Study Protocol with Analysis Plan

Study Title: Enhancing the Transition From Hospital to Home
for Patients With Traumatic Brain Injury and Families

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A. SPECIFIC AIMS

Traumatic brain injury (TBI) is defined as “a bump, blow or jolt to the head or a penetrating head injury that disrupts the normal function of the brain.”[1] Each year, more than 2.7 million U.S. people sustain a TBI.[1] Despite high risks of readmission and complex medical needs, there are no U.S. standards of care for patients with moderate-to-severe TBI discharged home from acute hospital care without inpatient rehabilitation.[2] Research suggests up to 65% of patients with moderate-to-severe TBI (age < 65 years) nationwide are discharged home from acute hospital care into a fragmented environment that does not integrate healthcare, community, and social services.[3] These patients have cognitive, physical, behavioral, and emotional impairments that affect their abilities to independently self-manage their health, wellness, and activities of daily living and are often dependent on family who have difficulty managing the patient’s care and needs.[4–9]

Transitional care is defined as actions in the clinical encounter designed to ensure the coordination and continuity of healthcare for patients transferring between different locations or levels of care in close geographic proximity.[10] There are many factors that contribute to gaps in the transition from hospital to home, including inadequate planning, insufficient patient/family education, and limited and fragmented access to essential services.[11] These gaps are often compounded by limited financial resources such as lack of insurance[12] and lack of social support.[13] Transitional care interventions can address these gaps with a variety of strategies, including individualized transitional care plans, post-discharge care coordination, and community-based service referrals.[14–16] **Currently, there are no transitional care standards for TBI.** The discharge home from the hospital is an ideal intervention point to guide improvements in health and quality of life for patients with TBI and families;[10–12,16–18] however, the current state of “usual care” has limited provider support or engagement to help patients and families navigate and access fragmented health and community-based services,[19,20] is ineffective in improving functional outcomes,[21] and does not incorporate family needs.[22–24]

Thus, the purpose of our study is to develop, examine the feasibility and acceptability, and assess the preliminary efficacy of a patient- and family-centered TBI transitional care intervention to support patients with moderate-to-severe TBI and their family caregivers during the transition home from acute hospital care.

The proposed specific aims are:

> **Specific Aim 1**: **<u>To develop and refine a patient- and family-centered TBI transitional care intervention</u>.** The intervention will aim to improve functional status for patients with TBI, reduce strain for family caregivers, and direct patients and families to appropriate resources and care that is concordant with their health-related goals. We will use a combination of existing clinical guidelines, our prior and ongoing research, and a scoping review of care transitions literature to guide intervention development. We will create a manualized, intervention protocol that will undergo iterative user-testing with 6 focus groups (total 45-60 people) of patients with TBI, families, and healthcare providers to determine acceptability and to refine to ensure the intervention meets specific needs and preferences of patients with TBI and families.
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> **Specific Aim 2**: **To <u>examine the feasibility and acceptability and assess the preliminary efficacy of the TBI transitional care intervention.</u>** The intervention will be tested with 15 dyads of patients with TBI discharged home from acute hospital care and their family caregivers. Recruitment, enrollment, data collection feasibility and intervention fidelity will be used to assess feasibility of implementation. We will develop a survey to assess acceptability. Preliminary efficacy will be estimated based on changes from baseline to intervention endpoint in the primary outcome of patient functional status at 8 weeks post-discharge (using Functional Status Examination).[25] We will also examine secondary outcomes at 8 weeks post-discharge, including family caregiver strain[26] and preparedness for the caregiving role[27] and patient and family caregiver self-efficacy[28] and healthcare utilization.[29]

The proposed research is being submitted in response to NCMRR PAR-18-211 *Early Career Research Award* and directly aligns with the funding opportunity due to an early career scientist’s focus on repair and recovery of function in patients with TBI and behavioral modifications of patients with TBI and families. As directed by the funding opportunity announcement, the preliminary data generated from this proposed research will guide our team in designing and conducting an NIH R01 implementation-effectiveness clinical trial of the TBI transitional care intervention. Our team’s program of research has the potential to enhance the standard of care for patients with TBI discharged home from acute hospital care and their families.

RESEARCH STRATEGY

B. SIGNIFICANCE

Devastating Effects of TBI. Annually, more than 275,000 people sustain a moderate or severe TBI that requires hospitalization for $\geq$2 days immediately after injury.[1] For those receiving TBI acute hospital care, typical discharge destinations include inpatient rehabilitation, skilled nursing facilities, or home.[31] After acute hospital care, patients with TBI would ideally receive interdisciplinary, inpatient rehabilitation before returning home.[3] Yet, up to 65% of patients with moderate-to-severe TBI nationwide are discharged directly home from acute hospital care without inpatient rehabilitation.[3] Many patients with TBI who follow this care pathway are racial/ethnic minorities.[33] Regardless of race, these individuals often return home with residual impairments in cognition,[34] coordination and balance,[35] and awareness and judgment[3] and have increased risks for poor long-term outcomes.[36] Up to 1 year after acute hospital care discharge home, patients with TBI have significant physical, mental, and social challenges that prevent return to pre-injury levels of functioning[6]: 43% have long-term disabilities,[37] 55% become depressed,[38] and 60% never return to work.[39] As the majority of patients with moderate-to-severe TBI sustain their injury at a young age,[1] they must deal with these chronic physical, mental, and social challenges across their lifespan.[6] These poor post-acute outcomes have tremendous implications for families of patients with TBI, especially for patients who were in school or working, may not yet be financially secure, and/or have small children.[40] National data suggest TBI is also very expensive at multiple levels: the annual cost of TBI care is $76.5 billion,[1] of informal caregiving is $6.1 billion,[41] and lost productivity due to low rates of return to work equates to $521 million.[42] Recovery from TBI is a significant public health problem with harmful effects at multiple levels.

Unmet Family Needs after TBI. Family members of patients with TBI play a major role in supporting patients after discharge,[43] yet, families report 30-60% of their needs after hospital discharge go unmet[7–9] and that they feel ill-prepared to support the patient with TBI.[44,45] Family members perceive the healthcare system to be difficult to navigate, unorganized, uncaring, and unresponsive.[9,46] Research on family caregivers of patients with TBI also indicates family caregivers can have substantial unmet mental health needs.[4,47] However, there is limited knowledge on family needs during the transition from acute hospital care to home, which is needed to provide guidance on how to manage the person with TBI's care and support their family.

Gaps in Clinical Guidelines on Discharge and Follow-Up of Patients with TBI. There are gaps in clinical guidelines related to transitional care of patients with TBI, regardless of severity, discharged home from acute hospital care. Although multiple U.S. guidelines have been published on care of patients with mild, moderate, or severe TBI,[48–52] these guidelines have limited recommendations on discharge and follow up plans for supporting patients as they transition home from acute hospital care. In contrast, clinical guidelines from the United Kingdom (U.K.) do address transitional care needs related to discharge and follow-up of patients with TBI; the U.K. National Health and Care Excellence (NICE) clinical guidelines on discharge and follow-up of children, young people, and adults with head injury provide detailed guidance for healthcare providers involved in caring for patients with TBI in-hospital as they transition home or after discharge.[53] The terms head injury and TBI are often used interchangeably.[54] Although there are differences in health systems in the U.S. and the U.K., the patient population described in the U.K. NICE clinical guidelines are similar to the U.S. patients with moderate-to-severe TBI that are the focus of our study; the NICE clinical guidelines can provide a foundation for development of TBI transitional care interventions.

Limitations of Current Transitional Care Research. Effective transitional care can bring important benefits to patients and families. Transitional care interventions tested with patients with stroke, myocardial infarction, and heart failure have been effective in improving health outcomes and reducing disability and readmissions.[12,55] However, the transition needs of patients with TBI discharged home from acute hospital care and their families are thought to be unique compared to other patient populations with acute conditions due to issues with: patient cognitive functioning, complex medical needs, and limitations in activities of daily living; family difficulty in managing care; and fragmented care and services with limited provider support.[2,7,19,20,56] The few available TBI transitional care interventions were ineffective in improving functional outcomes for all patients with TBI;[21] these interventions also did not include family needs or address patient and family behavior change or self-efficacy.[21–24] In addition, the strength of evidence on TBI transitional care interventions is low due to shortcomings in study design and analysis, like: 1) lack of sufficient power to determine effectiveness[12] and 2) use of multiple primary outcomes, which increases risk of false-positive errors.[57] The transition from hospital to home after acute care is a critical period where appropriate supports and resources are necessary to increase the likelihood of successful recovery;[58] however, research indicates coordinated transitional care, supports, and resources are lacking for patients with TBI and their families.[21] Thus, new insights are needed to direct interventions to improve the TBI transition from acute hospital care to home for patients and families.

Preliminary Research Related to Transitional Care of Patients with TBI and Their Families. Our team's research provides evidence of the need for interventions to support the unique issues[12,15] of patients with TBI and families in the transition home from acute hospital care,[4,47] as well as effectiveness of transitional care interventions in improving functional status and quality of life in other patient populations.[12,15] **Table 1** summarizes the 12 studies our research team has conducted, design/analytic approaches used, and key findings. Our team's research shows patients with TBI and families could benefit from interventions during the transition home that address issues with: 1) patient safety, independence, cognition, and communication; 2) management of the patient's mental health, overall health and wellness, and medications; 3) family needs; 4) access to community resources; and 5) behavior change and health-related goal activation. However, we have not yet developed or assessed the feasibility, acceptability, or preliminary efficacy of a transitional care intervention that addresses the above-listed areas, and research is limited on these topics.

Table 1. Our Research Team's Preliminary Research that Informs the Proposed Study

Study Name	Team Member	Design/Approach	Key Findings
Mental health in women with TBI[59]	Dr. Oyesanya (PI of R03)	Systematic literature review	Although being female is a risk factor for mental health issues, there is limited literature on sex-based disparities in mental health after TBI.
Hospital experience for patients and families[60]	Dr. Oyesanya (PI of R03)	Systematic literature review	Studies showed during the hospital stay, patients with ABI and families had a high need for information, difficulty adjusting, a desire to be prepared for life after discharge, and mixed feelings on staff support.
Role of families in the TBI hospital stay[61,62]	Dr. Oyesanya (PI of R03)	Qualitative: Grounded Theory	*N=16.* Families of patients with TBI perceived their role pre-discharge was to protect the patient's emotional and physical safety and had concerns about the patient's post-discharge independence.
Patient/family health, wellness, & safety[63,64]	Dr. Oyesanya (PI of R03)	Qualitative: content analysis	*N=27.* Patients with TBI and families had a desire for provider support early post-discharge to manage mental health, overall health and wellness, medications, and patient safety.
Med. Management intervention[65]	Dr. Oyesanya (PI of R03)	Experimental design	*N=205.* Patients with ABI and families in the treatment group had increased knowledge and confidence after educational intervention but had difficulty managing medications at 60-days post-discharge.
Nurses' perceptions of caring for TBI[66–70]	Dr. Oyesanya (PI of R03)	Instrument + latent class analysis	*N=713.* 1) Instrument is reliable/valid for assessing nurses' perceptions of TBI care; and 2) Nurses had inaccurate perceptions and little knowledge of post-discharge resources for patients with TBI & families.
Consensus on provider discharge criteria [71]	Dr. Oyesanya (PI of R03)	Survey research, descriptive	*N=27.* Criteria with majority consensus providers use to determine if a patient with TBI should go home from acute hospital care: 1) therapist recommendations (N=26); 2) plans for post-discharge family support (N=25); and 3) patient independence in activities of daily living (N=23).
Transition of care for acute stroke and MI[12]	Dr. Bettger (Co-I of R03)	Systematic literature review	Studies showed hospital-initiated transitional care can improve some outcomes in adults with stroke or MI. More interventions are needed that improve function and prevent readmissions for this patient group. The Transition of Care Taxonomy was also developed in this study, which describes the 8 domains of a transitional care intervention.
Interventions for caregivers of patients with TBI[4]	Dr. Van Houtven (Co-I of R03)	Systematic literature review	Studies showed mixed patterns of intervention effects on caregiver and patient outcomes; strength of evidence ranged from moderate to very low and intervention impact is inconclusive.
Neural correlates of personal goal activation[72]	Dr. Strauman (Co-I of R03)	Event-related fMRI design	*N = 75.* Participants rapidly exposed to their self-identified goals had significant neural activation compared to exposure to yoked-control words. Findings extend understanding of how goals influence behavior.
Cognitive performance of adults with TBI[56]	Dr. Byom (Co-I of R03)	Experimental design	*N = 44.* Adults with TBI compared to matched healthy peers demonstrated social communication and discourse impairments that were influenced by the cognitive demands of the communication task.
Social communication of adults with TBI[73]	Dr. Byom (Co-I of R03)	Systematic literature review	Communication needs of adults with TBI should be prioritized and assessment approaches should be contextual and feasible.

Abbreviations: TBI = traumatic brain injury; ABI = acquired brain injury; med = medication; MI = myocardial infarction

Ongoing Research Related to TBI Transitional Care. Dr. Oyesanya (PI of R03) is currently PI of an ongoing pilot award [co-investigator Dr. Bettger] funded by Duke School of Nursing. The aim of the study is to obtain perspectives of patients with TBI, families, and providers on needs and goals during the transition from acute hospital care to home. Findings will inform development of the TBI transitional care intervention. Dr. Bettger is currently co-investigator of the Comprehensive Post-Acute Stroke Services (COMPASS) study, a 40-site pragmatic trial funded by PCORI to assess the effectiveness of a comprehensive, evidence-based, post-acute care model on patient-centered outcomes for patients with stroke.[16] Patients with stroke discharged from intervention hospitals receive a 2-day telephone follow-up; a comprehensive clinic visit within 2 weeks that includes a neurological evaluation; assessments of social and functional determinants of health; and an individualized care plan integrated with community-specific resources. Findings from Dr. Bettger's study will be used to inform the patient-centered portion of the TBI transitional care intervention. Dr. Byom is currently PI of a retrospective study of factors contributing to cognitive-communication needs of adults with TBI. Findings will inform the patient-centered cognitive, communication, and social aspects of the TBI transitional care intervention. Dr. Van Houtven is currently PI of HI-FIVES, an evidence-based skills training program for family caregivers of veterans referred to home care services, funded by a VA HSR&D grant, which is currently undergoing an 8-site RCT. HI-FIVES includes group classes for family caregivers to learn clinical, psychological, and support-seeking skills to improve caregiver functioning. Findings from Dr. Van Houtven's study will inform the family-centered key processes of the TBI transitional care intervention.

Impact of Proposed Research. Despite advances in transitional care, we are without data to inform development and testing of a TBI transitional care intervention that addresses specific needs and preferences of patients with TBI discharged home from acute hospital care and their family caregivers. Input from patients, families, and providers on the acceptability of an intervention of this nature is critical, as is data on the intervention's feasibility and preliminary efficacy. With this proposed work, by 2021, we will have assessed the feasibility, acceptability, and preliminary efficacy of a TBI transitional care intervention that aims to improve patient functional status, decrease caregiver strain, and direct patients and families to appropriate resources and care that is concordant with their health-related goals.

C. INNOVATION

Our proposed work aims to develop a transitional care intervention to improve patient functional status and decrease caregiver strain. This research is novel as very little transitional care research addresses functional status or incorporates the needs of family caregivers. In addition, there is low strength of evidence for transitional care interventions to support patients with TBI discharged home from acute hospital care and families; our research aims to address the unique needs and preferences of this patient population. Finally, this study seeks to shift the paradigm of how care is provided to patients with TBI and families as they transition home, from interventions that separately focus on discharge preparation or on community needs to interventions that optimize and coordinate pre- and post-discharge care and needs to enhance care continuity.

E. APPROACH

Setting and Population. All patients with TBI meeting inclusion criteria admitted to Duke University Hospital (DUH) neuro units 8W and 4100 and the 6 DUH medical-surgical/trauma units will be invited to participate in studies for aim 1 and 2. Collaborators on this award, Dr. Jodi Hawes, MD, neurologist and Vice Chair of Neurology Clinical Operations and Dr. Suresh Agarwal, MD, trauma surgeon and Chief of Trauma and Critical Care Surgery, have agreed to facilitate recruitment from their respective areas (see letters of support).

Inclusion Criteria. Patients with TBI will be eligible if they meet the following requirements: a) age 18-64 years; b) diagnosed with moderate or severe TBI [admission Glasgow Coma Scale score of 3-12];[74] c) admitted to a DUH inpatient unit; d) plans to be discharged home from DUH; e) sufficient cognitive functioning to participate (i.e., able to follow 2-step commands), as determined by the Galveston Orientation and Amnesia Test (score $\geq$76 eligible);[75] f) sufficient oral communication skills to participate, as determined by the Bedside Western Aphasia Battery-Revised (score $\geq$93.8 eligible);[76] and g) English speaking (see Appendix A). Dr. Oyesanya has successfully interviewed patients with TBI pre- and post-discharge with these criteria.[61,62] Family members of patients with TBI will include biological relatives and friends[77] and are eligible if they: a) are an anticipated primary caregiver after discharge (i.e., plans to live in same home as person *or* have direct contact with person $\geq$10 hours/week);[78] b) age $\geq$18; and c) English speaking. Healthcare providers will be eligible if they: a) self-identify as a licensed provider and b) provide care to patients with TBI during the transition home (in hospital or within 8 weeks of discharge). All participants must be able to consent to participate.

Sample Size Justification (Aim 1 and 2). In Aim 1, we selected 45 to 60 total participants across 6 focus groups, guided by stage 1 of the NIH Stage Model for Intervention Development guidelines of including 15-30 participants per interviewee group (i.e., patients with TBI, family caregivers, providers).[79] In accordance with historical qualitative research, we will hold $\geq$3 focus groups, each with 6-10 participants, to yield rich data.[80] For Aim 2, we propose a reasonable sample size so we can sufficiently assess feasibility, acceptability, and preliminary efficacy of the intervention by using the rule of thumb of at least 12 participants per group for pilot studies.[81] Our desired sample size for Aim 2 is 30 total participants (15 patient/family dyads) who complete the full intervention. Based on prospective TBI studies with follow up to one year, attrition can be up to 33% attrition.[5] To be conservative, we plan to enroll 40 total participants (20 patient/family dyads), expecting 33% attrition, to reach our desired sample size of 30 total participants (15 patient/family dyads). We will recruit males and females and racial/ethnic minorities to explore sex- and racial/ethnicity-based differences. In 2018, DUH admitted 663 patients with TBI and discharged 380 patients with moderate-to-severe TBI (age < 65 years) home from acute hospital care.[82] Based on DUH estimates, a similar number should receive care annually.[82] Typical recruitment of persons with TBI is ≥50%,[83] leaving ≥190 patients/year and ≥15 patients/month to recruit. DUH does not collect family data, but research suggests family recruitment is ≥50%.[83] Dr. Oyesanya's research shows pre-discharge recruitment of patients with TBI and family caregivers in another hospital system was ≥60%.[61,62] DUH also employs ≥100 healthcare providers that care for patients with TBI during the transition (in the hospital or within 8 weeks of hospital discharge) for recruitment.[82]

Recruitment and Informed Consent (Aim 1 and 2). DUH staff identified by clinical leaders specified above will identify eligible patients with TBI, family members, and healthcare providers and ask if the PI or research assistant may discuss the study with them.[84] The PI or research assistant will then meet with the potential participant to inform them about the study. If the potential participant is interested in participating in the study, the PI or research assistant will walk the participant through the informed consent, clearly explaining the study purpose and planned activities and will answer all questions. Finally, the PI or research assistant will obtain a signed informed consent and will provide the participant with a copy for their own records. The primary threat to attrition in this study is loss to follow-up.[83] To reduce and prevent attrition, participants will receive $15 each after completion of each interview and each data collection time point.

Aim 1 Study Overview. We will use a combination of existing clinical guidelines, our prior and ongoing research, and a scoping review of care transitions literature to guide intervention development. Potential intervention components are described below in the section titled "Developing the Intervention (Aim 1)." We will create a manualized intervention protocol, which we will then refine with focus groups with patients with TBI, families, and healthcare providers. A trained research assistant will assist with intervention development and refinement. Intervention development (3 months) and refinement (6 months) will take 9 total months.

Description of U.K.'s NICE Clinical Guidelines on Discharge and Follow-Up of Patients with TBI. We will use the U.K. NICE clinical guidelines specific to discharge and follow-up of children, young people, and adults with head injury[53] as a guide for developing our TBI transitional care intervention. The U.K. NICE clinical guidelines were initially developed for patients with head injury discharged home from the emergency department or observation wards (also known as an inpatient units) without inpatient rehabilitation.[53] We elected to use the U.K. NICE clinical guidelines as our guide for development of our intervention because limited U.S. clinical guidelines on discharge and follow up exist for patients with TBI. The U.K. NICE clinical guidelines provide 7 recommendations for healthcare providers to follow when discharging patients with head injury home and providing subsequent follow up, listed in **Table 2**. The recommendations of the U.K. NICE clinical guidelines will serve as intervention components and as guidelines for intervention development.

Table 2. Recommendations on discharge and follow up of patients with head injury from U.K. NICE clinical guidelines[53]

Recommendations
1. Give verbal and printed age-appropriate discharge advice to patients with any degree of head injury who are discharged from an emergency department or observation ward, and their families and carers.
2. Offer information and advice on alcohol or drug misuse to patients who presented to the emergency department with drug or alcohol intoxication when they are fit for discharge.
3. Inform patients and their families and carers about the possibility of persistent or delayed symptoms following head injury and whom to contact if they experience ongoing problems.
4. For all patients who have attended the emergency department with a head injury, write to their GP [general practitioner] within 48 hours of discharge, giving details of clinical history and examination and provide a copy of the letter for the patient and their family.
5. All patients with any degree of head injury should only be transferred to their home if it is certain that there is somebody suitable at home to supervise the patient. If no carer is at home, discharge only if suitable supervision arrangements have been organized.
6. When a patient who has undergone imaging of the head and/or been admitted to hospital experiences persisting problems, refer from primary care to an outpatient appointment with a professional trained in assessment and management of brain injury.
7. Patients who return to an emergency department within 48 hours of transfer to the community with any persistent complaint relating to the initial head injury should be seen by or discussed with a senior clinician experienced in head injuries, and considered for a CT scan.

Developing the Intervention (Aim 1). We will first use the NICE clinical guidelines[53] as a starting point to develop our TBI transitional care intervention. Then, we will combine our prior and ongoing research and a scoping review of care transitions literature to guide intervention development. Our prior research indicates that patients with TBI and their families could benefit from a transitional care intervention that addresses issues with: 1) patient safety, independence, cognition, and communication; 2) management of the patient's mental health, overall health and wellness, and medications; 3) family needs; 4) access to community resources; and 5) behavior change and health-related goal activation. The intervention will be built to address these issues. In addition, the AHRQ funded evidenced synthesis generated the Transition of Care Taxonomy, a framework describing 8 domains of transitional care interventions[12] developed by Dr. Bettger (co-investigator) and colleagues, will be used to guide intervention development. **Table 3** lists the Taxonomy domains with pre-selected components for our intervention (based on our prior/ongoing research). It is important to note that, to date, clinical guidelines and research (such as that of the NICE guidelines[53] and Transition of Care Taxonomy[12]) address system structural components and processes but does little to explore behavioral mechanisms that empower families and patients to follow-through with training and treatment plans. Drawing on Dr. Strauman's (co-investigator) expertise in behavioral modifications, the intervention we develop will incorporate behavioral change mechanisms to increase the likelihood that patients and families follow-through with training and treatment plans. <u>The intervention's key processes will aim to improve patient functional status, caregiver strain, and to direct patients and families to appropriate resources and care that is concordant with their health-related goals.</u> We will create a manualized, intervention protocol, which will take 3 months.

Refining the Intervention (Aim 1). The manualized intervention protocol will undergo iterative user-testing to determine acceptability.[85] The 6 focus groups (6-10 participants each) will use a stratified, purposive sample to obtain informational representation.[86] Focus groups will be organized concordantly based on insurance status and group membership (patient, family, or healthcare provider). We will have one group with patients with TBI and family members with insurance and one group without; one group with only patients with TBI and one group with only family members; one group with healthcare providers who care for patients in hospital and one group with healthcare providers who care for patients with TBI after discharge. Individual interviews will be used if availability for a focus group becomes challenging. At each focus group, we will talk through the protocol and describe and show what the intervention could entail.[87] We will ask participants to discuss if intervention components address their transition needs and goals (discharge process and first months at home) and components that are missing or need revision.[87] We will also explore individual, cultural, and social factors that may influence transition needs such as individual experiences in the clinical encounter; cultural beliefs about healthcare, interaction with providers, and communication preferences; and social determinants such as economic stability after TBI, neighborhood environment, community resources, and access to post-TBI education, training, and providers. We will also establish, from the perspectives of the patients and families, additional secondary outcomes that matter the most to them. At the completion of the focus group, participants will complete a demographic questionnaire (Appendix B), including questions about age, sex, race/ethnicity, and education and employment; patients and families will also answer questions about the patient's injury cause and date, health insurance status, self-identified social economic status, pre- and post-injury living arrangements, and post-discharge support. Each focus group will be 90 minutes long.

Table 3. Transition of Care Taxonomy (TCT) Domains and Intervention Components

TCT Domain	Pre-selected Components
Transition Type	Acute hospital to home
Model Type	Hospital-initiated
Recipient(s)	Patient and family caregiver
Key Transitional Care Processes	Assessment of needs, patient/family education, goal setting, care coordination, referral to resources, and individualized care plan
Intervention Facilitators	Multi-disciplinary team (e.g., nurse, case manager/social worker, therapists, mental health counselor)
Contact Method	In-person home visit, clinic visit, and phone calls
Intensity and Complexity	In-person home visit 7 days post-discharge, weekly calls, and comprehensive clinic visit at 2 weeks post-discharge
Outcomes	Patient, proxy-, and family-reported outcomes (see Aim 1 and 2)

Dr. Oyesanya (PI of R03) is a qualitative expert with over 10 years' of experience in qualitative research methodologies and data collection, including conducting focus groups and analyzing focus group data. She will conduct all focus groups and analyze all qualitative data with assistance of a trained research assistant. The focus groups will be audio recorded and transcribed verbatim. Qualitative data from the focus groups will be analyzed using directed content analysis. Directed content analysis is defined as using existing research to confirm, validate, or extend knowledge in an area where more research is needed.[88] With directed content analysis, prior research on the needs and goals of persons with TBI discharged home from acute hospital care and their family caregivers[7,8,89–91] will be used as a starting point to provide our team with a structure of key concepts to use as initial categories of focus during data analysis, which will be our pre-determined codes.[88] Dr. Oyesanya and the research assistant will begin coding, highlighting data relevant to our pre-determined codes,[88] which will be our categories. Any data that does not fit with our pre-determined codes will be identified and analyzed to determine if it represents a new category, or a subcategory of an existing code, called a newly identified code.[88] Dr. Oyesanya and the research assistant will first code independently and then will meet weekly to compare coding and discuss any discrepancies in codes until agreement is met.[88] Dr. Oyesanya and the research assistant will keep all codes, their definitions, and corresponding quotation exemplars in a codebook.[88] The analysis will integrate all participants' perspectives, including analyzing patient and family member data together (where available) and incorporating healthcare providers' perspectives.[92] Findings from the focus group will be used to refine the intervention. Intervention refinement will take 6 months.

Aim 2 Study Overview. A research assistant will recruit, consent, and enroll 15 dyads of patients with TBI set to be discharged home from Duke University Hospital and their families to determine feasibility, acceptability, and preliminary efficacy of the TBI transitional care intervention. The intervention will be delivered by a multi-disciplinary team. Data will be collected at baseline (discharge), intervention midpoint (4 weeks post-discharge) and intervention endpoint (8 weeks post-discharge). The research assistant will assist with recruitment, consent, enrollment, and data collection. Assessing the feasibility, acceptability, and preliminary efficacy of the intervention will take 15 months.

Aim 2 Data Collection for Feasibility, Acceptability, and Preliminary Efficacy. Recruitment, enrollment, and data collection feasibility and intervention fidelity will be used to assess feasibility of implementation of the TBI transitional care intervention. For recruitment feasibility, the research assistant will record the number of patients and family caregivers eligible vs. number of patients and families consented to participate. For enrollment feasibility, the research assistant will record the number of patients and family caregivers eligible, consented, and enrolled into the intervention. For data collection feasibility, the research assistant will obtain in-person baseline data from patients with TBI up to 48 hours before discharge and will also obtain baseline data from family caregivers in person or by phone depending on availability. At 4- and 8-weeks post-discharge, the research assistant will call patients and families to obtain follow-up data. The research assistant will record for each follow up time point: 1) number of patients and family members called and reached; 2) number of call attempts per patient and family member; 3) number of patients and family members reached but unable to provide information; 4) completeness of data collected; 5) length of phone call; and 6) day of week and time of day patients and family members participated. Fidelity will be assessed by recording all components of the intervention delivered to each patient and family caregiver. Our team will review recruitment and follow-up rates weekly and identify strategies to improve recruitment, enrollment, and data collection. We will assess acceptability of the intervention using a survey we develop. The outcome data we collect will be used to assess preliminary efficacy. To assess the preliminary efficacy of the intervention, we will collect data on our primary outcome [patient functional status (Functional Status Examination)[25]]. Secondary outcomes for family caregivers will include caregiver strain (Modified Caregiver Strain Index[26]) and preparedness for the caregiver role (Preparedness for Caregiving Scale[27]); secondary outcomes for patients and family caregivers will include self-efficacy (Self-Efficacy for Management of Chronic Conditions[28]) and health service utilization (Health Service Utilization Inventory[29]).

Aim 2 Analysis Plan. All statistical analyses will be conducted by Dr. Yang who is co-investigator on this award and a statistician. We will use descriptive statistics to assess all feasibility data. Preliminary efficacy will be evaluated based on changes from baseline to intervention endpoint for primary and secondary outcomes. We will estimate the variance of the change in all outcomes and estimate the effect size of the intervention using Cohen's D.[93] We will estimate missing data and dropout rate at each time point based on these preliminary data. Combined with our clinical judgements, this information will provide important insights in proposing a clinical meaningful effect size to guide sample size calculation for our future R01 where we will conduct a full scale intervention RCT to formally establish the intervention effectiveness.

Potential Problems and Solutions. We recognize some patients with TBI may not have sufficient cognitive functioning at the time of discharge or within 8 weeks post-discharge. Thus, we have built in multiple opportunities to collect data from family caregivers of patients with TBI in Aim 1 and 2 to ensure we have collected, at the very least, family members' perspectives to inform intervention development and refinement (Aim 1) and assessment of the feasibility, acceptability, and preliminary efficacy of the intervention (Aim 2).

Timeline and Milestones (Table 4). Prior to beginning this award, we will obtain IRB approval and hire and train study staff. We will complete Aim 1 by third-quarter year 1 and Aim 2 by end-year 2.

Table 4. Timeline of Proposed Two-Year R03 Award

	Pre	Year 1				Year 2			
Study Activities	Pre	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Start up (e.g., IRB, hire & train study staff)	▨								
Develop intervention protocol (Aim 1)		▨							
Refine intervention (Aim 1)			▨	▨					
Test intervention (Aim 2)					▨	▨	▨	▨	▨

Significance and Future Research. Findings from the proposed research will provide us with new knowledge useful for informing intervention research on transitional support of patients with moderate-to-severe TBI discharged home from acute hospital care and families.[94] Our 5-year goal is to have developed and tested the feasibility, acceptability, and preliminary efficacy (with this R03) and the implementation-effectiveness (with a future R01) of an intervention that will ultimately shift the standard of care for patients with moderate-to-severe TBI and their families during the transition home from acute hospital care.

REFERENCES

1. Centers for Disease Control and Prevention. TBI data and statistics. Published 2019. https://www.cdc.gov/traumaticbraininjury/data/index.html

2. Turner B, Fleming JM, Ownsworth TL, Cornwell PL. The transition from hospital to home for individuals with acquired brain injury: A literature review and research recommendations. *Disabil Rehabil*. 2008;30(16):1153-1176.

3. Cuthbert JP, Corrigan JD, Harrison-Felix C, Coronado V, Dijkers MP, Heinemann AW, Whiteneck GG. Factors that predict acute hospitalization discharge disposition for adults with moderate to severe traumatic brain injury. *Arch Phys Med Rehabil*. 2011;92(5):721-730.e3. doi:10.1016/j.apmr.2010.12.023

4. Shepherd-Banigan ME, Shapiro A, McDuffie JR, Brancu M, Sperber NR, Van Houtven CH, Kosinski AS, Mehta NN, Nagi A, Williams JW. Interventions that support or involve caregivers or families of patients with traumatic injury: A systematic review. *J Gen Intern Med*. Published online 2018:1-10.

5. Cappa KA, Conger JC, Conger AJ. Injury severity and outcome: A meta-analysis of prospective studies on TBI outcome. *Health Psychol*. 2011;30(5):542.

6. Corrigan JD, Hammond FM. Traumatic brain injury as a chronic health condition. *Arch Phys Med Rehabil*. 2013;94(6):1199-1201. doi:10.1016/j.apmr.2013.01.023

7. Pickelsimer EE, Selassie AW, Sample PL, Heinemann AW, Gu JK, Veldheer LC. Unmet service needs of persons with traumatic brain injury. *J Head Trauma Rehabil*. 2007;22(1):1-13.

8. Heinemann AW, Sokol K, Garvin L, Bode RK. Measuring unmet needs and services among persons with traumatic brain injury. *Arch Phys Med Rehabil*. 2002;83(8):1052-1059.

9. Turner BJ, Fleming J, Ownsworth T, Cornwell P. Perceived service and support needs during transition from hospital to home following acquired brain injury. *Disabil Rehabil*. 2011;33(10):818-829.

10. Coleman EA. Falling through the cracks: Challenges and opportunities for improving transitional care for persons with continuous complex care needs. *J Am Geriatr Soc*. 2003;51(4):549-555.

11. Naylor M, Keating SA. Transitional care. *J Soc Work Educ*. 2008;44(sup3):65-73.

12. Bettger JP, Alexander KP, Dolor RJ, Olson DM, Kendrick AS, Wing L, Coeytaux RR, Graffagnino C, Duncan PW. Transitional care after hospitalization for acute stroke or myocardial infarction: A systematic review. *Ann Intern Med*. 2012;157(6):407-416.

13. Caplan B, Bogner J, Brenner L, Manskow US, Sigurdardottir S, Røe C, Andelic N, Skandsen T, Damsg\a ard E, Elmst\a ahl S. Factors affecting caregiver burden 1 year after severe traumatic brain injury: A prospective nationwide multicenter study. *J Head Trauma Rehabil*. 2015;30(6):411-423.

14. Naylor MD, Sochalski JA. Scaling up: Bringing the transitional care model into the mainstream. *Commonw Fund*. 2010;103(11):1-12.

15. Olson DM, Bettger JP, Alexander KP, Kendrick AS, Irvine JR, Wing L, Coeytaux RR, Dolor RJ, Duncan PW, Graffagnino C. Transition of care for acute stroke and myocardial infarction patients: From hospitalization to rehabilitation, recovery, and secondary prevention. *Evid ReportTechnology Assess*. 2011;(202):1.

16. Duncan PW, Bushnell CD, Rosamond WD, Berkeley SBJ, Gesell SB, D'Agostino RB, Ambrosius WT, Barton-Percival B, Bettger JP, Coleman SW. The Comprehensive Post-Acute Stroke Services (COMPASS) study: Design and methods for a cluster-randomized pragmatic trial. *BMC Neurol*. 2017;17(1):133.

17. McPherson K, Fadyl J, Theadom A, Channon A, Levack W, Starkey N, Wilkinson-Meyers L, Kayes N, Group TER. Living life after traumatic brain injury: Phase 1 of a longitudinal qualitative study. *J Head Trauma Rehabil*. 2018;33(1):E44-E52.

18. Koehmstedt C, Lydick SE, Patel D, Cai X, Garfinkel S, Weinstein AA. Health status, difficulties, and desired health information and services for veterans with traumatic brain injuries and their caregivers: A qualitative investigation. *PLoS ONE*. 2018;13(9):e0203804.

19. Nalder E, Fleming J, Foster M, Cornwell P, Shields C, Khan A. Identifying factors associated with perceived success in the transition from hospital to home after brain injury. *J Head Trauma Rehabil*. 2012;27(2):143-153.

20. Turner B, Fleming J, Cornwell P, Worrall L, Ownsworth T, Haines T, Kendall M, Chenoweth L. A qualitative study of the transition from hospital to home for individuals with acquired brain injury and their family caregivers. *Brain Inj*. 2007;21(11):1119-1130.

21. Bell KR, Temkin NR, Esselman PC, Doctor JN, Bombardier CH, Fraser RT, Hoffman JM, Powell JM, Dikmen S. The effect of a scheduled telephone intervention on outcome after moderate to severe traumatic brain injury: A randomized trial. *Arch Phys Med Rehabil*. 2005;86(5):851-856.

22. Salazar AM, Warden DL, Schwab K, Spector J, Braverman S, Walter J, Cole R, Rosner MM, Martin EM, Ecklund J. Cognitive rehabilitation for traumatic brain injury: A randomized trial. *JAMA*. 2000;283(23):3075-3081.

23. Martin EM, Coyle MK, Warden DL, Salazar A. Telephonic Nursing in Traumatic Brain Injury: A study shows the effect of psychiatric nurses. *Am J Nurs*. 2003;103(10):75-76.

24. Rosario ER, Espinoza L, Kaplan S, Khonsari S, Thurndyke E, Bustos M, Vickers K, Navarro B, Scudder B. Patient navigation for traumatic brain injury promotes community re-integration and reduces re-hospitalizations. *Brain Inj*. 2017;31(10):1340-1347.

25. Machamer J, Temkin NR, Manley GT, Dikmen S. Functional Status Examination in Patients with Moderate-to-Severe Traumatic Brain Injuries. *J Neurotrauma*. 2018;35(10):1132-1137.

26. Thornton M, Travis SS. Analysis of the reliability of the modified caregiver strain index. *J Gerontol B Psychol Sci Soc Sci*. 2003;58(2):S127-S132.

27. Pucciarelli G, Savini S, Byun E, Simeone S, Barbaranelli C, Vela RJ, Alvaro R, Vellone E. Psychometric properties of the Caregiver Preparedness Scale in caregivers of stroke survivors. *Heart Lung J Acute Crit Care*. 2014;43(6):555-560.

28. Lorig KR, Sobel DS, Ritter PL, Laurent D, Hobbs M. Effect of a self-management program on patients with chronic disease. *Eff Clin Pract ECP*. 2001;4(6):256-262.

29. Browne G, Gafni A, Roberts J. Approach to the measurement of costs (expenditures) when evaluating health and social programmes. *Hamilt Syst-Linked Res Unit McMaster Univ*. Published online 2002.

30. Faul M, Xu L, Wald M, Coronado V. *Traumatic Brain Injury in the United States: Emergency Department Visits, Hospitalizations and Deaths 2002–2006.* Centers for Disease Control and Prevention, National Center for Injury Prevention and Control; 2010.

31. Schumacher R, Walder B, Delhumeau C, Müri RM. Predictors of inpatient (neuro) rehabilitation after acute care of severe traumatic brain injury: An epidemiological study. *Brain Inj*. 2016;30(10):1186-1193.

32. de Koning ME, Spikman JM, Coers A, Schönherr MC, van der Naalt J. Pathways of care the first year after moderate and severe traumatic brain injury—Discharge destinations and outpatient follow-up. *Brain Inj*. 2015;29(4):423-429.

33. Arango-Lasprilla JC, Kreutzer JS. Racial and ethnic disparities in functional, psychosocial, and neurobehavioral outcomes after brain injury. *J Head Trauma Rehabil*. 2010;25(2):128-136.

34. Silver JM, McAllister TW, Arciniegas DB. Depression and cognitive complaints following mild traumatic brain injury. *Am J Psychiatry*. 2009;166(6):653-661.

35. Walker WC, Pickett TC. Motor impairment after severe traumatic brain injury: A longitudinal multicenter study. *J Rehabil Res Dev*. 2007;44(7):975.

36. Mellick D, Gerhart KA, Whiteneck GG. Understanding outcomes based on the post-acute hospitalization pathways followed by persons with traumatic brain injury. *Brain Inj*. 2003;17(1):55-71.

37. Selassie AW, Zaloshnja E, Langlois JA, Miller T, Jones P, Steiner C. Incidence of long-term disability following traumatic brain injury hospitalization, United States, 2003. *J Head Trauma Rehabil*. 2008;23(2):123-131.

38. Singh R, Mason S, Lecky F, Dawson J. Prevalence of depression after TBI in a prospective cohort: The SHEFBIT study. *Brain Inj*. 2018;32(1):84-90.

39. Van Velzen JM, Van Bennekom CAM, Edelaar MJA, Sluiter JK, Frings-Dresen MHW. How many people return to work after acquired brain injury?: A systematic review. *Brain Inj*. 2009;23(6):473-488.

40. Wongvatunyu S, Porter EJ. Mothers' experience of helping young adults with traumatic brain injury. *J Nurs Scholarsh*. 2005;37(1):48-56.

41. Hickenbottom SL, Fendrick AM, Kutcher JS, Kabeto MU, Katz SJ, Langa KM. A national study of the quantity and cost of informal caregiving for the elderly with stroke. *Neurology*. 2002;58(12):1754-1759.

42. Humphreys I, Wood RL, Phillips CJ, Macey S. The costs of traumatic brain injury: A literature review. *Clin Outcomes Res CEOR*. 2013;5:281.

43. Kreutzer JS, Stejskal TM, Godwin EE, Powell VD, Arango-Lasprilla JC. A mixed methods evaluation of the Brain Injury Family Intervention. *NeuroRehabilitation*. 2010;27(1):19-29.

44. Lefebvre H, Levert MJ. The close relatives of people who have had a traumatic brain injury and their special needs. *Brain Inj*. 2012;26(9):1084-1097.

45. Saban KL, Hogan NS, Hogan TP, Pape TLB. He looks normal but… Challenges of family caregivers of veterans diagnosed with a traumatic brain injury. *Rehabil Nurs*. 2015;40(5):277-285.

46. Graff HJ, Christensen U, Poulsen I, Egerod I. Patient perspectives on navigating the field of traumatic brain injury rehabilitation: A qualitative thematic analysis. *Disabil Rehabil*. 2018;40(8):926-934.

47. Van Houtven CH, Smith VA, Stechuchak KM, Shepherd-Banigan M, Hastings SN, Maciejewski ML, Wieland GD, Olsen MK, Miller KE, Kabat M. Comprehensive support for family caregivers: Impact on veteran health care utilization and costs. *Med Care Res Rev*. Published online 2017:1077558717697015.

48. American Association of Neuroscience Nurses. Nursing management of adults with severe traumatic brain injury. Published online 2008. http://www.aann.org/pdf/cpg/aanntraumaticbraininjury.pdf

49. Carney N, Totten AM, O'reilly C, Ullman JS, Hawryluk GW, Bell MJ, Bratton SL, Chesnut R, Harris OA, Kissoon N. Guidelines for the management of severe traumatic brain injury. *Neurosurgery*. 2017;80(1):6-15.

50. Department of Veterans Affairs. Polytrauma systems of care. In: *VHA Handbook 1172.01*. Veterans Health Administration; 2013.

51. Haddad SH, Arabi YM. Critical care management of severe traumatic brain injury in adults. *Scand J Trauma Resusc Emerg Med*. 2012;20(1):12.

52. Joint Theater Trauma System. Clinical Practice Guideline: Management of patients with severe head trauma. Published online 2014. http://www.usaisr.amedd.army.mil/cpgs/Mgmt_of_Patients_with_Severe_Head_Injury_16Jun2014.pdf

53. National Health and Care Excellence Clinical Guidelines. *Discharge and Follow-up of Children, Young People, and Adults with Head Injury*. National Institute for Health and Care Excellence (UK); 2014. Accessed March 21, 2019. https://www.ncbi.nlm.nih.gov/books/NBK332976/

54. Pushkarna A, Bhatoe HS, Sudambrekar SM. Head injuries. *Med J Armed Forces India*. 2010;66(4):321-324.

55. Feltner C, Jones CD, Cené CW, Zheng ZJ, Sueta CA, Coker-Schwimmer EJ, Arvanitis M, Lohr KN, Middleton JC, Jonas DE. Transitional care interventions to prevent readmissions for persons with heart failure: A systematic review and meta-analysis. *Ann Intern Med*. 2014;160(11):774-784.

56. Byom L, Turkstra LS. Cognitive task demands and discourse performance after traumatic brain injury. *Int J Lang Commun Disord*. 2017;52(4):501-513.

57. Andrade C. The primary outcome measure and its importance in clinical trials. *J Clin Psychiatry*. 2015;76(10):1320-1323.

58. Naylor MD, Aiken LH, Kurtzman ET, Olds DM, Hirschman KB. The importance of transitional care in achieving health reform. *Health Aff (Millwood)*. 2011;30(4):746-754.

59. Oyesanya TO, Ward EC. Mental health in women with traumatic brain injury: A systematic review on depression and hope. *Health Care Women Int*. 2015;37(1):45-74. doi:10.1080/07399332.2015.1005307

60. Oyesanya TO. The experience of patients with ABI and their families during the hospital stay: A systematic review of qualitative literature. *Brain Inj*. 2017;31(2):151-173. doi:10.1080/02699052.2016.1225987

61. Oyesanya TO, Bowers BJ. “I’m trying to be the safety net”: Family protection of patients with moderate-to-severe TBI during the hospital stay. *Qual Health Res*. 2017;27(12):1804-1815. doi:10.1177/1049732317697098

62. Oyesanya TO, Bowers B. Managing visitors during the hospital stay: The experience of family caregivers of patients with traumatic brain injury. *J Fam Nurs*. 2017;23(2):273-298. doi:10.1177/1074840717697673

63. Oyesanya TO, Arulselvam K, Thompson N, Norelli J, Seel RT. Health, wellness, and safety concerns of persons with TBI and their family caregivers: A qualitative content analysis. *Disabil Rehabil*. Published online 2019. doi:10.1080/09638288.2019.1638456

64. Oyesanya TO, Thompson N, Arulselvam K, Seel RT. Technology and TBI: Perspectives of persons with TBI and their family caregivers on technology solutions to address health, wellness, and safety concerns. *Assist Technol*. Published online 2019. doi:10.1080/10400435.2019.1612798.

65. Oyesanya TO, LeCroy T, Sweatman M, Hatch D, Nyankori L, Kang Y, MacCaughelty T, O’Pry L, Johnson S. A medication management intervention for SCI and ABI patients and families. *West J Nurs Res*. 2020;42(12):1113-1128. doi:10.1177/0193945920926436

66. Oyesanya TO, Royer HR, Turkstra LS, Bowers BJ. Nurses’ concerns about caring for patients with acute and chronic traumatic brain injury. *J Clin Nurs*. 2017;(27):1408-1419. doi:10.1111/jocn.14298

67. Oyesanya TO, Snedden TR. Pediatric nurses' perceived knowledge and beliefs of evidence-based practice in the care of children and adolescents with moderate-to-severe traumatic brain injury. *J Spec Pediatr Nurs*. 2018;23:1-11. doi:10.1111/jspn.12209

68. Oyesanya TO, Brown RL, Turkstra LS. Caring for patients with traumatic brain injury: A survey of nurses' perceptions. *J Clin Nurs*. 2016;(11-12):1562-1574. doi:10.1111/jocn.13457

69. Oyesanya TO, Thomas MA, Brown RL, Turkstra LS. Nurses' beliefs about caring for patients with traumatic brain injury. *West J Nurs Res*. 2016;38(9):1114-1138. doi:0.1177/0193945916636629

70. Oyesanya TO, Turkstra LS, Brown RL. Development, reliability, and validity of the Perceptions of Brain Injury Survey. *J Nurs Meas*. 2020;28(2). doi:10.1891/JNM-D-19-00007

71. Oyesanya TO. Selection of discharge destination for patients with moderate-to-severe traumatic brain injury. *Brain Inj*. 2020;34(9):1222-1228. doi:10.1080/02699052.2020.1797172

72. Strauman TJ, Detloff AM, Sestokas R, Smith DV, Goetz EL, Rivera C, Kwapil L. What shall I be, what must I be: Neural correlates of personal goal activation. *Front Integr Neurosci*. 2013;6:123.

73. Sohlberg M, MacDonald S, Byom L, Iwashita H, Lemoncello R, Meulenbroek P, Ness B, O'Neil-Pirozzi T. Assessment of social communication following traumatic brain injury: A state-of-the-art review. *Int J Speech Lang Pathol*. Published online in press.

74. Teasdale G, Maas A, Lecky F, Manley G, Stocchetti N, Murray G. The Glasgow Coma Scale at 40 years: Standing the test of time. *Lancet Neurol*. 2014;13(8):844-854.

75. Bode RK, Heinemann AW, Semik P. Measurement properties of the Galveston Orientation and Amnesia Test (GOAT) and improvement patterns during inpatient rehabilitation. *J Head Trauma Rehabil*. 2000;15(1):637-655.

76. Kertesz A. *Western Aphasia Battery-Revised (WAB-R)*. Pro-Ed; 2006.

77. Knight RG, Devereux R, Godfrey HP. Caring for a family member with a traumatic brain injury. *Brain Inj*. 1998;12(6):467-481.

78. Langa KM, Chernew ME, Kabeto MU, Regula Herzog A, Beth Ofstedal M, Willis RJ, Wallace RB, Mucha LM, Straus WL, Fendrick AM. National estimates of the quantity and cost of informal caregiving for the elderly with dementia. *J Gen Intern Med*. 2001;16(11):770-778.

79. Onken LS, Carroll KM, Shoham V, Cuthbert BN, Riddle M. Reenvisioning clinical science: Unifying the discipline to improve the public health. *Clin Psychol Sci*. 2014;2(1):22-34.

80. Cleary M, Horsfall J, Hayter M. Data collection and sampling in qualitative research: does size matter? *J Adv Nurs*. 2014;70(3):473-475.

81. Moore CG, Carter RE, Nietert PJ, Stewart PW. Recommendations for planning pilot studies in clinical and translational research. *Clin Transl Sci*. 2011;4(5):332-337.

82. Duke University Hospital Trauma Registry. Data on patients with mild-to-severe traumatic brain injury. Published online 2021.

83. Paterson B, Scott-Findlay S. Critical issues in interviewing people with traumatic brain injury. *Qual Health Res*. 2002;12(3):399-409.

84. Kripalani S, Bengtzen R, Henderson LE, Jacobson TA. Clinical research in low-literacy populations: Using teach-back to assess comprehension of informed consent and privacy information. *IRB Ethics Hum Res*. Published online 2008:13-19.

85. Bowen DJ, Kreuter M, Spring B, Cofta-Woerpel L, Linnan L, Weiner D, Bakken S, Kaplan CP, Squiers L, Fabrizio C, others. How we design feasibility studies. *Am J Prev Med*. 2009;36(5):452-457.

86. Palinkas LA, Horwitz SM, Green CA, Wisdom JP, Duan N, Hoagwood K. Purposeful sampling for qualitative data collection and analysis in mixed method implementation research. *Adm Policy Ment Health Ment Health Serv Res*. 2015;42(5):533-544.

87. Milstein B, Wetterhall S, Group CEW. A framework featuring steps and standards for program evaluation. *Health Promot Pract*. 2000;1(3):221-228.

88. Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. *Qual Health Res*. 2005;15(9):1277-1288.

89. Turner B, Fleming J, Ownsworth T, Cornwell P. Perceived service and support needs during transition from hospital to home following acquired brain injury. *Disabil Rehabil*. 2011;33(10):818-829. doi:10.3109/09638288.2010.513422

90. Leith KH, Phillips L, Sample PL. Exploring the service needs and experiences of persons with TBI and their families: The South Carolina experience. *Brain Inj*. 2004;18(12):1191-1208.

91. Rotondi AJ, Sinkule J, Balzer K, Harris J, Moldovan R. A qualitative needs assessment of persons who have experienced traumatic brain injury and their primary family caregivers. *J Head Trauma Rehabil*. 2007;22(1):14-25.

92. Creswell JW. *Research Design: Qualitative, Quantitative, and Mixed Methods Approaches*. Sage; 2013.

93. Gignac GE, Szodorai ET. Effect size guidelines for individual differences researchers. *Personal Individ Differ*. 2016;102(102):74-78.

94. Bettger JP, Nguyen VQ, Thomas JG, Guerrier T, Yang Q, Hirsch MA, Pugh T, Harris G, Eller MA, Pereira C. Turning data into information: Opportunities to advance rehabilitation quality, research, and policy. *Arch Phys Med Rehabil*. 2018;99(6):1226-1231.