BRITE Study Protocol
Version 15.0

Contract Title: Improving Transition from Acute to Post-Acute Care following Traumatic Brain Injury

Brain injury Rehabilitation Improving the Transition Experience (BRITE)

A 1:1 randomized controlled trial design will compare the effectiveness of two established methods of managing transition from Inpatient Rehabilitation Facility (IRF) discharge to the next phase of care, stratifying by site and discharge to another facility (e.g., skilled nursing facility) vs. discharge to home/community.

Principal Investigator:

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Contents

TOOL REVISION HISTORY

Version Number: 2.0 (Revisions made prior to human subject involvement)
Version Date: 01-03-18
Summary of Revisions Made:

1. Added reference of “Rehabilitation Discharge Plan” and “RehabilitationTransition Plan” when discussing Standardized Discharge Care and Optimized Transition Care, respectively;
2. Added name of patient member of DSMB;
3. Deleted reference to requirement that only blind researchers could participate in recruitment procedures;
4. Deleted reference to UWMC and HMC in Screening procedures given protocol applies to all sites;
5. Revised language to indicate de-identified basic demographic information of all potential participants will be entered and stored in the centralized NDSC database rather than in local databases;
6. Revised language to indicate de-identified screening and recruitment outcome information of all potential participants will be entered and stored in the centralized NDSC database rather than in local databases;
7. Added reference to mailing copy of signed consent form to patient participants enrolled following discharge (i.e. LAR provided original consent)
8. Added language clarifying use of information statement sheet to obtain verbal consent from caregivers;
9. Added language identifying the name of data collection forms;
10. Updated language regarding what data is collected as part of the discharge information form;
11. Changed frequency of TCM supervision meetings to “regular” vs. “bi-weekly”;
12. Update names of study sites;
13. Specified when site and discharge destination are entered into the NDSC database;
14. Added language clarifying that the relationship between adverse events and study procedures will be determined by study researchers;
15. Eliminated language regarding classification of severity of AEs (too confusing);
16. Clarified timelines of reporting to PCORI;
17. Clarified timeline of entering AE/SAE/Unanticipated Problem data into the NDSC database;
18. Revised description of data review (both external and internal) to be consistent with revised DSMP.
19. Added reference to provision of response key to both patient and caregiver participants.
20. Added reference to provision of medical services log to patient participants.
21. Added reference to possibility of sending reminder letters to participants in advance of questionnaires.
22. Added reference to possibility of sending letters to participants we cannot reach for questionnaires or RTP phase.
23. Added reference to research staff informing participants that their study participation has been completed.
24. Added reference to completion of study completion form by staff when participant completes study.
25. Added clarifying language for tables 3 and 4.

Version Number: 2.1 (Revisions made prior to human subject involvement)
Version Date: 02-05-18
Summary of Revisions Made:

1. Added language clarifying timing of Form II relative to post-discharge questionnaires;
2. Added language clarifying eligibility criteria for both patient and caregiver participants, specifically:
   a. revised this study's eligibility criterion in the following manner:

   "will be discharged from inpatient rehabilitation to home or nursing facility";
   to
   "will be discharged from inpatient rehabilitation to community (private residence, adult home, hotel, homeless) or facility (nursing home, subacute care i.e. skilled nursing facility)."

   b. added the following inclusion criterion:
   "Current admission to inpatient rehabilitation considered their first comprehensive rehabilitation experience, or extension thereof for most recent TBI (e.g. admitted to inpatient rehabilitation, discharged to acute care, then returns to inpatient rehabilitation to complete their initial stay)."

   c. revised this study's eligibility criterion in the following manner:

   "We will be unable to enroll individuals who are incarcerated due to federal restrictions on inclusion of prisoners in research";
   to
   "We will not enroll individuals who are in law enforcement custody at admission to the designated rehabilitation unit or who are taken into custody prior to discharge from the designated rehabilitation unit due to federal restrictions on inclusion of prisoners in research."

   d. eliminated the non-English speaking exclusion criterion, given its redundancy with the English speaking inclusion criterion.

   e. revised this study's eligibility criterion in the following manner:

   "We will need to limit enrollment to individuals who either have access to a phone or a computer with Wi-Fi"
   to
   "We will not enroll individuals who do not have access to a phone."

   f. Eliminated the following exclusion criterion:

   "Participants will be excluded if there are contraindications to being in the treatment trial, such as TBI resulting from self-inflicted injury or acute psychosis."

   g. added the following basic eligibility criteria for the caregiver participants:
   Inclusion Criteria-Caregiver Participants
   (1) individuals who will have primary care giving responsibility post rehabilitation care discharge of enrolled patient participants;

(2) English speaking (we will track non-enrollment due to other language to determine common languages and have consumer dissemination materials translated for more broad use if time and resources permit.);
(3) at least 18 years old;
(4) able to provide informed consent.

Exclusion Criteria-Caregiver Participants
(1) We will not enroll individuals who are in law enforcement custody due to federal restrictions on inclusion of prisoners in research.
(2) We will not enroll individuals who do not have access to a phone.

3. Added language indicating that all documentation of AEs/SAEs/Unanticipated Problems/Note-to-Files will be done by TCMs to minimize risk of unblinding/unmasking;
4. Added language indicating access to a phone will be assessed via the recruitment talking points;
5. Added language that certain eligibility criteria may be confirmed via conversation with clinical staff and family members;
6. Added language indicating different sub-categories of discharge destination;
7. Add language regarding completion of the Rehabilitation Plan Completion form by TCMs;
8. Added language clarifying that caregiver participants may be discontinued if the patient participant has a new caregiver;
9. Clarified proper documentation of both active and passive suicidal ideation;
10. Clarified proper documentation of unsafe living environments;
11. Clarified proper documentation of adverse change in mental/medical status;
12. Revised language regarding definition of adverse event that will be documented by research team;
13. Clarified that DSM chair will be contacted for all unanticipated problems and study-related SAEs.
14. Indicated location of various electronic forms on NDSC BRITE Website.
15. Added reference to the fact that each site will assign each potential participant assessed for eligibility an ID number unique to that research site. The patient participant will keep the same ID number if enrolled in the study.
16. Added reference to the fact that all sites will assign a patient participant's ID number to their respective caregivers. The caregiver participant will keep the same ID number if enrolled in the study.
17. Revised language regarding TCM supervision and fidelity to intervention procedures.
18. Updated IRB approval information across sites.
19. Revised language regarding baseline data for patient and caregiver participants to clarify the data will not be de-identified when entered into the NDSC database; data will be entered with study ID i.e. not name.
20. Revised 'Data Management' section to indicate identifiable data (street address, audio recordings, DOB, dates of injury and admission) that will be stored with the study data in the NDSC database.

Version Number: 3.0
Version Date: 03-12-18
Summary of Revisions Made:

1. Changed the number from 3.5 to 2.8 million individuals who sustain a traumatic brain injury (TBI) in the US annually based on more recent data;
2. Used reference of “Rehabilitation Discharge Plan” and “RehabilitationTransition Plan” when discussing Standardized Discharge Care and Optimized Transition Care throughout entire protocol;
3. Added language indicating TCMs may contact health care and service providers on behalf of participants as part of the RTP process. These contacts will only be made if the participant gives the TCM permission to do so;
4. Added language about uploading directly TCM process data on a semi-regular basis from sites to NDSC website;
5. Revised language describing participant flow via a consort diagram;
6. Added language regarding the letters sent to both the participants and relevant healthcare providers following completion of the RTP phase. The TCM would only send the letter with the permission of the participant;
7. Added reference to TCM sending participants randomized to RTP a general description of the role of the TCM and description of the particular TCM;
8. Added reference to TCM sending participants the needs assessment that will be reviewed during scheduled contacts as a point of reference to facilitate conversation;
9. Added reference that we will obtain information regarding recommended and received equipment;
10. Added language that injury date is recorded as part of the discharge destination and date form;
11. Added more detailed information regarding discharge destinations;
12. Removed IRB approval record from protocol (to be included only as part of MOP);
13. Removed Decisions Log from protocol (to be included only as part of MOP);
14. Added language indicating that the access to a telephone eligibility criterion may be assessed via observation and discussion with clinical staff in addition to the recruitment talking points;
15. Revised ‘Data Management’ section to indicate identifiable data (street address, audio recordings, DOB, dates of injury and admission) will be stored with the study data in the NDSC database.
16. Added language explaining the content of group supervision meetings.
17. Revised language providing overview of content of TCM manual.
18. Revised language regarding TCM fidelity supervision to describe initial fidelity review (first 4 scheduled contacts) and subsequent monitoring (24 contacts per year per TCM), and who will be reviewing recordings for fidelity purposes.
19. Added language indicating that research staff will attempt to complete the follow-up questionnaires with both patient and caregiver participants 15 days before and 30 days after 3, 6, 9, month assessment, use TBIMS window of 60 days either side of one year assessment with rule that at least 30 days pass between 9 month and 12 month assessments.
20. Eliminated reference to documenting receipt of basic elements of Rehabilitation Discharge Plan given all sites are meeting CARF standards.

21. Corrected study site names throughout protocol.

Version Number: 4.0
Version Date: 07-18-18
Summary of Revisions Made:

Deleted reference to one stakeholder who no longer is part of the study (Shafi);

1. Revised 'Rehabilitation Discharge Plan' section to reflect the actual commonalities of care across all sites;
2. Added all caregiver domains and measures to description of Aim 4.
3. Added the following exclusion criterion: We will not enroll individuals who are unable to complete study procedures due to cognitive/verbal limitations AND do not have a proxy to assist with study procedures;
4. Added language regarding approach with patient participants who are unable to provide consent in the 'Recruitment' section of the protocol;
5. Added language outlining our sampling enrollment approach to manage sites that have more participants eligible than they are able to handle relative to TCM availability, as well as provide example scenarios;
6. Added language indicating only one caregiver can be enrolled at any given time;
7. Provided an example of when the caregiver participant could change during study participation;
8. Added reference to the toll-free number 'BRITE helpline' will be local in nature, i.e. each site has own number;
9. Indicated scheduled contact between TCM and participant(s) may be in person if convenient for both participant(s) and TCM;
10. Added language indicating research staff will not complete a Form II with patient participants not enrolled into TBIMS if the patient is enrolled outside the Form II window described below, specifically more than 60 days after the ideal administration date (12 months following injury);
11. Added language indicating staff will continue with a post-discharge questionnaire even if unblinded during the questionnaire administration, but will attempt to have another staff member (if available) administer subsequent questionnaires;
12. Added language indicating we will record potential unblinding incidents by asking assessors during each post-discharge questionnaire: 1. if they believe they were unblinded during the questionnaire or any previous questionnaire; and 2. to guess which study arm they believe the participant was assigned to;
13. Added language indicating that staff will record unmasking/unblinding with the study note-to-file form only if an incident takes place between questionnaires and has no impact on any questionnaire/data (e.g. blinded staff member who has not been assigned to complete post-discharge questionnaires with patient participant is unblinded by patient participant during a clinic visit).
14. Added a description of unvalidated items developed by the study team to assess for the assistance each patient participant requires as well as time spent interacting with the patient participant. These items are administered as part of the caregiver post-discharge questionnaire;
15. Added language indicating a caregiver participant will remain enrolled in the study and kept on the schedule for data collection even if the respective patient participant

withdraws from the study unless the caregiver participant explicitly states s/he wishes to withdraw as well. Originally we had stated that staff would request permission from the patient participant to keep the caregiver participant enrolled if the patient participant withdrew;

16. Clarified that all protocol changes requiring IRB approval will be recorded in the 'Tool Revision History' section of this document;
17. Made minor revision to introduction of description of demographic data for caregiver participants;
18. Made minor revisions to 'Forms' subsection, including reference to where current CRFs exist on the BRITE website and indicated there were eCRFs;
19. Updated language regarding length of study questionnaires to make language consist across all study forms;
20. Added language indicating that the baseline caregiver questionnaire, post-discharge questionnaires, and the one year following injury questionnaire ("Form II") may be completed via postal mail if necessary. Added language clarifying when the "mailout option" should be initiated;
21. Added language indicating that the follow-up questionnaires that have been started or completed prior to the window start date should have a call back during the window to review the completed items to make sure nothing has changed. The date of the call back occurring within the follow-up window should be used as the questionnaire date. If a call back cannot be completed, the original questionnaire date outside the follow-up window should be used;
22. Added language regarding the "Two-Week Extension Rule": Follow-up questionnaires that have been started but cannot be completed by the time the data collection window closes can be completed within two weeks after the window closes. The questionnaire date should be the date the questionnaire was started;
23. Added language regarding the "Four-Week Completion Rule": Follow-up questionnaires that have been started but not completed during the first contact should be completed within 4 weeks. The follow-up date should be the date of initial data collection. If it takes longer than 4 weeks to complete the follow-up, data collected during the initial data collection period should be verified, and the follow-up date should be the second date that data was collected. In the unusual case where the 2 week extension window is used to complete the follow-up beyond the 4 week time frame, (e.g. interview started January 1st, follow-up window closes January 30th, interview completed February 5th), the follow-up date should be the date of data collection that was in the follow-up window (January 1st in this example);
24. Added language indicating that the mailing of the questionnaire will trigger the 2 week extension to the questionnaire window. Example if you mail the questionnaire July 18, 2018, and the end of the window is August 31st, you can then receive/collect data through September 14th;
    Added language indicating that the mailouts are exempt from the four-week extension rule listed above;

25. Added language indicating that if adequate data are not obtained from the participant by telephone or by mailout two weeks before the end of the window, the mailout questionnaire should be sent a significant other after personalized information has been added to the form, along with a self-addressed return envelope. Like the mailing of the questionnaire to the patient participant, the mailing will trigger the 2 week extension to the questionnaire window. Example if you mail the questionnaire July 18, 2018, and the end of the window is August 31st, you can then receive/collect data through September 14th;

26. Added language indicating that missing data may not be filled in using data obtained outside the follow-up window and two-week extension rule unless approved by the lead site;
27. Added language indicating that, to classify a questionnaire as “followed”, an interview or mailout must be started. There is no minimum number of data elements that need to be answered;
28. Clarified that the enrollment goal for caregiver participants is 607, not 675;
29. Added language indicating staff should follow Standard Operating Procedures 105B from the TBIMS for the One Year Following Injury Questionnaire (“Form II”) completed by non-TBIMS patient participants;
30. Added language indicating that we will collect insurance type/coverage during the 6- and 12-month post-discharge questionnaires;
31. Removed incorrect reference from “STUDY DATA” section that caregiver participants will have demographic data collected either as part of TBIMS or BRITE- all caregiver participants will be enrolled in the BRITE study only.
32. Eliminated language regarding a monthly report sent to investigators outlining protocol deviations/violations and AEs/SAEs. These types of events will be outlined as part of the quarterly reports that will be sent to investigators;
33. We revised Figure 2 to reflect the addition of measures/items to the post-discharge questionnaires.

Version Number: 5.0
Version Date: 09-04-18
Summary of Revisions Made:

1. Added Summer Ibarra and Oscar Guillamondegui, removed Lance Trexler from Professional Stakeholder list.
2. Replaced with ‘discharge plan’/eliminated reference to the Comprehensive Individualized Care Plan (CICP) in the Abstract, ‘Interventions and Comparators’ and ‘Planning the Study sections;
3. Clarified in the Abstract, ‘Interventions and Comparators’ and ‘Planning the Study sections that we will provide a telephone number staffed by the TCM during business hours to all patients/ families in the RTP group as well as others involved in their care so that they may contact the TCM between regularly scheduled calls. Originally we made reference to a helpline, which was confusing/inaccurate.
4. Clarified that multiple caregiver participants can be enrolled at the same time to accommodate if the caregiver role is assumed by different individuals at different points in time during participation (e.g. mother is caregiver at 3- and 9-months post-discharge, significant other is caregiver at 6- and 12-months post-discharge). Research staff will assess who has primary caregiving responsibilities both at each questionnaire period and the RTP phase (if applicable), and engage accordingly the particular participant who most clearly fits the role of primary caregiver. Originally we had planned to only have one caregiver participant enrolled at any given time, i.e. disenroll a caregiver participant if s/he does not fit the role of caregiver at any time during study participation.
5. Clarified that study researchers will cease to engage participants in study activities (i.e. RTP phase, study questionnaires) if they become incarcerated following randomization. Incarcerated participants will remain enrolled in the study, however. Study researchers will resume study activities with participants only once they are no longer incarcerated. Originally we planned to discontinue participants who were incarcerated due to federal

restrictions on inclusion of prisoners in research, but determined this approach was unnecessary as long as incarcerated participants were not engaged in study activities, i.e. study questionnaires or the RTP phase.

6. Revised sampling enrollment approach to factor in caregiver enrollment rate to the sampling enrollment equation (i.e. creates a combined projected patient and caregiver enrollment rate threhold), as well as base the formula on cumulative data rather than previous quarter data for a more accurate reflection of overall numbers.
7. Added reference to the satisfaction with care items administered during the 6- and 12-month patient post-discharge questionnaires.
8. Added a description of procedures regarding the RTP participant survey and cover letter sent to both caregiver and patient participants randomized to the RTP arm of the study about 6 months following discharge.
9. Added language indicating that study researchers will attempt to collect via telephone data from patients that complete the self-administration version of Form II via postal mail. The self-administration form does not include address, information regarding injuries to head/neck, the Supervision Rating Scale, the GOSE, and the FIM. Also, included language referring to a cover sheet that will allow study researchers to collect the data described above as well as administrative items if a site is using a paper version of the form for data collection.

Version Number: 6.0
Version Date: 02-19-19
Summary of Revisions Made:

1. Added two new stakeholders, removed Clingan and Kissinger, alphabetically ordered stakeholders;
2. Changed PI at Moss Rehabilitation from Tessa Hart to Thomas Watanabe, MD, added Monica Vaccaro as co-investigator at Moss;
3. Updated language in sampling enrollment approach to emphasize identification of eligible patients/ rate of eligible patients identified and/or enrolled within the sampling enrollment approach;
4. Revised language about TCM supervision, regarding frequency of supervision as well as the fact that investigators will no longer provide monthly feedback based on fidelity ratings;
5. Revised windows for 12 month post-discharge questionnaire and Form II non-TBIMS from 60 days to two months on either side of the ideal administration date.
6. Revised the description of procedures regarding the RTP participant survey;
7. Added revised power analysis by Dr. Ciol on 1/28/19;
8. Revised the “SAFETY MONITORING” section in the following ways:
    a) Made minor wording revisions to match the DSMP;
    b) Clarified that study researchers will contact the Chair of the DSMB when an unanticipated problem is discovered within one week of discovery;
    c) Eliminated language indicating that NDSC staff will send a reminder email to study coordinators to enter data for unanticipated problems within the past month- not necessary given training of staff;
    d) Indicated that a closed session of the annual DSM meeting may take place <u>if desired</u> by the DSMB members whereby the secretary and study statistician will be present during the closed session. They would discuss

the contents of the report, any concerns they might have, any unblinded analyses the DSMB members want the statistician to conduct, whether the study warrants continuation based on its risk/benefit ratio, and formulate any recommendations moving forward. The DSMB may opt not to conduct a closed session if deemed unnecessary;

e) Removed language indicating unblinded information would not be discussed during the "open" session of the DSM meeting. Rationale: no members present are blinded to assignment, thereby negating the need to discuss only blinded information;

f) Clarified that the meeting secretary OR DSM chair will send the meeting summary to the lead site PIs within two weeks of the meeting;

9. Updated Tables 3 and 4 to reflect the RTP Satisfaction survey.
10. Updated Figure 2 to reflect all assessments

Version Number: 7.0
Version Date: 03-28-19
Summary of Revisions Made:

1. Added language clarifying that the TCMs may share with medical providers/community resources information learned during the RTP phase that would maximize addressing any needs, including but not limited to contact information, details regarding the patient's TBI, and any other pertinent information. The TCMs will make it clear to the participants in advance what information will be shared during any contacts with medical providers/community resources.

Version Number: 8.0
Version Date: 10-17-19
Summary of Revisions Made:

1. Removed Scott Bloom and William Dane as professional stakeholders, and Kelly Gilliam as a patient and family stakeholder;
2. Revised Dr. Seidner's place of employment and title;
3. Decreased the targeted caregiver enrollment number from 607 to 540 participants given the actual percentage of potential eligible caregivers is 67% as opposed to the original projected percentage of 75%;
4. Decreased the targeted monthly caregiver enrollment number from 17-18 to 13-14 participants given the actual percentage of potential eligible caregivers is 67% as opposed to the original projected percentage of 75%;
5. Decreased the estimated number of eligible caregivers from 675 to 600 given the actual percentage of potential eligible caregivers is 67% as opposed to the original projected percentage of 75%;
6. Increased the number of lost patient participants from 90 to 180 participants given we anticipate having a more difficult time with retaining participants and therefore are planning for an 80% retention mark versus the original proposed 90% retention mark.
7. Increased the number of lost caregiver participants from 60 to 110 participants given we anticipate an 80% retention mark versus the original proposed 90% retention mark AND the decreased anticipated number of enrolled caregivers.

8. Clarified in the “Engagement Plan” section that the stakeholders will be involved in developing data collection procedures rather than actual data checking;
9. Removed reference to Dr. Hart as a TBIMS investigator (retired);
10. Added reference to the “Security of Records” section regarding a listing of exceptions to the separation of identifiers and study data in the “Data Management” section;
11. Clarified that staff will record an occurrence as an adverse event if the occurrence is a new symptom/condition for the participant, OR a symptom/condition that began before enrollment yet has become significantly worse following enrollment;
12. Added language that planned surgeries with no complications will not be documented as adverse events.
13. Revised the “REPLICATION AND REPRODUCIBILITY OF RESEARCH AND DATA SHARING” section to reflect PCORI’s policy approved by the Board of Governors of PCORI on September 7, 2018 regarding data management and data sharing.

Version Number: 9.0
Version Date: 04-06-20
Summary of Revisions Made:

1. Added Taylor Obata to study roster given expanded capacity;
2. Added Rebecca Chung and David Minor to the stakeholder roster, alphabetized the patient and family stakeholder;
3. Revise sampling enrollment approach to specify the recruitment/enrollment data reviewed on a quarterly basis will be based on recruitment/enrollment data from the previous six months. Also, broaden the language to allow sites to request initiation of the sampling enrollment approach even if they don’t meet criteria/ specify that sites may decline to initiate the sampling enrollment approach even if they qualify;
4. Added to the “Consent (PC-1)” section an explanation of the consent by phone process;
5. Updated “Randomization/Post-Discharge Transition Phase” to account for patients enrolled after discharge.

Version Number: 10.0
Version Date: 09-24-20
Summary of Revisions Made:

1. Added Monica Lichi as Co-I for Ohio
2. Removed Kevin Gertz as Research Manager
3. Removed Kelsey Hurm as Clinical Research Technician from Indiana
4. Replaced Emergency Problems Response Protocol with Suicidal Ideation Response Protocol

Version Number: 10.1
Version Date: 09-25-20
Summary of Revisions Made:

1. Corrected Monica Lichi’s title from Co-I to Research Team Director

Version Number: 11.0
Version Date: 02-08-21
Summary of Revisions Made:

1. Updated Milestone Schedule in Appendix 1
2. Added Data Quality Guidelines to Appendices
3. Added “Data Quality Targets – Enrollment” description to Recruitment section
4. Added “Data Quality Targets – Assessment Completion” description to Follow-up Data Collection section

Version Number: 12.0
Version Date: 06-24-21
Summary of Revisions Made:

1. Updated Milestone Schedule in Appendix 1
2. Updated “Table 1. Recruitment/Enrollment Assessment Timeline” to reflect changes to timeline
3. Added “Plan for analysis of COVID-19 Pandemic impact” section to Data Analysis Plan
4. Removed Stella Mandl from Study Roster

Version Number: 13.0
Version Date: 10-19-21
Summary of Revisions Made:

1. Updated Milestone Schedule in Appendix 1
2. Added Appendix 3: Engagement Evaluation Funding
3. Removed Christine MacDonnell from Professional Stakeholders and replaced with Terry Carolan

Version Number: 14.0
Version Date: 01-14-22
Summary of Revisions Made:

1. Updated Beverley Laubert description in Professional Stakeholder Roster

Version Number: 15.0
Version Date: 01-23-23
Summary of Revisions Made:

1. Removed Monica Lichi from Professional Stakeholder Roster and Study Sites and Investigator Roster
2. Updated Milestone Schedule in Appendix 1

STUDY ROSTERS

Professional Stakeholder Roster

Nicole Adams, *Pennsylvania DOH, Acting Public Health Program Manager; PA Brain Injury Advocacy*

Greg Ayotte, *Brain Injury Association of America, Director of Consumer Services, US Brain Injury Advocacy*

Jane Boutte, MA/SLP, *Baylor Institute for Rehabilitation (BIR), Program Manager; TX Brain Injury Advocacy*

Michael Choo, MD, MBA, *Paradigm Management Services, LLC, CMO; Private Insurance*

Maureen Correia, RN, *Molina Health Care, Supervisor, Case Management; Medicaid*

Deborah Crawley, CBIS, *Brain Injury Alliance of Washington, Executive Director; WA Brain Injury Advocacy*

Robert Fraser, PhD, *University of Washington, Professor, Vocational Rehabilitation*

Brian Giddens, LICSW, ACSW, *University of Washington Medical Center, Director, Social Work and Care Coordination & University of Washington School of Social Work, Clinical Professor; Social Work/Case Management*

Oscar Guillamondegui, MD, MPH; *Vanderbilt University Medical Center Professor of Surgery, Medical Director, Trauma ICU, Director Multidisciplinary Traumatic Brain Injury Clinic*

Summer Ibarra, PhD, *Dept. of Rehab Neuropsychology, Rehabilitation Hospital of Indiana, Clinical Neuropsychologist and Director, IN Brain Injury Advocacy*

Kurt Kroenke, MD, MACP*, Indiana University School of Medicine, Professor of Medicine & Regenstrief Institute, Senior Scientist; Primary Care*

Beverly Laubert, RN, *Ohio Department of Aging, State Long-Term Care Ombudsman, Long Term Care*

Jeff Lilly, MPA, *Brain Injury Association of Indiana, Board President; IN Brain Injury Advocacy*

Terry Carolan, *CARF International, Managing Director, Medical Rehabilitation and International Aging Services/Medical Rehabilitation; Rehabilitation Accreditation*

David Minor, MIPM, *TBI Council and Fund Coordinator, Home and Community Services Aging & Long-Term Support Administration*

Lisa Perla, MSN, *Veteran's Health Administration, National Polytrauma Coordinator; Veterans Administration*

Stephanie Ramsey, BSN and MPH, *Brain Injury Association of Ohio, President; OH Brain Injury Advocacy*

Risa Richardson, PhD, *Polytrauma Program, James A. Haley VAMC, Clinical Neuropsychologist & Department of Medicine, University of South Florida, Associate Professor; Veterans Administration*

Joel Scholten, MD, *Veterans Health Administration, National Director, Physical Medicine and Rehabilitation & Associate Chief of Staff for Rehab Services, Washington DC VA Medical Center; Veterans Administration*

Adam Seidner, MD, MPH, *The Hartford, Chief Medical Officer; Workers Compensation Insurance*

Caitlin Synovec, MS, OTD, *Health Care for the Homeless*, Occupational Therapist

Karen Thomas, CBIST, *Brain Injury Association of New York State, Director of Family Services*

Monica Vaccaro, MS, CBIS, *Brain Injury Association of Pennsylvania, Programs Manager; PA Brain Injury Advocacy*

Patient and Family Stakeholder Roster

Irene Ziaya, Patient and Family Stakeholder Board Member - Chair

Richard Anderson

Cavin Balaster

Rebecca Chung

Deborah Fandel

Susie Fitt

Paul Howard

Elaine Howard

Jonathan Leiser

Audrey Self

Julie Self

William Svihla

Gail Weingarten

Study Sites and Investigator Roster

LEAD SITE: University of Washington

PI: Jeanne Hoffman, PhD
PI: Jesse Fann, MD, MPH
Co-I: Megan Moore, PhD, MSW
Statistician: Marcia Ciol, PhD
Research Manager: Leslie Kempthorne
Research Coordinator: Taylor Obata

Baylor Institute for Rehabilitation

PI: Simon Driver, PhD
Co-I: Randi Dubiel, DO

Indiana University School of Medicine/ Rehabilitation Hospital of Indiana

PI: Flora Hammond, MD

Moss Rehab Hospital

PI: Thomas Watanabe, MD
Co-I: John Whyte, MD, PhD
Co-I: Monica Vaccaro

Mount Sinai Health System (NY)

PI: Kristen Dams-O'Connor, PhD
Co-I: Maria Kajankova, PhD

Ohio State University Wexner Medical Center

PI: Jenny Bogner, PhD
Co-I: John Corrigan, PhD

Data Coordinating Center

Cindy Harrison Felix, PhD
Dave Mellick, MA

Data Safety Monitoring Board

Thomas Novack, PhD, ABPP
Lillian Lin, Ph.D.
Scott Beckett – Patient Member

ABSTRACT

Background and Significance:

Each year about 2.8 million people sustain a traumatic brain injury (TBI) in the US, and at least 25% of these injuries are classified as moderate to severe. Nearly half of those hospitalized for TBI have long-term disability. The majority experience psychological, physical, social, or vocational problems, many of which become chronic. TBI outcomes are affected by the type, location and severity of injury and are impacted by the availability, expertise, and intensity, duration, and timing of rehabilitation treatment. Following inpatient rehabilitation, Interventions for TBI-related symptoms and impairments are not consistently delivered to those in need and individuals are challenged to manage their own care because of the nature of their brain injuries (e.g., poor memory, behavioral problems, social isolation). Community resources are limited and primary care providers are unprepared to care for TBI-related problems, leaving many TBI survivors with unmet healthcare needs. There is a dearth of comparative effectiveness research examining patient-centered approaches to overcome the personal and organizational barriers to receipt of appropriate care. Current clinical practice guidelines prescribe hospital-based education, reassurance, advice, and referral after TBI. Given the heterogeneity in severity and range of problems, more assistance following discharge may be required to improve outcomes. Recently, models that use (1) telehealth to reduce barriers to care and (2) case management to improve coordination of care have been found to be acceptable and effective in improving quality of life after TBI. Therefore, we plan to compare the effectiveness of Standardized Discharge Care (SDC) as labeled in our original application and grant proposal, henceforth referred to as the "Rehabilitation Discharge Plan" (RDP), vs. RDP plus Optimized Transition Care (OTC) as labeled in our original application and grant proposal, henceforth referred to as "Rehabilitation Transition Plan" (RTP) in improving patient-centered outcomes in people with recent moderate to severe TBI.

Study Goals:

The overall goal of our research is to determine the features of healthcare transition approaches that are most effective for improving outcomes of importance to patients after discharge from inpatient rehabilitation for TBI, as well as outcomes of importance to their families, caregivers, and healthcare providers. This project will provide critical information that will help optimize and guide the future of healthcare for survivors of TBI.

Specific Aims:

1. To compare the effectiveness of the Rehabilitation Discharge Plan (RDP) vs. Rehabilitation Transition Plan (RTP) on improving patient-reported outcomes of (1) participation and (2) health-related quality of life for individuals with moderate to severe TBI who receive inpatient rehabilitation
2. To compare the trajectory of improvement across the first year post-discharge (with measurement at 3,6, 9, and 12 months post-discharge) on patient-reported outcomes of (1) participation and (2) quality of life
3. To compare differences in healthcare utilization between RDP vs. RTP across the first year post discharge.
4. To compare the effectiveness of RDP vs. RTP on caregiver-reported caregiver outcomes including burden, quality of life, and caregiver participation.

Study Description:

We plan to enroll approximately 900 adults with moderate to severe TBI who are discharged from inpatient rehabilitation at one of six participating TBI Model Systems sites (WA, NY, PA, TX, OH, IN). Eligible patients will be recruited, consented and randomized into one of two treatment groups. We plan to enroll approximately 607 caregivers.

Randomization will be blocked on study site and discharge to another facility vs. home/community.

Treatment Conditions:
(1) Rehabilitation Discharge Plan (RDP): will consist of the standard elements of discharge care that are already in place at participating centers; these include: (1) patient and family education, (2) written discharge care instructions, (3) a follow-up plan, and (4) a brief phone call from an inpatient care provider within 3 days of discharge.
(2) Rehabilitation Transition Plan (RTP): RTP will include TBI case management, provided by a TBI Care Manager (TCM) who will contact the patient/ family by phone (or mobile teleconferencing) to provide assistance to connect them with resources, overcome obstacles to following the discharge plan, and address any new needs reported. With the participants' permission, the TCMs may contact healthcare and service providers on behalf of the participant to provide assistance with logistical (e.g. scheduling an appointment) and/or healthcare issues (e.g. informing a provider of an issue the participant is experiencing but has difficulty expressing to the provider).Calls will occur over 6 months: weekly, starting 1 week after discharge, for 4 weeks; biweekly for 2-3 months, depending on individual progress and needs; then monthly for 2-3 months. Patients, families, caregivers, as well as others involved in the patient's care may be provided the TCM's telephone number to contact her during business hours. The TCM can also be accessed via e-mail or text message.

Outcomes Assessment:
Early engagement with patients, family and other stakeholders revealed that survivors of TBI are primarily concerned about: (1) returning to pre-injury roles and activities and (2) regaining quality of life. We chose the Participation Assessment with Recombined Tools-Objective 17 (PART-O) and the Quality of Life after Brain Injury Scale (QoLIBRI) as primary outcomes because they capture content important to our stakeholders and are recommended by national TBI outcomes experts. Secondary outcomes will include assessment of healthcare utilization, caregiver burden, and process variables. Outcomes will be assessed at 3, 6, 9, and 12 months following discharge, with the primary outcome at 6 months. Analysis will be by intent to treat.

Dissemination:
In preparation for this project, we have engaged a team of patient and family stakeholders who participated in defining the study aims, study population, interventions, assessment strategies, and outcome measures and will participate in all phases of the study. We have also identified and sought partnerships with clinical, health system, policy/advocacy, and payer stakeholders who have agreed to work with us to implement and disseminate findings in order to improve standards of care and optimize healthcare systems for persons with TBI.

BACKGROUND (Criterion 1, RQ-1, RQ-3)

Traumatic Brain Injury is a common condition which can have lifelong consequences. About 2.8 million individuals annually in the United States sustain a TBI,[2] and at least 25% of these injuries are classified as moderate-to-severe.[3] According to the most recent data, there was a 19.5% increase in TBI-related hospitalizations from 2002 to 2006.[4] A recent estimate based on hospital discharge data suggested that 116,000 Americans older than 15 years of age are discharged each year after a moderate-to-severe TBI.[5] Nearly half of those who are hospitalized for TBI have long-term disability.[6] Moderate-to-severe TBI commonly results in a complex mix of physical, cognitive, behavioral, and psychosocial difficulties; the cognitive sequelae in particular may limit the ability of survivors to adjust to functional changes and to manage their long-term health and rehabilitation needs.[6] Growing evidence also suggests that moderate-to-severe TBI frequently evolves into a chronic disease process characterized by reduced life span and many secondary conditions, including the onset of Parkinson's disease.[7-9] Extensive reviews of the literature demonstrate that TBI outcome is affected by the type, location and severity of injury, mitigated by (1) treatment expertise; (2) intensity, duration, timing, setting and scope of rehabilitation; and (3) the availability of follow-up services.[10-19] Each of these mitigating factors is potentially modifiable. The over-arching goal of the proposed project is to impact outcome by identifying the best discharge planning and transitional care services model for maximizing functional gains for TBI survivors while minimizing burden on caregivers as patients with TBI make the transition from inpatient rehabilitation facilities (IRFs) to the next level of care (community or skilled nursing facility). In doing so, we will address gaps that commonly emerge during this transition.

Frequent Abbreviations

CARF	Commission on Accreditation of Rehabilitation Facilities
IRF	Inpatient Rehabilitation Facility
KTC	Knowledge Translation Center
NIDILRR	National Institute on Disability, Independent Living & Rehabilitation Research
PTA	Post-traumatic amnesia
RDP	Rehabilitation Discharge Plan
RTP	Rehabilitation Transition Plan
SAC	Study Advisory Committee
TBI	Traumatic Brain Injury
TBIMS	TBI Model Systems
TCM	TBI Care Manager
VHA	Veterans Health Administration

Gaps in the evidence exist for transition from IRF to next level of care for individuals with moderate-to-severe TBI (RQ-1, RQ-3). The standard of care within IRFs has been defined by the Commission on Accreditation of Rehabilitation Facilities (CARF)[20] and includes key elements such as education related to a patient's diagnosis and ongoing impairments, medications, and planning for follow up after discharge. These elements have been incorporated into evidence-based interventions such as Project RED (Re-Engineered Discharge),[21] BOOST (Better Outcomes for Older Adults through Safe Transitions),[22] and Care Transition Intervention[23] designed primarily to address the core pitfalls that frequently resulted in unplanned rehospitalizations. For example, Project RED includes recommendations for organizing outpatient follow-up and discharge medications, providing education on medication and the patient's condition (diagnosis) as well as the discharge plan, and ensuring the discharge summary gets to the patient's outpatient provider. While these recommendations were not standard for acute hospital discharges prior to the development of these programs, they are consistently followed at discharge from inpatient rehabilitation and are part of the CARF standards.[20] However, despite being the standard of care in CARF accredited IRFs, the standard discharge model has not been evaluated systematically for individuals with TBI.
A more intensive form of case management is a standard of care for complex populations, such as TBI, within the Veterans Health Administration (VHA)[24, 25] as well as in several organizations around the United States such as through some state Brain Injury organizations and through Labor and Industries for work injuries.[26, 27]

There has been increasing use of case management to assist in the transition of care between acute and post-acute activities for a variety of diagnoses.[28, 29] Research suggests that the use of case management can result in a reduction in 30-day readmission as well as improvement in function, and decreased health service use and spending.[30, 31] However, there is little consistency in the content, level of personal assistance, or timing of services. Systematic reviews of the impact of case management to facilitate the transition between IRF and community for individuals with TBI have been conducted and results suggest that the evidence remains mixed, due in large part to inconsistent definitions of case management, inadequate comparators and statistical power, selection bias, and varied follow up time periods.[32, 33] While research has not been extensive, in a report to Congress, there has been a call to "develop and evaluate service models that will assist patients to better navigate the post-acute rehabilitation setting."[34]

Given that both more and less intensive approaches to discharge from IRF support are currently in use, this poses a decisional dilemma for patients, their families, as well as providers and health care systems as to which method is most effective for the majority of individuals to maximize health and function as well as reduce complications and healthcare utilization and costs. As our group sought input from stakeholders, including patients, family members, clinicians, healthcare administrators, insurers, and advocacy organizations in the community, we consistently heard that individuals with moderate-to-severe TBI and their families often fall through the cracks in the system. Comparative evidence from well-defined approaches to transition of care would allow for improvements in the healthcare system.

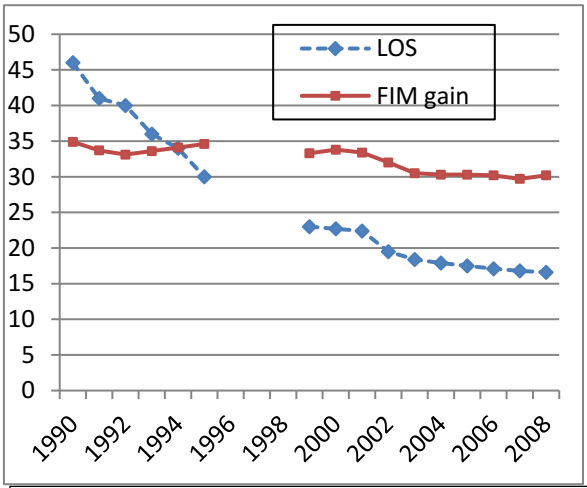


Figure 1. Average length of stay (LOS; days) and FIM™ gain from admission to discharge for TBI inpatient rehabilitation admissions, 1990-2008. (Data from the Uniform Data System for Medical Rehabilitation.[1] Data for 1996-98 have not been published.)

Currently healthcare service delivery for individuals with moderate-to-severe TBI is "front-loaded" to deal with the injury event, followed by fragmented and inconsistent long-term care. *Injured individuals require acute hospitalization and intensive inpatient rehabilitation, as well as individualized outpatient services to support continued recovery and community integration. Optimal outcomes depend upon individualized services being delivered with sufficient intensity and duration.* Due to the fragmented system of outpatient care in the United States, even patients who are treated in specialized TBI rehabilitation units may be lost to follow up thereafter. The TBI care system in the United States currently is focused on the acute event, such that resources are expended on emergency and acute hospital-based care with little attention to the long-term needs of survivors.

As the duration of inpatient rehabilitation has declined dramatically since 1990, patients with TBI are discharged "quicker and sicker" (see **Figure 1**). While there are many factors which contribute to variability in both length of stay (e.g., insurance coverage, discharge plan, etc.) and FIM gain (e.g., severity of injury, comorbid conditions, etc.), those admitted to inpatient rehabilitation for TBI continue to experience reduced lengths of stay, and are discharged from intensive rehabilitation at lower levels of functioning with less time to adjust to disability. More than half of individuals with moderate-to-severe TBI who receive inpatient rehabilitation are still in post-traumatic amnesia (PTA) one month after the injury,[35] which means they are still confused and disoriented to person, place and/or time, and are unable to remember daily events. Many individuals with TBI are discharged from acute care hospitals within this time frame.[36] The burden then falls on the patient and family to coordinate care, seek specialized services, and manage care needs, which may be extensive. A recent study of outcomes of over 9,000 patients within the National Institute for Disability, Independent Living and Rehabilitation Research (NIDILRR)-funded TBI Model Systems (TBIMS) found that reduction in IRF length of stay was accompanied by a decrease in the level of cognitive functioning upon inpatient rehabilitation discharge, as measured by the Disability Rating Scale, and reduction in the number of patients achieving higher levels of functional independence (measured using the FIM™) at one year post injury.[37] The implications of short hospital stays on functional outcomes not captured in the FIM™ and DRS (e.g., psychosocial adaptation, burden on families) are not known. However, our stakeholders have helped us to appreciate how abbreviated hospital care after a TBI affects the patient, family and community, particularly the stages of recovery that occur after discharge.

Inadequate transition from hospital-based care to the community negatively affects patients, their families, and their communities. Not surprisingly, TBI can have a profound effect on the family, as living with and caring for a TBI survivor can result in ruptured interpersonal relationships, high rates of divorce and separation, caregiver distress, caregiver burden, and depression among family members.[38] The literature is replete with evidence gathered from patients, families, caregivers, clinicians and other stakeholders that indicates a dire need for enhanced discharge planning and transitional care services following discharge from the hospital after TBI.[39-42] Discharge is often experienced as a chaotic and stressful time during which patients and families who have only recently emerged from the trauma of the injury are suddenly faced with the responsibility of caring for (or finding care for) a loved one with severe functional deficits. A recent study reported that more than half of caregivers felt that they were not provided enough information about TBI, and most felt that discharge planning services were inadequate.[43]

Similarly, population-based studies have documented a high rate of unmet needs following hospital care for TBI.[44] Numerous other survey, interview, and focus group studies of individuals with TBI and their caregivers indicate that after discharge from an IRF patients struggle with how to find information about TBI, how to manage their symptoms, and how to access relevant services.[45, 46] Specific needs identified after discharge from the acute or rehabilitation hospital include information about community resources, greater understanding of individualized prognosis and long-term outcomes, information about school or job re-entry, techniques for managing TBI-related symptoms, information on coping, adjustment and self-care for caregivers, financial assistance, and information about home-based services and assistive equipment.[45, 47-50]

While CARF regulation of rehabilitation facilities has helped to ensure that discharge planning guidelines are followed, the research literature and our stakeholders have affirmed that these protocols are insufficient. Indeed, for individuals with traumatic injuries who receive inpatient rehabilitation at a CARF-accredited Model System of care, 28% are rehospitalized within the first year of injury, and rehospitalization rates remain high up to ten years post-injury.[51, 52]

Current models of transition inadequately support individuals with TBI and their families. The need for help with care transitions is not unique to individuals with TBI, and we reviewed the general research literature for data that might inform the ideal content and timing of transitional services. However, some of the commonly recommended approaches to patient education may not be ideally suited for some or all TBI survivors and their families. For example, it is frequently recommended that patient and family education about home care begin almost immediately after hospital admission.[53] However, individuals who are in PTA for all or most of their hospital stay are by definition unable to retain information provided during this time. Throughout our focus groups we heard patients tell us that their hospital stay was a traumatic and chaotic time for their families and consequently, much of what was "taught" was soon forgotten. Similarly, in-hospital education guidelines suggest addressing both present and future needs,[53] but our focus group participants told us they were easily overwhelmed by discussions of future needs such that instead of feeling prepared or empowered, they felt burdened and sometimes hopeless. We also heard that accessing help in person was often a barrier even if the help was available. Therefore having access via the telephone or email was highly recommended. Consistent with these reports, a study of TBI survivors and their caregivers found that poor recall of information provided at hospital discharge was associated with perceived lack of personal relevance of the information, the timing of information provision, the manner of teaching, and the emotional state of the patient/caregiver at the time of information receipt.[45] Together these findings suggest that transitional planning and support would optimally extend beyond the time of hospital discharge and be available at a distance (via telephone or other method). Once patients and their families begin to develop a better sense of what their needs are in the weeks following discharge, individualized information about care strategies and resources could help address those needs as they unfold.

The study team is well-poised to successfully conduct a comparative effectiveness trial given their experience and prior collaborative engagement. All six study sites are NIDILRR-funded TBIMS sites.[54] NIDILRR competitively awards TBIMS grants to institutions that are national leaders in medical research. Each TBIMS enrolls individuals who receive inpatient rehabilitation for TBI into a longitudinal outcome study and contributes detailed data to the Traumatic Brain Injury Model Systems National Data and Statistical Center (TBI NDSC). These centers have demonstrated the ability to track outcomes of their patients for up to 25 years post-injury with excellent retention rates (average of 90% successful follow-up across years 1, 2, 5, 10, 15, 20, 25 years, with 94% successfully followed at 1 year for the six sites involved in this grant) and over 15,000 patients enrolled. The TBIMS has a long history of conducting innovative projects and research in the delivery, demonstration, and evaluation of medical, rehabilitation, vocational, and other services designed to meet the needs of individuals with TBI. More than 500 peer-reviewed publications have been authored by TBIMS investigators since 1987. A central goal of the TBIMS Knowledge Translation Center (TBIMS KTC) is to provide information and resources to individuals with TBI, their families, caregivers, and friends, health care professionals, and the general public.

The six collaborating centers involved in the current grant represent six states: Washington (WA; lead center), New York (NY), Ohio (OH), Indiana (IN), Texas (TX), and Pennsylvania (PA).

This existing infrastructure demonstrates: (a) prior experience with enrolling individuals with TBI and their families into research studies that begin at the time of inpatient rehabilitation, (b) successful tracking of outcomes over time, (c) an extensive track record of multi-center collaboration, and (d) extensive resources for disseminating knowledge gained through our research.

Our study team has experience with transitional care and evidence that telephone-delivered information and referrals after hospital discharge improves functional outcomes. The lead center on the current application (WA/University of Washington) conducted a telephone intervention from 1999 to 2002 (which enrolled 95% of eligible participants), which was delivered after discharge from inpatient rehabilitation. The intervention attempted to bridge the gap between hospital and community by proactively providing information, problem-solving advice, and referral services while also addressing survivor and family concerns early after discharge and as they unfolded.[55] Those who received the telephone intervention had better functional outcomes and quality of life[56] and fewer depression symptoms[57] than participants who received standard follow-up. Results suggested that telephone follow-up may enhance service provision after TBI, and 81% of the problems identified by patients and caregivers were able to be addressed via telephone (through psychoeducation and resource facilitation) as opposed to community medical referrals, tertiary care referrals or emergency services.[55] This study demonstrates: a) telephone follow-up is feasible in the weeks and months after discharge from inpatient rehabilitation, b) individual contact allows for the provision of tailored information and referrals to local resources, and c) the lead center has been successful in conducting a transitional care intervention.

SIGNIFICANCE (Criterion 2, 4, RQ-1)

This grant addresses PCORI's priority topic on TBI to "Compare the effectiveness of multidisciplinary rehabilitation programs for moderate-to-severe TBI in non-military or veteran adults." Consistent with this priority, we seek to improve the "transition between acute inpatient rehabilitation and subsequent care, and examine the impact on a patient's functional status." By leveraging our existing TBIMS infrastructure, which includes a high volume of patients with moderate-to-severe TBI, we can readily examine "pre-specified patient and clinical subgroups." Our grant is also consistent with several IOM priorities, e.g., to compare the effectiveness of comprehensive care coordination programs; diverse models of transition support services for adults with complex health care needs; different quality improvement strategies in disease prevention, acute care, chronic disease care, and rehabilitation services for diverse populations; and different strategies to engage and retain patients in care and to delineate barriers to care, especially for members of populations that experience health disparities. Our grant is also consistent with AHRQ priorities including outpatient case management for adults with medical illnesses and complex care needs, and multidisciplinary rehabilitation programs for moderate-to-severe TBI in adults.

Equally important if not more so, improving transition care is a high priority for our stakeholders. Given that our study team has been examining TBI as a chronic condition for several years, we have sought input from individuals with brain injury to understand how they interact with the healthcare system and this made us aware of the significance of getting individuals help early after TBI to connect them with resources and also with others with brain injury. We have heard from individuals with TBI and their families that even when they received excellent hospital care, the transition to the community was difficult. In addition, clinicians describe even more concern for those individuals who do not have available and invested family members to assist as they transition out of the hospital.

Our Professional Stakeholders who work for advocacy organizations describe a struggle in knowing the best approach to supporting members of the TBI community. For example, one of our Professional Stakeholders stated "*I have attended conferences to learn how we can best provide assistance to individuals with brain injury, but when I read about 'case management' everyone is describing something different. If you could provide evidence for a standardized approach following discharge you can improve how transitional care is given across the country. We will immediately adopt it*."

Evidence from this comparative effectiveness study will aid in decision making for health care systems and advocacy groups on best practices for transition and coordination of care (RQ-3, RQ-5). Rehabilitation administrators are faced with the question of how they can provide patients with discharge care that will reduce the likelihood of readmission into the hospital while optimizing patients' ability to successfully resume community living. Currently, accredited rehabilitation units utilize a discharge care plan that meets CARF standards under the assumption that these standards maximize outcome. However, the discharge approach within the VHA and other systems suggest that more intensive and temporally distributed case management as in our Rehabilitation Transition Plan (RTP) may be a more effective model. Unfortunately, while similar models have been shown to be effective with other populations, they have not been directly compared to the current standard approach used across the country. While requiring additional personnel, the RTP could reduce hospital readmissions that incur penalties levied by the Centers for Medicare and Medicaid Services which may balance any cost differential. In preparation for the current application, researchers from the six TBIMS sites partnering for this grant conducted a series of focus groups with patients, family members, and caregivers. Our group's preliminary data suggest that, despite following current CARF standards for discharge, there are unacceptably high rates of missed follow-up clinical visits, gaps or lapses in clinical care, and overall dissatisfaction with the information, education, and resource facilitation available. Additional discussion with our Patient and Family Stakeholders highlighted the need for improved follow up including education, communication, and support during the transition from inpatient rehabilitation to the next level of care.

In addition to our Patient and Family Stakeholders, members of our study team have been leading the research agenda on conceptualizing TBI as a chronic condition which requires setting individuals on an early positive trajectory to maximize their function and quality of life and reduce secondary conditions. The annual Galveston Brain Injury Conference (GBIC) convenes a group of experts in TBI with a goal of advancing research and clinical care. In the last 5 years, experts including consumer representatives, clinicians, researchers, and policy members focused on the topic of "Brain Injury as a Chronic Condition."[58, 59] GBIC leaders, including numerous members of our research team, actively participated in this initiative. Case management that supports a tailored comprehensive discharge plan was identified as an important component to improve outcomes and reduce chronic conditions. Conceptualizing TBI as a chronic condition given the vast, complex array of problems and the lack of centralized TBI care in the community makes the prevention or delay of chronic conditions through early detection and intervention an important goal.

As part of the GBIC, investigators from two study sites (WA and NY) conducted a series of focus groups to learn <u>how</u> individuals with brain injury seek and access health care. Groups were asked a series of open-ended questions about their experiences with health care after brain injury, including any barriers or facilitators that have affected their ability to access and manage health care. Participants were, on average, 17 years post-injury, and qualitative analysis of focus group content identified key themes.

Discharge from the hospital, whether from an acute care hospital, rehabilitation unit, or nursing facility, was frequently identified as a challenging time for the patient and family, with several participants reporting that they were given insufficient information or poorly timed information. Several focus group participants remembered having been given a packet or binder of information upon discharge from the unit, but indicated that they (or their families) were too overwhelmed to recall the information provided, and many indicated that they had never even looked at the materials. Another commonly identified theme centered on gaps in care in the community, and most of the examples given by participants occurred during the transition from IRF to the next level of care. Some participants acknowledged missing follow-up appointments and not knowing how to reschedule, others indicated they were never given follow-up appointments, and still others reported considerable lags in accessing rehabilitation therapies (such as physical therapy) because they were unsure how to find specialty providers in their communities.[60]

There has also been research to indicate access to care and TBI-related services are primary needs in the first years after injury. One study site (NY) conducted a survey of individuals with TBI (or their caregiver) to evaluate satisfaction across 26 aspects of daily life and identify unmet needs that contribute to dissatisfaction. Although the interview asked about a wide range of social roles and activities, some of the most commonly identified unmet needs in the first year post-injury were in access to information and resources about TBI or disability, access to TBI-related services, and understanding the challenges related to TBI.[61] This study was cross-sectional and did not follow participants over time, but individuals who were many years post-injury and reported similar needs for information, resources and services also reported dissatisfaction with their physical health and interpersonal relationships. These findings demonstrate that: (a) Insufficient information about TBI and inadequate access to local resources and services are common areas of unmet need and sources of dissatisfaction in the early post-acute stage after TBI, (b) failure to meet these needs early in the post-acute stage of recovery may represent a missed opportunity to help a person with TBI and his/her family establish systems of care and other resources needed for longer term medical management and maintenance of interpersonal relationships. In addition, there is evidence to suggest that assistance is needed to "negotiate the rehabilitation maze"[39] and in tailoring education to be specific to each individual's injury at the transition from hospital to the community.[40, 62, 63]

PATIENT POPULATION (PC-2, RQ-3, IR-1)

The target population is composed of all patients with moderate-to-severe TBI age 18 and older receiving inpatient rehabilitation in the United States. The sample will be composed of consecutive neurorehabilitation admissions of patients with moderate-to-severe TBI to one of six existing NIDILRR funded TBI Model System Centers, whose data have been shown to be representative of the target population (**PC-2**).[5, 36] Using the data from the six TBIMS sites for 2015, the gender and racial breakdown of the proposed sample is described below in the Human Subjects Section. The sample is expected to include individuals with TBI of sufficient severity to warrant inpatient rehabilitation. Those with TBI enrolled in the TBIMS have a median age of 38 years with predominantly moderate-to-severe TBI using Emergency Room Glasgow Coma Scale (GCS) scores which are captured in TBIMS data collection (Mean GCS= 9.91) in addition to multiple other severity indicators (imaging, duration of coma, PTA).

Data from the TBI National Data Center, which is the repository of longitudinal data from all TBIMS centers, provided historical data from 2015 across the six study sites. Rehabilitation admissions, TBIMS eligibility, and consent rates show that there were 764 individuals who were discharged from inpatient rehabilitation across the six study sites.

Of those discharges, 430 were found to meet eligibility criteria for the TBIMS as described in the Research Plan inclusion/exclusion criteria, which is a very conservative estimate of our volume as we will not limit enrollment in the current study to only those admitted into the system of care within 72 hours of injury (as required for TBIMS enrollment). The enrollment rate for the six sites involved in this grant is 81% from October 2015 through October 2016. In 2015 alone, 345 individuals who had a TBI and were eligible enrolled into the TBIMS across the 6 study sites. Over 3 years of enrollment, we conservatively estimate that 900 participants will consent to enroll into the proposed study.

Due to the existing infrastructure of the TBIMS at each study site, identification of eligible TBIMS participants is already in place. Each study site follows TBIMS Standard Operating Procedures (SOP) for enrollment, consent, and tracking of reasons for non-consent. Data regarding eligibility, enrollment success, and missing data are put into site-specific reports that are reviewed at each site and at the national level to ensure that barriers to successful enrollment and follow-up are addressed. This infrastructure will be utilized for the current project to monitor ongoing study enrollment and attrition. We will also use the existing TBIMS meeting infrastructure (teleconferences and TBIMS Project Director face-to-face meetings) to address study conduct on an ongoing basis. Finally, barriers such as patient inability to consent to the study are well addressed in the existing TBIMS infrastructure. Due to the cognitive impairments common after TBI, TBIMS staff have a SOP in place for determining patient capacity to consent or to obtain proxy medical consent. Once a patient has regained the capacity to consent, they are re-consented for TBIMS purposes. This study will use the same SOP for consenting participants.

Data Sources and Resources (IR-1)

Data collected as part of the national longitudinal TBIMS database during inpatient rehabilitation and at 12-months post-injury will be available for the majority of participants in the proposed study. These uniform data elements will be collected from individuals who are not enrolled in TBIMS but who enroll in the current study to ensure consistency. TBIMS data elements include demographic variables, information about pre-injury social history, detailed data on injury type and severity, and functional status at rehabilitation admission and discharge (https://www.tbindsc.org/Syllabus.aspx).

STUDY DESIGN OR APPROACH (Criterion 3)

A 1:1 randomized controlled trial design will compare the effectiveness of two established methods of managing transition from IRF discharge to the next phase of care, stratifying by site and discharge to another facility (e.g., skilled nursing facility) vs. discharge to home/community. We are stratifying on discharge destination based on the relatively lower frequency of discharge to facility (22% across all 6 TBIMS sites in 2015). However, we chose to include discharge to facility for inclusiveness and because our stakeholders encouraged it. For example, we heard "*It would be nice to have an extra advocate*" from a focus group member whose family member was discharged to a skilled nursing facility and experienced poor follow-through of rehabilitation recommendations.

Reporting of the results will follow the CONSORT guidelines (**IR-6**). The extent to which a study design is explanatory vs. pragmatic lies along a continuum, which Tosh[64] and Thorpe[65] have operationalized into evaluation tools. Using the Pragmascope tool,[64] which is an adaptation of Thorpe's PRECIS tool modified for mental health studies,[65] **our study design is highly pragmatic** as determined by the 10-item tool.

For example, our design ensures that our study includes the entire target population and allows for noncompliance based on participant preference. Both interventions are happening in everyday practice in other settings such as in CARF-accredited IRFs and the VHA, and both allow for flexibility based on participant needs and does not require high level expertise of the TBI Care Manager to be delivered. However, our primary outcomes are chosen by our Patient and Family Stakeholders, which will require patient-report and cannot be abstracted from medical records. Our secondary outcomes include objective indicators such as healthcare utilization and unplanned hospital readmissions. We also plan to compensate participants and their caregivers for the time spent to complete our outcome assessments.

The two established methods, described below (**RQ-5**), are (1) a standardized version of existing discharge procedures used at all six sites and (2) a standardized telephone-delivered case management approach that extends beyond the point of discharge, based on the protocol used within the VHA and enhanced with input from our Patient and Family Stakeholders. Research assistants (RA) will be blinded to participant group assignment and will conduct outcome assessments at 3, 6, 9, and 12 months post-discharge, with primary outcome of group comparison at the end of the intervention period (6 months post-discharge). The success of the blinding will be evaluated by having the outcome data collectors complete an assessment of each participant's group assignment after completing the outcome assessments and those will be reviewed for accuracy and reported with the final outcomes. We have successfully maintained blinding of outcomes assessment in trials previously.[56, 66]

The **Rehabilitation Discharge Plan (RDP)** condition is the CARF standard method[20] to prepare the patient and family for discharge from inpatient TBI rehabilitation. The RDP is already in place with few variations at the six participating TBIMS centers. This RDP approach is consistent with evidence-based approaches to discharge planning that have been supported by PCORI, AHRQ and NIH.[67] Considerable evidence exists demonstrating that this form of discharge planning results in reduced 30-day hospital readmissions and improved follow-up with outpatient appointments,[21] improved patient satisfaction,[68] and decreased duration of inpatient readmission and all-cause mortality compared to a non-standardized approach.[69]

The RDP includes elements common to all centers: specific details on follow up for ongoing medical care, safety recommendations, medication lists and instructions, common symptoms to monitor, and information on healthy behaviors such as an individual's home exercise program and diet. Recommended follow up care, such as physician visits, therapies, and/or home health care, is collected upon discharge to allow comparison between groups.

The **Rehabilitation Transition Plan (RTP)** protocol will include RDP with the addition of transitional care. RTP was chosen based on literature supporting a more intensive, temporally extended and coordinated approach for patients likely to experience significant and prolonged problems after injury,[27, 70, 71] i.e., those with moderate-to-severe TBI. The RTP intervention will be delivered by a TBI Care Manager (TCM) primarily via telephone. Focus group members emphasized the need for assistance beyond providing discharge education. As described in more detail below, the RTP comparator incorporates treatment elements with known efficacy from the VHA with input from our stakeholders.

Case management, including needs assessment and resource facilitation to address unmet needs, has been an important element in several successful post-acute TBI trials.[56, 66] Importantly, in response to the recent influx of war casualties that included many patients with TBI and polytrauma, the VHA established Case Management Standards of Practice designed to "avoid duplication, poor timing, or missed care opportunities" using a "process that assesses, advocates, plans, implements, monitors, and evaluates health care options and services so that they meet the needs of the individual patient" (p.2).[72] The VHA model is similar to the RTP model to be used in the proposed study, but has not been empirically tested against standard care. Resource facilitation, which is included as a key component of RTP, has been used successfully in TBI to improve community participation and return to work compared to standard care.[73] While these strategies have been recommended by several consensus practice guidelines,[70, 71] implementation and provision of such interventions are not consistent, therefore research is needed to examine a well-defined approach to resource facilitation. Telephone-based interventions have been successfully used to assist in transitioning from IRF to the community following TBI.[56] Like the RDP comparator, the RTP intervention has been standardized for the purposes of this trial, and we plan to measure individual elements provided to each patient to maximize our ability to associate care elements with primary and secondary outcomes.

Specific Aims and Hypotheses

Aim 1: To compare the effectiveness of Standardized Discharge Care (SDC) as labeled in our original application and grant proposal, henceforth referred to as the "Rehabilitation Discharge Plan" (RDP), vs. SDC plus Optimized Transition Care (OTC) as labeled in our original application and grant proposal, henceforth referred to as "Rehabilitation Transition Plan" (RTP), RTP on improving patient-reported outcomes of (1) participation, as measured by the Participation Assessment with Recombined Tools-Objective 17 (PART-O-17) and (2) health-related quality of life, as measured by the Quality of Life after Brain Injury Scale (QoLIBRI), for individuals with moderate-to-severe TBI who are discharged from inpatient rehabilitation.

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 one year post-discharge compared to patients randomized to RDP.

Aim 2: To compare the trajectory of improvement across the first year post-discharge (with measurement at 3, 6, 9, and 12 months post-discharge) on patient-reported outcomes of (1) participation and (2) 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.

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.

Aim 4: Caregiver outcomes: To compare the effectiveness of RDP vs. RTP on caregiver burden, health-related quality of life (HRQOL), satisfaction with roles and activities as measured by the Bakas Caregiving Outcomes Scale[104], the Zarit Burden Interview[129], SF-12[130], the PROMIS Satisfaction with Social Roles and Activities[131] and assessment of Required Assistance and Time Spent Caregiving.

Hypothesis 4a: Caregivers of patients randomized to RTP will report lower caregiver burden 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 burden over time, compared to caregivers of patients randomized to RDP.

Heterogeneity of Treatment Effects (HT-1, HT-2, HT-4, RQ-4)

The interventions being compared in this study are highly patient-centered and will be tailored to each patient's individual needs. The analytic plan will compare the two approaches (Rehabilitation Discharge Plan, RDP vs. Rehabilitation Transition Plan, RTP), as opposed to compare the specific elements which will vary across all participants based on their individual needs. Consequently, we expect that some patient subgroups may be more or less likely to reap maximal benefit from the interventions under study. We will examine the effects of the intervention on patient subgroups defined by factors known or hypothesized in the literature to have associations with poorer TBI outcome and which are relevant to the implementation of the RTP in a clinical setting: discharge to facility (as opposed to community), being of minority race/ ethnicity, older age, male, with lack of or low degree of caregiver involvement, high level of severity of TBI, presence of pre-injury psychosocial limitations (e.g., unemployment, substance abuse) and having medical or psychiatric comorbidity. In addition, we will explore whether there were differences according to study site, resource variability (e.g., community resources available) and insurance type.

For the subgroup analysis, the models for the primary outcome variables (Part-O and QoLIBRI) will include the intervention group, all the covariates that define the subgroups, and interactions between each covariate and the intervention group. Test of interactions will reveal if there are subgroups based on a certain covariate (or factor) that respond differently to the RDP or RTP intervention. It is possible that for some covariates, we will not have enough individuals to give information on the outcomes variation in a certain subgroup and that we will not be able to assess the effect for that covariate, while for other covariates, the sample size in each subgroup will be enough to provide information for the data analysis. These numbers cannot be determined a priori. For example, facility discharges are expected to occur in approximately 198 participants (22%) of our sample which will allow adequate sample size for comparison, and males are expected to make up approximately 612 participants and can be compared to females. We may have difficulty comparing race/ethnicity on more specific subgroups such as Asians (expected to be approximately 2% of our participants) and Hawaiian/Pacific Islander (expected to be <1%), but will likely have an adequate sample size to compare Hispanic (11%) to non-Hispanic and Black (17%), White (73%), and other (10%). In this situation, we may have to collapse the categories into a smaller number, such as White, non-Hispanic Black, Hispanic, and Other. Given multiple insurance options across the population as well as across the sites we may not have adequate power to detect differences between every provider, but will explore the effect of relevant subgroups such as private insurance vs. Medicaid vs. Medicare, for example.

We will explore the effects of the intervention on patient subgroups defined by factors known or hypothesized to have associations with poorer TBI outcome: facility vs. community discharge, race/ ethnicity (White, non-Hispanic Black, Hispanic, Other), age (as continuous), male vs. female, lack of or lower degree of caregiver involvement (yes or no), severity of TBI (moderate vs. severe), presence of pre-injury psychosocial limitations (e.g., unemployment, substance abuse, categorized in yes or no) and medical or psychiatric comorbidity (yes or no), as well as study site, resource variability and insurance type (private insurance vs. Medicaid vs. Medicare). 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. Interactions between each factor and the intervention group will be entered in the model and test of interaction will be the test of heterogeneity. Before constructing the model, we will assess whether the explanatory variables (factors) are correlated to each other.

When two or more variables are deemed highly correlated, to avoid problems with collinearity, we will construct the model with the variable that provides the best model (from fit and diagnostic tests).

From previous research,[74-80] we hypothesize that severity of TBI and presence of pre-injury psychosocial limitations will interact with the intervention group. With our expected sample size, we anticipate being able to address these questions. Some of the factors might not have a statistically significant effect, but have the effect in the expected direction. Effect sizes and confidence intervals will be calculated to express the potential effect of those factors. The results of these analyses will be valuable in designing future studies.

Study Timeline

Pre-Enrollment Activities (Months 1-6)

Startup activities will include hiring personnel, developing a formal study protocol, Institutional Review Board submission and approval, trial registration on Clinicaltrials.gov, and training of all study personnel on study procedures (see Milestones Schedule appendix). TCMs will be trained at a kick-off meeting to coincide with an investigator meeting during a regularly scheduled TBIMS Project Director's meeting. Research staff will be trained via teleconference and via a study dedicated website to increase familiarity with the measures and procedures. Once training of TCMs and RAs is completed, participant recruitment will begin.

Enrollment/Study Protocol Activities (Months 7-48) [RQ-2]

The methods used to identify and recruit participants, collect data, and minimize attrition and missing data will be drawn from the SOPs and data dictionary developed by the TBIMS National Data and Statistical Center (NDSC) and successfully employed by the TBIMS (see https://www.tbindsc.org/SOP.aspx). The success of these procedures is demonstrated by the 80% recruitment rate, 93% retention rate (and 94% retention rate at 1 year by our six sites), and <10% missing data rate of the TBIMS as a whole (while 10% is the missing data benchmark used by the TBIMS, actual missing data rates are considerably lower).

STUDY METHOD

Participants

Patient Participants

The target population is composed of inpatients on the rehabilitation unit and their caregivers (if available) who are aged 18 and older and have a diagnosis of moderate-to-severe TBI.

The case definition for TBI will be that used by the TBI Model System (TBIMS): TBI is defined as damage to brain tissue caused by an external mechanical force as evidenced by medically documented loss of consciousness or post-traumatic amnesia (PTA) due to brain trauma or by objective neurological findings that can be reasonably attributed to TBI on physical examination or mental status examination. Potential participants must meet at least one of the following criteria for moderate-to-severe TBI: (1) PTA>24 hours; (2) Trauma related intracranial neuroimaging abnormalities; (3) Loss of consciousness exceeding 30 minutes (unless due to sedation or intoxication); or (4) Glasgow Coma Scale in the emergency department of less than 13 (unless due to intubation, sedation, or intoxication).

Caregiver Participants

Caregiver participants will be those individuals who will have primary care giving responsibility post rehabilitation care discharge of patients with moderate to severe TBI. Identifying the primary caregiver will be done in consultation and collaboration with rehabilitation care staff, the TBI patient and the TBI patient's involved family and friends. All these sources will be involved in helping us to determine which individual will be most responsible for caregiving following discharge.

Identification

To identify participants, we will review medical records for individuals admitted to inpatient rehabilitation with a primary diagnosis of TBI as defined above. Research study staff will approach patients who meet basic eligibility criteria noted below.

Inclusion Criteria-Patient Participants

(1) Hospitalized with a moderate-to-severe TBI defined by TBIMS and this study as damage to brain tissue caused by an external mechanical force as evidenced by medically documented loss of consciousness or post-traumatic amnesia (PTA) due to brain trauma or by objective neurological findings that can be reasonably attributed to TBI on physical examination or mental status examination. Potential participants must meet at least one of the following criteria to be considered experiencing a moderate-to-severe TBI:

- (a) PTA>24 hours;
- (b) Trauma related intracranial neuroimaging abnormalities;
- (c) Loss of consciousness exceeding 30 minutes (unless due to sedation or intoxication); or
- (d) Glasgow Coma Scale in the emergency department of less than 13 (unless due to intubation, sedation, or intoxication).

(2) English speaking (we will track non-enrollment due to other language to determine common languages and have consumer dissemination materials translated for more broad use if time and resources permit.);
(3) at least 18 years old;
(4) will be discharged from inpatient rehabilitation to community (private residence, adult home, hotel, homeless) or facility (nursing home, subacute care i.e. skilled nursing facility);

(5) current admission to inpatient rehabilitation considered their first comprehensive rehabilitation experience, or extension thereof for most recent TBI(e.g. admitted to inpatient rehabilitation, discharged to acute care, then returns to inpatient rehabilitation to complete their initial stay);
(6) able to provide informed consent, or if unable to provide consent have family or legal guardian to provide informed consent for the patient.

Exclusion Criteria-Patient Participants
(1) We will not enroll individuals who are in law enforcement custody at admission to the designated rehabilitation unit or who are taken into custody prior to discharge from the designated rehabilitation unit due to federal restrictions on inclusion of prisoners in research.
(2) We will not enroll individuals who do not have access to a phone.
(3) We will not enroll individuals who are unable to complete study procedures due to cognitive/verbal limitations AND do not have a proxy to assist with study procedures.

Inclusion Criteria-Caregiver Participants
(1) individuals who will have primary care giving responsibility post rehabilitation care discharge of enrolled patient participants;
(2) English speaking (we will track non-enrollment due to other language to determine common languages and have consumer dissemination materials translated for more broad use if time and resources permit.);
(3) at least 18 years old;
(4) able to provide informed consent.

Exclusion Criteria-Caregiver Participants
(1) We will not enroll individuals who are in law enforcement custody due to federal restrictions on inclusion of prisoners in research.
(2) We will not enroll individuals who do not have access to a phone.

Screening
As noted above, the screening process involves an initial review of medical records by our research staff for patients with a diagnosis of TBI, or suspected TBI, (see inclusion/exclusion above for further detail) who are being admitted to the inpatient rehabilitation unit at the different study sites. Once a potential participant is confirmed initially eligible based on medical record review, a member of our research team will approach him/her using study talking points to make certain the subject has access to a telephone to participate in the study. The criterion regarding access to a telephone also may be confirmed via observation or via conversation with clinical staff and family members. In addition, certain eligibility criteria may be confirmed or corroborated further via conversation with clinical staff and family members (e.g. discharge destination).

Each site will assign each potential participant identified an ID number unique to that particular site. The patient participant will keep the same ID number if enrolled in the study.

Our research staff members have established communication lines with the clinical staff to ensure patients are approached at appropriate times that do not interfere with clinical care.

Recruitment

Patient Participants: Determining Orientation/ Emergence from PTA

If a potential participant meets eligibility criteria based on medical record review, our research staff will approach him/her on the inpatient rehabilitation unit to determine whether the patient is cognitively capable of providing consent by administering a measure of orientation/ emergence from PTA: the Galveston Orientation and Amnesia Test (GOAT), the Revised GOAT, the full version of the Orientation-Log (O-Log), or the non-verbal version of the O-Log(orientation scores are not entered as data, but used only to determine orientation.)[81, 82] It is the choice of each site which version to use while assessing orientation/ emergence from PTA. Alternating use of the scales in an individual patient is not acceptable, however.

Please note that administration of the orientation test(s) is also a procedure for consenting into the TBIMS. As typically enrollment for BRITE will occur immediately following enrollment for TBIMS, for purposes of subject burden, the orientation test will not be repeated prior to BRITE enrollment.

Study researchers will follow the same procedures as TBIMS to assess for orientation/ emergence from PTA as outlined below:

"With prospective tracking, emergence from PTA is defined as:
1) two consecutive GOAT scores of 76 or greater with no more than 2 full calendar days between assessments (Assessment 1 = Friday, Assessment 2 = Monday, two full days = Saturday, Sunday)
2) two consecutive scores of 11 or greater on the Revised GOAT with no more than 2 full calendar days between assessments (Assessment 1 = Friday, Assessment 2 = Monday, two full days = Saturday, Sunday)
3) two consecutive scores of 25 or greater on the Orientation-Log with no more than 2 full calendar days between assessments (Assessment 1 = Friday, Assessment 2 = Monday, two full days = Saturday, Sunday)
4) two consecutive scores of 8 or greater on the Non-Verbal version of the Orientation-Log with no more than 2 full calendar days between assessments (Assessment 1 = Friday, Assessment 2 = Monday, two full days = Saturday, Sunday), or
5) in the judgment of a qualified clinician (i.e., speech-language pathologist, physician, neuropsychologist), the person has cleared PTA but administration of an orientation test is not possible due to language functioning.

The day of clearance of PTA is the first day the person gets the first of 2 consecutive scores of 76 or greater on the GOAT, the first of 2 consecutive scores of 11 or greater on the Revised GOAT, the first of 2 consecutive scores of 25 or greater on the Orientation-Log, or the first of 2 consecutive scores of 8 or greater on the Non-Verbal version of the Orientation-Log."

As per standard TBIMS procedure, if the patient is deemed oriented, the research staff will introduce the study using a talking points script, and if the potential participant is interested, provide him/her with a brochure and a consent form.

Research staff will initiate the informed consent process if a) the patient is deemed oriented per definition above, and b) the patient expresses interest in participating. Research staff will visit the patient on a subsequent day and re-administer the orientation test prior to consent if needed.

Patient Unable to Provide Consent
If the patient is not deemed oriented as per the outline above, the patient is unable at that time to provide informed consent. Research staff may administer the orientation test multiple times to determine capacity to consent.

If patient is unable to provide consent either due to aphasia, non-emergence from PTA, and/or being non-verbal:

1. Staff will determine if patient has a Legally Authorized Representative (LAR) who is willing and available to provide consent as a proxy for the patient;
    a. If Yes: Staff may enroll the patient participant via proxy- go to #2 below;
    b. If No: Staff will deem the patient ineligible due to not being able to provide consent/no proxy- stop here.

2. Staff will determine if patient has an individual who is willing and available to assist with both participation in the RTP (if randomized to that arm)* AND the follow-up questionnaires** for the foreseeable future. Specifically, the individual would need to be present for all potential RTP contacts and questionnaires. This individual does not need to be the same person that provided proxy consent;
    a. If Yes: Staff may enroll the patient participant via proxy-stop here;
    b. If No: Staff will consult with trained clinical staff to conclude whether it is more likely than not that the patient participant will be able to participate on his/her own within one month following discharge given nature and degree of severity of limitations;
        i. If Yes: Staff may enroll the patient participant via proxy;***
        ii. If No: Staff will deem the patient ineligible due to inability to complete study procedures due to cognitive/verbal limitations AND not having a proxy to assist with study procedures.

*If the proxy individual is not enrolled as a caregiver participant in the study, the TCM would only engage the proxy individual in resource facilitation and the needs assessment as it specifically pertains to the patient participant. The TCM will not conduct a caregiver needs assessment with the proxy or provide resources that pertain specifically to the proxy individual as they are not enrolled as a caregiver. If the TCM infers that the proxy individual would like to participate in the needs assessments/resource facilitation as it pertains to them (e.g., as the caregiver), the TCM would remind the proxy individual in a non-coercive manner of the opportunity to participate as a caregiver participant. This would require the completion of the informed consent process with the proxy individual as per study protocol.

**In this scenario, the proxy individual would not complete the QOLIBRI as part of the post-discharge questionnaire. In addition, the individual would not complete the following items on the Form II: SWLS, GEN, GNHLTH, PHQ, GAD

***Staff will withdraw the patient participant following randomization if the participant is deemed unable to participate due to limitations within the following timeframes:

1. The TCM will withdraw the patient participant one month following discharge if randomized to RTP arm of the study;
2. Blinded staff will withdraw the patient participant three months following discharge if randomized to RDP arm of the study;

Caregiver Participants
Caregiver participants will be those individuals who will have primary care giving responsibility following rehabilitation care discharge of patients with moderate to severe TBI. Caregivers may be recruited while the patient is in the hospital or by telephone if not available during hospitalization. Research staff may enroll more than one individual as a caregiver following subject enrollment should a different individual assume the role of caregiver at a later time point (e.g. mother pre-discharge, significant other 3 months post-discharge). Multiple caregiver participants may be enrolled at the same time to accommodate if the caregiver role is assumed by different individuals at different points in time during participation (e.g. mother is caregiver at 3- and 9-months post-discharge, significant other is caregiver at 6- and 12-months post-discharge). Research staff will assess who has primary caregiving responsibilities both at each questionnaire period and the RTP phase (if applicable), and engage accordingly the particular participant who most clearly fits the role of primary caregiver.

Each site will assign a patient participant's ID number to their respective caregivers. The caregiver participant will keep the same ID number if enrolled in the study. Research staff will record which caregiver completes each questionnaire if more than one caregiver participant is enrolled at any given time.

Basic Demographic Information: All Potential Patient Participants
Basic demographic information including age, sex, and race will be collected via medical record review without consent from all patients including those who do not enroll to determine differences between enrolled patients participants and those who do not enroll. These data will be entered in de-identified form into the TBIMS National Data and Statistical Center at Craig Hospital.

Screening procedures do not require a physical examination or laboratory procedures.

Barriers to Recruitment
We anticipate minimal barriers to recruitment beyond those which exist within our current recruitment and enrollment into the TBIMS at each site. Given the nature of the current grant, and strong interest and support from our Patient and Family Stakeholders and Professional Stakeholders, we expect that our current rate of 80% enrollment of eligible participants will continue. To maximize enrollment we will offer the proposed study concurrently with TBIMS enrollment for those eligible for TBIMS to reduce patient and staff burden. Existing barriers to enrollment include competition by other research studies which can result in participant burn-out in research and enrollment into studies which limit participation in intervention studies.
Each site will work with known research studies to ensure minimal overlap or development of plans to ensure meeting enrollment numbers in all studies. Finally, we will work with our **Patient and Family Stakeholders to gather ideas on any modifications needed** should we have lower than expected enrollment.

Data Quality Targets - Enrollment
Target enrollment rate is set at 73%, and will be reviewed on a quarterly basis beginning December 2020. The lead site will review the rate for cases entered into the website screening form within the previous six months (e.g. 6/1/20-11/30/20 for the December 2020 check). Sites not reaching their target will be required to develop a written remediation plan for increasing enrollment numbers. This plan should be submitted to the lead site. The effectiveness of this plan will be reviewed at subsequent quarterly checks.

Table 1. Recruitment/Enrollment Assessment Timeline

Begin Recruitment	2/1/18
Recruit 25% of total study participants	11/30/18
Complete 25% of 3-month follow-	2/28/19
Complete 25% of 6-month follow-	5/31/19
Complete 25% of 9-month follow-	8/31/19
Recruit 50% of total study participants	9/30/19
Complete 50% of 3-month follow-	11/30/19
Complete 50% of 6-month follow-	2/28/20
Complete 50% of 9-month follow-	5/31/20
Recruit 75% of study participants	7/31/20
Complete 50% of 12-month follow-	9/30/20
Complete recruitment	10/31/21
Complete 100% of 3-month follow-	1/31/22
Complete 100% of 6-month follow-	4/30/22
Complete 100% of 9-month follow-	7/31/22
Complete 100% of 12-month follow-	10/31/22
Primary Completion Date	10/31/22

Targeted total participant enrollment N		900
Targeted total caregiver enrollment N		540
Number of sites		6
Site Names	- University of Washington - Indiana University School of Medicine/Rehabilitation Hospital of Indiana - Einstein Healthcare Network / Moss Rehab Hospital - Baylor Institute for Rehabilitation - Ohio State University Wexner Medical Center - Mount Sinai Health System (NY)	
Estimated patient volume	In 2015, 764 individuals with TBI were discharged from inpatient rehabilitation across the six study sites. In 3 years of recruitment in our study, a conservative estimate for screening would be approximately 2200 individuals	2200
Estimated number of eligible patients	Of those discharges in 2015, 430 (56%) would meet the eligibility criteria for the TBIMS as described in the Research Plan inclusion/exclusion criteria. We would expect	1230

	that approximately 1230 (about 56%) would be eligible for our study.	
Estimated number of eligible caregivers		600
Estimated yield/consent of patients	Enrollment rate for the six sites was 81% from October 2015 through October 2016. In 2015, 345 individuals who had a TBI and were eligible enrolled into the TBIMS across the 6 study sites. Over 3 years of enrollment, we conservatively estimate that at least 900 (73% of the eligible) participants will consent to enroll into our study.	900
Estimated yield/consent of caregivers		540
Estimated lost to follow up/attrition of patients	Historically, the procedures for participant recruitment and retention used in TBIMS sites has a 90% retention benchmark, and <10% missing data. Given this is a more complex trial requiring increased engagement over time, we anticipate having a more difficult time with retaining participants and therefore are planning for an 80% retention mark.	180
Estimated lost to follow up/attrition of caregivers		110
Estimated monthly enrollment of patients		23-24
Estimated monthly enrollment of caregivers		13-14

Our 80% estimate is based on both our benchmark expectation for enrollment into the TBIMS as well as recruitment rates from the prior intervention studies completed by our team detailed below that have enrolled from the TBIMS population.
Given the broad inclusion criteria and flexibility and provision of treatment that is standard care or higher in both intervention groups, we anticipate meeting our planned recruitment rate.

(1) The six TBIMS centers in this grant have an average enrollment of 81.35% for TBIMS.
(2) Bell et al.[56] had a 95% enrollment rate into a single-site study with similar study population and methodology.
(3) In a multi-site study[83] among 3 TBIMS sites with similar study population and methodology, we had a 90% enrollment rate among those who were eligible.

Tracking Potential Participant Flow
All data pertaining to the recruitment outcome and screening information for each patient will be entered by all study sites in de-identified form into the NDSC centralized database via the 'Screen' tab.

Sampling Enrollment
Study researchers have devised the following systematic approach to manage enrollment for sites that enroll more patient and caregiver participants than they are able to handle relative to TCM availability:

1. Determine a projected annual enrollment threshold of combined patient and caregiver participants that, if surpassed, would cause the sampling enrollment approach to be considered (based on likely maximum caseload for the TCM and staff): Study Researchers concluded that the projected annual enrollment threshold of combined patient and caregiver participants should be 90 participants per year (54 patient participants and 36 caregiver participants);

2. Review recruitment/enrollment data for all sites on a quarterly basis to determine if a site has surpassed the projected threshold by using the following formula:

    1) Subtract the number of pending eligible patients and those randomly selected not to be approached (if a sampling enrollment approach has already been initiated) from the total number of eligible patients over the past six months to get a true number of potential eligible patients that could have been enrolled over the past six months;
    2) Divide actual patient participant enrollment by #1 above to get the rate of enrollment of the potential eligible patients over the past six monthsfor that particular site;
    3) Divide number of enrolled caregiver participants by number of enrolled patient participants over the past six monthsto get rate of enrollment of caregiver participants for enrolled patient participants at the site;
    4) Divide total eligible patients approached by number of days over the past six months to get daily rate of eligible patients identified;
    5) Multiply #4 above by 30 days to get projected monthly number of eligible patients identified;
    6) Multiply monthly rate of patients approached (#5) by rate of enrollment of the potential eligible patients described above (#2) to get projected monthly enrollment of patient participants;
    7) Multiply projected monthly enrollment of patient participants by enrollment rate of caregiver participants to get projected monthly enrollment of caregiver participants;
    8) Add #s 6 and 7 above to get overall projected monthly enrollment rate of participants (patient and caregiver combined);
    9) Calculate the overall monthly enrollment goal- we are hoping for 4.5 patient participants and 67% of patient participants to have a caregiver participant enrolled, which is 3 for a total of 7.5 participants enrolled per month;
    10) Divide 7.5 by #8.

3. The result of this formula is the random sampling enrollment rate, i.e. the percentage of eligible patients that should be approached to meet the annual projected threshold. Any percentage above 100% indicates the center is under enrolling- no sampling enrollment is needed to be implemented as a result. Any percentage below 100% indicates the site should approach at maximum the percentage of eligible patients listed to equal the annual projected threshold. Example: if the result for #10 above for a particular site is 80%, than that particular site should approach at random 80% of all eligible patients to meet the annual projected threshold;

4. The lead site will approach any sites that are deemed to be overenrolling based on the formula above to see if they want to implement the sampling enrollment approach;

5. If a site elects to implement the sampling enrollment approach, the site will utilize local TCM backup when necessary for those weeks when unable to adequately cover caseload;

6. Once sampling is in place, the approach for each site will be reviewed each quarter by the lead site to determine whether to return to full enrollment, continue with sampling enrollment but with a different rate, or continue with sampling enrollment at the same rate based on the previous six months recruit/enrollment data.

Please note: Sites may decline to implement the sampling enrollment approach described above even if they are above the enrollment threshold but believe they can accommodate current enrollment numbers. Likewise, sites may request implementation of the sampling enrollment approach even if they don't meet the enrollment threshold but believe they cannot accommodate current enrollment numbers. It is left to the discretion of the lead site to approve/deny requests regarding sampling enrollment implementation.

Please see the section below for instructions on how to implement the sampling enrollment approach on the NDSC website.

Consent (PC-1)

Research staff will participate in and obtain informed consent from research participants after screening but prior to commencement of any further study procedures. For most patient participants, the informed consent process will take place during the participants' inpatient rehabilitation stay with our research staff, and for some patient participants it will occur directly after discharge when approaching in person or by phone durin their inpatient stay is not possible.

Determining Patient Participant Capacity for Consent

Due to the cognitive impairments common after TBI, TBIMS staff have a SOP in place for determining patient capacity to consent or to obtain proxy medical consent. Please see description of procedures regarding assessment for orientation/ emergence from PTA in the section '*Patient Participants: Determining Orientation/ Emergence from PTA'* above.

Patient Participant Capable of Consent while Inpatient (In-Person approach)

If the patient is deemed able to provide consent, a research staff member will review each section of the informed consent form (ICF) approved by the site IRB. Staff members are trained to ensure competency to discuss informed consent and strategies to ensure there is no coercion.

Participants will be provided with as much time as needed to review the ICF and ask the research staff member questions about the ICF, their rights as participants, and participation in the study. Potential participants will be fully informed of all risks and benefits prior to giving their written informed consent and prior to enrollment in the study.

If during the course of this contact the potential participant has questions that cannot be addressed by research staff, one of the study investigators or the research manager (depending on the nature of the questions) will follow up with the potential participant to answer the questions. Participants may take time to think about participating and render a decision in a

subsequent visit. Potential participants will be asked to repeat back understanding of this material as necessary.
The participant will then be asked to sign and date the ICF. Research staff will also date and sign the ICF. All participants will be offered a copy of the signed ICF for their records. Research staff will also review a HIPAA authorization form with the participant that permits research staff to collect data from his/her medical records regarding injury and medical history.

The patient participant may be given a response key to assist with completing the questionnaires described in the "Follow Up Data Collection" section below. The response key may be given in person following consent, or mailed at a separate time with a cover letter.

The patient participant may also be given a log to assist with keeping track of use of medical services during study participation. Medical services utilization will be assessed as part of the Cornell Services Index described in the "Follow Up Data Collection" section below. The log may be given in person following consent, or mailed at a separate time with a cover letter.

Patient Participant Incapable of Consent while Inpatient (In-person Approach)
If the patient is deemed unable to provide consent, consent of a legally authorized representative (LAR) will be sought and a family member or caregiver will be asked to provide consent on the patient's behalf. The caregiver/family member giving assent will be provided with as much time as needed to review the form and ask the research staff member questions about the form, the patient's rights as a participant, and participation in the study. The respective party will be fully informed of all risks and benefits prior to giving his/her written informed assent and prior to enrollment in the study.

The individual will then be asked to sign and date the form. Research staff will also date and sign the form. All individuals will be offered a copy of the signed form for their records.

Research staff will also review a HIPAA authorization form with the individual that permits research staff to collect data from the patient's medical records regarding injury and medical history.

Patient Participant Capable of Consent while Inpatient or Directly After (Telephone Approach)
If the patient is deemed able to provide consent, a research staff member will review each section of the Patient Information Sheet approved by the site IRB. Staff members are trained to ensure competency to discuss informed consent and strategies to ensure there is no coercion.

Participants will be provided with as much time as needed to review the information sheet and ask the research staff member questions about the sheet, their rights as participants, and participation in the study. Potential participants will be fully informed of all risks and benefits prior to giving their written informed consent and prior to enrollment in the study.
If during the course of this contact the potential participant has questions that cannot be addressed by research staff, one of the study investigators or the research manager (depending on the nature of the questions) will follow up with the potential participant to answer the questions. Participants may take time to think about participating and render a decision in a subsequent telephone call. Potential participants will be asked to repeat back understanding of this material as necessary.

The participant will then be asked to give verbal consent to participate. Research staff will document receipt of verbal consent per site protocol, as well as update the BRITE website Screening form to indicate consent and enrollment.

The patient participant may be mailed or emailed a response key along with a cover letter to assist with completing the questionnaires described in the “Follow Up Data Collection” section below.

The patient participant may also be mailed or emailed a log along with a cover letter to assist with keeping track of use of medical services during study participation. Medical services utilization will be assessed as part of the Cornell Services Index described in the “Follow Up Data Collection” section below.

Patient Participant Incapable of Consent while Inpatient or Directly After (Telephone Approach)
If the patient is deemed unable to provide consent, consent of a legally authorized representative (LAR) will be sought and a family member or caregiver will be asked to provide verbal consent on the patient’s behalf. The caregiver/family member giving assent will be provided with as much time as needed to review the Patient Information Sheet and ask the research staff member questions about the form, the patient’s rights as a participant, and participation in the study. The respective party will be fully informed of all risks and benefits prior to giving his/her written informed assent and prior to enrollment in the study.
The individual will then be asked to give verbal consent to participate. Research staff will document receipt of verbal consent per site protocol, as well as update the BRITE website Screening form to indicate consent and enrollment.

Patient Participant Capable of Consent Following Discharge
Research staff will re-assess all patients who enrolled into the study via LAR to determine capacity to consent as described in the section ’*Patient Participants: Determining Orientation/ Emergence from PTA’* above, albeit conducted by telephone. A research staff member will arrange a time to conduct the informed consent process via telephone.
The research staff member will then send a self-addressed, stamped envelope along with two copies of the consent form, the HIPAA authorization form and a cover letter.

The cover letter will specify that, although subjects may review the consent form in advance, they should not sign or complete the forms until they have reviewed the forms with research staff at the scheduled informed consent session via telephone. At the scheduled phone contact, a research staff member will follow the informed consent procedures as described above.

The patient participant will be instructed to sign one copy each of the consent form and HIPAA authorization form. The subject will then be asked to return all the signed, completed forms to the study staff via a self-addressed, stamped envelope previously mailed with the forms. The informed consent acquired directly from the participant will render the LAR consent obsolete.

Research staff will send a copy of the signed consent form to the patient participant with a cover letter.

Caregiver Participants
Caregiver participants may be initially recruited by telephone or in person. If the caregiver is not local and/or able to come in readily, or approach in person is not feasible, we request permission to waive written consent and instead obtain oral consent via use of an oral information statement sheet. Research staff may send an information statement sheet along with a cover letter if the caregiver will be enrolled following the discharge of the patient participant. Research staff would review the information statement sheet with the potential participant, then request verbal consent if the individual is interested in participating. Otherwise

the informed consent process may take place in person and will take place during the participant's inpatient rehabilitation stay with our research staff. Caregivers will provide written consent if enrolled in person.

All participants approached for possible enrollment in this study will be clearly informed that if they choose not to participate in this project, they and/or their loved one will still be able to receive any of the routine medical and rehabilitation services available to them.
They will be informed that their participation is voluntary and that they may withdraw their consent and discontinue participation in the study at any time. Any new information developed during the course of the study that might affect a participant's understanding of the research and willingness to continue to participate will be brought to their attention by study staff.

The caregiver participant may be given a response key to assist with completing the questionnaires described in the "Follow Up Data Collection" section below. The response key may be given in person following consent, or mailed at a separate time with a cover letter.

Baseline Assessment (RQ-2, IR-1)

Contact Information Sheet
Research staff will collect the following information from both caregiver and patient participants: (1) contact information; (2) best way to reach an individual if they have more than one line; best times/days to reach participant; and (3) names and contact information of people staff are allowed to contact if participant is lost to follow-up or otherwise cannot be contacted (i.e. collateral contacts). The purpose of this is to maximize the likelihood of reaching a participant to complete the study procedures. Furthermore, asking permission to leave a voicemail at a specified contact number ensures a greater level of privacy for the participant.

The information may be completed following enrollment either in person or over the telephone at a later time if more convenient for the participant. This information will be retained in a local, password-protected database on a secure server.

Baseline Information: Patient Participants
For those subjects who are also enrolled into the TBIMS, there will be no additional baseline measures to complete via self-report for this study.

Non-TBIMS: Form I (aka 'Baseline')
For those not enrolled into TBIMS, a Form I will be collected. The Form I collects demographic and injury related data from the electronic medical record ('Medical Record Abstraction'). Additional demographic and clinical history will be collected in interview format ('Pre-Injury History Interview'). The Form I also includes some cognitive tests focused on memory, concentration, and problem solving ('Brief Test of Adult Cognition by Telephone or BTACT'). The interview and cognitive testing will take about 25-35 minutes to complete.
These data will be entered with the participant's ID, i.e. not name into the NDSC centralized database by research staff.

Discharge Information: Patient Participants
Research staff will collect information from a patient participant's medical record regarding the presence/absence of recommended and/or scheduled appointments to different medical disciplines/services as well as documenting received/recommended equipment using the *BRITE Study Discharge Information* data collection form. These data will be entered into the NDSC centralized database by research staff. Specific information regarding the

recommended/scheduled appointments (e.g. name, phone number, email address, date of scheduled appointment, etc.) of patient participants randomized to the RTP intervention arm will be stored locally in a database used by the TBI care managers for referential purposes.

Research staff will also enter discharge destination and date as well as injury date into the NDSC database using the *BRITE Study Discharge Destination and Date* data collection form

Baseline Information: Caregiver Participants
If there is a caregiver enrolled, we may collect their baseline data in person, by phone or via postal mail (see 'Mailout Option' section below for more detail).

Baseline data collection will take approximately 5-10 minutes to complete. Specifically, we will collect information regarding the nature of the caregiver's relationship to the patient participant, as well as basic demographic information. We will ask that the patient participant not be present during their assessment so as to eliminate potential response bias.
These data will be entered with the participant's ID, i.e. not name into the NDSC centralized database by research staff.

All data described above unless specified will be entered into the NDSC centralized database via the 'Data' tab.

Randomization/ Post-Discharge Transition Phase
After the patient participant has been discharged or after they are consented post-discharge, s/he will be randomly assigned 1:1 into one of two study arms: RDP or RTP. We will stratify randomization on study site and discharge destination (another facility vs. home/ community):

Home/ Community
- private residence (includes house, apartment, mobile home, foster home, condominium, dormitory, military barracks, boarding school, boarding home, rooming house, bunk-house, boys ranch, fraternity/sorority house, commune, migrant farmworkers camp)
- adult home (includes adult foster care, independent living center, transitional living facility, assisted living, supported living, group home)
- hotel (includes YWCA, YMCA, guest ranch, inn)
- homeless (includes a shelter for the homeless)

Facility
- nursing home (includes med-center, residential, institutions licensed as hospitals but providing essentially long-term, custodial, chronic disease care, etc.)
- subacute care (includes subacute hospital bed, skilled nursing facility)

The actual act of randomization will be automated via the NDSC BRITE website. Specifically, research staff will click the 'Randomize' button located in the 'Keys' tab of the 'Patient Post-Discharge Information' section under the 'Data' tab once the discharge destination has been entered. The randomization assignment will be automatically recorded in the BRITE website database.

These randomization procedures have been used by our team in prior studies where telephone follow-up was randomly assigned following discharge.[56, 83]

Once randomization occurs, their random assignment will be communicated to the TBI Care Manager (TCM). The TCM will then send out a letter to the patient participant and caregiver (if applicable).

For those who are randomized to the RDP arm, the letter will state that they will be contacted for follow-up at 3, 6, 9 and 12 months post hospital discharge and one year following injury (if applicable)**.**

For those who are randomized to the RTP arm, in addition to a reminder of the follow-up data points as above, the letter will include a reminder of the specific goals of the study and the plan for follow-up calls with the TCM.

The meeting schedule will be modified throughout the intervention time period to fit the needs of both the patient and caregiver participants and may include evening or weekend appointments.

The TCM will also send patient and caregiver participants assigned to the RTP group a brief description of the general role of the TCM as well as a description of the specific TCMs at each site including education and work experience. This form may be mailed with the randomization letter, or part of a subsequent mailing.

Interventions and Comparators (RQ-5, PC-1)

(A) Rehabilitation Discharge Plan (RDP)
All participants will receive RDP, which will be documented in the medical record.
RDP will consist of the standard elements of discharge care that are already in place at participating centers; these include:

(1) patient and family education about TBI, both general and individualized to each person's symptoms and level of function, along with hands-on training for caregivers as needed as well as education on medications and symptoms to monitor following discharge;

(2) written discharge care instructions, which will include the follow-up plan, including recommended appointments with primary care, physiatry (Rehabilitation Medicine) and outpatient therapies, and medication list which are reviewed with the patient and family prior to discharge; and

(3) a phone call from an inpatient care provider or staff member within a few days of discharge to address any immediate problems and ensure that equipment has arrived, medications are being taken, etc.

Results of our preliminary work indicate these elements are already in place in each center, but specific content (e.g., educational materials, checklists, and templates) will be individualized for each patient and their family members.

(B) Rehabilitation Transition Plan (RTP)
This approach is based on the model successfully employed by the VHA.

Scheduling of Contacts
Participants randomized to the RTP comparator at the point of hospital discharge will receive about 12 scheduled contacts over the next 6 months from a TCM. The TCM will be a contract employee hired specifically for this study. The TCM will be responsible for managing both the

logistics and content of the treatment with the support of a team of experienced TBI clinicians. Training of the TCM will be a key aspect of this study. The TCM will be either an MSW or have comparable experience in health care and/or social services but will not necessarily be experts in the field of TBI. The contacts will at minimum be by telephone; although many of our patient and family partners were also enthusiastic about the idea of using a HIPAA-compliant screen-to-screen feature (e.g., Zoom®) based on individual preference. Contacts may be in person if convenient for both participant(s) and TCM, e.g. the patient has a medical appointment near the TCM's office. A typical schedule of contacts that was vetted through our Patient and Family Stakeholders will be as follows: weekly, starting 1 week after discharge, for 4 weeks; biweekly for 2-3 months, depending on individual progress and needs; then monthly for 2-3 months.

The duration of each contact will depend on the needs of the patient/caregiver. For example, if the patient is not reporting unmet needs on the needs assessment, the contact may be very brief. However, it was the emphatic recommendation of the Patient and Family Stakeholders that all 12 scheduled contacts take place. As one stakeholder put it, *'If you're under water, you don't know if it's raining!'*
Additional Interim contacts may also take place during RTP, e.g., for TCM follow-ups or urgent questions, respectively, depending on the needs of the patient/caregiver (see below for more details).

Content of Scheduled Contacts
The *content* of these contacts may include:

(1) Review of Discharge Plan: Particularly in the first few calls, review of discharge plans and assistance and/or directive problem-solving around any obstacles to following discharge plans;

	Discharge from Inpatient Rehabilitation	Post-Discharge
Standardized Discharge Care	Patient and Family Education on diagnosis/needs	Phone call within a few days of discharge to reinforce discharge plan
	Written Discharge Instructions	
	Organize outpatient service/appointments	
	Medication teaching and prescriptions	
	Discharge summary sent to Primary Care Physician	
Optimized Transition Care	Patient and Family Education	Phone call within a few days of discharge
	Written Discharge Instructions	Ongoing telephone contacts until 6-months post-discharge
	Organize outpatient service/appointments	Review discharge plan and provide assistance to ensure follow through
	Medication teaching and prescriptions	Assess unmet needs
	Discharge summary sent to Primary Care Physician	Connect with relevant resources in healthcare network, community, etc.
		Assist with scheduling appointments/arranging transportation
		Provide reminder calls
		Follow up letter/email
		TBI Helpline to receive questions/request

(2) Assessment of unmet needs: Assessment of unmet needs, which has been standardized into a checklist of areas of need that are relevant to TBI, culled from literature on need fulfillment in this population, will take place at each scheduled contact.[44, 84] As one stakeholder with TBI stated: "*One thing I'm concerned about is if the care manager just asks basic questions to people such as "are things going well?" You will actually miss out on a lot of important detail about people's lives problems and the issue they are having*." (Patient Stakeholder) This checklist assesses specific needs for help with practical issues such as medication management and coordinating rehabilitation services; managing problematic symptoms such as pain, or addressing substance use; emotional issues such as managing daily stress and

controlling temper; psychosocial issues such as re-engaging with friends and leisure activities; caregiver issues such as role changes and caregiver stress; and participation-related issues such as finding employment.

For each area of unmet need, the TCM will provide practical assistance and will connect the patient/ family with appropriate resources in the healthcare network, the resources available through the state Brain Injury Association/ Alliance, and/ or resources in the wider community. When appointments need to be made with service providers, the TCM will assist with scheduling those appointments, ensure transportation is available, and provide a reminder phone call to the participant to encourage them to attend the appointment.
The TCM may share with medical providers/community resources information learned during the RTP phase that would maximize addressing any needs, including but not limited to contact information, details regarding the patient's TBI, and any other pertinent information. The TCM will get the participants' permission first before contacting these providers, and make it clear to the participants in advance what information will be shared during the contact.
A system for organizing the patient's schedule will be developed based on patient and family preference (e.g., phone or computer organizing apps vs. hard copy calendars, etc.).

The TCM may also send to both patient and caregiver participants a basic version of the needs assessment (e.g. daily living, physical status, mood &behavior, etc.) that will be assessed during scheduled contacts.

Recipient of Contacts
In terms of the recipients of contact, we will follow the emphatic recommendation of our patient and family partners, that each person responsible for the patient's care (i.e., not only the patient but a family member or caregiver) be contacted *separately*, at least at first, to allow for the possibility of differing viewpoints (or lack of awareness of problems on the part of the person with TBI). We will also follow their recommendation that for persons discharged to a nursing facility, the phone contacts should include not only a family member but also a member of the facility staff if family provides permission and the facility is willing to allow contact (e.g., nurse manager or patient/ resident advocate).

Other Components of RTP
We will include several other components of the RTP condition to help establish continuity of care and to provide a "safety net" for patients experiencing problems between calls.

- A Follow-up letter will be sent by post or electronically (email, text) immediately after each scheduled contact summarizing the discussion points and mutually agreed-upon plans.
- A final letter will be sent to the patient and/or caregiver participant following the end of the RTP phase that provides a summary of the follow up plan, a list of resources provided during the contacts, and any reminders/suggestions/strategies moving forward.
- In addition, with the participants' permission, a letter may be sent to a primary care provider or other relevant provider after completion of the RTP phase to assist with coordination of care, provide updates, and explain participant has concluded study participation.
- Based on feedback from our stakeholders, we will provide a telephone number staffed by the TCM during business hours to all patients/ families in the RTP group as well as others involved in their care so that they may contact the TCM between regularly scheduled calls. "*A week for the introductory call is fine as long as we send them home with a telephone number to call in case something comes up sooner. A week can feel like a year when you need help*." (Family Stakeholder).

- The TCM will also be available during business hours via e-mail or text message. Reminder email or text messages may be sent by the TCM to patient or caregiver participants to remind of appointments or follow-up plans as requested

The TCMs will attempt to reach participants to complete the RTP scheduled contacts until: 1) a planned number of contacts have been completed, 2) the participant declines or is deemed unable to complete the RTP contacts (withdrawal, death, etc.), or 3) the RTP window expires six months following discharge. The TCMs will strategize with their supervisors ways to manage participants that are difficult to reach on a case-by-case basis. In addition, TCMs may send a letter to both patient and caregiver participants indicating that they have been unable reach them and request the participant contact research staff to arrange for upcoming contacts.

Documentation of RTP completion regardless of completion status (i.e. withdrawal, discontinuation, completion per protocol, etc.) should be entered in the NDSC database by the TCM using the Rehabilitation Plan completion form. These data will be entered into the NDSC database by the TCM within one week of rehabilitation plan completion.

RTP Process Variables
Individual elements of the RTP will be measured as they are administered to each patient/ caregiver or other recipient in the form of a treatment note as captured in a secure database, incorporating documentation elements used in the field.

Measures will include the clock time devoted to each contact, the recipient of each contact, total number of attempts/contacts, the type of need or issue discussed, and actions planned and implemented. These data will be uploaded in de-identified form to the BRITE website on a semi-regular basis.

Training and Quality Assurance
Our study's subject matter experts across all sites will assist in educating the TCMs regarding the effects of TBI on symptoms, cognition, and behavior, and will train them in how to help the participant address common TBI-related problems. In addition, TCMs will be trained in the practice of telephone administration, monitoring response to treatment, and dealing with medical emergencies. Initial training will take place in the kick-off meeting and include didactic instruction and role-play.

Regular individual and group supervision will be provided by study investigators from multiple sites to give support and guidance to TCMs as they work with a variety of patients and caregivers (resource facilitation and intervention supervision), ensure study protocols are followed at each site (study protocol supervision), and to ensure fidelity to the intervention (fidelity supervision, described below).

Update: As of February 2019,given that TCMs from 5 of the 6 sites have been fully trained and monitored for fidelity to current standards, group supervision consists of a monthly meeting with study investigators, and a separate monthly meeting with only the TCMs and Dr. Moore from the UW. TCMs may also meet as needed among themselves to discuss cases. Although all sites may differ, the recommendation is that an additional supervision meeting between the TCM and each site's investigators will take place on at least a monthly basis and as needed to discuss caseloads. Rationale: decreasing overall study supervision reflects a more pragmatic and sustainable approach that would be taken in a normal clinical setting.

Resource Facilitation and Intervention
Topics will be decided before each group supervision meeting via discussion with TCMs and supervisors about common questions and issues arising related to the intervention delivery. Possible topics may include understanding the flow of the phone calls, TBI sequelae and recovery in the context of patient presentation(s) that are confusing or challenging for the TCM (disinhibition, anger, etc.) complex caregiver/family dynamics that are interfering with TCM role, boundaries and the relationship to intervention goals. Supervision may include didactic trainings, videos, review of audio recorded contacts with patients and caregivers, role plays, modeling, among other strategies to enhance competence and confidence in intervention.

Study staff with the help of collaborating state Brain Injury Associations/Alliances will research and organize regional health care referral information for each participating state. Both this initial training and ongoing TCM supervision will be continued via telephone and video conferences.

Study Protocol Supervision
The TCM will be responsible for managing both the logistics and content of the treatment with the support of a team of experienced TBI clinicians. A training manual outlining the key components of care management has been created and will include the following key components:

1. TCM Training Activities
2. Development of Resources
3. Overview of Post-Discharge Activities
4. Overview of TCM Contacts for Patients Randomized to RTP
5. Details of RTP Protocol
6. Participant Engagement
7. Risk Management (mental health, physical)
8. TCM Supervision

Fidelity to Intervention
All RTP scheduled contacts will be digitally recorded and stored on a secure server. A random selection of these recorded contacts for each TCM will be reviewed and scored by study investigators,TCMs, and unblinded study personnel from multiple sites using standardized study fidelity measures. We expect that the needs to be addressed in the calls will be specific to each participant. Therefore, we are not attempting to assess fidelity to the provision of specific materials or resources, but to the *process* of the intervention as described above, including follow through on discharge instructions, standardized assessment of needs at each call; appropriate referral to locally available resources; and appropriate follow up of issues discussed on prior calls.

Fidelity Supervision
The first four recorded contacts for each TCM will be reviewed by study investigators to assess for fidelity to the RTP protocol. Following review of the initial four recorded contacts, the study fidelity team consisting of study investigators, TCMs, and unblinded personnel across all sites will review on average two scheduled contacts per month for each TCM, or a total of 24 contacts per year. Of the 24 recorded contacts that will be reviewed, approximately a third (8 contacts) will be with a caregiver. In addition, about 16 of the contacts that will be reviewed will be first and final contacts(4 each), with the 8 remaining sessions reviewed consisting of contacts 2-11.

The outcomes of these fidelity ratings and areas of strength and improvement will be conveyed to each TCM by study investigators responsible for study supervision (i.e. not other TCMs or non-investigators) on a monthly basis on average. The ratings and any appropriate feedback will be provided to the TCM via email if the fidelity percentage is >90%, or via telephone if <90%. Supervision may include role plays, modeling or other strategies to improve fidelity to model.

Update: As of February 2019, study investigators will continue to rate fidelity for each TCM, but will no longer provide regular feedback to each TCM based on fidelity ratings. Rationale: decreasing overall study supervision reflects a more pragmatic and sustainable approach that would be taken in a normal clinical setting.
We will select one recorded contact to review each month for the backup TCMs if a TCM completes at least one scheduled contact for the month under review. We will not attempt to control which type of contact will be reviewed (e.g. caregiver versus patient, first contact vs. final contact, etc.).

In addition, we will review the first two recorded contacts if the backup TCM has not conducted a scheduled contact in three months or more (example: backup TCM completes a scheduled contact March 30, then does not complete another scheduled contact until July 20. The fidelity reviewers will review the first two contacts starting with the one conducted July 20).

Language describing the audio recording procedure can be found in the study consent forms. Subjects can refuse to have any or all contacts recorded and still remain in the study.

Follow Up Data Collection

3, 6, 9 and 12 Months Post Hospital Discharge Questionnaires: Patient Participant
The 3, 6, 9 and 12 months post hospital discharge questionnaire will take approximately 25-30 minutes to complete, and will be completed by phone, in person, or via postal mail (see 'Mailout Option' section below for more detail).

The post-discharge questionnaire will consist of the following measures:

1. **Participation Assessment with Recombined Tools-Objective 17 (PART-O)** - measure of community participation.
2. **Quality of Life after Brain Injury Scale (QoLIBRI)** - The QoLIBRI is a patient-reported instrument specifically created to measure the patient's perception of their health-related quality of life following TBI.
3. **Cornell Services Index-** The Cornell Service Index is a widely used measure of healthcare services utilization, and will include number of hospitalizations and days hospitalized, number of emergency department visits, as well as number and type of clinic visits. We will be providing each participant at baseline a tool that will help participant's collect this information.
4. **Street Address:** We will collect street address for data analysis purposes during each of the discharge questionnaires. We would then send each participant's address to the national database at the National Data and Statistical Center.
   The National Data and Statistical Center uses the address to get information about the socioeconomic status of each participant based on the communities they reside, contracting with a service that helps with obtaining data from neighborhood databases. Both the National Data and Statistical Center and the contractor are required by law to keep the information confidential.

5. **Insurance Type/Coverage:** We will collect insurance type/coverage for data analysis purposes during the 6- and 12-month discharge questionnaires.
6. **Satisfaction with Care:** We will collect information about how satisfied participants were with their healthcare during the 6- and 12-month discharge questionnaires.

One Year Following Injury Questionnaire: Patient Participant
Patient participants not enrolled into TBIMS concurrently will complete a questionnaire about one year following injury ("Form II"). The questionnaire collects demographic and injury related data and clinical history will be collected in interview format. The questionnaire will take about 45-60 minutes to complete.

Research staff will attempt to administer the one year following injury questionnaire in tandem with one of the BRITE post-discharge questionnaires depending on the timing of the discharge relative to injury. Specifically, research staff will attempt to collect the Form II during a specific BRITE questionnaire period (e.g. 9 month questionnaire period) when the ideal date of that BRITE questionnaire period and the open date of the Form II are closest relative to the other BRITE questionnaire periods. Research staff would start attempting to collect data for both Form II and that BRITE questionnaire at either the open date of the BRITE window or the open date for Form II window, whichever comes last. The questionnaire may be done at a separate time, however, if necessary.

Research staff will not complete a Form II with non-TBIMS patient participants if the patient is enrolled outside the Form II window described below, specifically more than two months after the ideal administration date (12 months following injury).

Please follow Standard Operating Procedures 105B from the TBIMS for the One Year Following Injury Questionnaire ("Form II") completed by non-TBIMS patient participants:

https://www.tbindsc.org/StaticFiles/SOP/105b%20-%20Guidelines%20for%20Collection%20of%20Follow-up%20Data.pdf

3, 6, 9 and 12 Months Post Hospital Discharge Questionnaire: Caregiver
The 3, 6, 9 and 12 months post hospital discharge questionnaire will take approximately 15-30 minutes to complete, and will be completed by phone, in person, or via postal mail (see 'Mailout Option' section below for more detail).

The post-discharge questionnaire will consist of the following measures:
1. **Bakas Caregiving Outcomes Scale**- The Bakas scale is a 15-item measure, each with a 7-point scale that assesses change in social functioning, emotional well-being, and physical health related to caregiving.
2. **Zarit Burden Interview -** A 22 item measure that focuses on burden in caregiving.
3. **PROMIS Satisfaction with Social Roles and Activities Short Form-8 -** An 8 item measure that asks about satisfaction with social roles and activities
4. **SF-12-** The SF-12 is a well-known health questionnaire that will be used to characterize the overall health of the caregiver.
5. **Required Assistance and Time Spent Caregiving-** unvalidated items developed by the study team to assess the assistance each patient participant requires as well as time spent interacting with the patient participant**.**

Rehabilitation Transition Plan (RTP) Survey: Caregiver and Patient Participant
We will conduct a telephone survey with both caregiver and patient participants who were randomized and participated in the RTP arm of the study about 6 months following discharge. The survey consists of questions soliciting feedback about the RTP arm of the study. The interview should take about 10-20 minutes to complete depending on the responses of the participants. Participants will not be compensated for completing this survey.

A trained research staff member at Mount Sinai, one of the study's sites, will perform the interview described above. Contact information (e.g., name, phone number, email) for UW participants will be uploaded on a restricted access website at the TBI National Data and Statistical Center (NDSC) managed by study personnel at the Craig Hospital. Only Craig Hospital staff who manage the website and the staff conducting the interviews at Mount Sinai will have access to this identifying information.

All data listed above will be entered into the NDSC centralized database by research staff.

Mailout Option: Baseline Caregiver Questionnaire, All Post-Discharge Questionnaires, Year Following Injury Questionnaire
The postal mail or 'mailout' option will not be offered initially to participants; rather, this approach will be taken only with a participant who either:

1) has difficulty completing the questionnaire via telephone or in person; or
2) research staff has difficulty reaching via telephone to complete the questionnaire.

Regarding #1: Research staff may offer the mailout option to the participant if s/he either expresses difficulty completing the questionnaire via telephone, or s/he repeatedly re-schedules appointments to complete the questionnaire.

Regarding #2: Research staff should send the participant the mailout version of the questionnaire to him/her if research staff has not been able to reach a participant after two telephone attempts to schedule the questionnaire.

Research staff should send the participant the mailout version of the questionnaire after SUBID and date of mailing has been added to the form. The questionnaire would be mailed via postal mail along with a self-addressed envelope and the appropriate cover letter depending on the circumstances. Research staff should continue to call the participant until the questionnaire is received. Research staff should review the questionnaire thoroughly upon receipt, and contact the participant to solicit responses for unanswered/unclear items following the guidelines listed in the 'Questionnaire Scheduling and Timing' section below.

Study researchers will attempt to collect via telephone data from patients that complete the self-administration version of Form II via postal mail. The self-administration form does not include address, information regarding injuries to head/neck, the Supervision Rating Scale, the GOSE, and the FIM. A cover sheet has been created that study researchers can use to collect the data described above as well as administrative items if a site is using a paper version of the form for data collection.

Questionnaire Scheduling and Timing
Research staff will begin attempting to contact participants (patient and caregiver) for scheduling purposes one month prior to the ideal administration date for the 3-, 6- and 9-month post-discharge questionnaires. Research staff will attempt to complete the questionnaire no more than 15 days before or 30 days after the ideal administration date for the 3-,6-, and 9-month post-discharge questionnaires, with the exception of the two-week extension rule listed below). Research staff should attempt to complete each questionnaire as close to the ideal administration date as possible(e.g. 3 months following discharge for the 3-month post-discharge questionnaire).

Research staff will begin attempting to contact participants (patient and caregiver) for scheduling purposes two months prior to the ideal administration date for the 12-month post-discharge and one year following injury questionnaires. Research staff will attempt to complete these questionnaires no more than two months before or after the ideal administration date for the 12-month questionnaire and Form II (see two-week extension rule below). In addition, a minimum of 30 days must pass between the 9- and 12-month questionnaires.

Patient participants that started or completed the post-discharge questionnaires prior to the window start date should be contacted by research staff during the window to review the completed items to make sure nothing has changed. The date of the call back occurring within the follow-up window should be used as the questionnaire date. If a call back cannot be completed, the original questionnaire date outside the follow-up window should be used.

Two-Week Extension Rule: Post-discharge questionnaires that have been started but cannot be completed by the time the data collection window closes can be completed within two weeks after the window closes. The questionnaire date should be the date the questionnaire was started.
Four-Week Completion Rule: Post-discharge questionnaires that have been started but not completed during the first contact should be completed within 4 weeks. The questionnaire date should be the date of initial data collection. If it takes longer than 4 weeks to complete the questionnaire, data collected during the initial data collection period should be verified, and the questionnaire date should be the second date that data was collected. In the unusual case where the 2 week extension window is used to complete the questionnaire beyond the 4 week time frame, (e.g. questionnaire started January 1st, questionnaire window closes January 30th, questionnaire completed February 5th), the questionnaire date should be the date of data collection that was in the questionnaire window (January 1st in this example).

Mailout Option: The mailing of the questionnaire will trigger the 2 week extension to the questionnaire window. Example: if research staff mail the questionnaire July 18, 2018, and the end of the window is August 31st, research staff can then receive/collect data through September 14th.

Mailouts are exempt from the four-week extension rule listed above.

Patient Participants Only (i.e. Not Caregiver Participants): If adequate data are not obtained from the participant by telephone or by mailout two weeks before the end of the window, the mailout questionnaire should be sent a significant other SUBID and mailing date have been added to the form, along with a self-addressed return envelope. Like the mailing of the questionnaire to the patient participant, the mailing will trigger the 2 week extension to the questionnaire window. Example if research staff mail the questionnaire July 18, 2018, and the

end of the window is August 31st, research staff can then receive/collect data through September 14th.

Missing data may not be filled in using data obtained outside the questionnaire window and two-week extension rule unless approved by the lead site.

To classify a questionnaire as "followed" an interview or mailout must be started. There is no minimum number of data elements that need to be answered.

Research staff will attempt to reach participants to complete these questionnaires until: 1) the questionnaire is completed, 2) the participant declines or is deemed unable to complete the questionnaire (withdrawal, death, etc.), or 3) the questionnaire window (and two-week extension rule, if applicable) expires.

Research staff may send out a letter in advance to both patient and caregiver participants reminding them of the upcoming questionnaires.

Any administrations that fall outside of the windows described above will be documented as protocol deviations using the study note-to-file form.

All follow-up data described above will be entered in with the participant's ID, i.e. not name into the NDSC centralized database via the 'Data' tab.

Data Quality Targets – Assessment Completion

Target Assessment Completion rate is set at 80%, and will be reviewed on a quarterly basis beginning December 2020. The lead site will review the rate for cases with open windows during the previous six months (e.g. 6/1/20-11/30/20 for the December check). Sites not reaching their target will be required to develop a written remediation plan for increasing enrollment numbers. This plan should be submitted to the lead site. The effectiveness of this plan will be reviewed at subsequent quarterly checks.

Study Completion

All participants will be informed that their participation in the study has been completed once the final questionnaire window has ended regardless of questionnaire completion. This notification may take place via telephone and/or email/postal mail.

Documentation of study completion should be entered in the NDSC database using the Study completion form; the electronic form can be found under the 'Data' tab on the NDSC website. These data will be entered into the NDSC database by research staff within one week of study completion.

Participant Retention (MD-1, MD-4)

We will use participant retention strategies that we have refined in the TBIMS with specific SOP. We anticipate at least 80% enrollment rate in this study due to the broad eligibility criteria and flexible interventions being offered. In addition, the six TBIMS sites included in the study have a

retention rate of 94% at one-year follow up for TBIMS participants even though there is less contact with the patient across the first year than we will have in the current study, which may increase our ability to retain subjects over time. We will use culturally sensitive, evidence-based practices derived from other successful real-world trauma treatment trials.[85]

Key strategies include: attempting contacts at multiple times of the day and multiple days of the week, including weekends; collecting contact information on three or more people who will know the whereabouts of the patient one year later; obtaining multiple means of contacting each person (home phone, work phone, email), updating contact information frequently; sending birthday/holiday cards, requesting change of address notification from the post office; providing financial incentives for participation; and using fee-based Internet search engines such as TLO. In addition, research staff may send a letter to both patient and caregiver participants indicating that they have been unable to reach them and request the participant contact research staff to arrange for upcoming questionnaires. For any participants who do not complete a follow-up questionnaire, reasons for the lack of follow-up will be recorded (e.g., physically or cognitively unable and proxy not available, not available [e.g., hospitalized, incarcerated], death, withdrawal from study, no response to contact despite repeated attempts, etc.

Participant Flow Tracking

We will report the study participant flow following the Consolidated Standards of Reporting Trials (CONSORT) guidelines (http://www.consort-statement.org/CITE). The consort diagram will illustrate a) number of potential patients screened for eligibility, b) number of patients deemed eligible, and the final recruitment outcome for all patients screened(ineligible, declined, unable to consent, enrolled). The diagram will also illustrate the same information for caregiver participants, as well as outcome regarding questionnaire completion.

Masking (or Blinding)

This study uses **masked outcome assessment**, which means that staff members who collect outcomes data from both patient and caregiver participants at 3-, 6-, 9- and 12 months must be unaware of patient participants' treatment group allocation. Several procedures are used to help outcomes staff to remain unaware of group assignment.

Randomization will be automated via a NDSC database to minimize unblinding. Specifically, research staff or the TCM will enter discharge destination and study site into the specified NDSC database as part of the discharge destination and date form. Subsequently the TCM will be notified via email of group assignment. Ideally, group assignment will be known only by coordinators and the TCM(s) at a given site, and the data coordinator at Craig Hospital.

In addition, only TCMs will have access to the 'Notes' tab on the NDSC database where adverse events, serious adverse events (SAE), unanticipated problems and note-to-files are entered. The reason is that blinded assessors would be unblinded if they observed entries for these events if entered by a TCM. As a result, all information relating to adverse events, SAEs, unanticipated problems and note-to-files will be sent by blinded assessors to the TCMs at each site for entry into the database.

Other procedures for preventing inadvertent unmasking will be used such as ensuring that data collectors and TCMs are not using office spaces in close proximity while TCMs are contacting patient participants, and minimizing the meetings that data collectors and TCMs attend in

common. Also, data collectors will not have access to the treatment list serve to prevent inadvertent unmasking from that source.

Staff will continue with a post-discharge questionnaire even if unblinded during the questionnaire administration, but will attempt to have another staff member (if available) administer subsequent questionnaires.

We will record on each post-discharge questionnaire any potential unblinding incidents by asking assessors: 1. if they believe they were unblinded during the questionnaire or any previous questionnaire; and 2. to guess which study arm they believe the participant was assigned to.

Staff will record unmasking/unblinding with the study note-to-file form only if an incident takes place between questionnaires and has no impact on any questionnaire/data (e.g. blinded staff member who has not been assigned to complete post-discharge questionnaires with patient participant is unblinded by patient participant during a clinic visit).

Withdrawal/Discontinuation of Participants from Study Procedures

There are two ways in which a participant (patient and caregiver) may cease participation in the study after being consented:

1. **WITHDRAWAL**: The patient and/or caregiver voluntarily terminates his/ her participation, and withdraws:
    a. From the transition plan portion of the study (RTP only); or
    b. From both the transition plan portion and the remaining outcome assessments.
2. **DISCONTINUATION**: The patient and/or caregiver are discontinued by study staff (for reasons detailed below):
    a. From remaining treatment portion.
    b. The patient and caregiver are never discontinued from remaining data collection by study staff except
        i. in the unlikely event that further data collection would be against their best interests in the judgment of the site PI and the study PI; or
        ii. the patient participant has a new caregiver participant.

Documentation is also necessary to capture what aspect of participation is affected (transition plan, or both transition plan and data collection) and who is ceasing participation (patient, caregiver, both).

Withdrawal

Participants may elect to withdraw from the study at some point after they have signed consent.

Withdrawal from Transition Plan

Participants may wish to withdraw from (discontinue) the transition plan portion (RTP only). This is **not** the same as withdrawing from the study, which includes outcome assessments in addition to the transition plan phase. Once participants have been randomized, every effort should be made to follow participants with all of the subsequent outcome assessments, even if they do not attend *any* scheduled sessions.

It is highly advisable for the person who first hears of a desire to withdraw (TCM, assessor, etc.) to discuss the situation as soon as possible with the local and/ or national study team.

If a participant expresses a desire to discontinue the transition plan portion (usually, this will be brought up with the TCM):

- Never express disappointment or imply this is a bad thing for them to bring up. It happens in every research study, so expect it to happen. Be sympathetic to their wishes, take it in stride, and ask if they would be willing to discuss it a little further.
- Ask if they would give their reasons. Offer to have another person, such as the PI, contact them to hear their reasons if they would prefer.
    - Reasons will be documented via use of the 'Rehabilitation Transition Plan Completion' form.
- Sometimes participants wish to withdraw based on a misunderstanding or mis-remembering of their obligations. Try to explain the study procedures to make sure they understand expectations.
- If there is concern about confidentiality, remind the participant of the measures that are taken to protect his/ her privacy and emphasize that these are taken seriously. Offer a conversation with the PI as warranted.
- Depending on the reasons, ask if there is any kind of accommodation that would help enable them to continue.

  There are obviously certain changes we cannot make (e.g., switching to a different TCM if only one TCM at the site), but the attitude should be one of exploring concerns so that we might try to work around them—to make it easy and comfortable for them to continue participation.
- If the participant mentions any accommodations that might be helpful and are feasible, you may authorize them on the spot or, if you are unsure, ask for a short period of time (48 or 72 hours) to meet with your team and then respond to his/ her concerns.

If the participant is definite about stopping the transition plan phase,

- Let him/ her know that this is fine, and that future contacts will be cancelled.
- Remind him/ her that the study also includes periodic questionnaires which can be done over the phone.
- As appropriate,
    - Tell him/ her that continuing the questionnaires, if s/he is willing, will help to ensure the scientific validity of the study.
    - Remind him/ her that we will compensate him/her for her time completing the questionnaire.
    - Remind him/ her that s/he can always refuse to complete a questionnaire at the point of contact.

<u>Withdrawal from Data Collection / Entire Study</u>

If the participant expresses a desire to withdraw during a follow up assessment, offer to break it up or reschedule the questionnaire for a different day; emphasize that a bad day need not be a reason to discontinue the entire study and that we are committed to making his/ her participation as easy and as meaningful as possible.

While trying to work with the participant to make things better, do not pressure him/ her, and remember that s/he has a right to withdraw and is not obligated to explain his/ her decisions. This can be a balancing act for which consultation with the team may be helpful.
The participant may be withdrawn from the entire study if, after encouragement to continue, s/he says definitively that s/he does not wish to be contacted any longer by anyone involved in the study, even for outcome data collection.

- Let the participant know that s/he may speak with the PI if there are any concerns about his/ her experiences in the study.
- As above, ask for reasons and document them on the study completion form.

Caregiver Withdrawal
Caregivers may withdraw from the study independently from participants. The principles are the same as to encouraging the caregiver to remain involved for data collection. A caregiver participant will remain enrolled in the study and kept on the schedule for data collection even if the respective patient participant withdraws from the study unless the caregiver participant explicitly states s/he wishes to withdraw as well.

Also, after discussion with both the patient and caregiver participant, a caregiver participant may be discontinued if another individual has become the clear caregiver. For instance, the caregiver participant at the time of discharge could be the mother, but then the patient's significant other is the true caregiver at the time of the 3-month questionnaire.
In this scenario, the mother should be discontinued, and the significant other should be enrolled as the new caregiver participant.

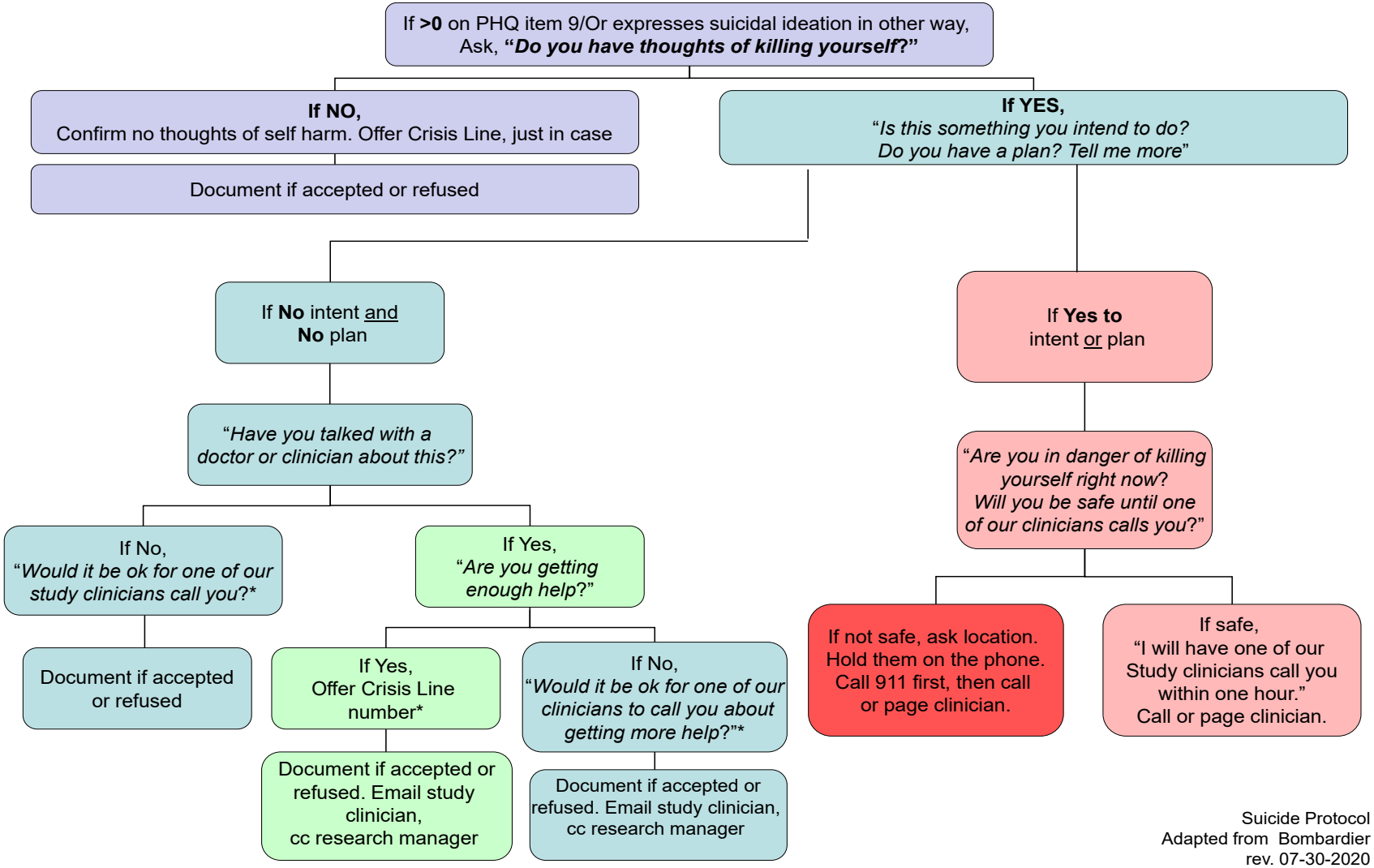
Discontinuation
Although rare, we anticipate the following circumstances may take place to warrant withdrawal of a participant without consent:
1. A participant/family member becomes verbally abusive/inappropriate with research staff members and/or TCMs.
2. At the discretion of the PI.
When possible, staff will notify participants of withdrawal via telephone. If this is not possible or prudent, research staff will send a letter informing the subject that s/he has been withdrawn. We do not anticipate partial withdrawal; once withdrawn, participants will no longer participate in any study procedures.

Documentation of Withdrawal/Discontinuation
Documentation of withdrawal/discontinuation from (a) RTP or (b) the whole study should be entered in the database using either the 'RTP' or 'Study' completion form. These data will be entered into the NDSC database by research staff within one week of withdrawal. Blinded assessors will not be able to see entries into the RTP completion form to ensure proper masking (TCMs will complete this form). The site PI will subsequently be notified of this occurrence. Withdrawals will also be documented in the quarterly reports generated by the NDSC.

The electronic form for the RTP Completion form can be found under the 'TCM' tab on the NDSC website. The electronic form for the Study Completion form can be found under the 'Data' tab on the NDSC website.

Incarceration
Study researchers will cease to engage participants in study activities (i.e. RTP phase, study questionnaires) if they become incarcerated following randomization. Incarcerated participants

will remain enrolled in the study, however. Study researchers will resume study activities with participants only once they are no longer incarcerated.



Suicide Protocol
Adapted from Bombardier
rev. 07-30-2020

REMEMBER: Log suicidal ideation as an adverse event according to protocol.

IMPORTANT PHONE NUMBERS:
Jeanne Hoffman, PhD (PI/Study Clinician): Office 206-221-6511; Cell 206-409-2654
Megan Moore, PhD, MSW: Office 206-616-2862 ; Cell 510-684-6053
Leslie Kempthorne (Research Manager): Office 206-685-1082; Cell 206-898-7025
Crisis Connections (King County Area): 206-461-3222 or 1-866-4-CRISIS (1-866-427-4747)
National Suicide Prevention Hotline: 1-800-273-8255; Spanish: 1-888-628-9454

What is Suicidal Ideation (SI)?
Suicidal Ideation (SI) includes passive or active suicidal thoughts. If the person in any way expresses a desire to hurt or kill themselves, you should follow the flow chart above. This often comes up during the PHQ-9.

OTHER INCIDENTS OF CONCERN

Unsafe living environment

→ Clarify details of problem with the participant and/or informant. Are they aware of unsafe environment?

- If they are unaware (in the neurological sense of the term) and in immediate danger (e.g., fire risk, hypothermia), call Adult Protective Services and report situation after consultation with site PI.
- If they are aware but in immediate danger and don't know what to do, assist them in finding emergency shelter until the problem can be addressed.
- If they are not in immediate danger, guide them in problem-solving and offer referrals if appropriate.

Incidents of an unsafe living environment that are life threatening and result in an adverse event will be considered an SAE and will be documented using the "Problems Report" form. Please review timing of entering SAEs below.
Incidents of an unsafe living environment that are not life threatening and do not result in an adverse event will be documented using the "Note-to-File" form. Please review timing of entering Note-to-File data below.

All other concerns
If you ever have any concerns for the immediate safety of the participant, contact the research manager and site PI right away to discuss the situation and take any necessary steps. Document the situation in a Note-to-File, and if applicable, as an AE or SAE.

ClinicalTrials.gov Requirements

The study will be registered on ClinicalTrials.gov, with the PI (Hoffman) named as the responsible party.

Maintenance of IRB Approval

All six sites will be responsible for obtaining and maintaining IRB approval from their respective institutions. This includes submission and approval of annual renewals. All sites will send annual renewal approvals to the University of Washington, the coordinating site of the grant, upon receipt. The University of Washington will maintain a list of approval dates for all sites in its MOP, and remind each site of upcoming approval expirations.

In addition, all changes to study materials and protocol requiring IRB approval will be initiated and coordinated by research staff at the University of Washington. Specifically, research staff at the UW will be responsible for finalizing any changes to the study protocol/study materials, submitting the revised materials to all respective sites, then monitor progress to ensure any significant protocol changes are approved at all sites prior to being initiated at that site.

All protocol changes requiring IRB approval will be recorded in the 'Tool Revision History' section of this document.

Major Decisions Documentation

All major decisions made during the implementation of this research study will be recorded in the MOP. In addition, research staff at the lead site (UW) will post any major decisions to the study's website list serve to ensure all study researchers are kept abreast of any major decisions that will affect some or all sites.

STUDY DATA
The following is a list and description of the data measures included in the study.
We list the demographic and descriptive information we propose to collect from the study participants in the next paragraph. Details regarding the measures are provided below. All outcome measures will be administered by research staff members blind to group allocation.

Descriptive/Demographic Variables
All patient participants will be asked to provide demographic data for descriptive purposes either as part of TBIMS or the BRITE study if not enrolled in TBIMS, including the following:

- Age
- Gender/Sex
- Height/Weight
- Race
- Primary Language
- Country of Birth
- Length in U.S.
- Marital Status
- Residential Status
- Years of Education
- Employment Status and History Prior to Injury
- Annual Earnings Prior to Injury
- Co-morbid Medical Conditions
- Cognitive Limitations Prior to Injury
- Tobacco/ Alcohol/ Illicit Substance Use Prior to Injury
- Psychiatric Conditions Prior to Injury
- Military/ Deployment Status
- Date of Injury
- Date of Discharge
- Cause of Injury
- Basic Functioning while Inpatient
- Insurance Type/Coverage

All caregiver participants will be asked to provide demographic data for descriptive purposes, including the following:

- Age
- Gender/Sex
- Race
- Country of Birth
- Length in U.S.
- Marital Status
- Residential Status
- Years of Education
- Employment Status
- Annual Earnings
- Relationship to Patient Participant
- Length of Relationship with Patient Participant
- Cohabitation Status with Patient Participant

Study Outcomes (RQ-6, PC-3, IR-4)

Our selection of outcomes was informed by focus groups held with patients and family members as well as discussions with our Patient and Family Stakeholders (see **Engagement Plan** below). The following key outcome domains were identified: (1) ability of patients to participate in the home and community as independently as possible, (2) health-related quality of life, (3) access to appropriate healthcare and reduced emergent or urgent healthcare, and (4) caregiver burden and stress. We will assess these outcomes at 3, 6, 9 and 12 months after discharge from inpatient care. We plan to combine the 12-month post-discharge outcome assessment interview with the standard TBIMS 12-month post-injury assessment, known as the Form II when the follow-up time periods overlap and participants are willing to do both assessments during the same phone call.

Primary Outcomes

Aims 1 and 2 will address the primary outcomes of 1) *Participation in Usual Roles and Activities*: Participation Assessment with Recombined Tools-Objective 17 (PART-O)[86] and 2) *Health-related Quality of Life*: Quality of Life after Brain Injury Scale (QoLIBRI)[87]

Participation Assessment with Recombined Tools – Objective 17 (PART-O-17):[88] Since the resumption of life roles and re-integration into the community drives patient and family decisions regarding rehabilitation care,[89] community participation, as measured by the PART-O-17,[88] was chosen as the primary outcome variable in the current study(**RQ-6, PC-1, PC-3**). The PART-O-17 is a patient-reported (or family member proxy-reported) measure of the International Classification of Functioning (World Health Organization[90]) construct of "participation," which is 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. All major conceptual models of disability (see, for example, Institute of Medicine's Disablement Model[91]) place considerable emphasis on fulfillment of social roles similar to the manner in which participation is defined in the International Classification of Functioning. The PART-O instrument is based on items derived or modified from three measures most commonly found in the TBI literature: Community Integration Questionnaire;[92] Participation Objective, Participation Subjective;[93] and the Craig Handicap and Assessment Reporting Technique.[94]

The PART-O-17 was chosen for the current study because: (1) consumer stakeholders provided input into its development, (2) it is a patient-reported outcome, (3) it has established reliability and validity, and (4) our Patient and Family Stakeholders felt that it and the QoLIBRI captured the outcomes that were most important to them. The measure maintains the strengths and overcomes some of the weaknesses of its component measures. Persons with brain injury, family members, and advocates assisted in the development of the PART-O-17, helping to ensure that it captured key roles and activities important to persons with TBI and their families (including important domains of participation: productivity, social relations, and being out and about in the community), and contributing to the development of an abbreviated version (PART-O-17, original version had 24 items). Test-retest reliability is strong for both the total score and the domain scores (ICC=.90 for total score and ranges from .79 to .87 for the domain scores, personal communication, Bogner, manuscript under review). Construct validity has been demonstrated in TBI populations through principal component analysis suggesting that the PART-O measures a unidimensional construct, and through correlations of the expected strength and direction with legacy measures of participation, as well as with measures of injury severity, functional limitations, subjective well-being, and mental and physical health.[88, 95-97] In addition, the PART-O-17 was found to be sensitive to disability status in a population-based study.[98]

A content analysis of the most frequently used participation measures (7 in total) indicated that the PART-O is the most representative of the ICF categories of participation.[99] A recent rating scale analysis created a new scoring algorithm for the total score that reflects a unidimensional numeric measure.[100] The PART-O 17 is a recommended outcome measure in the NIH Common Data Elements[101] and has been used in the NIDILRR TBIMS National Dataset since 2007 (https://commondataelements.ninds.nih.gov/tbi.aspx#tab=Data_Standards).

In preparation for the grant, we asked our Patient and Family Stakeholders to review a case example of a small change from baseline to 6-months post discharge. They stated that the change was meaningful and emphasized that "*any improvement after TBI is important*."

Quality of Life after Brain Injury Scale (QoLIBRI):[87] The QoLIBRI is a patient-reported instrument specifically created to measure the patient's perception of their health-related quality of life following TBI. It was developed by an international work group and subjected to rigorous validation in large samples of persons with TBI.[87] The resulting scale has 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 (.91).[87] Validity studies have shown strong associations between QoLIBRI scores and level of disability, as well as moderate associations to generic health-related quality of life measures (e.g., SF-36); however, the QOLIBRI is more strongly related to TBI outcomes than are the generic quality of life measures.[102] It has been noted that many of the items on the QoLIBRI, which ask about satisfaction with one's status in several domains and the degree to which one is bothered by various symptoms, reflect modifiable states that could change with interventions[102] such as the one in the proposed study. The QoLIBRI was selected as an outcome measure for the multi-agency TBI Common Data Elements and is part of the outcome assessment in the TRACK-TBI study. (https://tracktbi.ucsf.edu/sites/tracktbi.ucsf.edu/files/Outcome%20Assessment%20SOP.pdf)

Secondary Outcomes
Aim 3 is focused on ***Healthcare utilization***: Cornell Services Index;[103] Aim 4 addresses ***Caregiver burden***: Bakas Caregiving Outcomes Scale[104], Zarit Burden Interview[129], SF-12[130], and PROMIS Satisfaction with Social Roles and Activities[131] and assessment of Time Spent Caregiving. Program process evaluation will include ***process variables***: e.g., rate of call completion, number of additional calls needed, call duration and calls initiated by the patient/caregiver.

Cornell Services Index:[103] The Cornell Service Index is a widely used measure of healthcare services utilization, and will include number of hospitalizations and days hospitalized, number of emergency department visits, as well as number and type of clinic visits (both routine and those that address medical complications). It has been used in a number of TBI studies.[66, 105] The instrument allows one to modify it as needed, including specifically asking if a patient saw a provider for issues related to TBI. We will also modify it to include assessment of TBI-specific care, since our stakeholders were particularly interested in whether RTP improves the ability to access and follow through with care.

Bakas Caregiving Outcomes Scale:[104, 106] Since there are no TBI-specific caregiver quality of life (QoL) measures, the Bakas Caregiving Outcomes Scale, which was developed for use in stroke, will be adapted by replacing "stroke" with "traumatic brain injury" similar to a prior study.[107]

The Bakas is a 15-item measure, each with a 7-point scale that assesses change in social functioning, emotional well-being, and physical health related to caregiving. It has been shown to have good internal consistency (Cronbach α = 0.90), test-retest reliability (intraclass correlation = 0.68), and construct validity.[106] Following the recommendation from PCORI reviewers, we are currently exploring with our research team, including our patient and family stakeholders, other important caregiver domains (e.g., caregiver quality of life, role functioning and burden) as outcomes.

Zarit Burden Interview:[129] The Zarit Burden Interview was initially developed for caregivers of individuals with dementia.[108] Short forms have been developed,[109] and the 12 item version addresses the concerns that our stakeholders feel are most important and that we feel are most relevant to our study interventions. The Zarit Burden Interview has been used previously in studies on caregivers of individuals with TBI.[110-114] We hypothesize that caregivers for participants randomized into the RTP arm of the study will report lower burden compared to those caregivers of participants randomized into the RDP arm.

Prior research with this scale has been primarily descriptive and did not exactly match the timeline[111, 112] (within one year of TBI) nor injury severity[113] of our study population. We can use the published data to estimate a possible standard deviation and given our expected sample size, we have 80% power to detect approximately a 2.29 difference if one exists. This is based on data from a study conducted on caregivers of Veterans with TBI[112] who are broadly similar to our population with an average score of 15 and standard deviation of 10 on the 12 item Zarit Burden Interview. An assumption was made of equal sample sizes between the two groups which, with 80% power, alpha of .05, would require a .229 effect size to detect a difference between the two groups at 6 months post injury.

SF-12: [130] The SF-12 is a measure of health-related quality of life (HRQOL) and allows for 2 component scores to be determined: physical health and mental health. The SF-12 has been used in examining HRQOL in caregiver populations for other disorders,[115-117] but not as frequently assessed in caregivers of individuals with TBI.[118] However, the 36-item version has been found to show change over time in caregivers of persons with TBI.[119] We hypothesize that caregivers for participants enrolled in the RTP arm of the study will report better HRQOL in both physical and mental health domains compared to those caregivers of participants enrolled in RDP alone.

PROMIS Satisfaction with Social Roles and Activities:[131] The PROMIS Satisfaction with Social Roles and Activities has not been used in the study of caregivers in any population to date. Given the other measures that we are including that specifically assess caregiver functioning and engagement in activities directly related to caregiving, we chose this measure to add an understanding of engagement in roles and activities apart from those related to caregiving. We hypothesize that caregivers for participants enrolled in the RTP arm of the study will report better satisfaction with social roles and activities compared to those caregivers of participants enrolled in RDP alone.

Required Assistance and Time Spent in Caregiving has been assessed in a variety of studies to describe the use of caregivers for individuals with TBI. This measure was developed internally with input from our Patient and Family Stakeholder group and experience from prior studies.

Assessment of Variability of Resources and Processes

For RDP: During the preparation of our grant, we performed an assessment of the key resources and processes that are available at each of our inpatient rehabilitation sites, which include: (1) Patient and family education on diagnosis and anticipated needs, (2) written discharge instructions, (3) organization of outpatient services and appointments, (4) medication teaching and prescriptions, (5) discharge summary sent to primary care provider, and (6) post-discharge telephone call within a few days of discharge to reinforce discharge plan.

For RTP: We are aware that community resources will vary among our sites. Our patient and family stakeholders reported that the most important factors which contributed to them not getting their needs met following discharge from inpatient rehabilitation, were (1) lack of services to direct them to what resources were available or relevant to them and (2) limitations in insurance coverage (e.g., limiting availability of helpful services such as physical therapy, mental health treatment, etc.). Therefore, we will examine insurance coverage as a potential source of variability in outcomes. Moreover, during the start-up phase of the study, the TBI Care Manager (TCM) at each site will work closely with clinical and community stakeholders to familiarize themselves with all available resources at each site and across sites to increase the likelihood that all potential resources will be identified. Because the TCMs at all sites will be meeting via phone or videoconference on an ongoing basis, new resources that may be identified will also be shared to maximize awareness for all TCMs. We have agreement from our patient and family stakeholders and professional stakeholders to work with us to develop a list of key community resources across all sites, such as the availability of transportation, Department of Vocational Rehabilitation resources, support groups for patient and family, etc. that they feel may be relevant for individuals with TBI and their family/caregivers.

Also, during some sessions between the TCM and participant/ caregiver, the TCM will be using a checklist to determine needs as well as which patient-identified needs are met or unmet. If a need is unmet, we plan to document whether lack of available resources was the cause. While we cannot account for all variability in resources across the six sites/states, we will examine potential confounding and heterogeneity of treatment effects by study site and insurance coverage, which has significant influence on the resources available to patients. Finally, as described above, intervention fidelity will be closely monitored.

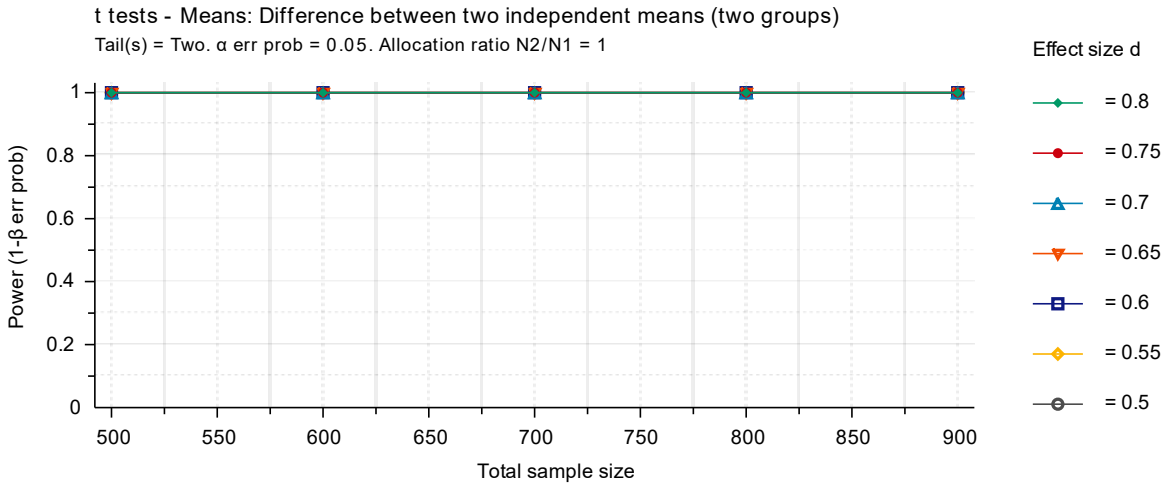
Power Analysis

As can be seen in the Recruitment/Enrollment table above (p. 26), we expect to enroll a minimum of 300 individuals per year for 3 years (total N = 900). We based our power calculation on the PART-O-17, the primary outcome for which we have the most relevant data in TBI. Unpublished data from a sample discharged from inpatient TBI rehabilitation showed a PART-O-17 Total (which can range from 0 to 5) average score of 1.51 (SD=0.65) at 3-months follow-up and 1.66 (0.72) at 9-months follow-up (publication in preparation). Minimal detectable differences (MDD) were 0.57 and 0.63 at 3 and 9 months, respectively. Using these results, we calculated the power of finding a difference of 0.60 (average of the two MDDs) between the two groups under various assumptions as follows:

Test: t-test for independent samples, two-tailed, allocation ratio=1
Significance level=0.05
Common standard deviations: 0.75 (higher than the observed in previous studies to be conservative)

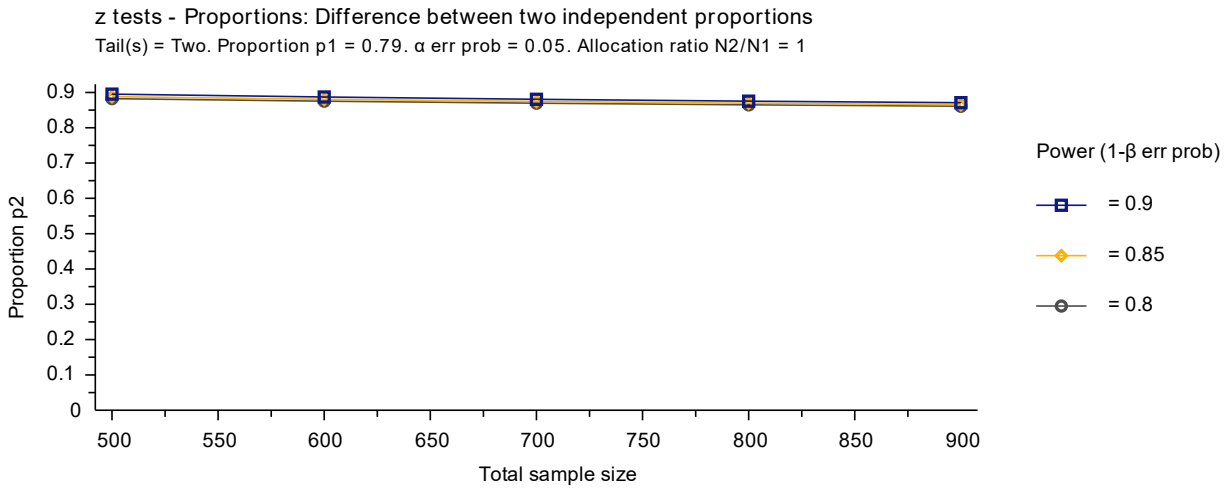
Mean PART-O scores (Intervention mean minus control mean): The minimal detectable difference of the instrument is 0.6. To be more conservative, we started the difference between the two means at 0.4. Assuming SD=0.75 (in the higher side of previous studies) the calculated effect size based on this mean and SD is 0.5333. Therefore, we used values of 0.5 to 0.8 by increments of 0.05 for the effect sizes.
Sample sizes: from 500 to 900 individuals (by 100)

The graph shows that even with an effect size of 0.5 (corresponding to a difference of 0.4 points between the two groups and under an SD larger than those observed in prior studies), we have practically 100% power to detect the difference between the two groups with sample sizes of 500 and above (we expect to have 900).



Power for Secondary Outcomes

For Aim 3, we consulted our stakeholders to determine what would represent meaningful differences in healthcare utilization. Based on these discussions, we will categorize completed planned outpatient visits in “less than 50%,” “between 50 and 75%,” and “more than 75%.” Based on highly conservative estimates from data collected on patients who were eligible (based on insurance, geography and preference) and referred to Moss Rehab Hospital (one of our study sites), 4%, 17%, and 79% of the individuals received “less than 50%,” “between 50 and 75%,” and “more than 75%” of their scheduled physical therapy, occupational therapy, and speech therapy care visits (these data do not include other outpatient visits, such as mental health and primary care visits, that are known to have low adherence rates). Under the assumptions that our RDP group would have a proportion of 0.79 of people going to more than 75% of their scheduled visits, with a significance level of 0.05, power of 0.80, and varying the sample size from 500 to 900, we calculated the size of change in the proportion of people receiving 75%+ visits in the RTP group that we would be able to detect. We would be able to statistically detect a proportion of 0.88 in the RTP group with a sample size of 500 and a proportion of 0.86 with 900 (see graph below). Therefore, we would have enough power to detect a small change in proportions.



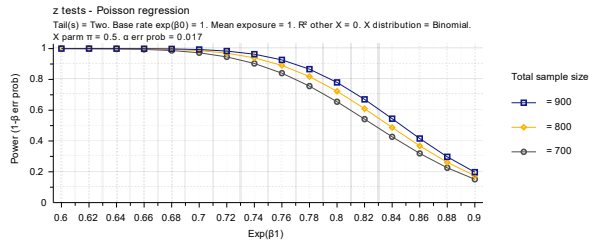
We will also test differences in number of hospitalizations, number of emergency department visits, and number of unplanned outpatient visits per year. These outcomes will be compared using a Poisson model. For the power analysis, we adjusted the significance level to 0.017 after using Bonferroni adjustment (0.05/3), and we considered sample sizes of 700, 800, and 900 (to assess the effect of attrition of roughly 10% and 20%). From our previous work, we only have rough estimates of the events of interest (0.42 hospitalizations per year from Dams-O'Connor et al.[52] and 2.25 medical encounters of any type (not distinguished as planned or unplanned) per year from Salisbury et al.[120]). Therefore, we considered the base rates of 1-5 events per year for the RDP group and calculated the power of detecting a decrease in that rate of 10%, 20%, 30%, and 40% in the RTP group. Using G*Power and the specifications above, the summary of the findings are as follows:

- The higher the base rate for the RDP group, the higher the power to find a difference;
- Power is at least 80% to find a decrease of 20% in the number of events, except when the base rate is 1, in which case the decrease would need to be 22-25% to be detected;
- Attrition (represented by sample sizes of 800 and 700) have an effect but might be important only for a small base rate (such as 1 visit/year);
- Power for secondary analysis will be high to find a decrease of 20% in mean number of events (equivalent to odds ratio of .8 when comparing the RTP to the RDP group), even when sample size is depleted by attrition.

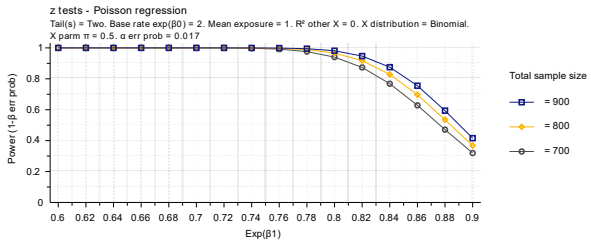
The analyses will be repeated adjusting for other factors (age, sex, race/ethnicity, education, injury severity, for example), to explore the effect of those factors on the outcomes (we are not powering the study for these analyses as they are exploratory in nature).

The graphs below show the power for each base rate (odds ratio in x-axis and power in the y-axis).

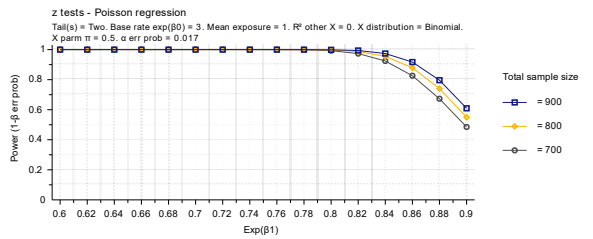
Base rate = 1 visit/year



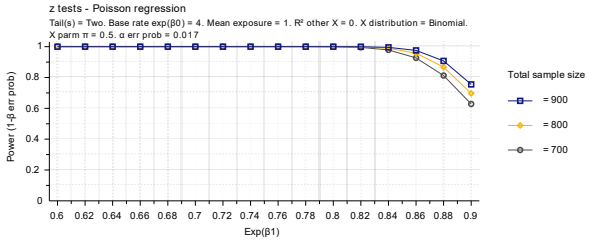
Base rate = 2 visits/year



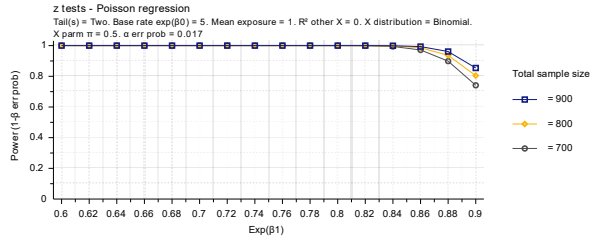
Base rate = 3 visits/year



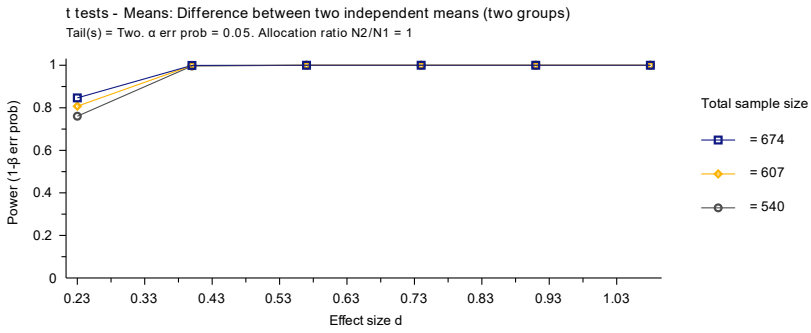
Base rate = 4 visits/year



Base rate = 5 visits/year



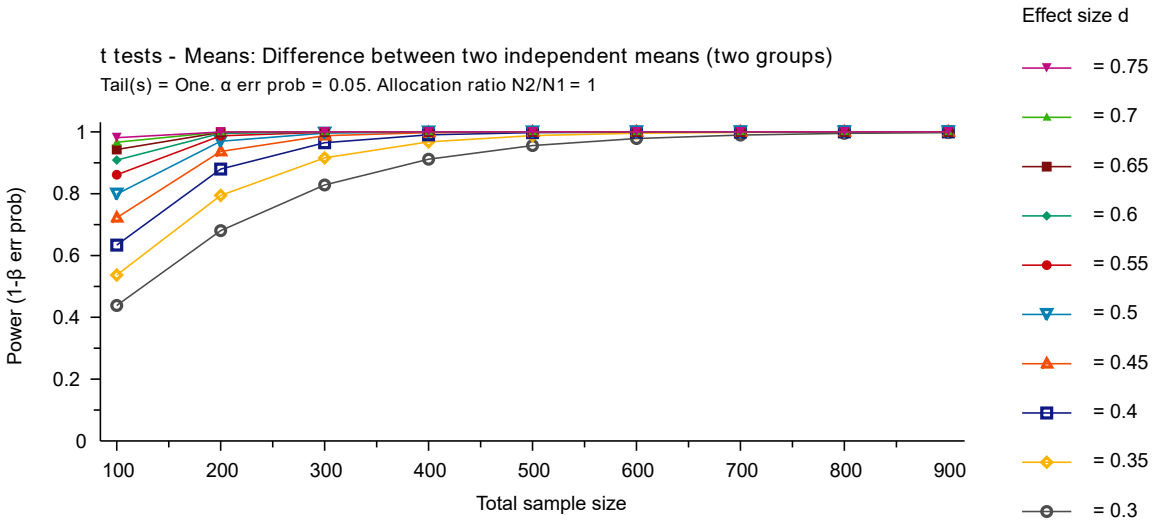
For Aim 4, the sample of caregivers is expected to have a size of 675. From Powell et al.[107], the estimated Bakas Caregiving Outcome Scale (BCOS) was 56.6 (SD=12.8) in the RDP group and 58.9 (10.7) in the RTP group. If we assume an attrition of 10% and 20%, we would have samples of 607 and 540 respectively. Assuming significance level of 0.05, power of 80%, SD=13 for both groups (based on the higher SD in Powell et al.), and a t-test (two-tailed), we calculated the power to find a change from 56 in RDP group to 59 - 70 in the RTP group, corresponding to about 5% to 20% increase in the BCOS (effect sizes of 0.23 to 1.08). The power was at least 80% (and mostly close to 100%) for all possible combinations of sample and effect sizes, except for the single circumstance of a very large attrition (n=540) and a low effect size (0.23), when the power was 0.76 (see graph below). Therefore, we will have enough power to test differences of at least 3 points in the BCOS.



For the Zarit Burden Interview, we can use the published data to estimate a possible standard deviation and given our expected sample size, we have 80% power to detect approximately a 1.14 difference if one exists. This is based on data from a study conducted on caregivers of Veterans with TBI[112] who are broadly similar to our population with an average score of 15 and standard deviation of 10 on the 12 item Zarit Burden Interview. An assumption was made of equal sample sizes between the two groups which, with 80% power, alpha of .05, would require a .23 effect size to detect a difference between the two groups at 6-month post-injury. As with the Zarit Burden Questionnaire, there are no prior studies which allow us to precisely estimate power to detect a difference between groups. No prior research has been conducted with the final two caregiver measures to provide data to conduct power calculations.

Power Analysis Revisited by Marcia Ciol, Ph.D., Study Biostatistician, January 28, 2019

Power Analysis for primary outcome:
The following reproduces the power analysis performed in the original proposal, except that it extends the range of sample size from 100 to 900 (by 100) and that we looked at smaller effect sizes (starting at 0.3 instead of 0.5). The specific parameters used in the calculations are as follows:
Test: t-test for independent samples, two-tailed, allocation ratio=1
Significance level=0.05
Mean PART-O scores (Intervention mean minus control mean): Effect sizes of 0.3 to 0.75 by increments of 0.05.
Sample sizes: from 100 to 900 individuals (by 100)

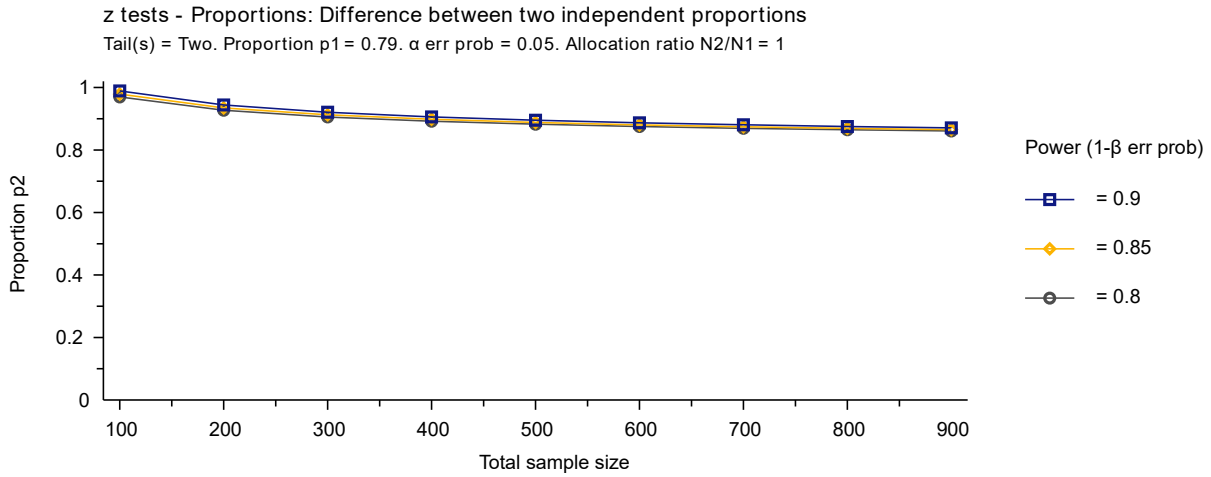


For the primary outcome, even a small sample size of 300 will have 0.80 power to detect a small effect size of 0.3. Therefore, it is unlikely that we would not find a difference between the two groups if the difference exists.

Power for Secondary Outcomes:

For Aim 3, under the assumptions that our SDC group would have a proportion of 0.79 of people going to more than 75% of their scheduled visits, we calculated the size of change in the proportion of people receiving 75%+ visits in the OTC group that we would be able to detect with a significance level of 0.05 (two-tailed proportion test), power of 0.80, and varying the sample size from 100 to 900.

With 80% power, we would be able to statistically detect a proportion in the OTC group of 0.91 with a sample of 300 individuals, 0.88 with a sample size of 500, and of 0.86 with 900 (see graph below).

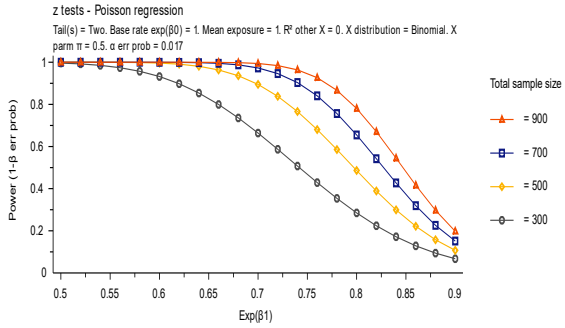


We will also test differences in number of hospitalizations, number of emergency department visits, and number of unplanned outpatient visits per year. These outcomes will be compared using a Poisson model. For the power analysis, we adjusted the significance level to 0.017 after using Bonferroni adjustment (0.05/3), and we considered sample sizes of 300, 500, 700, and 900. We considered the base rates of 1-4 events per year for the SDC group and calculated the power of detecting a decrease in that rate from 10% to 50% in the OTC group. Using G*Power and the specifications above, the summary of the findings are as follows:

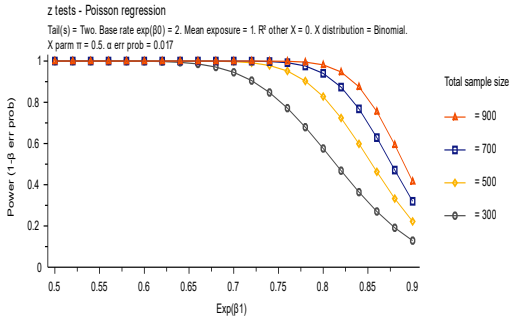
- The higher the base rate for the SDC group, the higher the power to find a difference;
- Power is at least 80% to find a decrease of 20% in the number of events, except when the base rate is 1, in which case the decrease would need to be 22-25% to be detected;
- Attrition or low enrollment (represented by sample sizes of 300, 500 and 700) have an effect but might be important only for a small base rate (such as 1 visit/year) and sample size 300 (unlikely to happen);
- Power for secondary analysis will be high to find a decrease of 20% in mean number of events (equivalent to odds ratio of .8 when comparing the OTC to the SDC group), except for sample lower than 500 (which is unlikely to happen).

The graphs below show the power for each base rate (odds ratio in x-axis and power in the y-axis).

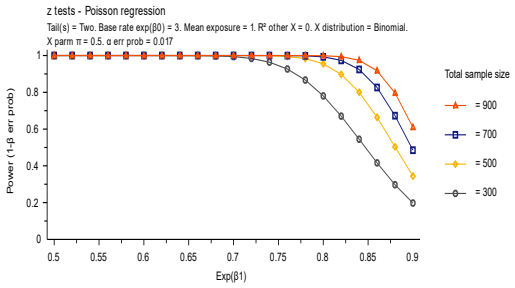
Base rate = 1



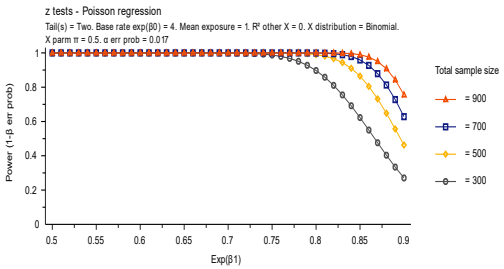
Base rate =2



Base rate =3

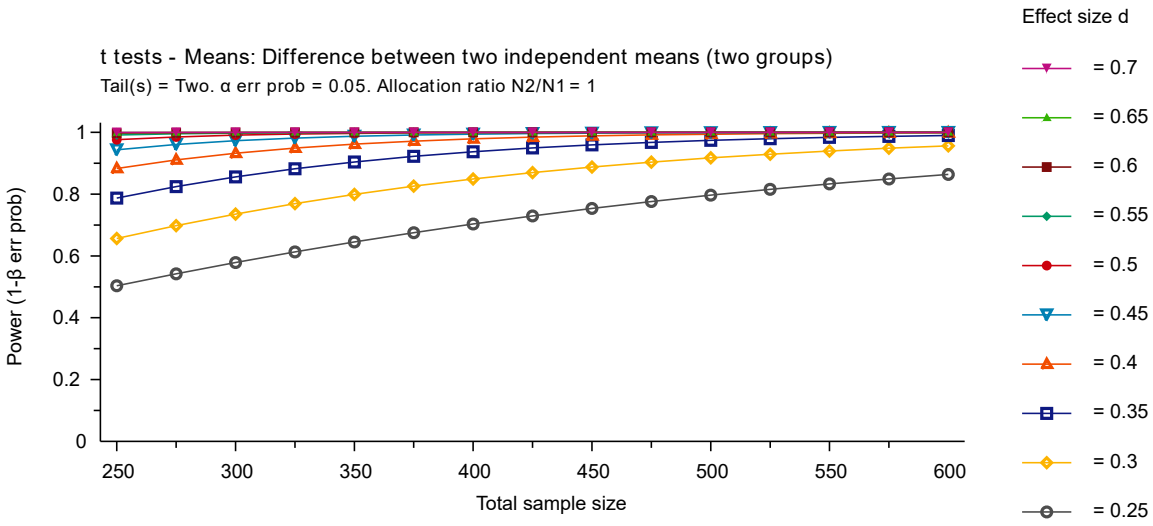


Base Rate = 4



For Aim 4, for caregiver outcome, we assumed the following parameters:

- Sample sizes from 250 to 600 (by 50);
- Significance level of 0.05,
- SD=13 for both groups (based on the higher SD in Powell et al.),
- T-test (two-tailed)
- Change in Bakas Caregiving Outcome Scale (BCOS) from 56 in SDC group to at least 59 in the OTC group, corresponding to at least 5% increase in the BCOS (effect sizes of 0.25 or more).



At the moment we have 142 caregivers and if we continue to enroll in the same rate, we will have about 471 caregivers by the end of the study. For that sample size, except when the effect size is smaller than 0.3, we will be able to detect a change in BCOS. If the effect size is larger, we will be able to detect it with 80% power even for smaller sample sizes (350 for an effect of at least 0.3, 275 for an effect of at least 0.35, and 250 for an effect of at least 0.4). For the smallest effect size of 0.25, we would need to have about 500 caregivers for a power of 80% to find that small difference. Given our current estimates of the total sample size for the caregivers, we are likely to have power to find a difference, if the difference exists.

Data Analysis Plan Specific to Each Aim (IR-3, IR-5)

General approach: The expected sample size is very large and we anticipate 100% power to find a difference in PART-O-17, if a difference exists. In addition, the sample size will allow us adequate power to examine our other aims and heterogeneity of treatment effects. We will use a significance level of 0.05 for all the analyses we will perform. Given the large sample size and the extremely high power for the primary outcome, we will not adjust the significance level for multiple comparisons for all the other tests, since it is highly likely that the p-values for those tests will be small. As it is well known and now stated in a publication by the American Statistical Association,[121] the p-value should not be the single deciding measure of the significance of a result. Therefore, we will interpret the results of all non-primary outcomes with caution and will examine effect sizes as well as explicitly report the secondary outcomes status when presenting the results. We will obtain input from our stakeholders regarding the meaningfulness and importance of the effects.

The analysis plan will conform to the intent-to-treat principle: all randomized cases will be included based on their assigned treatment group regardless of actual intervention received. Missing values will be prevented and minimized by implementing the following steps in the manual of operations: 1) Prompt data entry to allow timely detection of any missing data, 2) Procedures for monitoring and tracking data completeness will be in the manual of operations, 3) When missing data are identified, research staff will contact the participant to collect them (if not time-contingent or outside the specified time range for collection). At the end of the study, participants not assessed at the end of intervention will be considered as having missing outcome values.

When missing values are present we will check the missing mechanism,[122] and if it allows for imputation, we will do so according to the appropriate methods for a continuous variable, using multiple imputation strategies (most likely using maximum likelihood methods). We will perform sensitivity analysis of the results by performing the data analysis using the most conservative approach of removing the data from individuals with missing outcome values from the analysis, or if it 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 drop-out and missing data will be recorded and will be reported in all reports and publications (**MD-2, MD-3, MD-5**).

Plan for analysis of COVID-19 Pandemic impact: We propose to add the following steps to the data analysis in order to take the pandemic into account: 1) Analyze the patterns and

causes of refusal to participation in the study before and during the pandemic to determine if the populations in the two periods are coming from the same base population; 2) Analyze the patterns of missing data, comparing them between before and during the pandemic to determine whether we need to additionally add an indicator of the time of data collection (before or during pandemic) as another factor in the generation of the imputed outcome data; 3) analyze the primary and secondary outcomes in an intention-to-treat manner as proposed in the protocol. We will follow with another data analysis that will add in the model time of data collection (pre/post pandemic) and its interaction with intervention type as possible explanatory factors to determine the potential impact of change in timing of enrollment or unaccounted for changes in the intervention.

Aim 1, Hypothesis 1: 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-month 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.

Aim 2, Hypothesis 2: To compare the trajectory of improvement for 3-, 6-, 9- and 12-months post-discharge, we will plot individual trajectories over time and if it appears that the majority of people are leveling off over time we will consider a growth model. Otherwise, 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, and add intervention group and its interaction with time to test whether the interventions and time had an effect in the trajectory of the outcome.

Aim 3, Hypothesis 3: To compare the healthcare utilization in the first-year post discharge, the two groups will be compared on the distribution of categories of completed planned outpatients visits (less than 50%, between 50 and 75%, and more than 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 possibly adjusting 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.

Aim 4, Hypothesis 4a: To compare caregiver burden, HRQOL, and satisfaction with roles and activities, we will apply t-tests for difference of means for independent samples for those measures that are found to have a normal distribution. We will also conduct heterogeneity of treatment effects analyses as we planned for other measures.

Aim 4, Hypothesis 4b: Using the Bakas Caregiving Outcomes Scale, Zarit Burden Interview, Sf-12, and the PROMIS Satisfaction with Social Roles and Activities for caregivers at 3-, 6-, 9- and 12-month follow-ups as response variables, we will fit a linear mixed model or growth model similar to the ones in hypothesis 2.

Analysis of heterogeneity of treatment effects (HT-1, HT-3, HT-4)

We will explore the differential effects of the intervention on patient subgroups defined by factors known or hypothesized to have associations with poorer TBI outcome: 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) 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. Before constructing the model, we will assess whether the explanatory variables are correlated to each other. When two or more variables are deemed highly correlated, to avoid problems with collinearity, we will construct the model with the variable that provides the best model (from fit and diagnostic tests). From previous research,[74-80] 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 being able to address these questions.

Data Management (IR-2, MD-1)

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. 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, i.e. not name into a password protected NDSC database accessible via secured-internet connection.

Site-specific identifiable information such as name, address, medical record number, email or phone numbers will be stored on a secure server at each site in a password-protected database separate from study data. Study data that will be used for data analysis purposes will be stored separately on a restricted access server managed by the NDSC. We will maintain a link between the identifiers and study data via use of a unique subject identification number. The crosswalk between identifying information and the subject identification number will reside in the password-protected databases on a secure server at each site only accessible by study personnel.

There are a few exceptions to the separation of identifiers and study data as described above. One exception is street address, which will be collected at each time point and stored with identifying information on a secure server at each local site for contact purposes AND on a restricted access server at the NDSC at the Craig Hospital.

Another exception, as described above, will be the audio recordings of contacts between the patient and/or caregiver participants and the TCM. The audio recordings will be labeled with the subject's identification number. The only identifying information that will be contained in each recording will be the participant's voice and if the TCM or other parties state the participant's name during the contact. These recordings will be kept on a secure server of the NDSC which can only be accessed by study personnel.

Also, some data regarding "process variables" collected by the study TCMs during contacts with participants in the RTP group, e.g. time on phone calls, resources provided to subjects, basic needs assessed, etc., will be stored with some identifying information in the password-protected TCM database on a secure local server. These data will eventually be sent to the NDSC with subject identification number only for permanent storage.

Finally, certain dates that may identify subjects (e.g. date of birth, date of injury, date of admission) will also be obtained and entered into the NDSC database along with other study data.

Study databases will be automatically linked to existing TBIMS databases with demographic, injury severity, and rehabilitation outcome data collected as part of the TBIMS infrastructure. Study researchers will create a crosswalk between the BRITE ID number and original TBIMS ID number for all participants enrolled in both studies to allow for merging of the data between the proposed study and TBIMS data elements. Project investigators will audit all data entry prior to final submission as part of routine TBIMS study procedures. The database sits behind a Cisco ASA 5520 firewall on a separate Microsoft SQL 2013 Server and will utilize whole database encryption technology using NetLib Encryptionizer (FIPS 140.2 compliant). All local information security practices will be implemented.

Due to HIPAA and Institutional Review Board (IRB) guidelines, any personal identifying information transmitted from the participant to the research office needs to remain private and confidential. As a result, personal identifiable information (PII) of patients approached/enrolled at each study site used for contacting and tracking participants will be stored locally in a password-protected database on a secure server at each site**.**

To ensure data quality and minimize missing data, data collectors will be trained and tested on established criteria on both medical record abstraction and the measures used in the follow-up interview. In addition several levels of data checks will be implemented. First, when data collectors enter data into the web based data entry program they will be notified which fields have been skipped. In general all fields, with the exception of some text fields, will have valid codes associated with them, so no true blank variables should exist in the database. Furthermore, when appropriate, skip patterns will exist for some variables, which can automatically populate variables that would then be considered "not applicable".
The data entry program will also not allow an entry that isn't considered valid mostly through the use of drop down controls in which only valid answers are presented.

Second, while data is being entered there will be a process for a data collector to run various data checks like logical errors (e.g. injury date occurring before birth date) or data inconsistencies (e. g. currently working, but hours of work past week = 0) can be programmed into the system to alert the data collector to variables that need attention. Above and beyond the notifications of errors and missingness that occurs while a data collector is entering data, all authorized people of the study can run real time reports that reflect not only missingness by variable, but missingness by person as well. Missing data reports will be reviewed on a quarterly basis by staff at the NDSC as well as coordinators at each site. The success of the data quality management methods used by the TBIMS is demonstrated in the low levels of missing data typically observed. Among TBIMS participants in the 2012-2017 funding cycle, 94% completed their 1 year interview and of those, <3% had missing PART-O-17 data. We would anticipate similarly low rates of missing data with the current study (**MD-1**).

REPLICATION AND REPRODUCIBILITY OF RESEARCH AND DATA SHARING

Procedures for the current study will be carefully documented in a Manual of Procedures (MOP) document which will be created at the start of the project and updated as needed throughout the project period. Adherence to the MOP will be regularly monitored by the lead site, and each site PI will ensure adherence to the SOP at their study site. As described above, RDP is already being performed at all study sites and will be documented during the study. Likewise, the RTP protocol will be carefully delineated in the MOP to ensure the same core ingredients are implemented across sites. By using a detailed MOP and documenting procedures in such a way

that they can be followed uniformly across 6 study sites, it will be possible for other investigators to replicate the findings of the current study. Most importantly, it will be possible for other clinical teams to replicate the discharge planning protocol that is associated with optimal outcomes.

The MOP will include: (1) an overview of the study, including background information, study aims, and hypotheses to be tested; (2) a step-by-step description of recruitment procedures, including procedures for initial contact with potential participants, for determining participant eligibility (inclusion and exclusion criteria), and for tracking potential participant flow; (3) procedures for the informed consent process; (4) participant scheduling procedures; (5) randomization procedures; (6) outcome assessment protocols, including timing of assessments, detailed descriptions of all of the measures; (7) treatment procedures and logistics; (8) strategies for handling participants who drop-out or are unable to be contacted for treatment or outcome assessments; (9) a rationale for and strategies to ensure outcome assessors remain unaware of participants' group assignments; (10) general telephone procedures and etiquette; (11) data entry procedures, including rules for handling of missing data; (12) data management (data definitions, scoring syntax, coding instructions) and planned analyses procedures; (13) participant flow tracking procedures (CONSORT); (14) the location of facilities, forms, and materials; (15) strategies for handling and recording protocol deviations; (16) the data safety monitoring plan; (17) a plan for handling emergent situations (e.g., suicidal ideation in a study participant); and (18) procedures for maintaining Human Subjects approvals. Once Human Subjects approval is granted at each site, a log of all Human Subjects protocol changes and approvals will be kept as a supplement to the MOP. We will also include a tracking log of decisions made throughout the study that will be contained within the MOP.

Additional sections will be included in this study's MOP. The manual will include a section describing the Stakeholder Engagement Plan, which will include a list of all stakeholders and investigators, a governance plan, and a detailed description of the plan itself (e.g., engagement activities, frequency, and type). A final copy of the manual will be available to the public on our study website within six months of the end of Year 5.

Data Management and Data Sharing

Study investigators will comply with PCORI's policy for data management and data sharing. Specifically, investigators will make available at the end of the study the following: (1) a full data package which includes a final clean and locked data set containing all the data used in the analyses described in the PCORI final research report; (2) the study protocol including descriptions of study design, procedures and full statistical analysis plan (including all amendments); (3) data dictionaries; and (4) and any analytic code used. The study protocol will be submitted to the sponsor as a deliverable, whereas the remaining items will be depositied into a PCORI-designated repository. Study investigators will participate in a Data Contributor Agreement (DCA) with the PCORI-designated repository by the data when the study investigators submit the draft of the final research report to PCORI. The data set must be provided to the repository by the date the final research report is accepted by PCORI. The data will then become available to outside researchers when the final research report is uploaded to the PCORI website, or when the primary paper for the study has been published in a peer-reviewed journal, whichever comes first. Subsequently an independent committee representing the repository will review requests for the data by researchers outside the study.

Specific details regarding PCORI's policy for data management and sharing here:

https://www.pcori.org/sites/default/files/PCORI-Policy-for-Data-Management-and-Data-Sharing.pdf

Location of Facilities, Forms, and Materials

Facilities

The six TBIMS sites involved in the current project (University of Washington, Indiana University School of Medicine/Rehabilitation Hospital of Indiana, Moss Rehab Hospital, Baylor Institute for Rehabilitation, Ohio State University Wexner Medical Center, and Mount Sinai Health System (NY)) will enroll participants and collect primary data for this project. The TBIMS infrastructure with its demonstrated history of successful enrollment and research infrastructure is well positioned to participate in this project. All subcontracted organizations have had extensive experience in the TBIMS highlighting organizational support for TBI rehabilitation research. Investigators at each of these locations have already been identified and are identifying all eligible members of the target population and enrolling the majority who meet the eligibility criteria into TBI rehabilitation research projects.

In addition to participating in the primary research data collection, the Traumatic Brain Injury Model Systems National Data and Statistical Center at Craig Hospital, CO, will manage data collected using established data management and quality standards.

The six TBIMS sites agree that any Confidential Information obtained that is protected health information (PHI) of a patient will be kept confidential pursuant to the Standards for Privacy of Individually Identifiable Health Information at 45 CFR Parts 160 and 164 (“Privacy Rule”) and all other applicable federal, state, and local laws, statutes and regulations, as well as each sites own internal rules and regulations governing the confidentiality of patient records and information.

Forms

The case report forms will follow guidelines set forth by the NDSC to align with the database. Access to the paper CRFs /eCRFs will be limited to personnel directly participating in the study. Data should be entered into the CRFs/eCRFs completely by examining personnel or the study coordinator. The CRFs/eCRFs must be completed as soon as possible after any subject evaluation or communication.

Copies of the most recent CRFs are located on the BRITE website in the ‘Study Materials’ folder under the ‘SOP’ tab.

Security of records: The following protocol will be used to ensure the security on non-electronic study documents: a) Signed consent forms will be stored in a locked filing cabinet in a non-public area; b) All confidential documents that are disposed of will be placed in a locked confidential document–recycling container; c) All electronic identifying information will be stored in separate files from other data; and d) All files will be password protected and stored on a secured and restricted server.

Please see the “Data Management” section above for a listing of exceptions to the separation of identifiers and study data as described above.

Materials
Portions of medical charts will be reviewed to determine participant eligibility. These procedures will be approved by IRBs at all sites for TBIMS and meet HIPAA regulations. Once informed consent takes place, additional data regarding the injury will be gathered from the medical record including severity and cause of injury, demographic information (such as age), and comorbid diagnoses. All data obtained from participants or their proxies will be collected via interviews (either in person or over the phone).
The interviews will contain questions about current and past psychiatric history, current mood, post TBI symptoms, and need for assistance. Study data will be stored at the TBI National Data Center while all identifying personal contact and/or health information will be stored at each local site. These data will be linked via study code number and research staff will have access to participant identities.

Pertinent Websites

National Data and Statistical Center Main Support Website:

https://www.tbindsc.org/Contact.aspx

This website serves as the portal for all data collected for the TBIMS study, as well as basic SOPs pertaining to TBIMS.

National Data and Statistical Center BRITE Study Website:

https://brite.tbindsc.org/Default.aspx

This website serves as the portal for all data collected specifically for the BRITE study. It also houses all study materials, study protocol, and MOPs pertaining to TBIMS.

Pertinent List serves
Study researchers have created list serves to facilitate effective communication during the course of the study. Study researchers can sign up for each pertinent list serve to send and receive regular updates pertinent to study implementation.

Study staff: brite_studystaff@lists.osu.edu

Data Collectors: brite_datacollectors@lists.osu.edu

Investigators: Brite_investigators@lists.osu.edu

TCMs: Brite_tcm@lists.osu.edu

Professional Stakeholders: brite_professionalstakeholders@lists.osu.edu

Patient and Caregiver Stakeholders: brite_consumerstakeholders@lists.osu.edu

Website, Subscription to List serves: https://lists.osu.edu/mailman/listinfo/XXX

Example:
https://lists.osu.edu/mailman/listinfo/brite_professionalstakeholders

SAFETY MONITORING

Adverse Event and Serious Adverse Event Information: Definitions

Adverse Event
An adverse event (AE) is any untoward medical occurrence in a participant during participation in the study regardless of randomization assignment. An adverse finding can include a sign, symptom, abnormal assessment (laboratory test value, vital signs, electrocardiogram finding, etc.), or any combination of these. Staff will document any occurrence that:

1) meets the definition above;
2) is a new symptom/condition for the participant, OR a symptom/condition that began before enrollment yet has become significantly worse following enrollment; and
3) results in or warrants treatment by a health care provider.

The relationship between the event and study procedures will be determined by research staff. Research staff will be instructed to seek counsel from study investigators if the relationship is unclear.

Serious Adverse Event (SAE)
A serious adverse event (SAE) is any AE as described above which results in one or more of the following outcomes:

- Death
- A life-threatening event
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant disability/incapacity that began following enrollment
- A congenital anomaly or birth defect
- An important medical event based upon appropriate medical judgment

An AE is also considered serious when medical, surgical, behavioral, social or other intervention is needed to prevent such an outcome.

We do not document a planned surgery as an AE UNLESS the surgery stems from an acute untoward medical occurrence, i.e. surgery as an intervention to prevent a worse outcome based on the acute occurrence. Also, we will document a planned surgery if there are complications from the surgery that require hospitalization. In this scenario, the complications rather than the surgery itself is the SAE, but we will document the surgery as the primary factor that contributed to the SAE.

Any unplanned surgery will still be documented as an adverse event.

AE Attribution Scale

Relationship of event to study procedures:
None – the event can be readily explained by some other cause or no relationship exists between the study procedures and the event.
Unlikely – the temporal relationship between the event and the administration of the study procedures is uncertain and it is likely that the event can be explained by other causes.
Possible – there is some logical temporal relationship between the event and the administration of the study procedures and the event is unlikely to be explained by other causes. This category may include incidents that arise from use or attempted use of a strategy prescribed in a case management session.
Probable – the temporal relationship is compelling between the administration of the study procedures and the event cannot be explained by other causes. This category may include incidents that arise from use or attempted use of a strategy prescribed in a case management session.

AE Documentation

Each incident that meets the definition of an AE as listed above will be documented via entry into the appropriate data form on the NDSC website within a month of when the incident was detected by research staff. NDSC staff will send a reminder email to study coordinators to enter data for AEs within the past month.

SAE Reporting and Documentation

SAEs that are unanticipated and possibly related to the study intervention will be reported to the respective site PI, the lead site PI, chair of the DSMB, the respective IRB, and the PCORI Program Official in accordance with requirements.

1. Unanticipated fatal or life-threatening SAEs related to study procedures will be reported all parties listed above immediately.
2. Other unanticipated SAEs related to study procedures will be reported to the respective site PI and lead site PI within 24 hours. The SAE will be reported to the respective IRB according to that institution's requirements. The event will be reported to PCORI promptly but no later than 10 days after reporting the event to the IRB.
3. Anticipated or unrelated SAEs will be reported to the DSMB and PCORI as part of the bi-annual and annual DSM reports. These DSM reports will also be submitted to each site's IRB.

Study researchers will contact the Chair of the DSMB when an SAE that fits into the first two categories listed above is discovered within one week of discovery. The Chair of the DSMB will use his discretion to determine whether the other DSMB members should also provide additional consultation. The chair will then provide any suggestions for corrective action within two weeks of notification.

Each incident that fits into the first two categories listed above will be documented via entry into the appropriate data form on the NDSC website within 5 business days of when the incident was detected by research staff. Each incident that fits into the third category listed above will be documented via entry into the appropriate data form on the NDSC website within one month of when the incident was detected by research staff.

As per PCORI guidelines, any decision, finding, recommendation or action of the DSMB or IRB relating to any SAEs will reported to PCORI promptly but no later than 10 days after the decision, finding, recommendation or action has been made.

Unanticipated Problems Information: Definition

Study researchers consider *unanticipated problems*, in general, to include any incident, experience, or outcome that meets **all** of the following criteria:

- unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- at least possibly related to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.*
- An adverse event is an unanticipated problem if it meets the three criteria described above.

For the purposes of this study, breach of confidentiality or inappropriate access to protected health information are considered serious unanticipated problems and will be shared with the DSMB.

*** Source: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html#Q2**

Unanticipated Problems: Documentation and Reporting

Any event that is unanticipated, places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, and possibly related to the study procedures will be reported to the respective site PI, the lead site PI, chair of the DSMB, the respective IRB, and the PCORI Program Official in accordance with requirements.

1. Breaches of confidentiality or inappropriate access to protected health information will be reported to all parties listed above immediately.
2. Other serious unanticipated problems related to study procedures will be reported to the respective site PI and lead site PI, within 24 hours. The unanticipated problem will be reported to the respective IRB according to that institution's requirements. The event will be reported to PCORI promptly but no later than 10 days after reporting the event to the IRB.

Study researchers will contact the Chair of the DSMB when an unanticipated problem is discovered within one week of discovery. The Chair of the DSMB will use his discretion to determine whether the other DSMB members should also provide additional consultation. The chair will then provide any suggestions for corrective action within two weeks of notification.

Each incident that meets the definition of an unanticipated problem will be entered into the appropriate data form on the NDSC website within 5 business days of when the incident was detected by research staff.

As per PCORI guidelines, any decision, finding, recommendation or action of the DSMB or IRB relating to any SAEs will be reported to PCORI promptly but no later than 10 days after the decision, finding, recommendation or action has been made.

Protocol Deviations, Violations, Other Pertinent Documentation

Study researchers will document any protocol deviations, violations or events that may jeopardize the integrity of the study in a 'Note-to-File' using a standardized template across all sites. Regarding protocol deviations: staff will document only deviations that are within the control of research staff, for example completing a questionnaire outside of the questionnaire window. Research staff will not document deviations outside of the staff's control, however, for example when a patient fails to be available for a study questionnaire. Each incident will be entered into the appropriate data form on the NDSC website within a month of when the incident was detected by research staff. NDSC staff will send a reminder email to study coordinators to enter data for any pertinent incidents within the past month.

Data Safety Monitoring Board (DSMB)

A Data Safety and Monitoring Board (DSMB) will be led by Thomas Novack, PhD, PI of the University of Alabama Birmingham TBIMS, Lillian Lin, PhD a biostatistician from Montana State University and a currently unidentified TBI patient and family member. The DSMB will monitor the study and review the following: a) participant recruitment, accrual, retention, and withdrawal information; b) adverse events (AEs) and serious adverse events (SAEs); c) comparison of events that occur between treatment arms; d) individual events of particular concern; e) participant interview and/or performance status outcomes; f) other safety-supporting data requested by the DSMB; and g) summary of protocol violations, completeness and timeliness of study visit data, enrollment eligibility and ineligibility information, noncompliance, and unanticipated problems. Safety monitoring will focus on detection and monitoring of adverse events at the individual participant level.

Bi-Annual DSM Report
Starting six months following the onset of recruitment, research staff will generate a report that includes the rate of participant accrual and compliance with inclusion/exclusion criteria to ensure that a sufficient number of participants are being enrolled to allow for an adequate test of the primary study hypothesis and that they meet eligibility criteria. The report will also include information regarding the frequency, type and details of AEs, SAEs, unanticipated problems and protocol deviations/violations that warrant a note-to-file that occurred since the onset of recruitment. The report will also include information regarding participant progress and retention

in the form of a CONSORT diagram. This report will be provided to the chair of the DSMB for review. The chair of the DSMB may solicit input from the other DSMB members if he detects anything of concern (e.g., higher rates of AEs than anticipated). The Chair of the DSMB will generate a summary of concerns and recommendations, and sign the summary. The Bi-Annual DSM report (along with the DSM chair's summary if applicable) will be provided to all study researchers (excluding unblinded information), and respective IRBs as needed.
In addition, the DSM report will be submitted to PCORI as part of the subsequent interim progress report. This bi-annual report will take place every six months between annual reports.

Annual DSM Report and Meeting
One year following the onset of recruitment, research staff will generate a report that includes all information covered in the bi-annual report described above. In addition, the annual DSM report will address (1) whether AE rates are consistent with pre-study assumptions; (2) reason for dropouts from the study; (3) whether continuation of the study is justified based on the adverse events observed up to the specific meeting; and (4) conditions whereby the study might be terminated prematurely.

The Annual Report will be sent to all members of the DSMB to review two weeks prior to the meeting that will be conducted via phone or Zoom. The report will also be provided to the funder, PCORI, at the same time. PCORI will be informed of the date and time of the meeting should a representative(s) wish to attend.

Subsequently the DSMB along with the Lead PIs (Hoffman and Fann), PCORI program members (if desired), and an individual independent of the study serving as the secretary will convene via teleconference to review and discuss the report. The meeting may consist of the following sessions:

Open Session: This session will take place at the beginning of the meeting. The DSMB members, DSMB meeting secretary, lead site principal investigators (Hoffman and Fann), study statistician (Ciol) and site investigators as well as PCORI representative(s), if desired, will attend this session. The open session will consist of the investigators and study statistician reviewing the report with the DSMB members, and answering any questions from the DSMB members about any incidents/study procedures that warrant further investigation.

Closed Session (if desired by DSMB): Only the DSMB members, secretary and study statistician will be present during the closed session. They will discuss the contents of the report, any concerns they might have, any unblinded analyses the DSMB members want the statistician to conduct, whether the study warrants continuation based on its risk/benefit ratio, and formulate any recommendations moving forward. The DSMB may opt not to conduct a closed session if deemed unnecessary.

The meeting secretary or DSM chair will send the meeting summary, including summary of topics discussed and DSMB recommendations, to the lead site PIs within two weeks of the meeting. The lead investigators will then compose responses to each of the DSM's recommendations including any follow-up plans. These responses will then be sent to the DSMB chair for review and approval within four weeks of the meeting. The DSMB chair may request clarification or changes to the summary as needed. The DSMB chair will sign the summary to indicate approval.

The annual DSMB report along with the DSMB summary will be provided to study researchers (excluding unblinded information), and respective IRBs as needed. In addition, the DSM report will be submitted to PCORI as part of the subsequent interim progress report. This annual report and meeting will take place once annually following commencement of recruitment. The final report and meeting will take place on the anniversary that follows the end of all subject participation.

Table 1. Frequency of Data Review, External

Data type	Frequency of review	External Reviewer
Study-Related SAEs*	Per occurrence	DSMB Chair, PCORI, IRB
Unanticipated Serious Problems*	Per occurrence	DSMB Chair, PCORI, IRB
Participant accrual, eligibility criteria*	Monthly	PCORI
Participant Progress and Retention**	Bi-Annual	DSMB Chair, PCORI, IRB
Anticipated, Unrelated SAEs**	Bi-Annual	DSMB Chair, PCORI, IRB
AEs**	Bi-Annual	DSMB Chair, PCORI, IRB
Protocol Deviations/Violations**	Bi-Annual	DSMB Chair, PCORI, IRB
Reason for Drop Outs**	Bi-Annual	DSMB Chair, PCORI, IRB
Justification Continuation of Study, Risk/Benefit Ratio	Annual	DSMB Chair, PCORI, IRB

*These elements will also be included in the bi-annual and annual DSMB reports.
**These elements will also be included in the annual DSMB reports.

Data Quality Assurance and Monitoring

Description of Plan for Data Quality and Management
Research staff will review all data collected on an ongoing basis for data completeness and accuracy as well as protocol compliance.

TCM contacts with patients and caregivers will be audio recorded to ensure compliance to treatment procedures. A portion of these contacts will be randomly selected to be reviewed by study researchers to ascertain fidelity to protocol. TCMs will receive feedback as needed if they diverge from protocol.

In addition, research study staff will review the study data in detail on a quarterly basis to detect any systematic issues with data collection.

Internal Monthly Report
Review of the rate of participant accrual and compliance with inclusion/exclusion criteria will occur monthly to ensure that a sufficient number of participants are being enrolled to a) allow for an adequate test of the primary study hypothesis; and b) ensure all enrolled participants meet eligibility criteria. These reports will be shared across all sites and with PCORI.

Internal Quarterly Report
Each quarter NDSC staff will generate a report that includes the information contained in the monthly report as well as information regarding the frequency, type and details of AEs, SAEs, unanticipated problems and protocol deviations/violations that warrant a note-to-file that occurred per site for that particular quarter. The report will also include information regarding participant progress and retention in the form of a consort diagram. This report will be provided to all study researchers.

Frequency of Data Review
The frequency of data review for this study differs according to the type of data and can be summarized in the following table:

Table 2. Frequency of Data Review, Internal

Data type	Frequency of review	Reviewer
Study-Related SAEs*	Per occurrence	Site and Lead Site PI
Unanticipated Serious Problems*	Per occurrence	Site and Lead Site PI
Participant accrual, eligibility criteria*	Monthly	All Study Researchers
Participant Progress and Retention	Quarterly	All Study Researchers
Anticipated, Unrelated SAEs	Quarterly	All Study Researchers
AEs	Quarterly	All Study Researchers
Protocol Deviations/Violations	Quarterly	All Study Researchers
Reason for Drop Outs	Quarterly	All Study Researchers

*These elements will also be included in the quarterly reports.

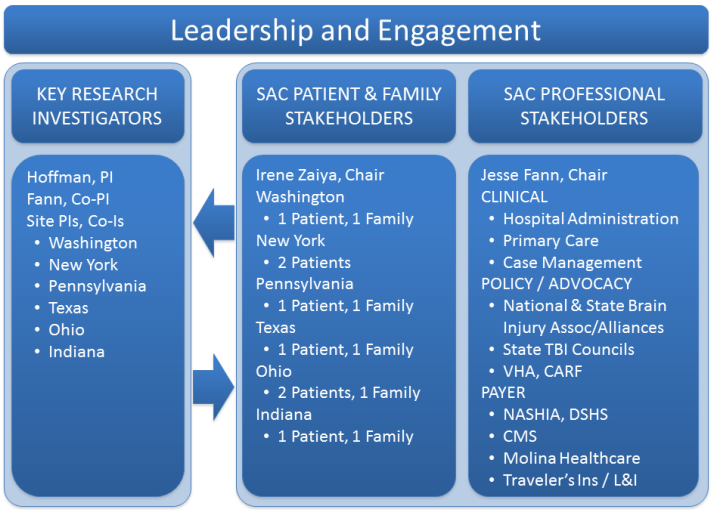
Study Discontinuation

Participation in the study will be stopped prior to its completion if: (1) the RTP approach is associated with adverse effects that call into question the safety of this approach; (2) any new information becomes available during the trial that necessitates stopping the trial; or (3) other situations occur that might warrant stopping the trial.

ENGAGEMENT PLAN (Criterion 2, 4, 5, PC-1, PC-3, PC-4, RQ-1, RQ-3, RQ-6)

Patient Partner and Stakeholder Engagement Activities

Members of our research team have over 20 years of experience conducting Participatory Action Research (PAR) in which people with TBI have participated actively on Consumer Advisory Boards that guide our research. The current grant grew out of focus groups held 3 years ago for the Galveston Brain Injury Conference (GBIC; mentioned above) by the Study PI (Hoffman) and Mount Sinai Health System (NY) Site PI (Dams-O'Connor). The themes that arose led us to want to address the fact that many people in our own communities were not getting the care they needed or were unaware of key resources in the community which would maximize their function. Their stories have been heard again and again as we have sought more specific guidance for this grant. We began by running focus groups at 4 of the 6 study sites to ensure that the concerns raised initially about transitions were still meaningful and what we learned only increased our desire to design a study which could make a meaningful impact for TBI Survivors and their families. We decided to recruit TBI survivors and family members to work with us on the design and focus of our grant. We have been overwhelmed by the desire and passion we have seen to participate with us as key personnel for research (including participating as they have with study decision making) and as members of our Study Advisory Committee (SAC). We were easily able to identify patient stakeholders who are part of our specific target population. That is, they include those with moderate-to-severe TBIs, all of whom had input on difficulties they experienced after being discharged from inpatient rehabilitation. The Patient and Family Stakeholders (which includes 8 TBI Survivors and 5 family members) will form one arm of our SAC. Irene Zaiya, a TBI survivor and social worker, will serve as Chair of the Patient and Family Stakeholder arm of the SAC and will be directly supported by the study PIs (Hoffman & Fann). The Patient and Family stakeholders will have ongoing direct support from our Project Manager (Kempthorne) to assist with all study related activities (including managing stipends, travel arrangements, managing information, training in technology, etc.).



Next, we recruited Clinical, Policy/Advocacy and Payer stakeholders to form the Professional Stakeholder arm of the SAC. One subset includes clinicians that serve people with TBI. This group has already shared important insights into the strengths and gaps in the system of care and will be crucial to enabling our comparator systems of care and in guiding dissemination and implementation of study results. Members of our team have reached out

systematically to regional and national advocacy groups and policy leaders to form an unprecedented collaboration between the TBI, healthcare, and payer communities. These individuals include leaders from hospital administration, state TBI Council and Support Systems, and national and state advocacy and policy leaders such including key persons at the Brain Injury Association of America, CARF, State Brain Injury Associations/Alliances, and the American College of Surgeons.

We have already gained stakeholders from large payer groups including Molina Healthcare, The Hartford / Labor and Industries, Paradigm Outcomes and Centers for Medicare and Medicaid Services. Study Co-Principal Investigator Fann chairs the Professional Stakeholder arm for the study.

Together, Ms. Zaiya and Dr. Fann co-direct the engagement process. They will be responsible for chairing regularly scheduled meetings and for maintaining the Engagement Log. As illustrated by the figure above, the Patient and Family Stakeholder and Professional Stakeholder arms of the SAC have a collaborative partnership with the research investigators and consultants. Because Patient and Family Stakeholder partners will participate in research decision making we will have more frequent meetings with them (once per month) and will meet for the first year separately in quarterly meetings to ensure that each group of stakeholders is able to have adequate time to contribute their expertise to the research process. The entire SAC will meet in person once a year to provide in person updates and allow for interaction around new issues or potential results as they arise. To ensure ongoing close communication between the investigators and stakeholders, the PI, Co-PI and site PIs will be ex officio members of the SAC and will be invited to attend all SAC meetings. Patient partners may attend monthly investigator team meetings to remain engaged in the research process and provide input and assist with decision making throughout the study, and Ms. Zaiya and Dr. Fann will have primary responsibility for ensuring robust communication among investigators and SAC members. Initial meetings will include some training to all interested SAC members (Patient and Family Stakeholders as well as Professional Stakeholders) on the research process to ensure that we are all speaking the same language around the conduct of the study. We have provided some initial education on the research process to our Patient and Family Stakeholders during planning teleconferences and plan to have another teleconference to conduct a training on research (such as a “Research 101” lecture) and the specifics around this grant, including timelines and requirements from PCORI. The figure below illustrates our meeting schedule and the overlapping attendance of our investigators and both groups of stakeholders to ensure robust communication across groups.

Investigator & Stakeholder Meetings

	Patient & Family (P&F) Stakeholders	**Professional Stakeholders**	**Lead Site PIs**	**Site PIs**
Weekly/Monthly Investigator Meetings	X (P&F Chair to attend at least 1x/mo. and review all minutes.)		X	X
Monthly Patient & Family	X		X	X

Stakeholder Meetings				(invited, particularly for targeted topics)
Quarterly Professional Stakeholder Meetings	(P&F Chair to attend)	X	X	X (invited)
Annual In-Person SAC Meetings	X	X	X	X

We held meetings early in the study timeline to focus on study development (reviewing informed consent materials, recruitment materials, resource list development) and creation of materials to assist the TCMs. Mid-study we anticipate ongoing input in the study and assistance in addressing any issues with recruitment or retention as well as development and dissemination of consumer focused materials. Towards the end of the study we plan to have the SAC involved with interpretation of study findings and input on plans for dissemination and implementation of results.

Planning the Study

The present study design is informed by over 20 years of patient-centered research conducted by our team, extensive literature review, and input from focus groups and individual and group meetings with our Patient and Family Stakeholder members. Patient and Family Stakeholders provided critical input on how the interventions should be delivered. The investigators were enthusiastic about using the telephone, as well as computers and mobile devices to deliver the interventions. However, several patient partners pointed out that knowing who to contact in case of problems was a significant concern. This led to us ensuring all parties had access to the TCM via telephone during regular business hours, and making sure all key contacts will be included in the TBI Care Plan. Another patient partner emphasized the importance of helping them connect with and inform their primary care provider about their TBI. Consequently, we have included primary care in our Professional Stakeholder group and will ensure that the discharge plan is communicated to each patient's primary care provider.

The upshot of these conversations has been that transition care must be flexible and tailored to individual patient needs and preferences. As we meet in the future we are certain to discover other ways the protocol will need to be adapted to the needs of this patient population.

Meetings with Patient and Family Stakeholders also led to the decision to have two primary outcomes: participation in roles and activities and quality of life. Input from clinician stakeholders, which included primary care, confirmed the notion that existing systems of care are inconsistent and inadequate to meet the requirements of people with TBI and that efficient, well-defined case management models of care should be used to facilitate a comprehensive TBI care plan to help those in need. Our patient partners and stakeholders all agreed that the lack of consistent and evidence-based patient-centered guidelines required the inclusion of at least 2 comparators: one that used a brief in-hospital approach and one that used a remote, temporally extended case management approach.

In addition to input from our Patient and Family Stakeholder members, we gathered information about experiences with different health care systems after TBI from patient and family/caregiver focus groups. Focus groups with patients highlighted the need for better patient and provider education *("I feel like I've spent a lifetime educating providers about a TBI"*) and support (*"I felt totally abandoned after leaving the hospital"*).

Conducting the Study

Patient and family partners, clinicians and TBI advocacy/policy representatives have agreed to participate in the conduct of the study as members of the SAC. During the start-up phase, Patient and Family Stakeholders and Professional Stakeholders will be recruited to be on the teams assigned to develop, refine or confirm aspects of the study such as consent forms, satisfaction assessment questions, intervention rollout, study advertisement and patient/provider information materials and care plans.

They will participate in conducting the study as follows:

Monthly SAC Patient and Family Stakeholder Meetings

The patient partners will be asked to help problem-solve issues that arise regarding patient satisfaction, utility of patient care resources, and recruitment. They will also be involved in helping to develop data collection procedures, interpretation of data, and implementation and dissemination activities.

Quarterly SAC Professional Stakeholder Meetings: Professional Stakeholders will participate in recruitment and developing the resources needed for the TCM at each site and ensuring consistent resources are sought in each area of the country. They will also be involved in data procedures and the interpretation of the data analyses. Stakeholders will meet to review progress toward study goals and discuss ways of improving study implementation and dissemination.

Annual Study-Wide Meeting

All key investigators and SAC members will attend an annual meeting in which study progress and problems are discussed. Workgroups will be formed to address study problems or lead work toward upcoming milestones. Every effort will be made to facilitate in-person attendance among patient stakeholders, although due to medical limitations it is expected that some patient SAC members may need to attend via teleconference or videoconference. Due to scheduling and work demands, some of our Professional Stakeholders can more conveniently attend via tele/videoconference.

Funding Support

Given that implementation of effective clinical interventions is a goal both for PCORI as well as for our stakeholders, we have partnered with key stakeholders that will be influential in developing a sustainable plan for future funding. We sought support from several hospital administrators at our sites (such as Peter Esselman, MD and Brian Giddens, LICSW, ACSW at UW Medicine; Alberto Esquenazi, MD and Thomas Smith, OTL/R, MBA at MossRehab Hospital; W. Jerry Mysiw, MD and Amanda Lucas, Med, MBA at Ohio State University Wexner Medical Center; and Fabien Polo, PhD, MBA at Baylor Institute for Rehabilitation). These individuals have endorsed the RTP intervention and have assured us that we are collecting the specific data needed to secure funding for TBI Care Manager positions if results of the study are favorable.

In addition, we have partnered with stakeholders from Labor and Industries (The Hartford) and the Veterans Health Administration to provide input on how the TCM is implemented within their system; from large insurers including Medicare (Centers for Medicare and Medicaid Services) and Medicaid (Molina Health) to address how an effective TBI transitional care intervention may be added to insurance plans; and from our state Brain Injury Associations/Alliances and Councils and CARF who provide input to policy makers in each state and at a national level on funding for individuals with TBI. In addition, we have heard from groups such as the WA State TBI Council that they would be interested in funding such a position in the future to cover the entire state, and would consider funding the research process, but would only be able to fund one (WA) site if they have funds available.

Disseminating the Study Results

During monthly meetings with investigators, including Patient and Family Stakeholder partners, and quarterly Professional SAC meetings, we will devote time to discussion of dissemination activities.

Patient and Family Stakeholders and other advisors will participate in all aspects of dissemination including authorship as appropriate (consumer/staff have previously authored papers with us).[123-125] In year 1, during the start-up phase, we will solicit input on how the study materials should be designed.

Input will be sought on content, wording and other media outlet options. We will discuss what information patients and other stakeholders might want to know about, optimal media types, and editing for other audiences. In year 5, we will solicit help to understand the implications of the study for different stakeholder groups. Following that, together we will design dissemination products that target different audiences and media. We will leverage our group's significant leadership positions in key organizations and platforms, such as the TBIMS Knowledge Translation Center, national (Ayotte) and state (various study members) Brain Injury Associations/Alliances, annual Galveston Brain Injury Conference (several study members), the National Association of State Head Injury Administrators (Rogers) to advance policy and clinical practice guidelines. We also plan to include at least one stakeholder from the American College of Surgeons and its Committee on Trauma to assist with dissemination and implementation activities. See **Dissemination and Implementation Potential** for more details.

Principles for Engagement

Reciprocal Relationships

Our approach is to operate on a non-hierarchical, team-based organizational model where all Patient and Family Stakeholders, Professional Stakeholders and investigators contribute equally and decision-making is by consensus. We use an evidence-based approach to creating smarter teams and better decisions.[126] That is, we emphasize that as far as possible in meetings, all team members participate equally, that teams have good representation of women, minorities and team members with diverse areas of expertise and opinions and pay special attention to the feelings, knowledge and beliefs of other team members. SAC Patient and Family Stakeholder and Professional Stakeholder chairs will be responsible for promoting and following these principles.

Co-learning

While it would be too cumbersome to include all investigators, Patient and Family Stakeholder and other Professional Stakeholders in all telephone-based meetings, we will ensure that there

is committee membership crossover and regular opportunities for interactions among investigators, Patient and Family Stakeholders and Professional Stakeholders. As noted above, selected investigators, patients and other stakeholders will routinely attend each other's committee meetings. The annual study-wide Investigator-SAC meeting will feature the perspectives and work of each of the teams as a means of co-learning.

Partnership
Patient and Family Stakeholder partners and other stakeholders will receive similar annual financial remuneration from the study for their participation and additional funds for travel to our annual in-person meeting.
We are asking patient partners to meet for shorter times but more frequently because we anticipate needing their input on an ongoing basis given their role as co-investigators.
The Professional Stakeholder group will meet quarterly as they will be engaged less in day-to-day operations and more attuned to overall trends in progress toward major milestones.

We have arranged to pay Patient and Family Stakeholders as consultants on this grant--not paid staff. This is because our study sites are equal opportunity employers and cannot lawfully limit job candidates to people with TBI. We are paying stipends for the time they will spend participating in the study and will make travel arrangements for all of our Patient and Family Stakeholders to reduce any financial burden. At this time we anticipate paying all of our Patient and Family Stakeholders as equal partners in our grant. However, we understand that some patients, due to funding for their medical care or disability related needs, may not be able to accept payment and will work with each member to address this individually.

We have also budgeted to compensate study participants for the time it takes them to complete their assessments. Our core budget will pay for teleconferences.

Trust, Transparency, Honesty
We will embody these principles in several ways. We will survey all study team members annually to measure their satisfaction with their engagement with the study, barriers and facilitators to engagement and opportunities to improve engagement and decision-making. Minutes of all study team meetings and raw data on study performance metrics (e.g., accrual, retention, satisfaction, engagement) will be disseminated to all team members to promote transparency. The roles and responsibilities of each member of the research, Patient and Family Stakeholder and Professional Stakeholder teams, as well as the rules for decision-making and conflict resolution will be developed by consensus and codified in the Manual of Procedures. Travel costs will be provided for all in-person SAC meetings.
The study website that will be designed for this study will contain a private chat function where members of our study team, including Patient and Family Stakeholders and Professional Stakeholders, can share ideas and concerns.

Program Evaluation

We will conduct a summative program evaluation with groups of stakeholders (i.e., patients, caregivers, clinicians) at the end of the study period and follow the Centers for Disease Control Framework for Program Evaluation on Public Health.[127] This program evaluation will (1) evaluate the effectiveness (merit, worth, and significance) of the intervention to stakeholders, and (2) identify suggested modifications to the intervention based on stakeholder experiences. Each site will randomly recruit 15-20 stakeholders who were involved with the intervention (participants, interventionist, clinicians, researchers) and complete a structured focus group to

discuss topics including barriers and facilitators to the intervention, positive and negative outcomes of participation, cultural applicability, and recommendations for modification (e.g., intervention intensity, duration, mode). Results from each site will be aggregated into a final report so that lessons learned can be shared with stakeholders to inform future iterations of the intervention and ensure appropriate modifications are made to maximize the benefit for stakeholders.[128]

RESEARCH TEAM AND ENVIRONMENT

The six study sites were chosen based on interest and patient engagement early in the process of the development of the grant. All sites, as mentioned previously, are TBIMS centers who have had experience working with each other through multi-site projects funded within the NIDILRR TBIMS (module projects) as well as with external funding (NIH, etc.). Specific interest in the comparative effectiveness trial is high for TBIMS sites that don't currently have a case management or other type of discharge model. But all six sites included have excellent resources.).

The TBIMS Partnership

The proposed project is enhanced by the fact that it will leverage resources and known collaborators from the multi-institutional TBIMS Program of research funded by NIDILRR. The TBIMS program is a longitudinal multi-center study which examines the course of recovery and outcomes following the delivery of a coordinated system of acute neurotrauma care and inpatient rehabilitation. To date, over 15,000 participants have been enrolled over the past 25 years in the civilian TBIMS centers.[54] The TBIMS lifetime study conducts annual follow-up at 1, 2, 5, 10, 15 and every 5 years thereafter. The TBIMS infrastructure has successfully yielded collaborations receiving additional funding from the Department of Defense, Centers for Disease Control, and National Institute of Health. To date, over 713 peer-review publications have been generated from TBIMS data and are logged in a registry online (http://www.msktc.org/publications?sys=T). This historical and well-established infrastructure will serve as an invaluable resource for completion of this proposed study.

The TBI Model System National Data and Statistical Center and Knowledge Translation Center

The NIDILRR TBIMS infrastructure includes a National Data and Statistical Center (www.tbindsc.org) that currently houses all TBIMS data with rigorous data quality procedures already in place. The National Data and Statistical Center organizes meetings for principal investigators and co-investigators meet twice per year in Washington DC for project management, collaboration, and strategic planning. Further, the NIDILRR funded Model System Knowledge Translation Center (MSKTC) which meets with TBIMS investigators in Washington, DC, is a resource for translating model systems science into products for various stakeholders including patients, caregivers, administrators, and policymakers. Their MSKTC website (www.msktc.org/tbi) is accessed internationally with downloadable material on topics generated by stakeholders with input from TBIMS scientists. Products generated on the topic of TBI include slideshows, fact sheets, short patient-focused videos on topics of interest, systematic reviews, publications database, research summaries, and links to other resources. The MSKTC meets with the TBIMS investigators in Washington DC twice yearly for input and development on new topics. This project will continue to leverage this resource for dissemination and implementation activities proposed in this project. Several study investigators serve on the TBI Model System Knowledge Translation Committee.

The TBI Model System Investigators

The TBIMS infrastructure with its demonstrated history of successful enrollment and research infrastructure is well positioned to support study investigators. TBIMS Principal Investigators (Hoffman, Bogner, Hammond, and Dams O'Connor) and co-investigators (Corrigan, Fann, Driver, Dubiel, Whyte, and Watanabe) from six TBIMS centers (WA, IN, TX, OH, NY, PA) are collaborators in this study and all have engaged in prior multi-site collaborations either funded through NIDILRR or other mechanisms highlighting organizational support for TBI rehabilitation research.

These investigators have already identified and are enrolling the population for this study into TBI rehabilitation research projects. The sites are members of a special interest group (SIG) within the TBIMS center which has been meeting for more than one year to develop the current project, including twice per year in Washington DC for face-to face meetings. The meeting schedule includes both teleconferences as well as face-to-face meetings built upon the pre-existing infrastructure.

Potential for disseminating and implementing the results of this research in other settings

As healthcare systems are incentivized to improve the health of populations and reduce longer-term costs and complications, programs like these that facilitate return to optimum functioning will be increasingly valuable to these entities. The evidence generated by the proposed study will be highly meaningful to our target audiences because our target audiences includes our stakeholders and their constituents (**PC-4**). Because the proposed trial emphasizes external validity, the results will have high generalizability for our target audiences. The inclusion criteria are broad and highly feasible to measure. Thus, the findings will be actionable by our target audience. Our VHA Stakeholders have also expressed interest in utilizing knowledge gained on more effective methods of case management delivery and plan to feed information back into their system. Comparative effectiveness trials are rarely conducted in TBI populations, and thus there is an enormous gap in the evidence base. With little information about how best to improve the management of patients with TBI following discharge from inpatient rehabilitation, there will be a high demand for the evidence that we will be disseminating.

The diffusion of our findings will be also expedited by our dissemination strategies that will be effectively tailored to our target audiences. Because the stakeholders in the SAC will have an in-depth understanding of both our target audience and our research findings, they will be particularly adept at customizing the dissemination messages and materials for our target audiences. We will work with our partners to develop policy briefs, plain language fact sheets, blogs and videos for distribution via stakeholder organization websites and other social media outlets (i.e., Twitter, Facebook, YouTube). We will also have the opportunity to give presentations at events hosted by our stakeholder organizations.

Dissemination of Intervention Materials

We plan to make available to other clinicians and healthcare systems the following RDP and RTP intervention materials: manual of procedures; needs assessment; outcome measures; patient, family/caregiver, and provider educational materials; and case management manuals. We have a strong partnership with NIDILRR's TBIMS Knowledge Translation Center (www.msktc.org), which specializes in dissemination of scientific research findings. The TBIMS KTC website will serve as a platform for many dissemination activities. Findings will also be disseminated through the recently formed Cochrane Physical and Rehabilitation Medicine collaboration.[129] Following study completion, our multi-purpose study website will serve as a

platform for many dissemination activities. For example, treatment manuals and educational materials will be available to clinicians and healthcare systems who want to implement or adapt components of our interventions to their unique system of care.

Knowledge Translation
We will work with influential national and international organizations involved with TBI knowledge translation and dissemination to inform clinical practice and policy development.

This will be accomplished by leveraging our research team's current leadership roles in rehabilitation organizations. Examples include the National Center for Medical Rehabilitation Research (NIH), NIDILRR TBIMC KTC, American Congress of Rehabilitation Medicine (ACRM), Galveston Brain Injury Conference, American Psychological Association, American Psychiatric Association, Society of General Internal Medicine, National Association of Social Workers, and Academy of Certified Brain Injury Specialists.

We will also work with the Brain Injury Association of American, the largest TBI advocacy group in the country, to disseminate key findings. Involvement in scientific presentations, committees, and working groups will lead to dissemination of study findings and adaptation of practice guidelines.

Implementation
Immediate efforts to implement key findings will include collaboration with regional TBI stakeholders, such as state Brain Injury Associations/Alliances and state TBI Councils and with our own hospital administrators. We will work with state and national payers, including those in our Study Advisory Committee (CMS, DSHS, Molina, the Hartford, L&I) to implement the most effective transition programs. Study findings will dictate whether and at what level clinical service enhancements should be provided in existing healthcare systems.

Possible Barriers to Dissemination and Implementation

A potential barrier to dissemination and implementation of study results in this trial is limited involvement by potential stakeholders who will be key for dissemination including administrators in key positions to approve funding as well as additional other organizational stakeholders who we may not have considered. As noted by Olkin,[130] people with disabilities are under-represented in teams designing and conducting research, resulting in a "rift between research and practice" and "a schism between those studied and those doing the studying" (p. 320). Accordingly, we have received excellent input from our Patient and Family Stakeholders who have all agreed to be key research partners in this grant and contribute to decision making throughout the study. Evidence from the rehabilitation and public health literatures suggests that extensive consumer involvement may maximize research quality, social validity, and knowledge translation,[131] and we will be learning how best to utilize our consumers to dissemination and implement results from the research. In preparation for this PCORI application, we have already had meaningful involvement of patient, family, clinician, policy, advocacy, payer, and organizational stakeholders; we believe that this plan engagement throughout the study with our

stakeholders will be a facilitator to dissemination and implementation of study findings.

Additional barriers to dissemination include a lack of financial resources for dissemination activities and implementation in clinical and community settings. We will brainstorm with stakeholders the potential for future research to address implementation barriers via such activities as implementation and dissemination research and cost-effectiveness research. **Several of our stakeholders have committed to assisting with dissemination and supporting funding**. In addition, all of our site PIs have considerable experience in knowledge translation of disability and rehabilitation research through their leadership in the TBIMS and will guide the team on knowledge translation.

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ADDITIONAL TABLES AND FIGURES

Table 3. Patient Participant Involvement

Time Point	When/How Often	Time Required	Compensation*
Baseline Information**	Once following consent session	25-35 minutes	$15**
Discharge Summary Information	Once following consent session	None	$0
Post-Discharge Transition Phase	After discharge	About 12 contacts, 10-60 minutes each contact over 6 months***	$0
3 Month Post-Discharge Questionnaire	Once about three months after discharge	25-30 minutes	$25
6 Month Post-Discharge Questionnaire	Once about six months after discharge	25-30 minutes	$25
Rehabilitation Transition Plan Group Phone Survey***	Once about six months after discharge	10-20 minutes	$0
9 Month Post-Discharge Questionnaire	Once about nine months after discharge	25-30 minutes	$25
One Year Following Injury Questionnaire**	Once about one year after injury	45-60 minutes	$15*
12 Month Post-Discharge Questionnaire	Once about 12 months following discharge	25-30 minutes	$25

*Compensation amounts reflect UW compensation amounts only. Compensation amounts will vary across sites.
**These questionnaires are completed and compensated as part of the TBIMS study if enrolled in that study as well. Otherwise, they will be completed and compensated as part of BRITE.
***Participants randomized to RTP only.

Table 4. Caregiver Participant Involvement

Time Point	When/How Often	Time Required	Compensation*
Baseline Questionnaire	Once following consent session	5-10 minutes	$25
Post-Discharge Transition Phase	After patient discharge	About 12 contacts, 10-60 minutes each contact over 6 months**	$0
3 Months Post-Discharge Questionnaire	Once about three months after patient discharge	15-30 minutes	$25
6 Months Post-Discharge Questionnaire	Once about six months after patient discharge	15-30 minutes	$25
Rehabilitation Transition Plan Group Phone Survey**	Once about six months after patient discharge	10-20 minutes	$0
9 Months Post-Discharge Questionnaire	Once about nine months after patient discharge	15-30 minutes	$25
12 Months Post-Discharge Questionnaire	Once about 12 months after patient discharge	15-30 minutes	$25

*Compensation amounts reflect UW compensation amounts only. Compensation amounts will vary across sites.
**Participants randomized to RTP only.

Figure 2. Study Assessment Schedule

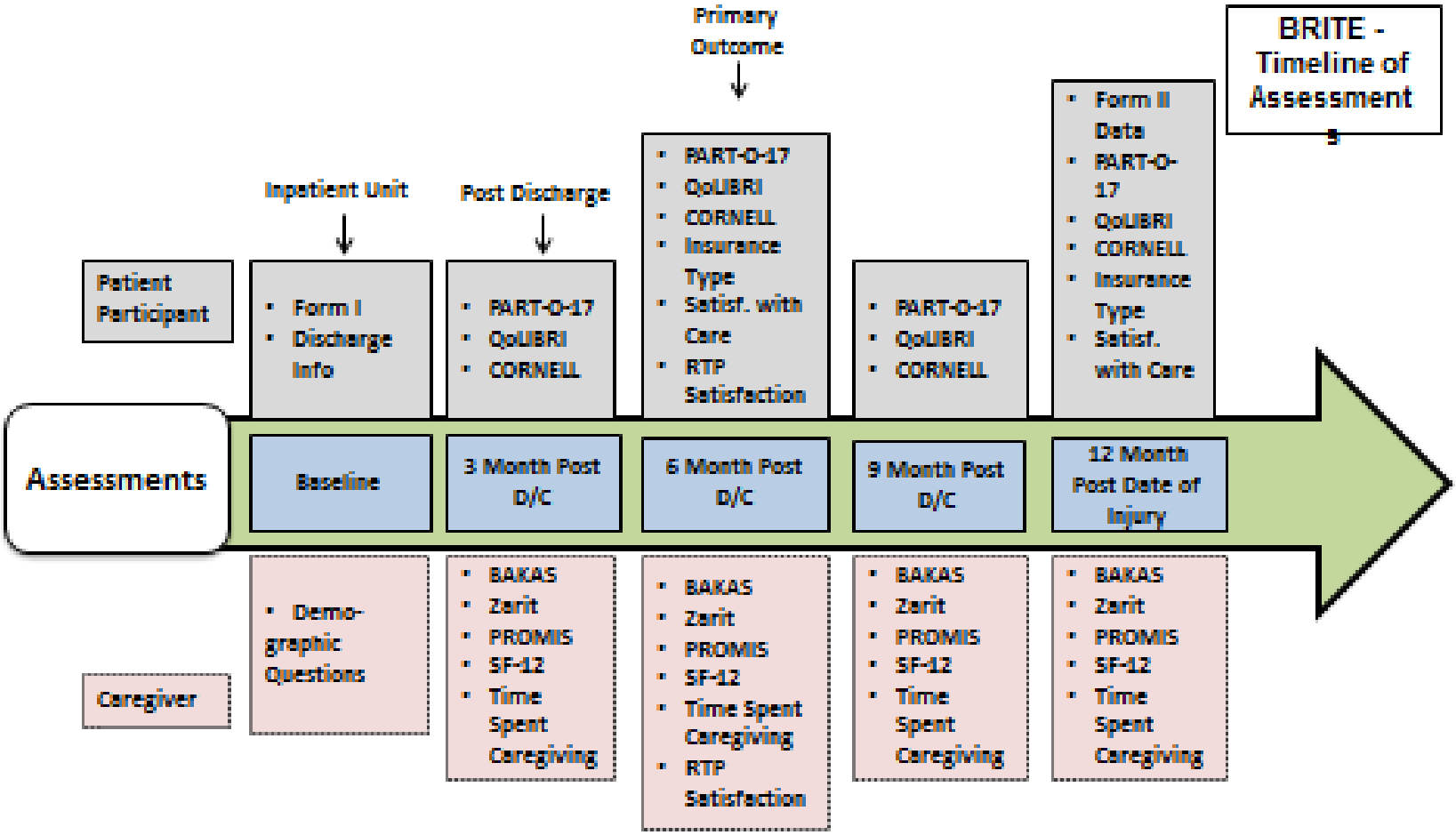
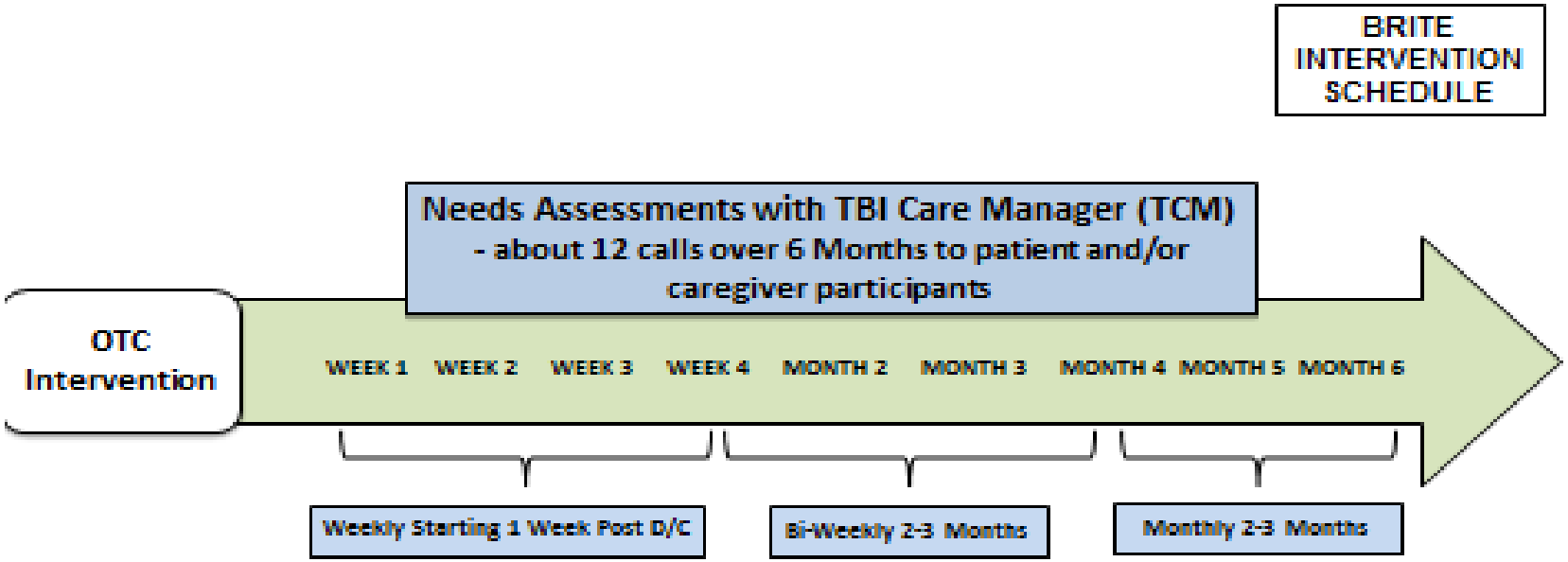


Figure 3. BRITE Intervention Schedule



Appendix 1: Milestone Schedule

MODIFIED MILESTONE SCHEDULE – 1/23/2023

Milestone Deliverable ID	Milestone Name	Description	Due Date
E	**Interim Progress Report Submission**	**Complete 24-month interim progress report (IPR) and submit via PCORI Online.**	**7/31/2019**
F1	Complete 25% of 9-month follow-ups	Complete 25% of 9-month follow-ups (180 patient and 108 caregiver participants).	8/31/2019
F2	Recruit 50% of total study participants	Recruit 450 patient and 270 caregiver participants (50% of total).	9/30/2019
F3	IRB Annual Review for lead site (UW)	Submit IRB annual review approval letter to PCORI	10/31/2019
F4	Complete 25% of 12-month follow-ups.	Complete 25% of 12-month follow-ups (180 patient and 108 caregiver participants).	11/30/2019
F5	Complete 50% of 3-month follow-ups.	Complete 50% of 3-month follow-ups (360 patient and 216 caregiver participants).	11/30/2019
F6	Monthly SAC Patient and Family AND Quarterly Professional Stakeholder meetings	Include a summary of the monthly SAC patient and family and quarterly professional stakeholder meetings in the interim progress report.	1/31/2020
F	**Interim Progress Report Submission**	**Complete 30-month interim progress report (IPR) and submit via PCORI Online.**	**1/31/2020**
G1	Complete 50% of 6-month follow-ups.	Complete 50% of 6-month follow-ups (360 patient and 216 caregiver participants).	2/28/2020
G2	Complete 50% of 9-month follow-ups.	Complete 50% of 9-month follow-ups (360 patient and 216 caregiver participants).	5/31/2020
G3	Annual in-person meeting for patient and family stakeholders and investigators (SAC)	Annual Stakeholder Meeting Meeting. Include a summary of the discussion in the interim progress report.	6/30/2020
G4	Recruit 75% of study participants	Recruit 675 patient and 405 caregiver participants (75% of total).	7/31/2020
G5	Conduct administrative review	PCORI will evaluate whether or not the study has everything in place to continue project progress.	7/31/2020

G	**Interim Progress Report Submission**	**Complete 36-month interim progress report (IPR) and submit via PCORI Online.**	**7/31/2020**
H1	Complete 50% of 12-month follow-ups.	Complete 50% of 12-month follow-ups (360 patient and 216 caregiver participants).	9/30/2020
H2	IRB Annual Review for lead site (UW)	Submit IRB annual review approval letter to PCORI.	10/31/2020
H3	Monthly SAC Patient and Family AND Quarterly Professional Stakeholder meetings	Include a summary of the monthly SAC patient and family and quarterly professional stakeholder meetings in the interim progress report.	1/31/2021
H	**Interim Progress Report Submission**	**Complete 42-month interim progress report (IPR) and submit via PCORI Online.**	**1/31/2021**
I	**Interim Progress Report Submission**	**Complete 48-month interim progress report (IPR) and submit via PCORI Online.**	**7/31/2021**
J1	IRB Annual Review for lead site (UW)	Submit IRB annual review approval letter to PCORI.	10/31/2021
J4	Complete recruitment	Recruit 900 patient and 540 caregiver participants (100% of total).	10/31/3021
J5	EEF - Schedule and conduct qualitative interviews with stakeholders, staff, investigators	Patient (N~5), family (N~5), professional stakeholders (N~5), study staff and investigators (N~5) interviews completed .	12/31/2021
J6	Annual in-person meeting for patient and family stakeholders and investigators (SAC)	Annual Stakeholder Meeting Include a summary of the discussion in the interim progress report.	12/31/2021
J7	Complete 100% of 3-month follow-ups	Complete 100% of 3-month follow-ups (720 patient and 432 caregiver participants).	1/31/2022
J	**Interim Progress Report Submission**	**Complete 54-month interim progress report (IPR) and submit via PCORI Online.**	**1/31/2022**
K1	Complete 100% of 6-month follow-ups	Complete 100% of 6-month follow-ups (720 patient and 432 caregiver participants).	4/30/2022
K2	EEF - Data analysis complete	Interview data is audio-recorded, transcribed, entered into Dedoose mixed methods software and analysis complete.	6/30/2022

K3	Complete 100% of 9-month follow-ups	Complete 100% of 9-month follow-ups (720 patient and 432 caregiver participants).	7/31/2022
K4	Monthly SAC Patient and Family AND Quarterly Professional Stakeholder meetings	Include a summary of the monthly SAC patient, family and quarterly professional stakeholder meetings in the interim progress report.	7/31/2022
K	**Interim Progress Report Submission**	**Complete 60-month interim progress report (IPR) and submit via PCORI Online.**	**7/31/2022**
L1	IRB Annual Review for lead site (UW)	Submit IRB annual review approval letter to PCORI.	10/31/2022
L2	Complete 100% of 12-month follow-ups	Complete 100% of 12-month follow-ups (720 patient and 432 caregiver participants).	10/31/2022
L3	Primary Completion Date	The last day the last participant is evaluated for the primary outcome.	10/31/2022
L4	EEF - Tip Sheets	Tip sheets providing guidance on thematic topics to improve the equitable engagement with individuals who have cognitive difficulties to accompany video fully completed.	10/31/2022
L5	EEF - Video Production and Editing	Engagement implementation guide in audio-visual format (video) completed.	11/30/2022
L6	EEF - Manuscript Preparation and Final Report	Manuscript completed and final report due.	12/31/2022
L7	Annual in-person meeting for patient and family stakeholders and investigators (SAC)	Annual Stakeholder Meeting. Include a summary of the discussion in the final progress report.	12/31/2022
L8	Ensure all follow-up data is complete and conduct quality check	Data complete and quality check is done.	12/31/2022
L9	Convene groups (study participants, TCM, clinicians, researchers) at each site (UW, IN, PA, TX, NY, OH)	Convene Groups to gather information for Process Evaluation.	12/31/2022

L10	Aggregate summative Program Evaluation feedback	Aggregate summative feedback.	12/31/2022
L11	Prepare cleaned dataset, annotated data dictionary, and codebook for sharing	Prepare data for sharing. Copies of the study codebook will be made available per PCORI's open science policy, if requested.	1/31/2023
L12	Begin development of manual delineating the discharge planning protocol found to be most effective	Begin development of a manual for discharge planning.	1/31/2023
L	**Interim Progress Report Submission**	**Complete 66-month interim progress report (IPR) and submit via PCORI Online.**	**1/31/2023**
M1	Submit Conference Presentations	Submit conference presentations.	6/30/2023
M2	Complete Analyses		7/15/2023
M3	Present to each BIA/TBI Council/HRSA group at each site	Present to relevant stakeholder groups at each site.	7/31/2023
M4	Present to hospital administration at each site	Provide update to PCORI on efforts to identify channels of distribution and incorporating findings into sustainable clinical practice.	7/31/2023
M5	Begin development of plans to adopt research findings into practice	Begin creation of a plan that includes a description of how the intervention was refined and provide examples of how it can be sustainable.	7/31/2023
M	**Final Progress Report**	**Complete final progress report (FPR) and submit via PCORI Online. This report should cover activities since the last report through the end of the research project period.**	**7/31/2023**
N	**Results submitted to ClinicalTrials.gov or**	**Awardee ensures results are submitted to ClinicalTrials.gov or**	**9/30/2023**

	appropriate database.	**appropriate database. For ClinicalTrials.gov, the generated tables are a required section in the Draft Final Research Report. Results must be submitted no later than 30 days before Draft Final Research Report Submission Milestone to provide time for ClincialTrials.gov to conduct quality checks.**	
O	**Draft Final Research Report Submission**	**Submit Draft Final Research Report according to instructions found at http://www.pcori.org/awardee-resources. *All Draft Final Research Reports must be submitted no later than 30 days from when results are posted to clinicaltrials.gov or other applicable website. Refer to Contract.**	**10/31/2023**
P	**Initial Data Sharing Conference Call with Data Repository**	**Hold initial data sharing conference call with Data Repository to set expectations for data deposition and curation, discussion of Data Contributor Agreement, and identification of any technical and/or governance issues.**	**10/31/2023**
Q	**Submit signed Data Contributor Agreement**	**Obtain signed Data Contributor Agreement and submit in PCORI Online**	**11/21/2023**
R	**Transfer initial Data Package**	**Transfer initial Data Package to Data Repository, and submit proof of submission in PCORI Online.**	**11/28/2023**
S	**Submit Verification of Data Package Completion**	**Mutual agreement between Awardee and Data Repository that curation of the Data Package is complete. Submit verification of completion in PCORI Online.**	**4/1/2024**
T	**Complete data sharing activities and provide update to PCORI.**	**Submit 3-page report* to PCORI summarizing experience and lessons learned from data sharing activities in PCORI Online.**	**4/15/2024**
U	**Complete all Draft Final Research Report Revisions (FRR Accepted)"**	**PI will respond to all requests to revise their DFRR within the given timeframe, until the Program Director for Peer Review accepts the report as final on behalf of PCORI.**	**7/31/2024**

V	**Approval / sign off of the Lay Abstract**	**PI to approve/sign off Lay Abstract no later than 5-7 calendar days after receipt of the draft from PCORI.**	**No date**
W	**Contract Term Date**	**The last day of the contract.**	**11/30/2024**
X	**Notification of Publication Acceptance**	**See Contract for Instructions**	

Appendix 2: Data Quality Guidelines

BRITE Study Data Quality Guidelines
Version 1.0

Introduction:
The BRITE study has established data quality guidelines and strategies to ensure that all study data are of the highest quality, and are being collected in the same way across the collaborating sites.

Purpose:
Integrity of data will be preserved through standardized practices for data quality.

Scope:
University of Washington is the lead site for the BRITE study. The TBIMS National Data and Statistical Center (NDSC), located at Craig Hospital serves as the Data Coordinating Center (DCC) for this study. BRITE sites that participate in data collection for this project are:

- University of Washington, Jeanne Hoffman, Jesse Fann, Site PIs
- Indiana University School of Medicine/Rehabilitation Hospital of Indiana, Flora Hammond, Site PI
- Baylor Institute for Rehabilitation, Simon Driver, Site PI
- Moss Rehab Hospital, Thomas Watanabe, Site PI
- Mount Sinai Health System, Kristen Dams-O'Connor, Site PI
- Ohio State University Wexner Medical Center, Jenny Bogner, Site PI

Responsibilities:
The lead site, with assistance from the DCC, is responsible for overall coordination and monitoring of data quality for this study, including review of this SOP with the data collectors at each site during the biweekly Data Collectors teleconference. Each Site Principal Investigator (PI) is responsible for the integrity of data being collected within his/her site. The Site PI is also responsible for tracking and assuring that the Data Quality Guidelines outlined below are followed in his/her site. A copy of this Standard Operating Procedure (SOP), signed by each Site PI, will serve as documentation that these guidelines are being followed and will be submitted to the lead site.

Procedural Steps

1. **Screening Data**
   - Demographic data should be entered into the website the same day the subject is first screened
   - Eligibility status should be entered as soon as possible after it is determined
   - Consent, decline, or other final enrollment status should be updated as soon as it is determined
   - **Lead site will communicate as needed about screening entry issues outside of the quarterly cleanup**

2. **Baseline Data (Non-TBIMS Pre-Injury, BTACT, and Medical Abstraction; Caregiver Baseline)**
   - Non-TBIMS Patient Participants
     - Pre-injury and BTACT data should be entered within two weeks of collection
     - Medical Abstraction data should be entered within 3 months post-randomization
   - Caregiver Participants
     - Caregiver Baseline Questionnaire should be entered within two weeks of collection
   - **Lead site will conduct monthly checks of the Baseline Status Report, and email sites about pending data collection/entry and status updates**

3. **Post-Discharge Data (Patient Post-Discharge Information, Patient Post-Discharge Questionnaire, Year 1 Interview Non-TBIMS; Caregiver Post-Discharge Questionnaire)**
   - Patient Participants
     - Post-Discharge Destination data should be entered and saved when the participant is randomized
     - Post-Discharge Information data should be entered within two weeks of randomization
     - Post-Discharge Questionnaires and Non-TBIMS Year 1 (Form II) interviews should be entered within two weeks of collection or receipt of mailout survey
   - Caregiver Participants
     - Post-Discharge Questionnaires should be entered within two weeks of collection or receipt of mailout survey
   - **Lead site will conduct monthly checks of cases past the ideal date or window close using the Cases Due Report, and email sites about any pending cases that are overdue or ≤10 days from window close**

4. **Note-to-Files**
   - Note-to-Files should be completed and entered within 30 days of detection of event requiring the NTF

5. **Problems Reports**
   - Problems Reports should be completed and entered within 30 days of detection

- Reminder: SAEs that are unanticipated and possibly related to the study intervention will be reported to the respective site PI, the lead site PI, chair of the DSMB, the respective IRB, and the PCORI Program Official in accordance with requirements.
    - Unanticipated fatal or life-threatening SAEs related to study procedures will be reported all parties listed above immediately.
    - Other unanticipated SAEs related to study procedures will be reported to the respective site PI and lead site PI within 24 hours. The SAE will be reported to the respective IRB according to that institution's requirements. The event will be reported to PCORI promptly but no later than 10 days after reporting the event to the IRB.
    - Anticipated or unrelated SAEs will be reported to the DSMB and PCORI as part of the bi-annual and annual DSM reports. These DSM reports will also be submitted to each site's IRB.

6. Data Checks by the Lead Site

- The lead site will conduct quarterly checks of the data to look for missing and inconsistent data. Each site will be notified of any data issues, and asked to correct those issues within 60 days of notification.

Data Cleanup Calendar

We will conduct staggered quarterly cleanups of the following data collection forms.

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Caregiver Baseline			X			X			X			X
Patient Post-Discharge Questionnaire		X			X			X			X	
Caregiver Post-Discharge Questionnaire			X			X			X			X
Patient Post-Discharge Information		X			X			X			X	
Medical Record Abstraction			X			X			X			X
Non-TBIMS Year 1 Follow-up		X			X			X			X	
Screening Data	X			X			X			X		
Note-to-File*	X			X			X			X		
Problems Report*	X			X			X			X		
RTP Completion*	X			X			X			X		
Study Completion Form	X			X			X			X		
RTP Satisfaction*		X			X			X			X	

*Unblinded forms

7. Data Quality Targets

- Each site should attempt to meet the data quality targets established by the lead site as follows:
    - Target enrollment rate is set at 73%, and will be reviewed on a quarterly basis beginning December 2020. The lead site will review the rate for cases entered into the website screening form within the previous six months (e.g. 6/1/20-11/30/20 for the December check). Sites not reaching their target will be required to develop a written remediation plan for increasing enrollment numbers. This plan should be submitted to the lead site. The effectiveness of this plan will be reviewed at subsequent quarterly checks.
    - Target Assessment Completion rate is set at 80%, and will be reviewed on a quarterly basis beginning December 2020. The lead site will review the rate for cases with open windows during the previous six months (e.g. 6/1/20-11/30/20 for the December check). Sites not reaching their target will be required to develop a written remediation plan for increasing enrollment numbers. This plan should be submitted to the lead site. The effectiveness of this plan will be reviewed at subsequent quarterly checks.

Enrollment & Assessment Completion Rate Checks; Reports Calendar

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
6-month Follow-up Rate Check			X			X			X			X
6-month Enrollment Rate Check			X			X			X			X
Sampling Enrollment Rate Adjustment		X			X			X			X	
Quarterly Internal Reports, Data and Safety					X						X	
DSM Reports		X						X				

8. **Guidelines Sign-off by Site PIs:** Each Site PI should submit a signed copy of this SOP to the lead site, to indicate their assurance that these guidelines are being followed within his/her site. The submission of this document will be due at the end of November 2020.

Signature of PI:

_____ _____

Print PI Name PI Signature Date

Appendix 3: Engagement Evaluation Funding (Starting on following page)

PI Full Name: Hoffman, Jeanne M.

Contract Number: PCS-1604-35115

Funding for COVID-19 Related Engagement Evaluation

Directions: Through responses to the specific questions below, provide a brief summary of the request and rationale. Please limit your responses to each question to no more than a paragraph. Please make relevant changes to your Budget and Budget Justification documents to reflect this work.

PCORI is offering projects the opportunity to receive funding **to document and evaluate their engagement practices during the COVID-19 pandemic**. This opportunity is suitable for projects that have:

- Developed innovative engagement approaches in response to the pandemic, or
- Redesigned their existing engagement approaches and/or goals in response to the pandemic, or
- Demonstrated a commitment to maintaining engagement with groups experiencing disproportionate impact from COVID-19 (e.g., historically under-represented populations, vulnerable populations, healthcare and public health professionals, etc)

Evaluations should utilize a systematic approach, relying on quantitative, qualitative, or mixed methods for the evaluation of engagement, drawing on perspectives from various stakeholders. The final deliverable will be a manuscript or white paper that makes findings available to the public. More information about this engagement evaluation funding can be found here.

Original Engagement Approach

1. Provide a brief summary of the original engagement goals and approach for your study.

The *Brain Injury Rehabilitation: Improving the Transition Experience (BRITE)* study is a six site, pragmatic, randomized clinical trial aimed at improving the transition from inpatient rehabilitation to community following moderate to severe traumatic brain injury (TBI). Our stakeholder advisory committee is comprised of a patient and family (n=13) group which includes individuals who have personally experienced TBI or cared for someone who has had a brain injury, and a group of multi-disciplinary professionals (n=22) who represent clinical practice, hospital administration, state TBI Councils, national and state advocacy and policy leaders such as the Brain Injury Association of America, CARF International, state Brain Injury Associations/Alliances, the American College of Surgeons, and payer groups. The groups meet over Zoom monthly (patient and family) and quarterly (professional). Our lead stakeholder from the patient and family stakeholder group, Irene Ziaya, acts as liaison across the SAC groups and investigator steering committee by attending all stakeholder and steering committee meetings and reporting progress among groups. In addition, our full SAC comes together for our annual meeting. Our original engagement goals were to ensure our stakeholders were involved throughout all phases of the research, including planning, conducting and dissemination. Our approach to engagement includes best practices and incorporates the six PCOR Engagement Principles, including reciprocal relationships, co-learning, partnership, transparency, honesty, and trust (1).

Modified Engagement as a Result of COVID

2. For projects changing engagement goals or approach as a result of the COVID-19 pandemic: What are the new engagement goals or approaches that your project is utilizing? Describe if/how stakeholders were involved in determining these changes. *Projects not changing engagement goals or approaches: please skip this item and proceed to question 3.*

Prior to the COVID-19 pandemic our approach to engagement included conducting monthly and quarterly SAC meetings virtually due to the fact that our study involved stakeholders from across the country. The pandemic highlighted the effective strategies that we had been using to engage with our stakeholders. As a result, much

of our engagement work was uninterrupted due to the pandemic. One notable exception was converting our in-person Annual Engagement Meeting to a virtual format. Moving the meeting from in-person to online raised new complexities that we had not yet addressed despite our smaller group meetings being online. In the smaller group format, our engagement challenges had centered around equitable engagement with individuals with cognitive difficulties who have limited experience using computers or being live on-screen. For our large virtual annual meeting that included all study stakeholders, staff, investigators, and funders, we specifically needed to consider the negative cognitive impact of extended screen time on persons with TBI, the challenge of internet connectivity issues, as well as how to manage having many people on the screen (versus the smaller group format for our regular monthly patient and family meetings), and discomfort with online meeting participation in large groups that included both patients/families and professional stakeholders.

The patient and family advisory group was critical to developing the virtual meeting and working with the study team to proactively address these challenges. In particular, based on their recommendations, we shortened the meeting to reduce online, live screen time. In place of our typical all-day meeting, we opted for a half day meeting that was preceded by engagement in several ways to prepare for and benefit from the online annual meeting. The patient and family group collaborated with the engagement study staff (Moore, Kempthorne) and our study case managers to create a video that described challenges they faced during their rehabilitation transition and how the BRITE intervention addresses these challenges. The patient and family group worked closely with the engagement study staff to develop the concepts for the video and many were filmed for the video itself. The video served as an important primer for the meeting attendees, allowed for participation from the stakeholders in a comfortable and less intense environment than the live online setting, and will serve as an educational tool during our dissemination efforts.

Additional strategies were suggested by the patient and family advisory group and the professional advisory group to increase the interactive nature of the Annual Engagement Meeting. These included incorporating smaller breakout sessions that were planned, discussed, and prepared for by members of the patient and family advisory group in pre-conference meetings with study staff and case managers. Discussion questions were provided ahead of time to allow participants to prepare for discussion. The synergy developed among the stakeholders, study staff, and case managers during these pre-conference meetings was critical to our successful meeting. Everyone was prepared and many potential issues or questions were addressed in these small group meetings so that during the Annual Engagement Meeting, participants were able to focus on and engage with the meeting content. All of the sessions were recorded so that participants could review sessions and also listen to sessions that they could not attend. We were also able to take advantage of the virtual platform of the Annual Engagement Meeting by inviting 'guest' stakeholders (chosen with input from investigators and stakeholders) who provided important information and recommendations related to our meeting themes of dissemination and implementation. For example, Rebeccah Wolfkiel, Executive Director of the National Association of State Head Injury Administrators (NASHIA) attended to discuss dissemination opportunities provided by her organization and their interest in being a key partner going forward, and Peter Thomas, an attorney with unique experience in TBI legislation and policy, gave his presentation from Boston on current and future opportunities and challenges for policy change to improve the long-term care of persons with TBI.

Some of the strategies we employed were not as successful as we had hoped, and we learned from those experiences as well. For instance, our small breakout sessions were not long enough or small enough to allow for maximal participation and engagement. We did not prepare speakers sufficiently in strategies to increase accessibility of slides and other materials, and we did not provide a closed captioning option for presentations, a practice that is now common on Zoom meetings. These experiences helped us realize that we needed to increase the level of adaptation in our regular meetings as well, not just in the Annual Engagement Meeting. *We believe the information we have learned from our successful engagement strategies will be useful for other groups working to engage patient stakeholders with cognitive difficulties, including those with TBI, other neurological disorders, or intellectual and developmental disabilities.*

3. Describe how your engagement strategies will support or have supported stakeholder engagement in your project during the COVID-19 pandemic. What challenges will these strategies address? If applicable, how will your strategies strengthen engagement with groups experiencing disproportionate impact from COVID-19 (e.g., historically under-represented populations, vulnerable populations, healthcare and public health professionals, etc)?

Many persons with TBI face challenges to engagement that stem from their injury, and some face challenges that stem from conditions that were present before their injury such as limited access to resources, isolation, poverty, and other social determinants of health. All of these challenges have been exacerbated during the COVID-19 pandemic. Because BRITE is a multi-site trial with participating centers across the country, following best practices for engagement necessitated pre-COVID participation using a secure tele-video communication platform (Zoom) and collaboration on study development and ongoing science via phone and email. Additionally, the BRITE intervention delivery is via telemedicine, so the study was well-poised to maintain communications remotely during the COVID-19 pandemic. Our study team has developed specific strategies to provide direct support to patient and family stakeholders regarding computer and phone access issues and offers opportunities for participation in study-related activities via a variety of mechanisms (phone conversation, Zoom, written documents), depending on stakeholder preference. We also video record all of our stakeholder sessions and calls and provide detailed minutes that are posted on our study website so that stakeholders can review the meetings later as desired. We integrate unique and specific engagement strategies to meet the needs of our patient stakeholders who may have ongoing cognitive challenges in their rehabilitation journey. Our strategies aim to both value the strengths and honor any accommodations needed for active engagement; we incorporate frequent reminders to attend meetings via text, phone, and email and provide collaboration opportunities in multiple aspects of the project and in multiple formats (e.g. audio-visual, written). This has led to genuine relationship building within the patient and family stakeholders and between the group and the steering committee. Having regular contact with the stakeholders and the ability to call/text/email has been critical to maintaining engagement. In addition, there are times when some stakeholders have not been able to attend to BRITE-related activities as challenges have emerged in their lives. We maintain engagement with stakeholders via phone/text/email during these times, and check in with them at the beginning of each call, which has been critical for sustaining participation during the stressful COVID-19 pandemic and after temporary absences. In addition to genuine professional relationships with the advisory boards and study staff and steering committee members, our stakeholders have developed supportive and professional relationships with each other. This support has been important for ongoing engagement over the course of the study and during the pandemic.

Proposal for Study of Engagement

4. Briefly describe your plan for evaluation of your engagement strategies. What questions about your engagement goals or approach will you answer? What methodologies, data sources, and analytic approaches will you utilize?

The goals of this Engagement Evaluation project are to identify and disseminate specific patient-centered strategies and processes employed in our study that enabled our stakeholders, investigators and study staff to remain mutually engaged during the COVID-19 pandemic. As noted above, we anticipated and prepared for engagement challenges, identified some new challenges, and adjusted our engagement strategies throughout the study and during the pandemic. In this application, we propose to rigorously answer engagement questions in three domains: 1) Challenges, 2) Strategies and Processes to address challenges, and 3) Impact. See Table 1. Members of the Patient and Family and Professional stakeholder groups as well as the investigator team will participate in the Engagement Evaluation project as part of their current roles. In addition, study investigator (Moore) and study staff (Kempthorne, Research Coordinator and Research Assistant TBD), and stakeholders (N=4) will contribute additional effort.

Table 1. Research Questions to Identify Successful Engagement Strategies for Persons with Cognitive Difficulties	
CHALLENGES	• **What were the unique and specific engagement challenges faced by individuals with brain injury and their families before and during the COVID-19 pandemic?**

	• **How do we engage equitably with stakeholders in different roles (patient, family, provider or researcher), different life stages, or different socioeconomic or cultural groups?**
STRATEGIES and PROCESSES	• **Which successful engagement strategies and processes were used by BRITE stakeholders, investigators, and study staff to address engagement challenges?** • **Which strategies addressed equitable engagement across stakeholders facing different challenges? Which strategies were effective for stakeholders in different roles, life stages, socioeconomic or cultural groups?**
IMPACT	• **How did maximizing engagement for individuals with cognitive difficulties benefit the scientific goals and protocols of the BRITE study (e.g., via the opportunity to interact with the study case managers who are working with individuals with TBI)?** • **What new engagement impacts were seen during the COVID-19 pandemic?** • **Which engagement strategies were not effective or need modification?**

To answer these questions, we will conduct semi-structured qualitative interviews or focus groups, depending on stakeholder preference, by Zoom videoconference with patient (N~5), family (N~5), professional stakeholders (N~5), and study staff and investigators (N~5) to elucidate in detail the specific engagement challenges faced at different time points throughout the study, strategies or processes used to address challenges, and what impact these strategies had on the study and on stakeholder engagement before and during the COVID-19 pandemic. We will purposively sample from our stakeholder groups to incorporate the perspectives of those from diverse regions, time since injury, age, and profession; we will continue to conduct interviews until we have reached saturation. The interview guide will be developed iteratively using the expertise of the team and will elucidate information about each of the engagement questions listed above. Interview data will be audio-recorded, transcribed, and entered into Dedoose mixed methods software for analysis (1). We will utilize thematic analysis (2) to identify common experiences as well as unique challenges and strategies that were particularly useful. We will also identify impact of these strategies. To ensure trustworthiness of the analysis, we will incorporate member checking with the stakeholder and study team groups (3), use of multiple coders, and iterative group dialogue (4). We have utilized similar methods in previous research (5-8). The main goal of the analytic process is to identify and operationalize common and innovative themes in participant responses. Those will then be incorporated into an *engagement implementation guide in an audio-visual format* to highlight the unique and specific strategies used to successfully engage and maintain engagement with BRITE stakeholders throughout the study and specifically during the COVID-19 pandemic. We anticipate creating a series of short videos and tip sheets to provide guidance on major thematic topics to improve the equitable engagement with individuals who have cognitive difficulties. We will also submit a manuscript for peer-review to a rehabilitation, trauma or TBI journal. Content of the videos and tips sheets will be focused on the target audiences including patients, families, healthcare stakeholders, providers, and researchers. We plan to disseminate the findings via collaboration with PCORI, at the national presentation at the Society of Social Work Research and via our stakeholders at the National Association of State Head Injury Administrators (NASHIA) and the Case Management Society of America (CMSA) conferences. *These products will assist other groups to successfully engage with people who have had a TBI and their families, as well as those working with others who may face similar cognitive challenges, such as those impacted by neurological disorders or intellectual and developmental disabilities.*

Table 2. Deliverables and Impact

Deliverable	Purpose	Target Audience	Impact
Engagement Implementation Guide in Audio-Visual Format	Provide guidance on equitable engagement with individuals who have cognitive difficulties using accessible format	We will create videos that target 1) patient and family stakeholders to provide strategies on how to engage when you have cognitive difficulties, 2) researchers and professional stakeholders on to	**Engagement tool for PCORI's Resource Repository focused on equitable engagement across diverse stakeholders in accessible format (video)**

		engage with individuals with cognitive difficulties in research partnership	
Creation of written material to accompany videos	Provide guidance on key practices for equitable engagement with individuals who have cognitive difficulties using simple and straightforward language	We will create written material for the target audience to summarize key points from each video	**Engagement tool for PCORI's Resource Repository focused on equitable engagement guidance available in a simple and straightforward format (summary)**
Peer Reviewed Manuscript	**Disseminate findings to professional audience**	**Researchers, Funders, Professional Stakeholders**	**Advancing shared commitment to advancing patient-centered, stakeholder-engaged research**

5. How will this work contribute to transferable knowledge for the science of engagement and the PCOR community?
The deliverables of this Engagement Evaluation project are an engagement implementation guide to improve engagement with researchers, individuals with cognitive difficulties including TBI, neurological disorders or intellectual and developmental disabilities and their family members, as well as professional stakeholders who are invested in improving the health of this population, which we plan to disseminate in an audio-visual format and a peer-reviewed manuscript in an academic journal. We anticipate creating a series of short videos featuring our stakeholders and study staff and accompanying tips sheets on major thematic topics. We anticipate that some of the content will be targeted towards researchers and professional stakeholders developing patient-centered research projects, and some will be targeted towards patient and family stakeholders engaging in this work. Developing a guide in an audio-visual format is aligned with the preferences of our patient and family stakeholders, for whom extensive written documents can be challenging. This guide will contribute to the science of patient-centered engagement in research related to TBI, neurological disorders or intellectual and developmental disabilities.

6. Provide supporting evidence of appropriate patient and stakeholder engagement to help plan your evaluation.

This proposal has been developed in collaboration with our large and diverse patient, family and professional stakeholders. The initial challenges and strategies, as well as ideas for the proposal were developed via discussion with our stakeholders at our monthly (patient and family stakeholders) and quarterly meetings (professional stakeholders). We plan to continue to collaborate with all of the stakeholders at these regular meetings at each stage of the Engagement Evaluation project, including interview guide development, interviews, analysis and member checking, and development of the engagement implementation guide. The stakeholders will be featured in the audio-visual engagement guide. In addition, four patient and family stakeholders have agreed to join the Engagement Evaluation project team to guide the research and to liaison with the larger stakeholder groups. This smaller group of stakeholders will be trained to conduct qualitative research, including foundational concepts, interviewing skills, and analysis. With guidance from the study investigators, they will participate in two half day trainings on methods and ongoing bi-monthly training and analysis sessions for the duration of the study. They will assist with developing the interview guide, conducting the interviews, identifying the themes to be featured in the implementation guide from the primary data, and conducting the member checking with the larger stakeholder groups. This Engagement Evaluation project will be stakeholder driven and the work will be completed concurrently and within the timeframe of the overall BRITE study. This proposal is also in alignment with PCORI's research priorities.

1. Dedoose Mixed Methods software: Dedoose Version **8.0.35**, web application for managing, analyzing, and presenting qualitative and mixed method research data **(2018)**. Los Angeles, CA: SocioCultural Research Consultants, LLC www.dedoose.com.
2. Thematic analysis: https://journals.sagepub.com/doi/full/10.1177/1609406917733847
3. Member checking: https://journals.sagepub.com/doi/10.1177/1049732316654870
4. Iterative group dialogue: https://methods.sagepub.com/reference/encyc-of-case-study-research/n185.xml

5. Conrick, K.M., Davis, A., Rooney, L., Bellenger, M.A., Rivara, F.P., Rowhani-Rahbar, A., Moore, M. Extreme Risk Protection Orders in Washington State: Understanding the Role of Health Professionals. (epub ahead of print.). *Journal of the Society for Social Work Research.*
6. Erlick, M.R. Vavilala, M.S., Jaffe, K.M., Blayney, C.B., Moore, M. (2021). Provider Perspectives on Early Psychosocial Interventions after Pediatric Severe Traumatic Brain Injury: an Implementation Framework. *Journal of Neurotrauma,* 38(4): 513-518.
7. Moore, M., Conrick, K.M., Reddy, A., Allen, A. & Jaffe, C. (2019). From their Perspectives: The Connection between Life Stressors and Healthcare Service Use Patterns for Homeless Frequent Users of the Emergency Department. Health and Social Work.
8. Moore, M., Cristofalo, M., Dotolo, D., Torres, N., Lahdya, A., Ho, L., …Fouts, S. (2017). When high pressure, system constraints, and a social justice mission collide: a socio-structural analysis of emergency department social work services. *Social Science and Medicine, 178,* 104-114.

Project Timeline & Milestones

7. Describe an expected timeline for this new work, by month, resulting in a final deliverable of a draft manuscript or white paper and including any relevant milestones. Please note the proposed evaluation should not increase the current project timeline.

Timeline (months) and Milestones (IRB will be submitted and approved prior to start of project)																
Month/Yr	Sept 21	Oct 21	Nov 21	Dec 21	Jan 22	Feb 22	March 22	Apr 22	May 22	June 22	July 22	Aug 22	Sept 22	Oct 22	Nov 22	Dec 22
Milestone	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
IRB Modification Submitted	X															
Development of interview guide	X															
Schedule and Conduct Interviews with Stakeholders, Staff, Investigators		X	X	X												
Data Analysis		X	X	X	X	X	X	X	X	X						
Video Production and Editing				X	X	X	X	X	X	X	X	X	X	X	X	
Creation of Tips Sheets to Accompany Videos								X	X	X	X	X	X	X		
Manuscript Preparation and Final Report												X	X	X	X	X