complete prior to next session (D) and criteria for evaluation (E). Criteria are based on Goal Attainment Scaling [45].
Sessions 3–5	Apply the PST steps to caregiving-related problems: Review and evaluate previous plan of action (E) and choose a new problem or change plan as appropriate (F). Continue to apply the PST steps (ABCDEF) to selected problems.
Session 6[a]	Review progress and discussion generalization: Review the problems addressed to date and the progress made. Discuss how to generalize PST to daily life, including anticipated problems that may arise post-discharge. At the end of the last session, the care partners rate how confident are they in using the PST strategy, by which session they felt confident in using the PST strategy, and how many PST sessions they would prefer.
Between sessions	Put plans into action (D): Between sessions, care partners will try selected plans for addressing selected problems. Success of these plans is reviewed at the beginning of each session (E). Noncompliance (not putting the plan into action) is discussed and plans are modified to improve compliance.

[a] If the interventionist cannot complete 6 sessions prior to discharge, this should be the content of the final session, which can be completed via telephone within 1 week following discharge.

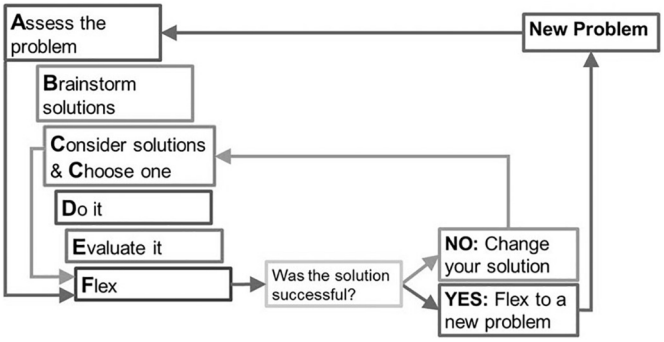

Fig. 1. Problem-Solving Training (PST) Steps.

acquiring self-management problem solving skills that will be applicable to future problems. The final session includes a review and generalization of the PST steps and progress made and focuses on successful strategies and future application to new and unexpected problems that may arise. The advantage of this model is the mastery afforded by the success of relatively independent problem solving, which may improve self-efficacy and enable care partners to become independent for future problem solving.

2.4. Education intervention (attention control)

The Education Intervention consists of six points of contact (~15 min each). During session 1, we will provide the Care Partner Workbook to participants, which we developed for a previous care partner study [31]. The workbook consists of 12 educational modules for self-study: four modules on common sequelae of TBI, five modules on issues encountered by care partners, one module on work and school concerns for individuals with TBI, and two modules on navigating the rehabilitation system and accessing resources. These modules are short, each consisting of a brief introduction, key definitions, examples, resources, and a summary. Some chapters also include self-directed activities, such as worksheets or checklists. In session 1, we provide a brief orientation to the contents of the workbook. Sessions 2–5 include open-ended questions about any need for clarification about the education material participants reviewed between sessions. Interventionists briefly summarize the content of the next three chapters, assigned as "homework" between sessions. We scripted delivery of these summaries to ensure that interventionists do not engage in active problem solving or resource facilitation with the participants. Session 6 consists of an open discussion about expected problems that may arise post-discharge and how the Care Partner Workbook can serve as a resource for participants.

2.5. Participants

Participants will be care partners of individuals with TBI in inpatient rehabilitation at three TBI Model System Centers funded by the National Institute of Disability, Independent Living, and Rehabilitation Research: North Texas TBI Model System, Northern New Jersey TBI System, and JFK Johnson Rehabilitation Institute TBI Model System. Centers will recruit care partners as close to the time of patient inpatient rehabilitation admission as possible, to maximize the number of PST sessions completed prior to discharge. Care partners of patients who may be discharged to institutional settings will also be included, as informal caregiving still occurs even when an individual is institutionalized. See Table 2 for inclusion/exclusion criteria. Recruitment will occur through flyers and physician referrals in cases where the patient with TBI is not enrolled in the TBI Model Systems study or by approaching care partners during recruitment of patients for the TBI Model Systems.

Table 2
Inclusion/Exclusion Criteria.

Inclusion criteria	Rationale
Identified as care partner	Individual (spouse, partner, family member, friend, or neighbor) involved in assisting the patient with activities of daily living and/or medical tasks or responsible in any way for the patient's well-being after discharge from inpatient rehabilitation.
≥1-year relationship	Care partners must have a pre-existing relationship with patient.
Ability to communicate in English	The PST intervention and Education are delivered in English and have not yet been translated to other languages.
≥18 years old	A legal adult who could make independent decisions and is developmentally capable of engaging in active problem solving.
Capacity to self-consent	Cognitively able to engage in problem-solving intervention.

Exclusion criteria	Rationale
Dispute over care partner's role in the care of patient	Such as dispute over the care partner's ability to participate in the care of the individual with TBI

2.6. Assessment schedule and rater training

A trained research staff, blinded to intervention allocation, will perform all assessments in person or via telephone at baseline, 1-month, and 6-months post-discharge. Blinding will be ensured by allocating to group assignment after baseline assessment is complete, having different staff performing assessments vs delivering the intervention, scheduling meetings with assessors and interventionists separately, and instructing participants to not discuss the intervention with the person calling to complete follow-up assessments.

2.7. Randomization

Participants are randomized and allocated after baseline assessment to PST + Education or Education only via stratified, blocked randomization. Randomization is stratified by participating TBIMS center and by single versus multiple care partners participating for the same patient. Of note, in the case of multiple care partners, randomization occurs at the patient level – that is, care partners associated with the same patient are allocated to the same intervention, to avoid contamination. We use a block size of four to ensure equal numbers across groups and to account for potentially small numbers of participants at any given TBIMS Center. Randomization is computer-generated and maintained by the TBI Model Systems National and Statistical Data Center. Allocation assignments for each center are accessible by each site PI and interventionists. Outcome assessors are blinded to intervention allocation.

2.8. Outcomes measures

In addition to the feasibility metrics detailed previously, we will collect data on demographic (age, gender, race, ethnicity, education), care partner relationship information (nature, duration, living status, relationship quality), and the outcomes measurements (caregiver burden and self-efficacy, emotional distress, coping skills) outlined in Table 3, in person or via telephone.

2.9. Treatment fidelity

2.9.1. Interventionist training

The study Interventionists are trained jointly in PST and Education delivery, and clinical supervisors from each site are trained in key areas to supervise and reinforce fidelity at their sites. Interventionists first watch the online PST Training video (http://www.contact4tbi.com/) and read the CP-PST Manual. Interventionists are also given resources on Motivational Interviewing, Behavioral Activation, and Goal Attainment Scaling. Training includes both didactics and practice supervised by investigators. Prior to formally starting the intervention, the study PI certifies all interventionists. The first full set of sessions with a participant undergoes fidelity assessment by the study PI. The study PI conducts fidelity assessment for 20% of ongoing sessions. Additionally, Interventionists will have an annual “refresher”, in which they will complete one full set of supervised sessions with a participant.

We will maintain intervention continuity through: 1) overlap of any outgoing and incoming personnel; 2) standardized one-to-one training via the use of printed educational materials, online videos, and an established training checklist; 3) ongoing teleconference calls among including the Interventionists and study Investigators; and 4) ongoing fidelity checks for all interventionists (10% of each interventionist's sessions per calendar year).

2.9.2. Fidelity assessment

We established guidelines and fidelity checklists to assess both treatment integrity and treatment differentiation of intervention delivery. Independent raters trained in the respective protocols will listen to audio recordings of intervention sessions and complete fidelity

Table 3
Measurement tools.

Measure	Psychometric properties
Demographics and Care Partner Relationship	Age, education, race, ethnicity, living status, duration of the relationship, quality of the relationship.
Alcohol Use Disorders Identification Test (AUDIT) [46]	The AUDIT is a 10-item screening tool for alcohol use behaviors designed by the World Health Organization to screen for alcohol abuse. The AUDIT assesses consumption, drinking behaviors, and alcohol-related problems, with a score of ≥8 indicating harmful alcohol use. Collected at baseline, with reference to alcohol use over the past year, and at 1 and 6 months post-discharge, with reference to the past month.
Brief Coping Orientation to Problems Experienced [47,48]	The Brief COPE is a shorter version of the COPE Inventory, composed of 28 items rated on 4-point ordinal scale and measuring 14 subscales of coping style. Collected at baseline, with reference to coping skills over the past year, and at 1 and 6 months post-discharge, with reference to the past month.
Patient Health Questionnaire (PHQ9) [49]	The PHQ-9 assesses the frequency over the past two weeks of each of the nine symptoms of DSM-IV-TR that define a major depressive episode. Total scores range from 0 to 27, with established interpretative symptom cut-off scores of 0–4 (none), 5–9 (mild), 10–14 (moderate), 15–19 (moderately severe), and ≥ 20 (severe). Collected at baseline, 1 month, and 6 months post-discharge, with reference to the past two weeks.
Zarit Burden Interview (ZBI) [50]	The ZBI is a self-reported measure of perceived caregiver burden, including psychological health, well-being, social and family life, finances, and perceived control. We use the 22-item version (each item scored on a 5-pt Likert Scale), because it has been found to have good internal consistency reliability ($\alpha = 0.92$) and established reference values for interpretation (mild: 2–20; mild to moderate: 21–40; moderate to severe:41–60; severe: 61–88). Collected at 1 and 6 months post-discharge.
Positive Aspects of Caregiving (PAC) [51]	The PAC is a self-reported measure of the positive aspects of providing care to a care recipient. It includes 9 items measured on an ordinal scale and resulting in a total score. Collected at 1 and 6 months post-discharge.
Caregiver Assessment of Function and Upset (CAFU) [52]	The CAFU measures care recipient dependence and caregiver upset via 15 questions related to the amount of daily care or assistance provided. Scoring follows the structure of the Function Independence Measure [53], ranging from 0 (dependent) to 7 (independent). The CAFU has seven items for activities of daily living and 8 items for instrumental activities of daily living. Collected at baseline, with reference to assistance the patient required preinjury, and at 1 and 6 months post-discharge, with reference to the past week.
Revised Scale for Caregiving Self-Efficacy (RSCSE) [54]	The RSCSE is a 15-item measure of caregiving self-efficacy that includes subscales for self-efficacy for obtaining respite, self-efficacy for responding to disruptive behaviors, and self-efficacy for controlling upsetting thoughts about caregiving. Care partners rate their confidence on each item on a 0–100 point scale. Collected at 1 and 6 months post-discharge.
Working Alliance Inventory - Client Short Form (WAI) [55]	The WAI is a 12-item measure of how a client/participant might think or feel about their therapist/interventionist. Care partners rate each item on a 7-point scale, ranging from never to always. Collected at 1 month post-discharge.
Client Satisfaction Questionnaire-8 (CSQ-8) [56]	The CSQ-8 is a frequently used measure of an individual's satisfaction with health-related services that they have received. The CSQ-8 includes 8 questions, each rated on a 4-point scale, that yield a single summed score (ranging from 8 to 32) measuring overall satisfaction. Collected at 1 month post-discharge.

assessments for 20% of sessions in each treatment group, distributed equally across interventionists. Treatment Integrity refers to both adherence to the manualized intervention protocol and to the interventionist's competence in delivering the intervention as specified.

To measure adherence, we developed a Yes/No checklist based on the components of the manualized PST intervention and characterized each component as: 1) an "Active Ingredient", indicating it was a critical/essential component to the PST intervention; 2) important to the outcome of interest, but not an "active ingredient" or essential component; or 3) part of the protocol but not likely to affect the outcome directly. When assessing adherence, raters marked items as "Yes" (present), "No" (not present but *should have been* present), or "NA" (*appropriately* not present). We calculate the total number of "Yes" indicators for factors labeled as "1 – Active Ingredient" divided by the total number of factors labeled as "1 – Active Ingredient" as a measure of overall adherence for a session.

We classify competence in intervention delivery as "High", "Medium", or "Low" for *each* component category labeled as "1 – Active Ingredient". "High" indicates that all subcomponents within that category on our fidelity checklist were addressed, that the interventionist facilitated the participant through the process > 80% of the time (vs being directive), that overall clarity of communication and rapport with the participant were high, and that the interventionist demonstrated a strong knowledge and confidence in delivering the PST intervention. A rating of High indicates exceptional competence. "Medium" indicates that most subcomponents within that category were addressed, that the interventionist facilitated (rather than directed) the participant through the process 50–80% of the time, that overall clarity of communication and rapport with the participant were sufficient, and that the interventionist demonstrated adequate knowledge and confidence in delivering the PST intervention. A rating of Medium indicates adequate competence. "Low" indicates that the interventionists omitted multiple active ingredients or multiple important components within that category, that the interventionist was directive rather than facilitating > 50% of the time, that there was lack of clarity in communication or poor rapport with the participant, and/or that the interventionist demonstrated a lack of knowledge or confidence in delivering the PST intervention. A rating of Low indicates poor or inadequate competence.

Whether or not the interventionist takes a facilitating or directive approach is considered when rating competence *only* for components marked as "1 – Active Ingredient". Interventionists who facilitate demonstrate respect for the participant's individual strengths and ability to problem-solve independently. Facilitating involves shared goal setting and decision-making, with participants taking the lead role in the process. Facilitating interventionists may use probing questions and gentle prompts to guide a participant through the problem-solving process. They allow participants to make their own decisions and their own mistakes. By contrast, directive interventionists lead the process and make the decisions. They specify the goals, solutions, and tasks. They control the process and do not allow participants to set their own goals, develop their own plans, or make their own mistakes. Directive interventionists tell participants what goals to work on and how to solve problems. They may ask questions, but the questions are not open-ended or guiding, but instead direct the participant to a specific response or make assumptions about what the interventionist believes the participant *should* do or feel.

Treatment differentiation refers to the degree to which the control/comparison intervention *did not include* components that it *should not include*. That is, did the PST Intervention differ as it should from the Education only (attention control) condition? To assess treatment differentiation, fidelity raters assess adherence of the Education only intervention to the PST fidelity checklists to determine the degree to which the Education sessions *did not include* components labeled as "active ingredients" of PST. The two interventions were considered to be differentiated if adherence ratings were significantly higher for PST sessions than for the Education sessions [57].

2.10. Power and sample size justification

We plan to enroll 172 patients (86 per group) based on data from our previous work on PST in care partners of adults with TBI:[42424242424242] Effect size (group differences in burden and depression at 1 month) of Cohen's d = 0.40; $\alpha = 0.05$, power = 80%, and attrition = 10%.

2.11. Statistical analysis plan

For our first aim, the primary outcome for feasibility is the completion of a minimum of 3 sessions of PST. We will record the number of sessions completed prior to discharge and method of completion (in person or via telephone) to inform future intervention design and descriptively present reasons for non-compliance for those allocated to a treatment group. We will divide the participants into two groups, based upon completion of < 3 sessions or ≥ 3 sessions, then compare the two groups and explore demographic or other baseline differences (e.g. in outcomes of interest, in inpatient length of stay, etc.) to identify factors associated with compliance. We will compare the level of client satisfaction (CSQ-8) with the intervention in both groups. For all group comparisons, we will use *t*-tests, Mann-Whitney *U* test, or Chi Squared tests, as appropriate.

For our second aim to assess efficacy, we will calculate measures of central tendency or numbers and percentages for all demographic baseline variables and descriptively compare PST Intervention to Education groups, to reduce the overall number of comparisons and the likelihood of a type I error. If there are group differences, we will conduct formal statistical testing (t-tests, Mann Whitney *U* tests, or Chi Square tests, as appropriate) to determine potential confounding variables resulting from initial group differences and adjust for these variables accordingly. This includes demographic factors, baseline outcome measures, and total time spent in sessions, as well as controlling for dependence in the data in instances of multiple care partners. We will use intent-to-treat analyses to measure the differences in each outcome measure between PST Intervention vs. Education groups at 1-month follow-up using *t*-tests or Mann Whitney *U* tests, as appropriate. If covariate adjustment is determined to be necessary based on baseline differences between the two groups, we will conduct Analysis of Covariance (ANCOVA) for each outcome, adjusting for relevant factors. To address our second hypothesis, we will assess group by time interactions, including baseline, 1-month, and 6-month time points, using repeated-measures ANOVA/ANCOVA. For the coping skills outcome, we will use baseline data from all participants and conduct exploratory factor analysis to identify second-order factors in our sample as a means of data reduction and analyze total scores within the second-order factors.

2.12. Ethics

Each participating site's Institutional Review Board approved all research procedures, and we will obtain written informed consent from all participants. Further, we have established protocols for managing any crises that may arise in the context of intervention delivery (e.g. a participant endorsing suicidal ideation).

2.13. Data sharing

The TBI Model Systems National Data and Statistical Center established protocols for data sharing off all data collecting as part of the TBI Model Systems. Entities wishing to use data collected through the TBI Model Systems Centers may request access by completing a Data Request and Use Agreement Form available for download at www.tbindsc.org.

3. Discussion

The impact of moderate to severe TBI is lifelong and has pervasive effects on the individual, family, community, and society as a whole [58,59]. Individuals with TBI navigate their cognitive, behavioral, and physical health challenges with varying levels of success, depending upon their resilience, skills, and resources. Managing these changes after TBI is particularly challenging due in part to their unpredictability. Substantial burden is placed on care partners to assist with managing the chronic consequences of TBI [10–14,16,17]. Eighty percent of care partners experience significant psychological and physical burden [18], leading to depression, anxiety, poor physical health, and reduced quality of life [12,16–18,60,61]. Hence, it is critical to identify unique approaches to support and lessen the burden of care partners.

Inpatient rehabilitation programs provide education to care partner during the inpatient stay, but little to no attention is given to facilitating behavioral change for the care partners to improve self-management skills they can apply after discharge. To date, all but one intervention for care partners of adults with TBI have occurred after discharge from acute care [34,62]. This means that care partners, who had no way to predict or prepare for the sudden and significant change in their lives and the lives of their loved ones, experience the transition of care without the necessary skills, training, or resources to manage the new challenges they will face. We believe that there is a critical need to provide evidence-based self-management training to care partners as early as possible, so they can manage issues that arise over time, especially during the transition from acute care back to the community. Without this self-management training, a large proportion of care partners will continue to experience high levels of burden, emotional distress, and poor quality of life.

We have described a randomized-controlled trial of a self-management intervention, compared to education alone, for care partners of adults with TBI, delivered during the care recipient's inpatient rehabilitation stay. At the completion of this study, we will have determined the feasibility and initial efficacy, compared to care partner education only, of delivering PST to care partners of adults with TBI during inpatient rehabilitation and factors associated with intervention compliance. This would be the first study deliver a self-management intervention to care partners during the care recipient's inpatient hospitalization stay, maximizing the capacity and likelihood for implementation if found to be efficacious. Our standardized PST intervention could be incorporated into service delivery by various hospital staff members (e.g. case managers, nursing, occupational/speech therapy) to care partners of patients with TBI. If feasible for care partners of patients with TBI, PST intervention delivery could be "scaled up" to care partners of patients with other traumatic injuries or acquired conditions.

There are challenges associated with a study of this nature. The timing and nature of our study present unique challenges to recruitment. We discussed this study with the Consumer Advisory Panel for our NIDILRR-funded North Texas TBI Model Systems Center study – a group composed of survivors of TBI and their care partners. They acknowledge that acute hospitalization is an overwhelming time for care partners, but they enthusiastically supported the idea of providing self-management skills training to care partners during this time. Our primary aim on feasibility, rather than efficacy, is in direct response to the specific concerns about care partners' readiness for a self-management intervention delivered during this time.

Intervention fidelity is another challenge in studies such as this, as the ability to be flexible and adapt to each participant's individual situation, needs, and personality are critical to developing therapeutic rapport and engaging in a goal-oriented, problem-solving intervention. To address this, we followed previously published recommendations and established a rigorous protocol for evaluating fidelity [57,63,64]. Further, we are assessing not only participant satisfaction with the intervention, but also participant "uptake" (e.g. confidence using the PST strategy) and therapeutic rapport (working alliance). Therefore, we are also measuring the likely "active ingredients" of the PST Intervention that are not present in the Education only intervention, including therapeutic rapport, a facilitated (vs directed) approach to global strategy training, and training in a simple, systematic problem-solving strategy. It is especially important to identify the unique aspects of PST associated with improved outcomes, as we anticipate that care partner education will also have a positive impact on care partner outcomes.

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