

**Cicerone KD, Mott T, et al. A Randomized Controlled Trial of Holistic Neuropsychologic Rehabilitation After Traumatic Brain Injury. Arch Phys Med Rehabil 2008;89:2239-2249.**

Design: Randomized clinical trial

Population/sample size/setting:

- 68 post-TBI patients (46 men, 22 women, mean age 36) treated at a specialized rehabilitation institute and TBI Model System of Care in Edison, NJ
- Eligibility criteria were medical stability, independence in basic self-care, documentation of TBI at least 3 months previously, age 18 to 62, adequate language expression and comprehension for group interaction, capability of attending treatment 3 days per week, and judgment by a clinician that at least 4 months of treatment were required
- Exclusion criteria were active psychiatric illness, substance abuse, or pain sufficient to prevent compliance with treatment

Main outcome measures:

- Randomized into two groups: an Intensive Cognitive Rehabilitation Program (n=34) and a Standard Neurorehabilitation Program (n=34)
- Both groups attended treatment for 15 hours per week for 16 weeks
- Intensive and Standard programs had the same therapists in the same setting; therapists were aware that a study was being done but were not told of the study hypotheses
- Intensive intervention based on self-monitoring, self-regulation, and emotional regulation through the use of a “Cognitive Energy Scale” developed specifically for the intensive intervention; this required participants to identify and monitor fluctuations in their cognitive, emotional, somatic, and motivational levels throughout each treatment day
  - o Theoretical emphasis was on adapting to chronic limitations but application of residual cognitive abilities, rather than restoration of underlying cognitive deficits per se
  - o All participants received 11 hours of group treatment per week, with 3 hours of individual therapy from a primary therapist and 1 hour per week with a neuropsychologist
- Standard intervention was an interdisciplinary program aimed at retraining discrete cognitive functions, primarily through individual therapy
  - o Like the intensive group, the standard group had 1 hour per week with a neuropsychologist, but no more than 3 hours per week of group treatment
- Primary outcome measures were the Community Integration Questionnaire (CIQ) and the Perceived Quality of Life Scale (PQOL)
  - o CIQ assesses participation within the home, in social interactions, and in productive activities; the PQOL appraises life satisfaction on 10 areas of functioning, and is interpreted as a measure of global life satisfaction

- On both the CIQ and the PQOL, there were gains in the Intensive group but not in the Standard group
  - o On the CIQ, the group difference was 0.59 standard deviations; on the PQOL the group difference was 0.30 SD
- There were some secondary outcomes involving neuropsychological test batteries; there were improvements in both groups, but no differences between intervention groups
- There was no measured effect of time since injury on the success or failure of the interventions
- Both groups were eligible for follow-up treatment after the end of the program; the Standard group was more likely to receive continued comprehensive treatment than the Intensive group
- At baseline, based on available records, 59% of the participants had sustained a severe TBI, 24% a moderate TBI, and 13% a mild TBI; severity could not be ascertained for 3%

Authors' conclusions:

- The Intensive intervention, with its emphasis on error self-regulation, self-monitoring, and effective use of compensatory strategies, appears to be an effective model for increasing functional skills after TBI, more effective than standard multidisciplinary rehabilitation
- Group cohesion and therapeutic alliance were part of the effectiveness of the Intensive rehabilitation model

Comments:

- The Intensive and Standard interventions differed in a variety of ways, making it difficult to credit any one aspect of the Intensive program for the treatment effect (e.g., meta-cognition vs. group coherence)
- The Cognitive Energy Scale, which was developed specifically for the Intensive intervention group, may not be well known or widely validated, but may be familiar in the TBI Model Systems, and may need such a system in which to operate in order to be effective
- The randomization is adequately done; the fact that the same therapists provided both interventions would, if this created any bias, would be expected to create a bias toward minimizing rather than inflating group differences

Assessment: Adequate for evidence that a group intervention based on self-monitoring and recruitment of residual cognitive abilities is more effective than a standard multidisciplinary program at increasing community participation after severe TBI, even though both types of intervention are equally effective at improving neuropsychological test performance