ORIGINAL ARTICLE

Scheduled Telephone Intervention for Traumatic Brain Injury: A Multicenter Randomized Controlled Trial

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ABSTRACT. Bell KR, Brockway JA, Hart T, Whyte J, Sherer M, Fraser RT, Temkin NR, Dikmen SS. Scheduled telephone intervention for traumatic brain injury: a multicenter randomized controlled trial. Arch Phys Med Rehabil 2011;92: 1552-60.

Objective: To evaluate the effect of a Scheduled Telephone Intervention (STI) compared with usual care (UC) on function, health/emotional status, community/work activities, and well-being at 1 and 2 years after traumatic brain injury (TBI).

Design: Two group, randomized controlled trial.

Setting: Telephone contacts with subjects recruited in inpatient rehabilitation.

Participants: Eligible subjects (N=433) with TBI (age>16y) were randomly assigned to STI plus UC (n=210) or UC (n=223) at discharge. STI subjects (n=169) completed the outcome at year 1 (118 at year 2) and 174 UC subjects at year 1 (123 at year 2).

Interventions: STI subjects received calls at 2 and 4 weeks and 2, 3, 5, 7, 9, 12, 15, 18, and 21 months consisting of brief training in problem solving, education, or referral.

Main Outcome Measures: A composite outcome at 1 year was the primary endpoint. Analysis on intent-to-treat basis used linear regression adjusted for site, Glasgow Coma Scale, race/ethnicity, age, FIM, sex, and Disability Rating Scale (DRS). Secondary analyses were conducted on individual and composite measures (FIM, DRS, community participation indicators, Glasgow Outcome Scale [Extended], Short Form-12 Health Survey, Brief Symptom Inventory-18, EuroQOL, and modified Perceived Quality of Life).

Results: No significant differences were noted between the groups at years 1 or 2 for primary (P=.987 regression for year 1, P=.983 for year 2) or secondary analyses.

Conclusions: This study failed to replicate the findings of a previous single center study of telephone-based counseling. While telephone mediated treatment has shown promise in other studies, this model of flexible counseling in problem solving and education for varied problems was not effective over and above usual care.

Key Words: Brain injuries; Rehabilitation; Telephone; Treatment outcome.

TRAUMATIC BRAIN INJURY (TBI) is common in the United States with incidence estimated by the Centers for Disease Control to be over 1.7 million annually.[1] With the high cost and variability in health care, individuals with moderate to severe injuries may or may not receive hospital-based rehabilitation after emergency care. Even when they do, they are typically discharged with remaining and evolving clinical needs. Given that recovery from moderate to severe TBI can be prolonged, with needs changing as cognitive and behavioral abilities also change,[2-4] a wide variety of problems may become apparent after discharge from acute care and rehabilitation. In addition to persisting physical complaints (which may vary from headache to paralysis depending on injury severity), persons with TBI and their families often must deal with memory impairment and behavioral disorders such as irritability, anxiety, or depression.[4,5] People with TBI and their caregivers may need assistance with personal care, scheduling, transportation, and locating appropriate services.[4,6,7] Social stressors, such as job and income loss or changes in social roles, may impact both the person with TBI and the caregiver. Moreover, premorbid problems, such as substance abuse, may reemerge and be challenging to manage.

While some patients with moderate to severe injuries receive continued rehabilitation therapies after discharge, few have the resources for comprehensive therapy for as long as they may benefit.[8,9] Additionally, many patients live in rural areas or lack transportation, prohibiting treatment at centers with specialized brain injury rehabilitation programs.[10] For these reasons, there has been an interest over the last decade in developing methods to deliver therapy or rehabilitation consultation to persons with TBI from a distance using telephone- or computer-administered treatments.

Telephone-based interventions have been studied in general populations for improving the management of chronic disorders, such as arthritis and diabetes, and for fostering and supporting positive life style changes (eg, smoking cessation

List of Abbreviations

DRS	Disability Rating Scale
GCS	Glasgow Coma Scale
RCM	Research Care Manager
RCT	randomized controlled trial
SO	significant other
STI	Scheduled Telephone Intervention
TBI	traumatic brain injury
TBIMS	Traumatic Brain Injury Model Systems
UC	usual care

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and enhanced physical activity).[11-13] Telephone counseling has been demonstrated to be effective in reducing symptoms and enhancing treatment compliance in those with depression.[14-17] In rehabilitation, the study of telephone- and computer-based interventions is more recent. Telephone training has been successfully used for caregivers of patients with stroke and TBI and for cognitive training.[18,19] Telephone contacts for TBI treatment have been used in a number of other studies, but the techniques and goals have not always been well-defined.[20,21]

We have developed a treatment model called scheduled telephone intervention (STI). The STI was designed to help meet the multiple, evolving needs of people with TBI and their families after discharge from hospital-based care. In essence, the treatment consists of "outreach" telephone calls placed by a trained and supervised counselor at scheduled, gradually increasing intervals after discharge from inpatient rehabilitation. STI is intended to help identify and meet the needs of people with TBI who may not have access, or who have limited access, to traditional rehabilitation services. We previously tested the efficacy of STI compared with usual care (UC) in 171 subjects with moderate to severe TBI over the first year postinjury in a randomized controlled trial (RCT). That study demonstrated superior outcomes for STI based on a composite measure encompassing measures of global function, mood, community integration, and well-being.[22] A further study of 386 persons with mild TBI demonstrated that 5 telephone follow-ups using a self-management structure aimed at reactivation during the first 12 weeks after injury resulted in decreased frequency and severity of symptoms in those treated compared with controls.[23] Persons in the STI arm of this study also had fewer complaints that symptoms negatively impacted work and community activities.

In the current study, we sought to replicate and extend the findings regarding the benefits of STI treatment for patients with moderate to severe TBI in a multicenter RCT. We assessed the impact of a similar treatment approach, delivered over 2 years rather than 1, in a sample that was more diverse with respect to severity, ethnicity, and geographic region. We wished to establish that the benefits of this treatment could be obtained with a larger set of individuals delivering treatment and to determine whether the benefits were long lasting. In particular, we were interested in whether the STI might have an impact on employment after the first year, an outcome that was not affected by the previous study that only ran to 1-year postinjury. Moreover, in the original study, there was a finding that the STI model was more beneficial for white than nonwhite participants, and we hoped to explore this in centers that had a more racially diverse population. In summary, our hypothesis was that STI for persons with moderate to severe TBI and their family or primary support person will result in improved function and quality of life for the affected person and family compared with UC. The primary aim of the current study was to evaluate the effect of scheduled telephone contact on functional level, health and emotional status, community integration, and perceived quality of well-being over 1 and 2 years after TBI. Secondary aims were to examine differences in outcome by geographic area or demographic subgroups as well as outcome domain.

METHODS

Participants

Three centers, all sites for the Traumatic Brain Injury Model Systems (TBIMS) funded by the National Institute on Disability and Rehabilitation Research and located in different states, participated in this study. Subjects were consecutively recruited over a 3-year period (May 2005–June 2008) from persons admitted to acute rehabilitation units. Inclusion criteria were those for enrollment into the TBIMS program, that is, all participants (1) presented to the designated TBIMS acute care hospital within 72 hours of injury; (2) were transferred to the TBIMS rehabilitation unit within 72 hours of discharge from acute care; (3) had sustained a penetrating or nonpenetrating TBI with at least 1 of the following characteristics: Glasgow Coma Scale (GCS) score of less than 13 on emergency department admission (not due to intubation, sedation, or intoxication), loss of consciousness for more than 30 minutes (not due to sedation or intoxication), posttraumatic amnesia for more than 24 hours, or trauma-related intracranial abnormality on neuroimaging; (4) were aged 16 years or older. In addition, this study required: (1) consistent telephone access, (2) sufficient fluency in English to communicate by telephone without an interpreter, and (3) discharge to a community setting. Informed consent was obtained as approved by the institutional review boards of all 3 institutions. Subjects were encouraged to identify a significant other (SO) (family member or close friend) who would participate in the study as well. These identified SOs were consented in the same way.

Procedures

Subjects were enrolled in the current study as part of their enrollment in the TBIMS prior to discharge from the acute rehabilitation centers but had the option of declining participation in this study. In the TBIMS, baseline data on participant characteristics, cause and severity of injury, and early recovery course are gathered from the acute and rehabilitation hospital records and patient/family interview prior to rehabilitation discharge. Follow-up interviews are conducted by phone or in person at 1 year (12 ± 2mo) and 2 years (24 ± 2mo) post-TBI, with additional follow-ups thereafter. The current study used the baseline, 1- and 2-year data collection waves, incorporating many elements of the TBIMS dataset with supplemental measures specific to this project (see Measures section below). Outcome measurement was conducted by research assistants who were masked to group assignment. Because of the time limit imposed by the overall duration of the study, the sample size for the 1-year assessment was planned to be larger than for the 2-year assessment. That is, for participants recruited later in the study, only 1-year outcomes were measured.

Randomization was stratified by enrollment site and discharge FIM score. Because discharge FIM scores varied among sites, FIM stratification differed by site as determined by the median observed discharge FIM score for TBIMS patients at each site for the year prior to study initiation. Baseline measures were obtained prior to randomization. Randomization was assigned by the lead center using a computerized random number generator.

Intervention

Those assigned to the UC group received a letter immediately after discharge, notifying them of assignment and reminding them that they would receive a telephone call in approximately 1 year for outcome assessment. These subjects received UC in their community and follow-up from their medical and rehabilitation providers. Those assigned to the STI group received assignment notification after discharge along with a letter identifying the research care manager (RCM) who would be calling them in 1 to 2 days for a brief introduction. The RCM, who had access to medical records for the subject, called the subject at 3 to 4 days postdischarge, 2-, 4-, 8-, and 12-weeks postdischarge, and 5-, 7-, 9-, 12-, 15-, 18-, and 21-