ICARE Primary Results: A Phase III Stroke Rehabilitation Trial

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Background

Task-oriented training is a rehabilitation intervention used to improve recovery of paretic arm function after stroke. Its effectiveness has not been established relative to content or dose. The Accelerated Skill Acquisition Program (ASAP) is a principle-based, structured, task-oriented intervention focused on skill acquisition, capacity building, and motivational enhancements.

Methods

Between 14 and 106 days after stroke, 361 adults were randomized into one of three outpatient therapy groups: ASAP, Dose-Equivalent Usual and Customary Care (DEUCC), each at 1 hour, 3x/week for 10 weeks, or Usual and Customary Care (UCC), at a dose specified by clinician prescription and/or insurance coverage. The primary aim was to compare the effect of therapy contents at equivalent doses, with secondary comparisons of dose, and both dose and contents, at 12 months post randomization on Wolf Motor Function Test (WMFT) log-transformed time score and a > 25 point increase on the Stroke Impact Scale (SIS) hand domain.

Results

The average dose by treatment group was ASAP = 28 ± 6, DEUCC = 27 ± 6, and UCC = 11 ± 9 hours. Of those randomized to ASAP or DEUCC respectively, 79% (94/119) and 74% (89/120) completed at least 90% of the prescribed 30 hours. At 12 months, the attrition rate was similar across groups, ASAP = 12.6%, DEUCC = 12.5%, and UCC = 21.3%, well below a priori projection (25%). Missed evaluations varied across groups with 19.3% of ASAP, 24.2% of DEUCC and 35.2% of UCC participants missing at least one evaluation, but the occurrence of missing all 3 evaluations was similar, ASAP = 10.1%, DEUCC = 7.5% and UCC = 12.3%. At 12 months, the overall cohort decreased WMFT from 14.9 ± 18.5 s to 6.8 ± 13.0 s; SIS hand function increased from 30.7 ± 23.4 to 67.8 ± 26.9 (max 100), and UE Fugl Meyer increased from 41.6 ± 9.4 to 52.9 ± 10.9 (max 66). There were 168 serious adverse events involving 109 participants, with 98% expected and 2% deemed related. The most common events were hospitalization (85%), and recurrent stroke (25%). Conclusions: To maintain the embargo, results of the primary and secondary group comparisons are not included here, but will be reported in February at ISC
Disclosure

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