A Culturally Sensitive Intervention for TBI Caregivers in Latin America

PI: Paul Perrin, PhD

NCT #: 02207803

Virginia Commonwealth University Internal Review Board (IRB): HM20001660

Document approval date: 5/6/2014

Document Type: Protocol

Research Strategy

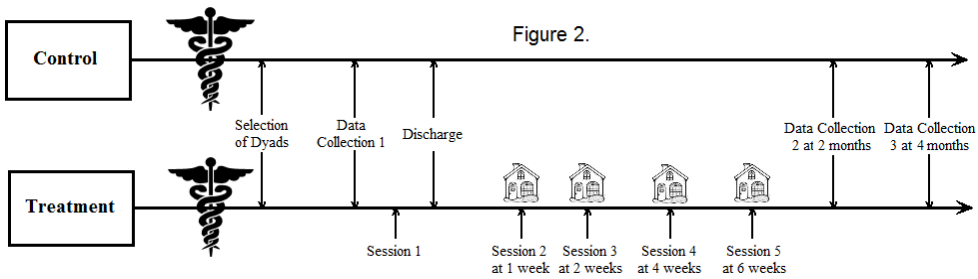

Figure 2.

Recruitment and Retention. Clinicians working on the rehabilitation units will inform TBI patients of the study. If the patient is interested, the site-PI will discuss the study and obtain informed consent, which will include their permission for the caregiver to participate. The site-PI will then invite the caregiver to participate and obtain informed consent. We selected a 12-month enrollment period because, based on TBI admissions data and previous studies conducted at the 3 sites, this window is necessary to enroll 110 dyads. Dyads will be randomly assigned to the treatment or control group, and each patient and caregiver will be paid the local currency equivalent of $10 per data collection. Demographic and baseline data will be collected prior to discharge, as well as outcome data at 2 and 4 months post-discharge (Figure 2). A 4-month follow-up period was selected instead of a longer follow up because our research[60] has suggested that the inpatient stay on an acute unit and the first 3 months post-discharge are the most stressful time periods for family TBI caregivers, and that their mental health and health related quality of life only increase marginally between 3 months and 1 year post-discharge. Therefore, the first several months after discharge are a critical time frame for intervention and follow up, as these variables remain fairly constant after initiating a particular trajectory.

TBI Patient Inclusion Criteria. All patients treated for TBI and discharged home will be invited to participate if they meet the following criteria: (1) give permission for their caregiver to participate; (2) sign an informed consent giving permission to obtain demographic and health information; (3) have the ability to communicate over the phone for data collection; and (4) are between 18-60 years of age. If a patient is aphasic (estimated 10%), arrangements will be made to collect data with self-administered paper-pencil reports via postal mail.

Caregiver Inclusion Criteria. TBI caregivers are eligible to participate who meet the following criteria: (1) have a telephone in the home or cellular phone and are able to talk on the phone; (2) sign an informed consent; (3) score at least a 13 on a health literacy screening tool; and (4) are between 18-85 years of age. Caregivers with scores below 13 will identify a family member or friend to review the guidebook with the caregiver. If no one is identified, the TAP clinician will review the materials with the caregiver.

Sample Estimation and Power. We anticipate that during a 12-month enrollment period, we will enroll approximately 110 caregiver-patient dyads (n = 220), of which 55 will be in the treatment group and 55 will be in the control group. Of the 110 dyads, 20 will be in Cali, Colombia; 20 in Neiva, Colombia; and 70 in Mexico City, Mexico. Allowing for a 25% attrition rate based on our previous data collection[1] with the TAP, over the 4-month data collection period, we estimate complete data on 84 dyads.

In order to determine the effect size that a final n of 84 dyads would be able to uncover, we performed a power analysis using G*Power 3 software for a repeated measures multivariate analysis of variance (RMANOVA) with three time points and two groups. This RMANOVA would uncover all large and medium-size effects, as well as many small-size effects. Our prior pilot study on the TAP generally showed medium-size effects on caregiver strain and depression, so our estimated sample size should be sufficient. Additionally, in the proposed study, the intervention will include in-home interventions of 60-minute duration, as opposed to the 30-minute duration in our previous pilot study. We are therefore expecting a larger effect size in the proposed study. If the TAP is found to be effective based on these analyses, at the end of the study, caregivers in the control group will receive the caregiving guidebook that had been provided to the intervention group as well as a written summary of the problem solving techniques and skills addressed in the intervention.

Transition Assistance Program Intervention. Dr. Perrin, Dr. Arango, and the site-PI will train a clinical psychologist at each rehabilitation facility to provide the TAP. Only clinical psychologists will serve as clinicians in order to reduce possible confounds from differing professional specialties of clinicians. The TAP involves three components to improve caregiver mental health and informal care: (1) skill development, (2) education, and (3) supportive problem solving. The TAP includes one face-to-face meeting between the clinician and caregiver prior to discharge, as well as an in-home visit to the caregiver in weeks 1, 2, 4, and 6.

Guidebook Development. Our research team will develop a guidebook entitled “A Guidebook for TBI Caregivers” based heavily on our research examining the needs of TBI caregivers in Latin America, as well as on other published studies on TBI. Our research[25] has shown, for example, that the top reported needs of TBI

caregivers in this region include “To have a professional to turn to for advice,” “To have my questions answered honestly,” “To have enough resources for the patient,” and “To have explanations from professionals given in terms I can understand.” This guidebook will be created to target these needs directly and therefore likely include chapters addressing (1) basic medical information about TBI, (2) common caregiver experiences, (3) TBI recovery issues such as disability, disruption in sense of self, social isolation, and depression, and (4) resources to assist TBI caregivers. An extensive formative evaluation of the guidebook will include focus groups with TBI clinicians at the rehabilitation facilities in Mexico and Colombia, as well as with TBI clinicians and researchers at Virginia Commonwealth University. The guidebook will be translated into Spanish and piloted with TBI clinicians and caregivers at the rehabilitation sites in Colombia and Mexico who will provide quantitative and qualitative feedback on the guidebook’s appropriateness for Latino TBI caregivers. After the feedback is incorporated into the guidebook, it will be ready for further evaluation in this study. In the TAP for stroke caregivers which we implemented in Puerto Rico and Texas[1], we developed and piloted the guidebook in the first 2 months of that study’s timeline. For the current proposal, we doubled the estimated time for this deliverable in order to account for possible challenges in piloting the guidebook at 3—instead of 2—sites.

Session 1. In preparation for Session 1 with the caregiver, the rehabilitation clinician delivering the TAP will meet with the facility’s rehabilitation team to identify the primary difficulties anticipated for the TBI patient after discharge. The clinician will take notes on the particular needs of the patient and bring these notes to Session 1 with the caregiver. Before discharge, the clinician will implement Session 1, a 1-hour meeting with each caregiver in the intervention group only. The primary focus of Session 1 is to orient the caregiver to the TAP and prepare the caregiver for discharge home. The clinician will provide the caregiver a guidebook and orientation to it, encouraging the caregiver to use it as a resource.

The clinician will also administer the health literacy screening tool, and with caregivers who score below a 13, the clinician will help identify a family member or friend to review the guidebook with the caregiver. The clinician will then ask what concerns the caregiver has about taking care of the TBI patient after discharge, taking notes on the caregiver’s responses. The clinician will also share with the caregiver the primary difficulties that the rehabilitation team had anticipated the TBI patient experiencing after discharge. The clinician will provide support and help the caregiver problem-solve caregiving related to these issues.

Sessions 2-5. The clinician will make four 1-hour in-home visits to the TBI caregiver at 1, 2, 4, and 6 weeks after hospital discharge. The TBI patient may or may not be present during these visits, depending on the needs and wishes of the caregiver. These visits will involve the same general format. The clinician will bring his or her notes from the previous sessions and from the rehabilitation team’s input. The clinician will review the content of these notes with the caregiver, checking in to see whether the problems are still present and to what extent. The clinician will engage in supportive problem-solving and will refer the caregiver to the guidebook sections relevant to the issues, walking the caregiver through those sections. Because of this format, the TAP is specifically designed for clinicians to tailor its use not only according to possible cross-site differences in what may be necessary for the intervention, but also for differences in caregiver care responsibilities and needs within a single site. The entire structure of the TAP is centered around the caregiver’s most pressing needs. The clinician will take notes on the continued problems and the strategies for resolving them.

Data Collection 1. After enrollment and immediately before discharge (as well as before Session 1 for the treatment group), demographic and baseline data will be collected from the TBI patient and caregiver. The site-PI will meet with the patient and caregiver separately. The site-PI will read items aloud from an assessment packet to the patient and caregiver, circling participants’ responses. The caregiver packet will include validated measures of caregivers’ health status, health care utilization/cost, burden, depression, sense of coherence, quality of informal care provided, and relationship satisfaction. The patient packet will include validated measures of patients’ functional and health status, health care utilization/cost, self-perceived burden, depression, quality of informal care received, and relationship satisfaction.

Data Collection 2-3. At 2 and 4 months after hospital discharge, the site-PI will collect follow-up data from the TBI patient and caregiver over the phone using the same validated measures and in the same format as during Data Collection 1. For the treatment group only in Data Collection 2, the site-PI will also collect qualitative information from the

Outcome Measures. The majority of outcome measures have previously been translated and validated among Spanish speakers. For the four that have not (Exemplary Care Scale, Relationship Assessment Survey, Self-Perceived Burden Scale, and Brief Health Literacy Screening Tool), we will use Chapman and Carter’s[31] methodology to translate and back-translate the measures, whereby a bilingual and bicultural researcher will translate the original measure into Spanish, and a separate bilingual and bicultural researcher blinded to the

original measure will then back-translate it into English. Any discrepancies between the original English and back-translated English will be resolved mutually. We will pilot the four translated measures with rehabilitation teams at each site and amend the instruments to improve their face validity in the three local cultures[54] while ensuring the standardization of each instrument across the three sites. We will then administer the instruments over the course of our study, and after collecting outcome data, we will run exploratory factor analyses to establish each measure's factor structure, as we have done and advocated for in our own research investigating measure psychometrics among individuals after acute TBI[54] and across various global regions[55]. Based on these analyses, we will remove items that do not accurately measure the constructs under scrutiny[57].

Functional Independence Measure (FIM; patient functional status). The FIM is the most widely used method of assessing function and assistance needs in individuals with a disability. The FIM has a total score and six subscales: self-care, sphincter control, transfer capability, locomotion, communication, and social cognition. The FIM[32] consists of 18 items, and responses use a 7-point ordinal scale. The reliability of the FIM is well established: in a meta-analysis[33] the median inter-rater reliability for the total FIM was 0.95 and the median test-retest and equivalence reliability values of 0.95 and .92 respectively.

Exemplary Care Scale (ECS; patient and caregiver rating of quality of informal care). The ECS is an 11-item self-report questionnaire that assesses the extent to which caregivers engage or do not engage in activities that help care recipients maintain dignity and respect.[34] Response choices are on a Likert scale (1 = never; 2 = sometimes; 3 = often; 4 = always), and higher scores indicate higher exemplary care. Parallel caregiver and care recipient versions are available, with equivalent measurement properties. The ECS has been shown to be a valid measure of the quality of informal care for individuals with disabilities.[34]

Patient Health Questionnaire-9 (PHQ-9; patient and caregiver depression). The PHQ-9[35] is the depression-specific module of the Patient Health Questionnaire. The 9-item instrument directs the respondent to indicate how often he/she has been bothered by each item using a response from 0 (not at all) to 3 (nearly every day). Total score range from 0 to 27, and higher scores represent high depression. The Spanish version used for this study[36] is reliable and valid in assessing depression in Spanish speakers.[37,38]

Relationship Assessment Survey (RAS; patient and caregiver relationship satisfaction). The RAS[39] is a 7-item scale originally developed to assess quality of marital relationships but was later adapted to apply for multiple types of interpersonal relationships (RAS-G[40]). Item responses are on a 5-point Likert scale (1 = not satisfied and 5 = very satisfied), and higher scores represent higher satisfaction.

Self-Perceived Burden Scale (SPBS; patient self-perceived burden). The SPBS assesses care recipients' feelings of dependence and guilt over responsibility for their caregiver's difficulties.[41] The SPBS contains 10 items which respondents rate with a 5-point Likert scale (1 = none of the time and 5 = all of the time), with higher scores indicating higher self-perception of a being a burden.

Sense of Coherence Scale (SOC; patient and caregiver sense of coherence). The SOC[42] is a 13-item self-report questionnaire that assesses a person's tendency to perceive life events as meaningful, understandable, and manageable.[43] Item responses range from 1 (never) to 7 (very often), and higher scores reflect a stronger sense of coherence.[44] The Spanish SOC has good internal reliability and validity.[43]

Zarit Burden Interview (ZBI; caregiver burden). The ZBI[45] is one of the most widely used scales measuring subjective caregiver burden. It is a 22-item, self-report questionnaire with items referring to the caregiver/patient relationship and evaluating the caregiver's health condition, psychological well-being, finances, and social life. Responses can range from 'never' to 'nearly always,' and higher scores indicate greater levels of caregiver distress.[46] The Spanish version of the ZBI has good internal reliability.[47]

36-Item Short Form (SF-36; patient and caregiver health status). The SF-36 is one of the most widely used instruments to assess self-reported Health-Related Quality of Life (HRQoL) in individuals with TBI.[48] The items address eight dimensions of health: physical function, role-physical, bodily pain, general health, energy/vitality, social function, role-emotional, and mental health. Scores range from 0-100, with higher scores indicating better health. It has been translated Spanish, and has well-established reliability and validity in Spanish-speaking populations.[49]

Brief Health Literacy Screening Tool (BRIEF; caregiver health literacy). The BRIEF[50] is a 4-item measure of health literacy level. In its initial construction, a factor analysis indicated that the BRIEF measures one distinct construct: "health literacy" (Eigenvalue = 2.4) accounting for 60% of score variance. The BRIEF has good convergent validity with other longer measures of health literacy.

Overall Study Timeline. An activity and milestone timeline for the 2-year grant cycle appears in Table 1.

Table 1. Grant Cycle Timeline

Activity	Before Start	1-4 Months	5-8 Months	9-12 Months	13-16 Months	17-20 Months	21-24 Months
IRB	■						
Guidebook Development		■					
Guidebook Piloting		■					
Clinician Hiring		■					
Training		■					
Enrollment			■	■	■		
Intervention			■	■	■	■	
Data Collection			■	■	■	■	
Data Analyses						■	
Reports							■
Publications							■