

**Vanderploeg RD, Schwab K, et al. Rehabilitation of Traumatic Brain Injury in Active Duty Military Personnel and Veterans: Defense and Veterans Brain Injury Center Randomized Controlled Trial of Two Rehabilitation Approaches. Arch Phys Med Rehabil 2008;89:2227-38.**

Design: Randomized clinical trial

Population/sample size/setting:

- 360 active duty military or veterans (335 men, 25 women, mean age 32, 221 active duty military at time of injury) treated for TBI rehabilitation at 4 Veterans Administration inpatient programs in 4 states
- Inclusion criteria were (1) moderate to severe TBI in past 6 months, with postresuscitation GCS of 12 or less, or coma 12 hours or more, or post-traumatic amnesia of at least 24 hours, or CT/MRI with focal cerebral contusion or hemorrhage; (2) Rancho Los Amigos cognitive level of 5 to 7, (3) anticipated need for acute interdisciplinary TBI rehab of 30 days or longer
- Exclusion criteria were (1) prior inpatient acute rehab for the current TBI, (w) prior moderate to severe TBI, (3) any preinjury psychiatric condition, stroke, spinal cord injury, or multiple sclerosis

Main outcome measures:

- Randomized to either cognitive-didactic rehab (n=180 analyzed) or functional-experiential rehab (n=180 analyzed)
- Both interventions were embedded in a hospital-based interdisciplinary TBI rehab program
  - o Both interventions were done from 1.5 to 2.5 hours daily
  - o In addition to the cognitive and functional interventions, all participants had 2 to 2.5 hours of daily occupational and physical therapy
  - o All participating VA centers were certified by CARF (Commission for Accreditation of Rehabilitation Facilities)
  - o Duration of treatment was set between 20 to 60 treatment days (26-84 calendar days), depending on the progress of each participant
- Cognitive-didactic program targeted executive functions such as self-awareness, mental tracking, and awareness of functional problems; real-life tasks and real-life settings were not part of the program, which was primarily individual in an office setting
- Functional-experiential program focused on developing skills in group sessions and in real-life settings, using error-free learning, with no focus on self-awareness of functional problems
- Evaluation of outcome data was done by assessors who were blinded to group assignment, and was done 1 year after the end of treatment in a structured telephone interview
- Main outcomes were (1) ability to live independently with less than 3 hours of assistance per week, and (2) return to work or school full or part time, not in a sheltered workshop

- At the 1 year evaluation, 56.6% of the cognitive group and 61.6% of the functional group were living independently (no statistically significant difference)
- At the 1 year evaluation, 38.9% of the cognitive group and 35.4% of the functional group were working or in school (no statistically significant difference)
- Numerous secondary measures were also taken to provide additional information about the effectiveness of the interventions; some were preplanned and some were exploratory in nature
  - o Preplanned secondary outcomes included the cognitive Functional Independence Measure (FIM), which was higher (mean score 27.3) than in the functional group (mean score 25.6),  $p=0.01$ ; baseline cognitive FIM scores were 19.1 and 18.4 respectively
  - o Mean motor FIM scores were similar in the cognitive group (82.7) and the functional group (80.5); baseline motor FIM scores were 19.1 and 18.4 respectively
- No adverse effects of either intervention were reported
- One exploratory analysis showed that among patients younger than 30, those in the cognitive arm had a higher rate of returning to work or school than those in the functional arm; however, among patients older than 30, those in the functional arm had higher rates of returning to independent living than those in the cognitive arm

Authors' conclusions:

- Functional improvements occurred in both the cognitive-didactic and the functional-experiential interventions
- Cognitive-didactic intervention led to higher cognitive function at 1 year than functional -experiential intervention; this was not due to a practice effect, but was due to generalization of the cognitive skills acquired during the intervention period
- Although based on different strategies and learning theories, the interventions had much in common; both used compensatory techniques and memory notebooks; the overlap may have minimized the ability of the study to find differences in outcomes between groups
- Many factors determine return to independent living and to work; even though recommendations were made to each group upon discharge for further treatment with similar approaches, this was not controlled, further minimizing the likelihood of finding group differences
- Subgroup analyses found that older participants and those with more education benefited more from functional treatment in terms of independent living, and younger patients benefited more from cognitive treatment in terms of return to work or school

Comments:

- The authors allude to improvements seen in both groups, but the analysis did not make good use of opportunities to demonstrate this

- That is, they report that for continuous measures, t tests were used to compare groups
- This could refer to independent samples t-tests to compare groups (with most analyses not showing treatment differences)
- Alternately, they could have done paired t-tests on each group, which would have shown differences in both cognitive and motor FIM between baseline and follow-up for both groups; this analysis was not reported
- In many other similar studies, these separate analyses are reported as time effects (before-after differences) and as time by treatment interaction terms (for contrasts between treatment groups on the amount of improvement)
- The between-group difference in cognitive FIM scores is statistically significant, but it is not clear that the difference is clinically important
- There was not a group which received only the OT/PT inpatient intervention; this would have provided evidence whether the two test interventions differ from that of the natural history of improvement of TBI; since only 50 days on average had elapsed since injury, most of the interventions were begun early in the recovery period, and a comparison with a third group would have been very useful
- It is not clear what kind of decision is aided by the results of the study; the discussion does not explain why there is a need to choose one intervention or the other; it does not answer the question, "why not do both?"
  - There is no reason to suspect that there is anything analogous to a drug interaction which can occur if two or more medications are used together
- The subgroup analyses are strictly exploratory and should not be enumerated among the study conclusions
- The fact that a large number of patients were living independently or working at 1 year after a significant TBI does suggest that the interventions were probably helpful, even though the amount of additional advantage over the natural history is undefined

Assessment: Adequate for evidence that both cognitive-didactic and functional-experiential inpatient programs may be beneficial in leading to functional independence in moderate to severe TBI.

For evidence that cognitive-didactic intervention produces greater cognitive function than functional-experiential intervention: Inadequate