Cognitive Rehabilitation for Traumatic Brain Injury

A Randomized Trial

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Context Traumatic brain injury (TBI) is a principal cause of death and disability in young adults. Rehabilitation for TBI has not received the same level of scientific scrutiny for efficacy and cost-efficiency that is expected in other medical fields.

Objective To evaluate the efficacy of inpatient cognitive rehabilitation for patients with TBI.

Design and Setting Single-center, parallel-group, randomized trial conducted from January 1992 through February 1997 at a US military medical referral center.

Patients One hundred twenty active-duty military personnel who had sustained a moderate-to-severe closed head injury, manifested by a Glasgow Coma Scale score of 13 or less, or posttraumatic amnesia lasting at least 24 hours, or focal cerebral contusion or hemorrhage on computed tomography or magnetic resonance imaging.

Interventions Patients were randomly assigned to an intensive, standardized, 8-week, in-hospital cognitive rehabilitation program (n=67) or a limited home rehabilitation program with weekly telephone support from a psychiatric nurse (n=53).

Main Outcome Measures Return to gainful employment and fitness for military duty at 1-year follow-up, compared by intervention group.

Results At 1-year follow-up, there was no significant difference between patients who had received the intensive in-hospital cognitive rehabilitation program vs the limited home rehabilitation program in return to employment (90% vs 94%, respectively; $P=.51$; difference, 4% [95% confidence interval {CI}, –5% to 14%]) or fitness for duty (73% vs 66%, respectively; $P=.43$; difference, 7% [95% CI, –10% to 24%]). There also were no significant differences in cognitive, behavioral, or quality-of-life measures. In a post-hoc subset analysis of patients who were unconscious for more than 1 hour (n = 75) following TBI, the in-hospital group had a greater return-to-duty rate (80% vs 58%; $P=.05$).

Conclusions In this study, the overall benefit of in-hospital cognitive rehabilitation for patients with moderate-to-severe TBI was similar to that of home rehabilitation. These findings emphasize the importance of conducting randomized trials to evaluate TBI rehabilitation interventions.

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Traumatic brain injury (TBI) is a principal cause of death and disability in young adults, with consequences ranging from physical disabilities to long-term cognitive, behavioral, and social deficits. Partly for these reasons, the total cost of TBI in the United States is estimated at more than $37 billion per year.[1,2] Postacute TBI management differs from that of other neurological disabilities, and most TBI patients have seemed to benefit from at least some level of specialized, interdisciplinary rehabilitation.[3-9] However, most rehabilitation strategies have not been subjected to the degree of scientific scrutiny for effectiveness and cost-efficiency that is expected of other medical therapies.[5,10-15]

For editorial comment see p 3123.

Thus, the question remains whether interdisciplinary cognitive TBI rehabilitation as currently practiced is an effective and cost-efficient method of returning TBI patients to their maximum potential. This lack of rigorous scientific evaluation creates difficulties in focusing rehabilitation efforts on therapeutic elements most likely to benefit patients with TBI.

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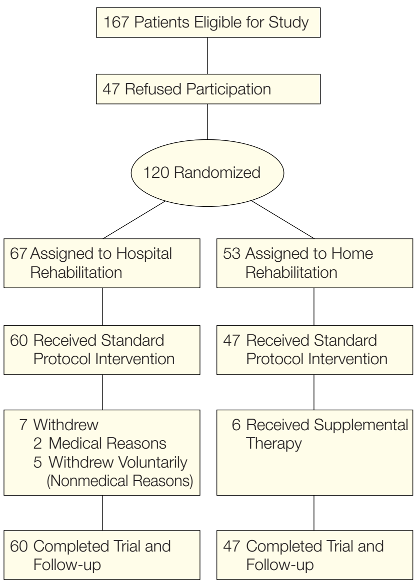
Figure. Patient Flow Diagram



Six patients assigned to the home rehabilitation group required supplemental therapy, 4 after completion of the program.

The military health care system offers a unique opportunity to address this issue. Military populations are large and their injuries are similar to those of civilians.[16,17] Military personnel are also relatively young, healthy, educated, and 100% employed preinjury, thus minimizing the potential impact of many of the confounding variables that can complicate TBI studies. In this article, we report the results of a single-center, parallel-group, prospective randomized controlled trial comparing institutional cognitive rehabilitation with a limited home program for military personnel who sustained a moderate-to-severe closed head injury in peacetime.

METHODS

Study Participants

Patients were recruited from 273 consecutive hospitalized TBI patients who were referred to Walter Reed Army Medical Center (WRAMC) during the study accession period of January 1992 through February 1997; 167 of these patients met eligibility criteria, according to the study protocol (FIGURE). Forty-seven eligible patients who refused participation were similar to the 120 study participants in demographics, injury severity, and clinical status at study entry

Inclusion criteria were (1) moderate-to-severe closed head injury, manifested by admission Glasgow Coma Scale score of 13 or less, or posttraumatic amnesia of 24 hours or more, or focal cerebral contusion or hemorrhage on computed tomography or magnetic resonance imaging (MRI); (2) head injury within 3 months of randomization; (3) Rancho Los Amigos cognitive level of 7 (oriented, appropriate)[18]; (4) active duty military member, not pending medical separation; (5) accompanied home setting with at least 1 responsible adult available; (6) an ability to ambulate independently; and (7) no prior severe TBI or other severe disability that would preclude return to active duty after study treatment. All patients provided signed volunteer informed consent. This study was approved by the institutional review board of the WRAMC.

Patients with mild TBI were excluded. Although almost half of the participants had severe TBI by conventional criteria, eligible patients had recovered sufficiently by the time of randomization to participate in the cognitive rehabilitation program or be safely returned to an accompanied home setting. Previously, most such patients had been medically discharged from the military outright or after a trial of military duty following unstructured convalescent leave.

Study Interventions

After admission to the WRAMC neurosurgery or neurology service, patients had extensive standardized multidisciplinary evaluation including neuropsychological, neurological, psychiatric, rehabilitation, and psychosocial tests, electroencephalogram, and MRI. They also had standardized TBI counseling and education. About one third in both treatment groups had received brief, unstructured basic rehabilitation services before the time of randomization. After confirmation of eligibility, patients were randomly assigned to receive in-hospital or home rehabilitation. Blocked randomization was done by an independent study statistician (K.S.) using variable-sized blocks to prevent investigators from guessing the code. Randomization for the first 40 participants was weighted at a 2:1 ratio in favor of the in-hospital group to help build that program. The last 79 patients enrolled were randomized at a 1:1 ratio. Analysis of outcomes stratified for these 2 cohorts did not change results.

Treatment Programs

The 2 standardized rehabilitation programs[19] (D.L.W., et al, unpublished data, 2000) are described in detail elsewhere. Programs were implemented by separate teams of therapists who generally functioned independently of each other and of the outcome evaluation personnel, although complete blinding was not possible. Intermittent reviews and continuing education were conducted to ensure uniformity of treatment over time.

In-hospital Rehabilitation. The standardized in-hospital interdisciplinary cognitive rehabilitation program combined group and individual therapies that were modeled after Prigatano's[3,13] milieu-oriented approach and that were modified to fit into a military framework. The program was conducted by a board-certified physiatrist (S.B.). Staff included a certified neuropsychologist experienced in milieu TBI rehabilitation (J.S.), a certified occupational therapist, speech pathologist, and 2 rehabilitation assistants. Physical therapy and neurological and psychiatric consultations were obtained as needed.

Patients were admitted to a minimum care hospital ward and were encouraged to conform to military standards. There was free time in late afternoons and evenings and a relatively liberal pass policy after the first week, depending on clinical status. The standardized, protocol-defined structured daily routine included physical fitness training and group and individual cognitive, speech, occupational, and coping skills therapies. Specific group therapies were planning and organization, cognitive skills, pragmatic speech, milieu, psychotherapy, and community reentry. The afternoon integrated work therapy program was modeled after those described by Ben-Yishay et al[20] and Burke et al.[21] The occupational therapist coordinated placement in various work settings that were as similar to the patient's previous military specialty as possible. Goals were established and feedback from patient and supervisor helped to gauge progress.

Home Rehabilitation. Patients assigned to the home group (and their families when available) received TBI education and individual counseling from a psychiatric nurse. Patients were given educational materials and recommended strategies for enhancing cognitive and organizational skills. They were trained in various home number and card game exercises, were encouraged to watch news programs, and read magazines and books. They also resumed daily physical exercise at their own pace. At 2 months, 76% reported spending at least 30 min/d on their mental and physical exercises. While at home, patients received weekly 30-minute telephone calls from the psychiatric nurse inquiring about the week's events and offering support and advice in addressing problems. Some patients resumed various vocational activities on their own.

Outcome Assessment

Patients had a repeat multidisciplinary evaluation 8 weeks after randomization, which included the baseline evaluation, and were returned to a 6-month trial of limited active military duty. The in-hospital group also received 2 weeks of convalescent leave before returning to duty. Patients were reevaluated at 6, 12, and 24 months with the multidisciplinary baseline test and additional psychosocial outcome measures, including return to work. We used structured telephone interviews and military records to collect selected essential outcome data on 42 patients who were unable to return for their 1-year follow-up.

The primary outcome measures were actual return to work and fitness for military duty at 1-year posttreatment as determined from interview, military records, or both. Work was defined as either full-time (≥35 h/wk) or part-time (<35 h/wk) gainful military or civilian employment. Fitness for duty included all patients who were still on active military duty or had received a normal discharge from the service, but excluded those who had a medical discharge or whose discharge was pending. Cognitive, psychiatric, and neurological outcomes, quality of life, and estimated treatment costs were also compared between the groups.

Patients who were unfit for military duty because of persistent disabilities, as defined by standard military regulations,[22] received medical discharge from the military. Recommendations for medical separation were made by the patient's primary physician and reviewed by 1 senior staff member and the chief of the clinical service. A completely independent military physical evaluation board that had 1 physician and 2 senior military officers reviewed all medical recommendations and determined final disposition. Although treatments could not be blinded and study participation was recorded in the patients' chart, the specificity of Army regulations and the various levels of review helped protect against systematic biases in duty fitness determinations.

Statistical Analysis

We hypothesized that an in-hospital rehabilitation program would yield greater return to work and fitness for duty rates than a limited home program at 1-year follow-up.

The originally projected study cohort of 200 subjects gave 80% power ($\alpha = .05$) to detect a treatment difference in return to work of 20% (60%-80%). Data were analyzed using the intent-to-treat analysis that included all randomized patients. The in-hospital and home treatment groups were compared using the Fisher exact test; 95% confidence intervals (CIs) were separately calculated for the differences in the percentage of individuals who had returned to work or who were fit for duty. Fisher exact or *t* tests were also used as appropriate in analyses of secondary outcome measures (cognition, behavior, mood, and quality of life).

Investigators were blind to results of the planned interim analysis conducted at n=120. Given the small differences found between groups in the primary outcome measures, post-hoc power calculations indicated that more than 500 patients would be needed per group to reach statistical significance in those measures. After independent consultation with the study statistical consultant, study accruals were terminated. The first 120 patients had reached the 1-year study follow-up point at the time of this analysis.

RESULTS

Sixty-seven patients were randomly assigned to the in-hospital program, and 53 to the home program. There were no significant differences between groups in demographic and injury characteristics, including age, sex, military rank, education, race, type and severity of injury (and if alcohol-related) (TABLE 1). However, there were fewer motor vehicle-related injuries, more assault injuries, and fewer patients who were unconscious for an hour or more in the in-hospital group. Patients in both groups had relatively severe traumatic brain injuries, as indicated by the rates of axonal shear injury on MRI (95% and 92%), cerebral contusions (51% and 54%), posttraumatic amnesia of 7 days or more (41% and 42%), and traumatic unconsciousness for 24 hours or more (30% and 38%), respectively, in the hospital and home treatment groups.

Groups were similar in postinjury symptoms at the time of randomization, including headaches, violent behavior, seizures, Mini-Mental State Examination scores, major depression or generalized anxiety (by *Diagnostic and Statistical Manual of Mental Disorders,* *Fourth Edition* criteria). Neuropsychological test performance was not different between groups at baseline (Table 1 and **TABLE 2**). Patients also had a disability profile similar to that associated with Vietnam veterans with head injuries, including posttraumatic epilepsy, hemiparesis, visual field loss, verbal or visual memory loss, psychological problems, and violent behavior.[23]

Outcome Measures

The primary outcome measures were no different between groups 1 year after treatment (**TABLE 3**). Return to work was 90% for the hospital group and 94% for the home group (*P*=.51; difference, 4%; 95% CI, −5% to 14%). Among those patients working at 1 year, 91% of the hospital group and 93% of the home group were working full time (*P*>.99).

Fitness for active military duty was 73% for the hospital group and 66% for the home group (*P*=.43; difference, 7%; 95% CI, −10% to 24%). Mean time to initiation of medical separation proceedings was 6 months from study entry for the hospital group and 5 months for the home group (*P*=.37).

Table 1. Treatment Group Characteristics*

	Hospital Group (n = 67)	Home Group (n = 53)	*P* Value
Premorbid Status			
Age, mean (SD), y	25 (6.63)	26 (6.22)	.36
Male sex	93	96	.46
Education (≥some college)	41	44	.85
Rank (sergeant or above)	28	30	.84
Married	30	34	.70
Right-handed	90	91	>.99
White race	69	70	>.99
Prior traumatic brain injury	11	18	.29
Brown-Goodwin Life Aggression score ≥7	8	11	.53
Prior substance abuse	40	34	.57
Prior psychiatric diagnosis	19	25	.51
Injury			
Time postinjury, mean (SD), d	38 (23.6)	39 (33.2)	.93
Injury as a result of assault	27	9	.02
Injury from motor vehicle crash	49	72	.02
Alcohol at time of injury	30	29	>.99
Period of traumatic unconsciousness			
>1 h	53	76	.01
>24 h	30	38	.44
Admission Glasgow Coma Scale score, mean (SD)†	9.4 (3.7)	9.5 (3.4)	.97
Period of posttraumatic amnesia >7 d	41	42	>.99
Cerebral MRI hematoma or contusion	51	54	.85
Shear injury on MRI	95	92	.70
Third ventricle width on MRI, mean (SD), mm	2.8 (1.8)	3.3 (2)	.13
Status at Randomization			
Headaches	55	58	.84
Violent behavior (against persons or things)	9	10	>.99
Aggressive behavior (physical or verbal)	18	19	>.99
Seizures	11	10	>.99
Major depression‡	18	19	>.99
Psychotropic medication	5	2	.63
Mini-Mental State Examination score <28	18	22	.80

*Values are expressed as percentages unless otherwise indicated. MRI indicates magnetic resonance imaging.
†Reliable Glasgow Coma Scale score available from records on only 44 patients.
‡Diagnosis based on definition from *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*.

There was also no significant difference between groups in quality of life as measured by Katz Adjustment subscores at 1 year (Table 3), which includes belligerence, social irresponsibility, antisocial behavior, social withdrawal, and apathy scores.[24,25] There were no significant differences between groups in verbal and visual memory or attention, or in general measures of cognitive or psychiatric function at baseline or 12 months (Table 2). Although most patients showed cognitive improvement during the first year after TBI, there was an increase in self-reported (and mostly verbal) aggression in both groups.

The proportion of patients with 1 or more unscheduled inpatient or outpatient visits during the first year after study treatment was 41% for the hospital group and 42% for the home group (*P*>.99).

Patient Subsets

There were too few patients who had not returned to work at 1 year to perform a subset analysis of work. However, there were no significant differences in fitness-for-duty rates between the 2 groups when year of randomization or Halstead neuropsychological impairment index at randomization were taken into account separately or in combination. Subgroup analysis suggested a trend toward beneficial effect of the hospital program for patients who were unconscious for more than 1 hour following TBI (*P*<.05) and of the home program for those who were unconscious for 1 hour or less following TBI (*P*=.13), but sample sizes were small (**TABLE 4**).

Seven patients failed to complete the full hospital program, 2 for medical reasons and 5 who voluntarily withdrew an average of 3 weeks into the program. Six of them were fit for duty or gainfully employed at 1 year. Likewise, 6 patients in the home treatment group required supplemental therapy because of persistent behavioral or mood problems, 4 of them after completing the home program. Four of the 6 were working or fit for duty at 1 year.

All these randomized patients were included in the principal intent-to-treat analysis. However, excluding them from repeat analysis did not change the results substantially.

COMMENT

In this study, the outcomes at 1 year after treatment for patients with TBI who received inpatient cognitive rehabilitation did not differ from those of patients who received a limited home rehabilitation program with respect to return to work or fitness for military duty rates, or in measures of social adaptation, cognition, mood, or behavior. These results should be examined in light of the outcome measures selected, severity of the TBI, relevance of treatments to the study population, and costs, as well as the relatively small number of patients, and the statistical power of the study.

Outcome measurement after TBI includes a variety of cognitive, behavioral, and psychosocial scales, but gainful employment generally is considered the best overall measure of a desirable outcome,[26] and the best correlate of patient quality of life.[27]

With its unique requirements, fitness for military duty is an even more stringent measure of work capacity; about 22% of patients who were gainfully employed at 1 year had previously been medically separated from military service as a consequence of their injury. Given that all participants were fit for duty before their injury and that both treatment programs emphasized return to duty as a goal, this measure was thought to represent a more appropriate index of a successful outcome for this study population. However, although equal percentages of patients from each treatment group were medically separated using predefined standards, and an independent board made final discharge decisions, it was impossible to completely eliminate all possibility of bias in determinations of fitness for duty, partly because the study could not be blinded.

Our study population had moderate-to-severe injuries by standard criteria (eg, prolonged unconsciousness or amnesia, evidence of cerebral lesions and axonal shear injury on MRI), but had nevertheless recovered to a Rancho level 7 (oriented) by 12 weeks after injury (Table 1). Their extraordinarily high return-to-work rates suggest that this recovery following TBI might limit any benefits that could be derived from inpatient rehabilitation. However, this argument is countered by the less than optimal return to full military duty and by the differential effects found in our subset analysis (Table 4). Historically, patients with this severity of TBI appeared to have even poorer return-to-duty rates, and generally were judged to be candidates for rehabilitation. Our hospital program was selected for this study because it was typical of programs in use at the time for such patients.[3,28]

Table 2. Cognitive Behavioral Function at Baseline and 1 Year After Randomization*

	Time, mo	Hospital Group	Home Group	*P* Value
Buschke Selective Reminding Test (consistent long-term retrieval [reference mean {SD}, 115 {19.7}])†	0	53 (34)	47 (33)	.33
	12	67 (34)	63 (40)	.68
Trahan Continuous Visual Memory Test (true-positive responses [reference mean {SD}, 37 {2.4}])†	0	34 (6)	36 (5)	.08
	12	38 (3)	39 (3)	.29
Paced Auditory Serial Addition Test (4-trial sum total correct [reference mean {SD}, 134 {NA}])†	0	117 (33)	109 (32)	.18
	12	147 (42)	145 (50)	.84
Wisconsin Card Sorting (perseverative responses [reference mean {SD}, 13 {9.1}])†	0	12 (10)	16 (16)	.15
	12	7 (5)	9 (9)	.34
Wechsler Memory Scale Revised (general memory quotient <75)	0	12	14	.79
	12	3	6	.58
Auditory Consonant Trigrams (total correct ≤40)	0	37	39	>.99
	12	12	29	.08
Halstead-Reitan Neuropsychological Impairment Index (≥0.5)	0	36	30	.55
	12	8	15	.46
Major depression‡	0	18	19	>.99
	12	16	27	.26
Generalized anxiety‡	0	9	10	>.99
	12	9	20	.33
Aggression (verbal or physical)	0	18	19	>.99
	12	37	41	.82

*The number of patients with neuropsychological testing in the hospital group was 67 at baseline and 42 at 12 months; home group, 53 at baseline and 34 at 12 months. Values are expressed as percentages unless otherwise indicated. NA indicates not available.
†Values are expressed as mean (SD).
‡Diagnosis based on definition from *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*.

Table 3. Main Outcome Measures 1 Year After Randomization

	Hospital Group (n = 67)	Home Group (n = 53)	*P* Value
	Main Outcome Measure, No./Total (%)		
Return to work in 12 mo	60/67 (90)	50/53 (94)	.51
Fitness for duty in 12 mo	49/67 (73)	35/53 (66)	.43
	Quality-of-Life Measure,* Mean (SD)		
	(n = 32)	(n = 28)	
Belligerence	17.1 (4.8)	19.8 (9.7)	.19
Social irresponsibility	29.3 (6.1)	29.4 (6.1)	.99
Antisocial behavior	9.5 (3.2)	11.1 (6.8)	.24
Social withdrawal	10.8 (2.9)	11.6 (4.2)	.40
Apathy	6.9 (3.0)	8.2 (4.4)	.21

*Based on the Katz Adjustment Scale.

Table 4. Patients Fit for Duty 1 Year After Randomization*

Patient Subset	Total No. of Patients	Hospital Group	Home Group	*P* Value
Period of unconsciousness, h				
>1	75	28/35 (80)	23/40 (58)	.05
≤1	44	21/31 (68)	12/13 (92)	.13
>24	41	16/20 (80)	11/20 (55)	.18
≤24	78	33/46 (72)	24/33 (73)	>.99
Period of posttraumatic amnesia, d				
>7	49	19/27 (70)	12/22 (55)	.37
≤7	70	29/39 (74)	23/31 (74)	>.99
Halstead-Reitan Neuropsychological Impairment Index				
>0.5†	37	17/23 (74)	9/14 (64)	.71
<0.5	74	29/41 (71)	23/33 (70)	>.99

*Values are expressed as No./total (percentage) of patients unless otherwise indicated.
†Score at randomization.

Other important factors are this population's high preinjury education (all had high school degrees), their 100% employment and military fitness status, the supportive military environment, and the ready availability of (military) employment after injury. Thus, our results might be most applicable to comparable civilian TBI patients with high-preinjury function. Another important advantage of studying our population is the ability to minimize multiple confounding variables that potentially could affect outcome.

Rehabilitation for TBI should facilitate and guide natural recovery, reinforcing positive compensation, and suppressing maladaptive behaviors. A critical element is time and rest for natural recovery. Additionally, there are at least 2 general approaches to rehabilitation that are based on different assumptions about learning and the brain's compensation for injury. The first, a cognitive-didactic approach, assumes that treatment of specific neurological, cognitive, communication, or behavioral deficits is a prerequisite for maximum recovery.[9,28-30] The second, a functional-experiential approach, focuses on overall functional goals and assumes that any relevant-specific deficits will improve or be compensated to meet those goals.[31]

Although much of what therapists do is still intuitive and reflective of their own training and experience, most rehabilitation programs use various combinations of the 2 approaches, with or without adjunctive pharmacotherapy. For example, our standardized inpatient program had morning cognitive, speech, and psychotherapy sessions complementing structured job placement in the afternoon. In contrast, our home program was almost completely functional, providing counseling, exercises, and support, but otherwise minimal intervention in a home setting.

Our results challenge whether a didactic cognitive rehabilitation approach is generally appropriate for patients recovering from moderate-to-severe TBI, but also suggest that institutional therapy may be beneficial for selected patients with severe TBI. It is unknown whether this or a different cognitive rehabilitation program might have provided a greater advantage to our patients, to a more disadvantaged or older group of patients, or to patients treated at a different time postinjury. (The time window postinjury for our study was guided in part by the goal of timely return to military duty.) Given the known deficits in long-term job retention after severe TBI, it is also important to follow up our cohort longer. The Defense and Veterans Head Injury Program is also conducting a second, larger multicenter, randomized controlled trial of cognitive therapy for patients with more severe TBI (B. Sigford, et al, unpublished data, 2000).

Our results also highlight the potential therapeutic benefits of the home setting. A more cost-effective approach to rehabilitation might focus on identifying and enhancing the key elements of a home program, including decreased stress of the home environment and the support of loved ones at home, along with appropriate medical evaluation, and education[32,33] (D.L.W. et al, unpublished data, 2000). While there are no apparent contraindications to a home program in this population, the increase in aggression in both groups at 12 months (Table 2) suggests that ongoing monitoring and support is an important part of treatment in all TBI patients.

Another important consideration is that of cost. Both study groups received basic TBI evaluation, education, and counseling over an average of 5 days in the hospital. The estimated additional rehabilitation cost for each patient in the hospital group was \$51 840, based on the standard WRAMC physiatry service costs of \$864 per day. In contrast, home program rehabilitation costs were estimated at \$504 per patient, based on therapist time for the weekly home telephone calls (\$63 per hour), including overhead and occasional physician back-up consultation.

This study also illustrates the importance and advantages of using prospective randomized designs to evaluate the efficacy of TBI rehabilitation strategies. Doing so will require the concerted education and collaboration of patients, families, physicians, other caregivers, clinical researchers, and third-party payers to improve outcomes for patients with TBI.

Defense and Veterans Head Injury Program (DVHIP) Study Group: The study group is listed by specialty. Physicians: Ashish Mody, MD, John Jaccard, MD, Robert Labutta, MD; data management and analysis: Jehue Wilkinson, H. R. Brown, HCMC; therapists: Tracey E. Ellis, OTR, Bethany C. Wilson, MA, Alex Chervinski, PhD, Michael Bamdad, MA, Leslie Freeman, MA, Adair Robinson MA, Melissa Sinot, MA, Tara Coleman, OTR; nurses: Judith A. Brooks, RN, MSN, Maria Graves, RN, Patricia Knapp, RN, Mary Coyle, RN, Mary Pyne Gaziano, RN, Kelly Gourdin, BS (case manager). Barry Festoff, MD (Veterans Affairs Medical Center, Kansas City, Mo) and COL Praxedes Belandres, MD (WRAMC) participated in early protocol design and

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