Improving transition from inpatient rehabilitation following traumatic brain injury: Protocol for the BRITE pragmatic comparative effectiveness trial

Jesse R. Fann a,*, Tessa Hart b, Marcia A. Ciol c, Megan Moore d, Jennifer Bogner e, John D. Corrigan e, Kristen Dams-O’Connor f, Simon Driver g, Rosemary Dubiel h, Flora M. Hammond i, Maria Kajankova j, Thomas K. Watanabe k, Jeanne M. Hoffman c

a Department of Psychiatry and Behavioral Sciences, University of Washington School of Medicine, 1595 NE Pacific Street, Box 356560, Seattle, WA 98195, United States of America
b Moss Rehabilitation Research Institute, 50 Township Line Road, Elkins Park, PA 19027, United States of America
c Department of Rehabilitation Medicine, University of Washington School of Medicine, 1595 NE Pacific Street, Box 356490, Seattle, WA 98195, United States of America
d School of Social Work and Harborview Injury Prevention and Research Center, University of Washington, 4101 15th Avenue NE, Seattle, WA 98105, United States of America
e Department of Physical Medicine and Rehabilitation, The Ohio State University, 480 Medical Center Drive, Columbus, OH 43210, United States of America
f Department of Rehabilitation Medicine, Department of Neurology, Icahn School of Medicine at Mount Sinai, One Gustave Levy Place Box 1163, New York, NY 10029, United States of America
g Department of Sports Therapy and Research, Baylor Scott and White Research Institute, 3434 Live Oak, Dallas, TX 75204, United States of America
h Department of Physical Medicine and Rehabilitation, Baylor Scott and White Institute for Rehabilitation, 909 N. Washington Avenue, Dallas, TX 75246, United States of America
i Department of Physical Medicine and Rehabilitation, Icahn School of Medicine at Mount Sinai, 4141 Shore Drive, Indianapolis, IN 46254, United States of America
j Department of Rehabilitation Medicine, MossRehab at Elkins Park/Einstein Healthcare Network, 60 Township Line Road, Elkins Park, PA 19027, United States of America

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ABSTRACT

Moderate to severe traumatic brain injury (TBI) is a common cause of long-term disability. Due to challenges that include inconsistent access to follow-up care, persons with TBI being discharged from inpatient rehabilitation facilities (IRFs) are at risk for rehospitalization, poor reintegration into the community, family stress, and other unfavorable outcomes resulting from unmet needs. In a six-center randomized pragmatic comparative effectiveness study, the BRITE trial (Brain Injury Rehabilitation: Improving the Transition Experience, ClinicalTrials.gov NCT03422276), we compare the effectiveness of two existing methods for transition from IRF to community living or long-term nursing care. The Rehabilitation Discharge Plan (RDP) includes patient/family education and referrals for continued care. The Rehabilitation Transition Plan (RTP) provides RDP plus individualized, manualized care management via phone or videoconference, for 6 months. Nine hundred patients will be randomized (1:1) to RDP or RTP, with caregivers also invited to participate and contribute caregiver-reported outcomes. Extensive stakeholder input, including active participation of persons with TBI and their families, has informed all aspects of trial design and implementation planning. We hypothesize that RTP will result in better patient- and caregiver-reported outcomes (societal participation, quality of life, caregiver well-being) and more efficient use of healthcare resources at 6-months (primary outcome) and 12-months post-discharge, compared to RDP alone. Planned analyses will explore which participants benefit most from each transition model. With few exclusion criteria and other pragmatic features, the findings of this trial are expected to have a broad impact on improving transitions from inpatient TBI rehabilitation.

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* Corresponding author.
E-mail addresses: fann@uw.edu (J.R. Fann), thart@einstein.edu (T. Hart), marciac@uw.edu (M.A. Ciol), mm99@uw.edu (M. Moore), Jennifer.Bogner@osumc.edu (J. Bogner), John.Corrigan@osumc.edu (J.D. Corrigan), Kristen.dams-o’connor@mountsinai.org (K. Dams-O’Connor), simon.driver@bswhealth.org (S. Driver), rdubiel@bswrehab.com (R. Dubiel), Flora.hammond@rhin.com (F.M. Hammond), Maria.kajankova@mountsinai.org (M. Kajankova), watanabt@einstein.edu (T.K. Watanabe), jeanneh@uw.edu (J.M. Hoffman).

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1. Introduction

Moderate to severe traumatic brain injury (TBI) is a common cause of long-term disability, with a complex mix of physical, cognitive, and psychosocial difficulties that often limit survivors’ ability to manage health and rehabilitation needs [1]. Healthcare delivery for TBI is “front-loaded” to deal with the acute medical and functional needs, with often fragmented and inconsistent services thereafter. Many inpatient TBI rehabilitation facilities (IRFs) in the US follow CARF International standards of care for discharge planning, including patient/family education and coordination of further medical and rehabilitative care [2]. However, over half of patients with moderate to severe TBI who receive inpatient rehabilitation are still experiencing post-traumatic amnesia (PTA) one month after injury [3], meaning that many are discharged from inpatient care with little ability to learn and remember the information provided. The burden then falls to caregivers, if available, to coordinate care, seek specialized services, and manage needs. Studies reveal a dire need for enhanced discharge planning and transitional care services for this patient population [4–6]. Assistance is needed to “negotiate the rehabilitation maze” [7] with individually tailored education and support [4,8,9], not only to help achieve optimal outcomes but also to prevent the unacceptably high rehospitalization rates in this group [10,11]. In a recent qualitative study of people with TBI and their families, participants cited barriers to healthcare access following hospitalization and advocated for improved communication and knowledge exchange with care providers during this critical transition [12].

While the need to develop and test transitional services is evident, few evidence-based models exist. Case management approaches are increasingly used to ease the transition between acute and post-acute care for several medical conditions [13,14], and this model can reduce 30-day readmissions and other healthcare expenditures [15,16]. The Veterans Health Administration (VHA) incorporates an intensive case management approach for complex conditions such as TBI [17,18], but evidence is lacking as to which components are effective. Overall, the evidence for case management following TBI remains inconclusive, due to inconsistent definitions of services, variability in interventions, and methodologic limitations [19,20].

We describe a protocol for a six-center pragmatic comparative effectiveness study designed to examine the effects of two established methods of managing transitions from IRF discharge to the next stage of care for moderate to severe TBI. All participants will receive a Rehabilitation Discharge Plan (RDP) providing the CARF-recommended model of patient/family education and training, with referrals for further care. Half of the sample will also be randomized to receive a Rehabilitation Transition Plan (RTP) during the first 6 months after discharge. This includes individualized care management and support, akin to the VHA model, that focuses on education regarding TBI recovery, identification of unmet needs, facilitation of resources toward meeting their needs, and coordination of care delivered by phone or secure videoconference [21–25]. We hypothesize that addition of RTP will result in improved community participation and quality of life and more effective use of healthcare resources, compared to RDP alone. In addition, we anticipate this support will improve caregiver-reported burden, quality of life and role satisfaction.

2. Materials and methods

2.1. Overview of design, specific aims, and research hypotheses

The BRITE trial (Brain Injury Rehabilitation: Improving the Transition Experience, ClinicalTrials.gov identifier NCT03422276) is a six-center pragmatic clinical trial with masked outcome assessment in which a projected 900 persons with moderate to severe TBI will be randomized 1:1 into RDP alone or RDP plus RTP. For simplicity, we refer to the interventions as RDP and RTP, although all participants receive RDP, as described below. Randomization is stratified by site and discharge destination (community versus skilled nursing facility). When a caregiver is available for a randomized patient, he/she will also be approached for consent with a goal of enrolling 540 caregivers. Outcomes are assessed at 3, 6, 9, and 12 months after discharge from inpatient rehabilitation. An overview of the study design is shown in Fig. 1.

2.1.1. Aim 1

To compare the effectiveness of RDP versus RTP on two patient-reported outcomes: Societal participation and health-related quality of life. Hypothesis 1: Patients randomized to RTP will report better participation and health-related quality of life at the end of intervention (6 months post-discharge; primary outcome) and at 12 months post-discharge, compared to patients randomized to RDP.

2.1.2. Aim 2

To compare the trajectories of improvement across the first year post-discharge on patient-reported outcomes of participation and quality of life. Hypothesis 2: Patients randomized to RTP will experience a steeper trajectory of improvement in participation and quality of life over 12 months, compared to patients randomized to RDP.

2.1.3. Aim 3

To compare differences in healthcare utilization between RDP vs. RTP across the first year post-discharge. Hypothesis 3: Patients randomized to RTP will complete a higher proportion of planned outpatient visits and have fewer urgent care visits or unplanned hospitalizations across the first year post-discharge, compared to patients randomized to RDP.

2.1.4. Aim 4

To compare the effectiveness of RDP vs. RTP on caregiver outcomes of caregiver burden, health-related quality of life, and satisfaction with roles and activities. Hypothesis 4a: Caregivers of patients randomized to RTP will report improved caregiver outcomes at 6 months post-discharge, compared to caregivers of patients randomized to RDP. Hypothesis 4b: Caregivers of patients randomized to RTP will report a steeper trajectory of improvement in caregiver outcomes over time, compared to caregivers of patients randomized to RDP.

2.1.5. Aim 5

In this exploratory aim, we will examine heterogeneity of treatment effects among subgroups of patients defined by factors known or hypothesized to have associations with TBI outcome: facility vs. community discharge, race/ethnicity, age, sex, degree of caregiver involvement, severity of TBI, and pre-injury psychosocial factors such as employment and substance abuse.

2.2. Pragmatic focus

This study was designed as a pragmatic trial. In contrast to a tightly controlled trial that seeks to uncover mechanisms of action for a given treatment in a narrowly defined participant group, a pragmatic trial aims to generalize findings to a broad range of persons in the affected population and uses treatment methods that should be applicable in a variety of real-world treatment settings [26]. In establishing the pragmatic features of the trial we were guided by the PRECIS-2 tool [27], which defines pragmatic choices within such domains as participant selection and recruitment, the setting and other features of the intervention, and the relevance of the primary outcome(s) to the target population. Thus, the BRITE trial includes a diverse patient sample that is representative of patients who may benefit in the future and who will be enrolled from the clinical settings where the intervention is most relevant. It also provides streamlined, flexible intervention procedures which are likely to lead to improvements in the outcomes of interest. Measurement of these key outcomes are also chosen with input from...
patient and family stakeholders [28].

2.3. Participating sites

The six study sites are Traumatic Brain Injury Model Systems (TBIMS) centers, funded by the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR). The TBIMS program, in existence since 1987, provides competitive awards to institutions providing a full continuum of clinical care for TBI. These institutions conduct collaborative studies and contribute common elements to a database for longitudinal research [29]. The TBIMS tend to have similar treatment protocols and staffing ratios, and the six study sites are accredited by CARF International. Although not all BRITE participants will be co-enrolled in the TBIMS database, the trial will benefit from the collaborative experience and longitudinal data collection infrastructure established among the six centers. Additionally, we will use the TBIMS Standard Operating Procedures [30] for participant tracking and maximizing data quality and completeness. The BRITE study sites also provide geographic diversity, with two centers in the Northeast, two in the Midwest, one in the South, and one in the Pacific Northwest.

2.4. Stakeholder input

In keeping with the pragmatic focus of the trial and the priorities of the funding agency, the Patient-Centered Outcomes Research Institute (PCORI), we have included extensive input from important stakeholders, both for planning the trial and for guiding its implementation. We developed a patient and family stakeholder advisory group to provide input into the desired outcomes from a transitional care intervention, as well as the choice of specific measurement tools to assess the outcomes of interest. Our stakeholders also were key in designing the RTP intervention and adapting it for the civilian population. This group, plus a diverse group of professional stakeholders, comprise our two Study Advisory Committees. The professionals represent relevant medical specialties, healthcare administration and accreditation, TBI advocacy organizations, and the insurance industry. The Advisory Committees will meet with the Principal Investigators and other key personnel annually in-person, and monthly to quarterly via teleconference. The importance of stakeholder input to this trial cannot be overstated: for example, consumer input was critical in selecting the two primary outcome domains (participation and quality of life), developing the participant satisfaction surveys, adapting the RTP intervention to maximize patient-centeredness and flexibility, identifying important TBI resources, training the interventionists, and improving recruitment and retention practices.

2.5. Participants

We will recruit two types of participants: people with moderate to severe TBI, and for those participants who have someone identified to assist them after discharge, we will also recruit their caregivers.

2.5.1. Participants with TBI

Participants will be recruited from consecutive admissions to each site’s IRF. Each participating IRF facility followed their site’s admission policy and each patient cleared preadmission screening by a rehabilitation physician to confirm compliance with medical necessity criteria [31]. There is slight variation in admissions criteria among sites based in large part on regional differences in insurance interpretation of the criteria. In general, patients are expected to tolerate, actively participate in and benefit from 3 h of therapy a day for at least five days per week and require more than one therapy discipline (including at least physical therapy or occupational therapy, but in practice almost always requiring physical, occupational and speech/language therapies). They also have needs that can only be met by the 24 h availability of nurses specialized in rehabilitation, as well as a social worker and/or case manager to coordinate care. The patients also require active management of ongoing medical problems provided by a physician specialized in rehabilitation at least 3 days per week. In practice, all of the patients have functional, medical and nursing needs that preclude a safe discharge to home, provided by the aforementioned clinicians using a transdisciplinary approach. Upon admission, individuals will be recruited who meet the following inclusion criteria:

1. Diagnosis of moderate to severe TBI meeting the case definition of the TBIMS, i.e., damage to brain tissue caused by an external mechanical force with one or more of the following severity indices present and not caused by intoxication, sedation, intubation, or chemical paralysis:
   a. PTA > 24 h
   b. Trauma related intracranial neuroimaging abnormalities
   c. Loss of consciousness exceeding 30 min
   d. Glasgow Coma Scale score in the emergency department <13
2. English speaking (we will track non-enrollment due to other languages to determine languages that might be appropriate for translation of consumer dissemination materials).
3. Age ≥ 18 years.
4. Discharged from IRF to community (private residence, adult home, hotel, homeless) or facility (nursing home, skilled nursing facility).
5. Provides informed consent directly or through a Legally Authorized Representative (LAR).

![Fig. 1. Overview of study design. TBI = traumatic brain injury, IRF = inpatient rehabilitation facility, RDP = Rehabilitation Discharge Plan, RTP = Rehabilitation Transition Plan.](image-url)
Individuals with TBI will be excluded for:
1. Being in custody of law enforcement at or during admission to the rehabilitation unit.
2. Lack of access to telephone following discharge.
3. Inability to participate in the intervention due to cognitive/communication limitations, and there is no one available or willing to provide consent as a proxy informant (defined below).

2.5.2. Caregiver participants
Every effort will be made to enroll a caregiver, under separate consent, for each participant enrolled in the trial. Caregiver participants are those individuals who will have primary caregiving responsibility for the enrolled patient following hospital discharge, as determined by consultation with the patient, family, and inpatient treatment staff. Caregivers are recruited for consent only after patients have consented, either themselves or via LAR. Inclusion criteria for caregivers are:

1. English-speaking.
2. Age ≥ 18 years.
3. Provides informed consent.

Caregivers will be excluded for:
1. Being in law enforcement custody.
2. Lack of access to telephone.

2.5.3. Special considerations regarding participants
There are two aspects of moderate to severe TBI that require special consideration regarding consent and participation in this study. First, participants with TBI may be discharged from rehabilitation before they are able to consent for themselves or participate in a telephone- or video-based treatment (if randomized to the RTP condition). In such cases, the LAR providing their consent or another person (e.g., a caregiver) may consent to act as a proxy to participate in the intervention and assessment procedures on the injured person’s behalf. If the person with TBI becomes able to consent and participate actively in intervention and to complete assessments during the study period, he or she will be consented at that time and will become his or her own respondent. Of note, the proxy respondent may or may not be the same person who consents to participate as a caregiver.

The second consideration has to do with the fact that the TBI population is often characterized by social instability, including changes in residence and relationships in the post-acute phases [32]. We therefore anticipate that following randomization into the trial, a primary caregiver may change from one person to another, or become less necessary as the person with TBI becomes more independent. To deal with these eventualities, we will monitor both the need for caregiving, defined as provision of help with at least some day to day activities, and the identity of the caregiver throughout the study period. We will request consent from new caregivers as needed and will cease caregiver involvement in the trial if and when the patient or caregiver indicates that the patient has no further need for assistance from others.

2.6. Measures
Patient and caregiver assessments are shown in Table 1.

Baseline variables are extracted from medical records or supplied by interviewing patients/caregivers following consent. These include demographics, cultural variables, socioeconomic variables, and data pertaining to social and medical history. Date of injury and dates of acute care and inpatient rehabilitation, as well as discharge destination, are recorded as well as cause of injury and injury severity indices. Further information about these variables is available in the TBIMS syllabus [33]. Patients are administered the Brief Test of Adult Cognition (BTACT) [34], which comprises part of the TBIMS baseline assessment, at 4 ± 2 weeks post-TBI. Caregivers are asked to supply many of the same baseline variables as collected for patient participants (Table 1). In addition, we record the type and duration of the relationship of the caregiver to the patient and whether they live together.

Data pertaining to participants’ discharge status, including the details of scheduled or recommended follow-up appointments, are recorded for use in the intervention (see Intervention section below).

Outcomes assessment (3, 6, 9, 12 months post discharge) includes the following measures administered to participants with TBI: the Participation Assessment with Recomcombined Tools-Objective-17 items (PART-O-17) [35] and the Quality of Life after Brain Injury (QOLIBRI) [36] (primary outcomes), and the Cornell Services Index [37].

The PART-O-17 is a patient-reported (or proxy-reported) measure of the World Health Organization [43] construct of participation, defined as involvement in life situations at the societal level, as reflected in fulfillment of developmentally and culturally appropriate roles such as worker, student, spouse, parent, or citizen. The PART-O-17 was developed as a collaborative TBIMS project [44], has well established reliability and validity, and is recommended outcome measure in the NIH Common Data Elements for TBI [45]. In addition to a Total Average Score across items, the scale produces 3 subscale scores in the areas of Productivity, Social Relationships, and Out and About (community activity). For this study we will use the Rasch-Total Average score derived from rating scale analysis, which has psychometric properties amenable to advanced statistical analysis [46].

The QOLIBRI is a patient-reported measure of health-related quality of life, which was developed by an international work group, subjected to rigorous validation in large samples of persons with TBI [36], and selected for inclusion in the TBI Common Data Elements [45]. There are 37 items in 6 subscales confirmed by factor analysis: Self, Daily Life and Autonomy, Social Relationships, Emotions, Restrictions and Problems, and Physical Condition. Test-retest reliability is good to excellent for all subscales and the total score (0.91) [36]. Validity studies have shown strong associations between QOLIBRI scores and level of disability, and the measure is more strongly related to TBI outcomes compared to generic quality of life scales [47]. Notably, many of the items on the QOLIBRI reflect modifiable states that could change with interventions such as the one used in the BRITE study.

The Cornell Services Index is a widely used measure of healthcare services utilization which assesses number of hospitalizations and days hospitalized, number of emergency department visits, and number and type of clinic visits (both routine and those addressing medical complications). It has been used in a number of TBI studies [23,48]. We will document whether healthcare visits were planned or unplanned and the reasons for urgent care/emergency department visits.

Additional patient outcome measures include: Satisfaction with healthcare (6- and 12-month intervals), assessed by 5 questions about participants’ ability to get their healthcare questions answered, attend scheduled appointments, get help with coordinating their healthcare, connect with community resources, and receive help when needed; insurance type and coverage (6- and 12-month intervals); and street address (at all intervals). Street address is used to obtain information about the communities in which participants reside, including barriers and facilitators affecting health and wellness [49].

Caregivers will complete the following measures at each outcome assessment interval: (1) The Bakas Caregiving Outcomes Scale, originally developed for use in stroke and adapted by replacing “stroke” with “traumatic brain injury,” was done in a prior study [38]. The Bakas is a 15-item measure that assesses change in social functioning, emotional well-being, and physical health related to caregiving. It has good internal consistency (Cronbach α = 0.90), test-retest reliability (intraclass correlation = 0.68), and construct validity [50]. (2) The Zarit Burden Interview, initially developed for caregivers of individuals with dementia [39]. Short forms have been developed [40]; we will use the 12-item version as it addresses the concerns that our stakeholders feel are most important and relevant to our interventions. This measure has been
Table 1
Patient and caregiver assessments.

<table>
<thead>
<tr>
<th>Construct</th>
<th>Scales/variables</th>
<th>Baseline</th>
<th>Outcomes (months)</th>
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<td>Quality of Life after Brain Injury (QOLIBRI) [36]</td>
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<td>Health care utilization</td>
<td>Cornell Services Index</td>
<td>3, 6, 9, 12</td>
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<td>Insurance type and coverage</td>
<td>6, 12</td>
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<td>Ability to get their healthcare questions answered, attend scheduled appointments, get help with coordinating their healthcare, connect with community resources, receive help when needed</td>
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<td></td>
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<tr>
<td>Caregiver</td>
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</tr>
<tr>
<td>Demographics</td>
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<td>Cultural status</td>
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<tr>
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<td>Type, duration, living situation</td>
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<td>Assessment of amount of assistance provided and time spent</td>
<td>3, 6, 9, 12</td>
<td>3, 6, 9, 12</td>
</tr>
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</table>

used previously in studies of caregivers, including those providing care to individuals with TBI [51-54]. (3) PROMIS Satisfaction with Social Roles and Activities, 8-item short form [41]. To date, this measure has not been used to study caregivers. However, we selected it to provide an assessment of engagement in roles and activities apart from those directly related to caregiving. (4) The SF-12 [42], a widely used measure of health-related quality of life that provides component scores in the domains of physical and mental health. The SF-12 has been used in caregiver populations [55-57], including caregivers of individuals with TBI [58]. (5) Required Assistance and Time Spent Caregiving, a set of questions developed for the current study to assess the assistance given to each patient participant and the amount of time spent by caregivers interacting with the patient.

Process variables will also be collected for the RTP group to capture the number and duration of intervention contacts, the needs identified and addressed during the intervention, and the resources provided (see Interventions section below). In addition, RTP participants with TBI and caregiver participants will be surveyed by phone following completion of the treatment phase to gather qualitative information about more or less helpful aspects of the intervention.

2.7. Procedures

This study complies with the procedures for protection of human subjects set forth in the Helsinki Declaration. The project is approved and overseen by the Institutional Review Boards at each participating site.

Randomization to RDP or RTP occurs at discharge from the IRF and is based on a permuted block design with even-numbered block sizes of 4 to 20, stratified by site and discharge disposition (home vs skilled nursing facility). Treatment allocation is computer-generated and performed by the data manager at the Data Coordinating Center, which is remote from clinical sites. This manager sends the allocation in a secure email to the study interventionist at the appropriate site.

Outcome assessments are conducted by phone by site-specific data collectors who are masked to treatment allocation. A number of strategies are employed to maintain masking, including centralized randomization, protected electronic access to treatment allocation information, and the use of “scripts” read aloud prior to each assessment, to remind the patient/caregiver not to divulge group assignment. The success of the masking is evaluated by having the data collectors document instances of unmasking as well as asking them to guess each participant’s group assignment. These strategies have proven effective in previous trials [23,25].

For participants co-enrolled in the TBIMS, we will examine outcome assessment schedules for overlap with the first TBIMS follow-up, which occurs at ±2 months from the date of injury, so that both assessments might be completed in the same phone contact to reduce participant burden. The database will be developed by the National Data and Statistical Center (NDSC) at Craig Hospital which has the existing infrastructure and IRB-approved clearances to accept both civilian and VA data for the Tbims program [29]. Only registered TBIMS users will be assigned a password to access the database for online data entry. Once data collection is complete, study information (recruitment and screening outcome, basic demographic information, data collected to test study hypotheses) will be entered with a participant’s study ID into a password protected NDSC database accessible via secured-internet connection.

2.8. Interventions

Because all participants receive one of the treatment conditions (RDP) and half of them receive additional intervention (RTP), it is particularly important to maintain and convey an attitude of equipoise throughout the trial. We emphasize to all study personnel, clinical teams, and potential participants during the recruitment process that no
one will be denied any needed care during the study, that we do not know if one approach will prove superior to the other, and that “more is not necessarily better.” Indeed, in initial recruitment we have encountered patients and family members who decline participation because they do not think they will need additional care or because they do not want to engage in extra contacts. In addition to determining if one condition is superior to the other, our data analysis plan (described below) includes a process for examining which types of participants do better under the two conditions.

The Rehabilitation Discharge Plan (RDP) condition is based on the discharge preparation components specified by CARF International for inpatient TBI rehabilitation [2] and on the routine pre-discharge preparation provided to patients and caregivers at the participating sites which are designed to promote transition to next level of care with the ultimate goal of returning patients back to their communities as healthy and independent as possible given their severity of injury. The key elements of RDP include: (1) TBI education and training concerning the stages of recovery and expected physical, cognitive and emotional changes, safety issues, caregiver symptoms to monitor and health promotion through appropriate nutrition, activity and hygiene that improve awareness of the impact of TBI which can impact ongoing participation; (2) an individualized Discharge Plan with goals and instructions from all rehabilitation disciplines, recommended follow-up appointments for ongoing medical care and rehabilitation, and medication instructions to continue with ongoing recovery and lead to appropriate utilization of healthcare and reduce the risk of unplanned rehospitalization; and (3) a brief follow-up phone call from an inpatient staff member within 3 days of hospital discharge, to address any immediate problems, ensure that equipment has arrived and medications are being taken as directed, and address unmet needs in the 6-month interval following discharge from inpatient care which could hinder one’s ability to return to community activities (participation) or reduce quality of life. Although the schedule is flexible depending on individual needs and preferences, about 12 contacts are placed as follows: weekly for 4 weeks, biweekly for 2–3 months, then monthly for 2–3 months. Participants may contact the TCM in between these scheduled contacts, and the TCM may contact participants if needed to complete a referral or follow-up. The duration of each contact is dependent on the needs of the patient or caregiver but is generally not expected to exceed one hour. At the beginning of the RTP intervention, contacts are conducted with patients and caregivers separately, when possible, to ensure that both can speak freely about their concerns and that caregivers can have their own needs addressed to reduce their experience of burden, as well as the impact of the patient’s injury on the caregiver’s ability to engage in activities and their own quality of life. As the intervention progresses, the TCM and patient/caregiver may decide to continue separate contacts, to conduct them jointly, or to use a combination of joint and separate contacts. Each intervention contact is documented in a secure database developed for the study, which includes participant-specific resources needed by the TCM and details of the discussed content of each call. A follow-up letter or email with details of the agreed-upon plan is sent to the participant after the call.

For patients discharged to a skilled nursing or long-term care facility, the TCM attempts to make a pre-intervention contact with the facility to ascertain the best ongoing contact person (e.g., a nurse manager or patient/resident advocate) and to explain the study. Subsequent contacts may include this facility liaison as well as the caregiver and the patient (if able), as desired and permitted by the patient/family to ensure that any unmet needs are addressed.

Table 2 provides a description of the core components of the RTP intervention. The most important foundational principles include the following:

1. **Focus on culturally resonant engagement, support, education, and problem solving.** An important feature of the intervention is that the TCM’s clinical skills focus on support, problem-solving, and TBI education as opposed to clinical treatment (psychotherapy). The TCM assists in adjusting to changes consequent to the TBI and helps the patient and family understand and engage as fully as possible in the follow-up plan with the goal of aiding recovery and setting realistic expectations for return to participation in the community. This includes assessing values and goals and using practical problem-solving strategies to overcome barriers to accessing needed services in the community, both external (e.g., logistical) and internal/psychological (e.g., reluctance, resistance, or cognitive issues). If extensive counseling of a psychotherapeutic nature is needed by either the patient or caregiver participant, the TCM works to facilitate an appropriate referral for those services.

2. **Focus on needs assessment.** The primary purpose of the intervention is to improve community participation and quality of life by preventing or addressing unmet needs. Thus, most sessions with a patient or caregiver include a Needs Assessment to identify and prioritize needs to address via case management. Needs are assessed within the following domains:
   - Appointments and Medical Providers (e.g., making and keeping scheduled appointments, communication with care team)
   - Daily Living (e.g., self-care, chores, eating well, taking medications, financial issues, housekeeping)
   - Physical Status (e.g., fatigue/energy, pain, headache, safety at home, sleep for both patient and caregiver)
   - Thinking (e.g., memory, concentration, planning, expressing oneself)
   - Mood and Behavior (e.g., emotions, mood, alcohol/drug use)
   - Social and Family Interactions (e.g., need for support groups)
   - Restarting Activities (e.g., balancing work/school/recreation for caregivers)
   - Help-seeking behavior (e.g., respite, self-care for caregiver)
   - Other needs important to patient or caregiver

3. **Focus on resource facilitation.** Another goal of the intervention is to facilitate and coordinate engagement and participation in healthcare and community resources and services that will best meet the patient’s and caregiver’s needs. This means helping the patient and family to build a support network and to access the best services available that will maximize their quality of life.

4. **Focus on care coordination and continuity of care.** To ensure follow-through with recommended appointments and optimize TBI recovery, TCMs facilitate coordination of patient care between providers and systems, either directly or via providing information and support for the patient or caregiver to do so. TCMs are expected to initiate planning for a warm handoff early in the course of the intervention. This term refers to the transition of care at the end of the intervention, in which the TCMs link patients and caregivers with appropriate healthcare providers and community resources. With permission from participants, the TCM provides relevant, personalized information to these providers to facilitate a smooth transition. As part of the pragmatic RTP intervention, the TCM has access to the inpatient and outpatient clinicians who are familiar with the participant’s injury and status. Thus, for example, if medical needs arise with which the TCM may not be familiar, the TCM may consult the participant’s treatment team for information or guidance.

The TCMs who deliver the RTP intervention are bachelors- or masters-level personnel, typically social workers, as these are the types of hospital-based providers who might carry out the intervention in the future, should it prove successful. Prior to beginning work in the study,
TCMs are required to study the RTP treatment manual, review a standard set of educational materials on TBI and the BRITE trial, and become familiar with TBI-related resources in the local community. This last task is accomplished by compiling resources provided by the Brain Injury Association of America and the local Brain Injury Association/Alliance chapters in the catchment area of the TCM’s rehabilitation center, as well as resources within the IRF. TCMs are also given training and resources on how to adapt their interactions with persons affected by TBI who may exhibit cognitive or communicative impairments such as short attention span, memory problems, impulsivity, word-finding issues, and impaired self-awareness. This last impairment is particularly important to understand and circumvent, as it may distort the injured person’s perception and reporting of his/her own problems and needs. Comparison of patient/caregiver reports, monitoring and investigating inconsistencies in patient reports, are emphasized. Clinical skills in motivational interviewing and problem-solving are also included in the TCMs’ training. To help participants set priorities when there are many and perhaps competing needs, TCMs are encouraged to use Maslow’s hierarchy of needs [59] as a reminder that basic human needs such as food, shelter, sleep, and physical safety must be met before focusing on needs such as recreation, socialization, and self-actualization. When there are multiple needs at the same level on the hierarchy, TCMs use a person-centered approach to elicit participant priorities and choices, while also bearing in mind that first addressing “easier” problems may result in earlier success, thus enhancing participant self-efficacy and willingness to engage with intervention.

**Table 2:** Rehabilitation Transition Plan (RTP) core components.

<table>
<thead>
<tr>
<th>Core component</th>
<th>TBI Care Manager (TCM) actions that deliver each component</th>
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<tbody>
<tr>
<td>1. Resource Network</td>
<td>Building and maintaining a resource network is key to successful case management. TCM will engage with TBI resources and other professionals in the community via in person or phone contacts on an ongoing basis. This can be done to introduce the TCM to the providers at referral sources and also when making a referral with or on behalf of a patient. TCM identifies new resources and changes to existing resources on an ongoing basis. TCM engages with local and national network of providers to best serve patients and caregivers. This also facilitates warm hand-offs.</td>
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<tr>
<td>2. Culturally Resonant Engagement, Support, and TBI education</td>
<td>Engagement, support, and TBI education are the core clinical skills provided throughout the intervention. TCM utilizes active listening, reflection, validation, and other patient-centered techniques to engage with participants. TCM explores relevant cultural factors and gains an understanding of patient and caregiver priorities for recovery. TCM provides education on TBI recovery and supports adjustment to disability in a culturally resonant manner.</td>
</tr>
<tr>
<td>3. Follow-up on status of Rehabilitation Discharge Plan</td>
<td>TCM systematically reviews with the patient/caregiver whether each component of the plan given at discharge (a) has been followed and what has been difficult to follow (b) has been effective in the view of the recipient. For components not followed or difficult to follow, TCM probes for obstacles; for ineffective components, TCM probes for details on what has fallen short and provides resources and coordination of care to address these. TCM can also text and send reminders regarding plans after calls.</td>
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<tr>
<td>4. Ongoing structured Needs Assessment</td>
<td>TCM leads patient/caregiver through a structured needs assessment to determine unmet needs in key domains of function. This action is not simply an assessment; it is part of the intervention because it conveys to the recipient that there is a person who wants to discover unmet needs and help to meet them. The TCM may query each domain—even if, in previous contacts, the recipient has indicated no needs in a given area—because needs can arise at different times. The needs assessment is an ideal time to incorporate education about TBI recovery, provide support and validation, and suggest resources that might meet the need. Assessment of each need on the Needs Assessment should be conducted at a minimum during the first contact and then once per month after that.</td>
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<tr>
<td>5. Identifying strategies to address needs</td>
<td>TCM probes for sufficient information about each area of need to determine whether need might best be met by (a) re-engaging or overcoming obstacles to a portion of the discharge plan that has not been fully followed; (b) connecting recipient with a different resource (therapy, referral, agency, etc.); and/or (c) developing a different goal or plan to address the need.</td>
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<tr>
<td>6. Resource Facilitation</td>
<td>In order to manage identified needs, TCM facilitates access to appropriate resources. This can include calling the resource directly, either with or on behalf of the patient, or providing the information and a thorough description of the referral process to the patient or caregiver. In addition, providing resources discussed on the call to patients and caregivers via text or email can be helpful. Developing written resource information to distribute to patients and caregivers is another method for ensuring active participation and resource facilitation. The established resource network and relationships built between TCM and community resources is utilized to facilitate connections and to provide context to patient and caregiver for what to expect.</td>
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<tr>
<td>7. Care Coordination</td>
<td>TCM also serves as a source of knowledge about the system of care and strategies for coordinating patient care. TCM provides care coordination between providers when needed and provides support to patient and caregiver to coordinate care.</td>
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<tr>
<td>8. Development of Follow-up Plan</td>
<td>Based on the above information, TCM collaborates with patient and caregiver to develop a detailed action plan for resolving unmet needs. This includes a plan (date, time) for the next contact between TCM and recipients of care. Follow-up plans also include assisting the patient/caregiver to coordinate post-acute RTP care.</td>
</tr>
<tr>
<td>9. Communicate Follow-up Plan</td>
<td>TCM reviews the action plan verbally to ensure patient/caregiver comprehension and agreement. TCM informs them that she will send the plan in writing by email or regular mail (recipient’s choice)</td>
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<tr>
<td>10. Post intervention transition</td>
<td>The TCM helps the patient/caregiver prepare for ongoing success following RTP care. This includes providing them with a compilation of helpful resources and coordinating ongoing care and communication with their primary care provider (PCP) and other healthcare providers.</td>
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Supervision of TCMs is provided both in-person at the local sites and at the national level, via videoconferencing. The national supervision is intended to allow peer consultation on difficult situations and to help ensure a degree of standardization across sites. By plan, the frequency of supervision is higher during the training phase, then decreases to approximate the conditions that might be experienced by a case manager delivering the RTP in a clinical setting.

**Fidelity assessment** of the RDP condition is reassessed annually by review of each site’s adherence to ongoing CARF requirements. Fidelity to the RTP condition is assessed during RTP training with a formal review of recorded intervention contacts, followed by monitoring through local site supervision and review of records in the RTP intervention database.

### 2.9. Statistical methods

We will use the intent-to-treat principle, by which all randomized cases will be analyzed in their randomly assigned intervention group regardless of the actual intervention received. Missing values will be minimized by constant tracking of follow-up data. We will check for the reasons for any missing values and, if these allow for imputation, will use multiple imputation methods appropriate for continuous variables [60]. We will perform sensitivity analysis by performing the data analysis using the most conservative approach of removing the data from individuals with missing outcome values from the analysis or, in the case of a missing value in a covariate, removing the covariate from the model.
The results of the analysis with imputed data and complete data will be compared to assess whether they differ, and both results will be reported. The analyses for aims related to longitudinal trajectory rely on statistical methods (mixed generalized linear models) that are robust to missing data at individual time points. In addition, all reasons for dropout and missing data will be recorded and will be reported in all reports and publications.

Both the PART-O-17 and the QOLIBRI measures are numeric with a fairly large range that can be considered as continuous for data analysis. We will test the difference in means for PART-O-17 and QOLIBRI between the two groups at 6 months post-discharge using a two-sided t-test for independent samples. We will also test if the intervention has a long-term effect by comparing the two groups at 12 months post-discharge using the same type of t-test.

To compare the groups with regard to healthcare utilization in the first year post-discharge, we will examine the distribution of categories of completed planned outpatient visits (<50%, 50–75%, >75%) by using a Chi-Square test. Both the number of urgent care visits and the number of unplanned hospitalizations will be compared by means of a Poisson regression, which will include group and possible adjustment for other factors (age, sex, race/ethnicity, education, injury severity). A statistically significant coefficient for intervention groups will show that the two groups differ in emergency and unplanned medical visits.

To compare the groups on caregiver burden using the Bakas Caregiving Outcomes Scale, Zarit Burden Interview, SF-12, PROMIS scale of satisfaction with social roles and activities, and time spent in caregiving, we will apply t-tests for difference of means for independent samples. We will also conduct heterogeneity of treatment effects analyses, as planned for other measures.

To analyze the trajectories of improvement across 3-, 6-, 9- and 12-months post-discharge, we will use a linear mixed model, with the outcome (PART-O-17 or QOLIBRI) as the response variable, and time and other factors (such as age, sex, race/ethnicity, education, injury severity) as explanatory variables. We will add intervention group and its interaction with time to test whether the interventions and time had an effect in the trajectory of the outcome. Similar analyses will be done for the Bakas Caregiving Outcomes Scale, Zarit Burden Interview, SF-12, PROMIS scale, and time spent in caregiving for caregivers at 3-, 6-, 9- and 12-month follow-ups as response variables.

Analysis of heterogeneity of treatment effects will explore the differential effects of the intervention on patient subgroups defined by factors known or hypothesized to have associations with poorer TBI outcomes: facility vs. community discharge, minority race/ethnicity, older age, male gender, lack of or lower degree of caregiver involvement, greater severity of TBI, presence of pre-injury psychosocial limitations (e.g., unemployment, substance abuse), spinal cord injury, and medical or psychiatric comorbidity, as well as study site, resource variability and insurance type. These factors will be entered in a single linear regression model in addition to the intervention group, using PART-O-17 as the response variable. Based on previous research, we hypothesize that severity of TBI and presence of pre-injury psychosocial limitations will interact with the intervention group, and those interactions will be included in the model. With our expected sample size, we anticipate sufficient power to address these questions.

### 2.9.1. Power calculations

The sample size of 900 was based on the expected rate of accrual of patients in the six sites over the period of the study, taking into account the ineligibility and refusal rates of previous studies at these sites. A recent study showed that the PART-O-17 has minimal detectable differences of 0.57 and 0.63 at 3 and 9 months, respectively. Additionally, PART-O-17 change scores averaged 1.51 (SD = 0.65) at 3-month follow-up and 1.66 (0.72) at 9-month follow-up [61]. Based on that study, power calculations for changes in PART-O-17 with sample sizes varying from 500 to 900, using a t-test with alpha = 0.05, yielded power values approximating 1.0 even for the smaller sample sizes. Power/sample size calculations for secondary outcomes all yielded power of at least 80% to find an effect size of at least 0.3.

### 2.10. Data and safety monitoring

Adverse events (AEs) and serious adverse events (SAEs) will be monitored and reported according to standard procedures at all sites. We have convened a Data and Safety Monitoring Board (DSMB) composed of a neuropsychologist with expertise in TBI, a biostatistician otherwise unconnected with the trial, and a person who has experienced a TBI. The DSMB is charged with reviewing the following study metrics: a) participant recruitment, accrual, retention, and withdrawal; b) AEs and SAEs; c) comparison of events that occur between treatment arms; d) individual events of particular concern; e) participant interview and/or status outcomes; f) other safety data requested by the DSMB; and g) summaries of protocol violations, completeness and timeliness of study visits, enrollment eligibility and ineligibility information, noncompliance, and unanticipated problems. The DSMB will meet once per year to review documents on the data and safety indices and provide feedback and guidance to the study team.

### 3. Discussion

We have presented what we believe to be the first pragmatic trial comparing the effectiveness of two currently employed strategies for assisting patients with moderate to severe TBI to transition from inpatient rehabilitation to the next steps of recovery and care, either in community living or long-term care facilities, to facilitate participation and maximize quality of life. In addition to determining which approach is associated with better participation and health-related quality of life throughout the first year post-discharge, the study will examine differences in the trajectory of these outcomes over time, as well as completion of planned outpatient visits, urgent care visits, and hospitalizations. We will also compare the effect of the interventions on caregiver burden, health-related quality of life, satisfaction with roles and activities, and time spent caregiving.

An important aspect of this study is the involvement of our large and diverse stakeholder groups, which include persons with TBI and family members as well as professionals. These stakeholders have been instrumental in all aspects of the study including conceptualization, design, and procedures involved in both assessment and intervention. Our consumer advisors have contributed significantly to adaptations that make the intervention more pragmatic, such as modifying the fidelity assessment process and planning for dissemination of findings.

The BRITE study will be one of the largest randomized controlled trials aimed at improving participation and quality of life outcomes among persons with moderate to severe TBI and their caregivers. We believe that the results will be generalizable to the larger population of persons being discharged from inpatient rehabilitation following moderate to severe TBI, as we have few exclusions for participation. Importantly, the large sample and diverse geographic area covered by the study will allow robust analyses of heterogeneity of treatment effects, leading to understanding of who might benefit most from each of the interventions. Given that all participating centers are in the US, there is no guarantee that findings will generalize to persons with TBI of equivalent severity who are treated in other healthcare systems across the world, both in developed and developing countries. To the extent that the supports supplied by the RTP are already provided by national healthcare policy, the need for the additional services tested in this trial may be obviated. On the other hand, if the RTP proves successful, regions with less developed TBI treatment pathways, especially outpatient/community-based programming, may benefit from evidence that low-cost follow-along services may help patients and families to access community resources to maximize recovery.

In the US, the RDP approach is already in place at CARF-accredited IRFs such as those in the participating TBIMS centers. The RTP
intervention is designed to be readily implemented in clinical practice, by virtue of its applicability to a wide range of patients and caregivers and its flexibility to be tailored to specific needs. Strengths of the RTP intervention include its remote delivery via telephone or video, which stand to overcome potential access barriers such as transportation and cost. Another strength is the person-centered approach of systematically assessing and addressing common TBI-related needs through proven case management strategies such as culturally sensitive engagement, resource facilitation and care coordination. In addition, the inclusion of training in basic clinical skills such as motivational interviewing and problem-solving strategies should allow case managers with varying types and levels of training to deliver evidence-based care. Despite these strengths, it remains to be seen whether the treatment procedures, and trial findings, will generalize readily to institutions with less TBI experience and expertise than are found in the TBIMS network.

Our hope is that this study will answer key questions about how best to help diverse patients and their caregivers to navigate the transition from the hospital to the community following a moderate to severe TBI, in order to achieve optimal long-term outcomes. If the RTP approach proves to be beneficial, it has the potential for successful implementation with a broad reach. Further research should help to elucidate the generalizability of this treatment model to healthcare systems outside the US, in both developed and developing countries. If the RTP is effective, it would be of great interest to attempt to analyze the “active ingredients” most responsible for change, either by using a dismantling design or by a priori definition and careful measurement of candidate treatment components. Comparative cost-effectiveness of the two models tested within this trial is another important target for future research.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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