

**Powell J, Heslin J, Greenwood R. Community based rehabilitation after severe traumatic brain injury: a randomised controlled trial. J Neurol Neurosurg Psychiatry 2002;72:193-202.**

Design: Randomized clinical trial

Population/sample size/setting:

- 110 moderate-severe TBI pts from East London with injury severity indexed retrospectively from estimate of post-traumatic amnesia or from documented evidence of neurological complications in medical records
- Demographics given on 94 of the 110 who completed intake and follow-up of clinical trial; mean age 34 (range from 16 to 65), 71 men, 23 women, median time since injury of 1.37 years (minimum time 3 months, maximum 20 years)
- Some pts referred after discharge from inpatient neuro rehab hospital; others from community (referral pattern not specified)
- Inclusion criteria were verification of TBI by medical records, age between 16 and 65, residence within 1 hour travel time from hospital, and agreement with the team about treatment goals
- Severity of TBI was at least moderate based on retrospective estimate of post-traumatic amnesia of more than 24 hours or by documented neurosurgical procedures
- No exclusion criteria are stated except for concurrent neurological diagnoses; psychiatric disorders and drug/alcohol abuse were deliberately not used as exclusion criteria in order to have a representative study population

Main outcome measures:

- Randomized to “outreach” multidisciplinary (OT, PT, speech/language therapist, clinical psychologist) team program (n=54) or “information” group (n=56) which received single home visit & given a booklet with information listing local and national resources for TBI
- Outreach group seen twice weekly in community (home, workplace, day centers) by multidisciplinary team members for individualized program therapy; average duration of intervention was 28 weeks
- Follow-up done 6-40 months after allocation by researcher who was unaware of group allocation
- Barthel Index (BI) is measure of ability to do basic activities of daily living; it was completed by researcher at follow-up
- Brain Injury Community Rehabilitation Outcome-39 (BICRO-39) is self-report questionnaire with subscales for personal care, mobility, self-organization, socializing, employment, and psychological well-being; it was completed without assistance from researcher, with complete baseline & follow-up data on 35 outreach and 40 information patients
- Maximum Gain Index (MGI) taken from the single subscale of BICRO-39 on which individual patient showed greatest improvement from intake to follow-up, e.g. mobility, personal care, employment, socializing

- Outcomes not normally distributed; most group comparisons done on P values of nonparametric rank tests of significant differences between groups
- 60 % of all pts already had maximum BI scores at intake; improvement seen in 35% of outreach pts and 20% of information group (p<.05)
- BICRO-39 changes between intake and follow-up greater in outreach than in information group (p=.05)
  - o There are 6 subscales of the BICRO-39; personal care, mobility, self-organization, socializing, productive employment, and psychological well-being
  - o Neither group showed meaningful change in the socializing or productive employment subscales
  - o Outreach group had significantly greater improvement in self-organization and psychological well-being subscales; for mobility and personal care, the differences were not statistically significant
- MGI also showed superiority for outreach group (p<.05), with 71% of outreach group achieving gains of 1.5 points or more on 6 point scale vs. 40% of information group achieving 1.5 points on same scale; gains in mobility were greater than gains in socializing or productive employment
- Several secondary measures were done, based on the Functional Independence Measure and the Functional Assessment Measure (FIM/FAM); the changes were modest and similar in both groups
- Time since injury was not correlated with total or MGI change scores

Authors' conclusions:

- Multidisciplinary rehab program produces functional gains which last beyond the period of direct support during the program
- Both groups had only minority employed at follow-up (5 in outreach group and 8 in information group), suggesting need for specialized employment program for TBI population
- Large proportion of both groups were near top of BICRO-39 scale at baseline, but larger proportion of outreach group improved submaximal scores
- Time since injury was not related to gains made after rehab began; this contradicts common assumption that rehab is useful only if done early
- Because analysis was by intention to treat, estimates of effectiveness of outreach may be conservative
- Blinding may have been imperfect since researcher doing follow-up may have learned group assignment from patient; however, BICRO-39 scale was completed without assistance from researcher
- Study is exploratory, since there are no data documenting gains that can be expected in severe TBI pts after hospital discharge

Comments:

- Nonparametric statistics used for comparison of groups, while necessary because of distribution of scores, does not allow an estimate of the magnitude of the effectiveness of rehab program (P values only could be reported)

- Large amount of missing baseline data (BICRO-39 available for only 35 outreach and 40 information group pts) erodes power of study to detect differences in groups; possibly this tends to produce more conservative estimate of group differences
  - o The missing BICRO-39 scores were not the result of dropout but due to the fact that data collection began after the first patients had been recruited; for these patients there was no baseline data
- MGI scale seems to have been improvised because of distribution of BICRO-39 scores near ceiling of scale; it is not clear whether MGI was part of original plan of study design and may be a post hoc artifact
- Multiple scales were used, with p values based on ranks; there appears not to have been an adjustment for multiple comparisons
  - o This increases the probability of Type I error, of random chance accounting for the differences in group scores
- Some of the subscales of the BICRO-39 are confusing; specifically, on page 195, productive employment is scored on a scale where 0 is no work and 5 is several hours per day (low score bad, high score good); on page 197, 75% of the participants at baseline are within 0.5% of the ceiling, where 5 is no activity, and a high score is bad
- Based on the scale descriptions on page 195, a high score is bad for personal care, mobility, self-organization, and psychological well-being; a high score is good for socializing and employment
  - o Therefore, if change scores are added, improvements on one subscale will be subtracted from improvements on other subscales, making the comparisons of BICRO-39 change scores of uncertain meaning
- There is no problem with including persons with psychiatric disorders or with alcohol or drug abuse, but the distribution of these should have been included in the baseline characteristics of the two groups in Table 1
- Since the authors concede that the randomization procedure (with sealed but not opaque envelopes) may have compromised allocation concealment, baseline comparisons become especially important
- The success of blinding is not certain; the authors note that the outcome evaluator may have been inadvertently informed of the group assignment during the follow-up evaluations, but how often this happened is not reported
- Although it is not certain to have occurred, there are signs of possible data manipulation in search of statistical significance (no adjustment for multiple comparisons, reporting “trend toward significance” for p values >0.05, and lack of a priori specification of the method for arriving at the MGI)
- The group comparisons, given all of these factors bearing on their interpretation, cannot be rated as having a low risk of bias

Assessment: Inadequate for evidence statement regarding the outreach intervention (uncertain blinding, uncertain allocation concealment, unclear effect size, possible inflation of Type I error, large amount of missing baseline data for one of the primary outcome measures )