

Supplemental Materials

Minimal Clinically Important Differences of ICARE Secondary Outcome Measures

The “smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's management”¹ (p. 408) is termed the minimal clinically important difference (MCID). A number of methods for determining this meaningful difference have been advanced, including anchor-based comparisons to patient^{2,3} or clinician⁴ ratings of global change and distribution-based, such as comparison relevant to a scale's scoring range (e.g., 10% of a scale's possible scoring range⁵ or 10% of the middle 90% of the actual scoring range, removing the upper and lower 5% tails⁶).

In the limited stroke rehabilitation literature that has examined MCID values of common outcome measures, there is similarity in the relatively small sample sizes but noticeable variation in the chronicity of study samples, ranging from participants in the VECTORS trial of acute early inpatient stroke rehabilitation² to patients within 6 months of stroke⁷ to heterogeneous and more chronic samples (mean of 17 months post-stroke^{3, 8} and approximately 5 years after stroke⁴). In the table below, we present literature-derived patient-anchored estimates of MCID values where available and a study-derived distribution-based method⁶ when unavailable. In the table, proportions of participants in each ICARE group who exceeded the reported MCID value are noted.

As has been described, “It is critical to appreciate that there is no single true MCID value for a given measure. MCID values are dynamic and context-specific” (² p. 1694). Factors that may affect MCID values include time since stroke,^{2,7} type and degree of initial deficits, patient expectations,² small sample sizes, and cultural differences in the value and utility of particular changes.^{9, 10} Of interest, we found only one study with a published MCID value established in a sample of patients in the subacute phase 2 months after stroke, similar to our sample⁷ and note that a majority of the patient-reported outcome MCIDs were derived from a single sample of 65 patients with chronic stroke.^{3,8}

Table. Minimal Clinically Important Differences of Secondary Outcome Measures

Measure (Possible Scoring Range)	MCID (literature)	MCID (ICARE distribution-based)	Proportion of Group Exceeding MCID*		
			ASAP	DEUCC	UCC
Fugl-Meyer Assessment-Upper Extremity (FMA-UE)	5.25 ⁴		65	60.6	57.4
SIS Strength	9.2 ³		44.2	37	38.5
Patient Health Questionnaire-9 (PHQ-9)		-1.1	67.6	72.7	73.4
SIS Mood and Emotion		4.4	50	46	41.1
Confidence in Arm and Hand Movements (CAHM)		7.3	86.1	72.7	69.9
SIS Perception of Recovery		6	79.8	60.6	53.7
Euroqol-5D-Visual Analog Scale (EQ-5D-VAS)	8.61 ⁸		52.9	46.9	34.4
SIS Hand	17.8 ³		71.2	70	65.3
SIS Mobility	4.5 ³		68.3	71	61.1
SIS ADL/IADL	5.9 ³		76.9	79	81.1
SIS-16	9.4 ⁷		66.3	59	57.9
SIS Communication		5.4	30.8	34	15.8
SIS Memory and Thinking		5.7	37.5	38	40
Reintegration to Normal Living Index (RNLI)		5.8	76.2	69.7	59.1
SIS Participation		6.9	76.9	73	71.6
Satisfaction with Living Scale (SWLS)		2.2	36.3	34.7	32.3

Note: Literature-derived minimal clinically important differences (MCID) were taken from patient anchors (perceived improvement). When these estimates were not available, values were derived from the distribution of baseline scores from the ICARE sample, following the approach of Mayo and colleagues,⁶ in which 10% of the middle 90% of the participant scores (removing the bottom and top 5% of the scoring distribution) was calculated.

*The proportions of participants in study groups that exceeded these MCIDs are reported. Measures are presented in the order consistent with Table 2 of the paper.

References

1. Jaeschke R, Singer J, Guyatt G. Measurement of health status: ascertaining the minimally important difference. *Control Clin Trials* 1989;10:407–415.
2. Lang CE, Edwards DF, Birkenmeier RL, Dromerick AW. Estimating minimal clinically important differences of upper-extremity measures early after stroke. *Arch Phys Med Rehabil* 2008;89:1693-700.
3. Lin K-C, Fu T, Wu C-Y, Wang Y-H, Liu J-S, Hsieh C-J, Lin S-F. Minimal detectable change and clinically important difference of the Stroke Impact Scale in stroke patients. *Neurorehabil Neural Repair*. 2010;24:486-492.
4. Page SJ, Fulk GD, Boyne P. Clinically important differences for the upper-extremity Fugl-Meyer scale in people with minimal to moderate impairment due to chronic stroke. *Phys Ther*. 2012;92:791–798.
5. van der Lee JH, Wagenaar RC, Lankhorst GJ, Vogelaar TW, Devillé WL, Bouter LM. Forced use of the upper extremity in chronic stroke patients: results from a single-blind randomized clinical trial. *Stroke*. 1999;30:2369-2375.
6. Mayo NE, Anderson S, Barclay R, Cameron JI, Desrosiers J, Eng JJ, Huijbregts M, Kagan A, MacKay-Lyons M, Moriello C, Richards CL, Salbach NM, Scott SC, Teasell R, Bayley M. Getting on with the rest of your life following stroke: a randomized trial of a complex intervention aimed at enhancing life participation post stroke. *Clin Rehabil*. 2015; 29:1198–1211.
7. Fulk GD, Ludwig M, Dunning K, Golden S, Boyne P, West T. How much change in the Stroke Impact Scale-16 is important to people who have experienced a stroke? *Topics Stroke Rehabil*. 2010;17:477-483.
8. Chen P, Lin K-C, Liing R-J, Wu C-Y, Chen C-L, Chang K-C. Validity, responsiveness, and minimal clinically important difference of EQ-5D-5L in stroke patients undergoing rehabilitation. *Qual Life Res*. 2016; 25:1585–1596.
9. Algurén B, Fridlund B, Cieza A, Sunnerhagen KS, Christensson L. Factors associated with health-related quality of life after stroke: a 1-year prospective cohort study. *Neurorehabil Neural Repair*. 2012; 26:266–274.
10. McLaughlin N, Ong MK, Tabbush V, Hagigi F, Martin NA. Contemporary health care economics: an overview. *Neurosurg Focus*. 2014;37(5):E2. http://thejns.org/doi/abs/10.3171/2014.8.FOCUS14455_

Figures

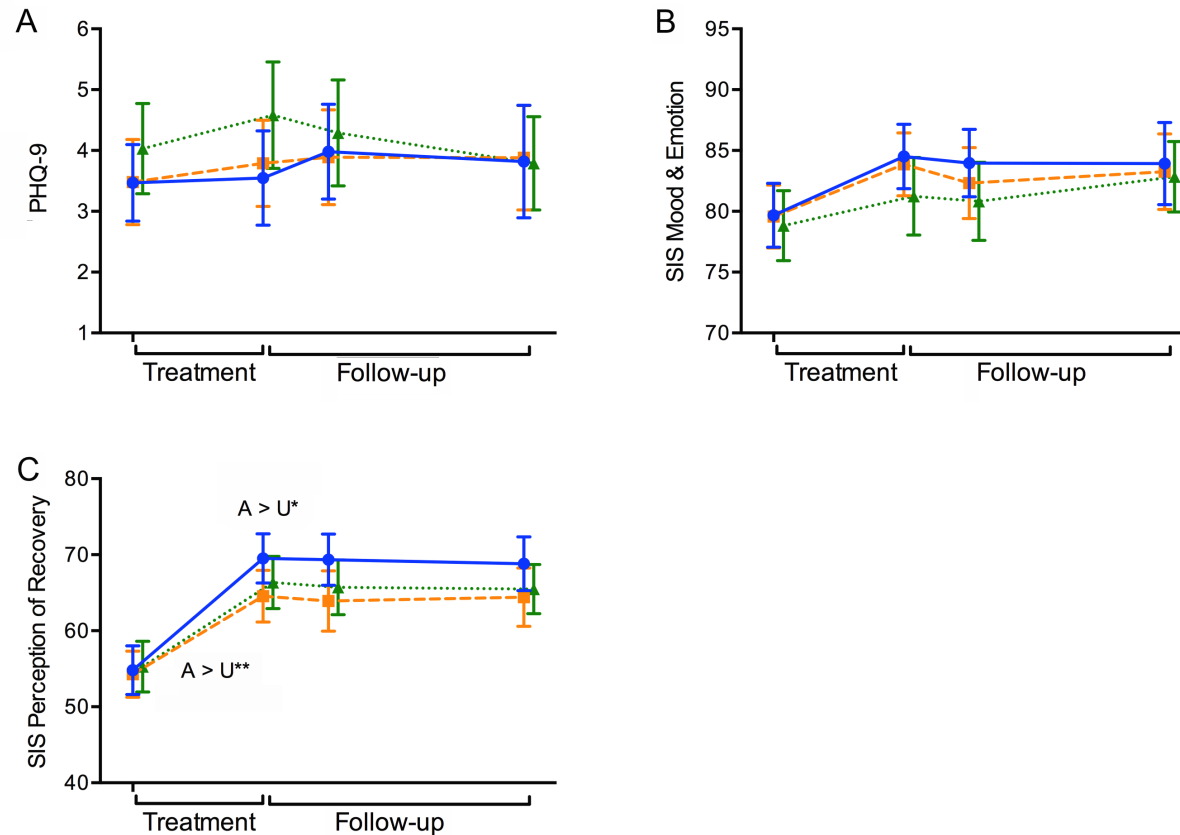


Figure S1. Body Structure and Function. Longitudinal plots across treatment and follow-up phases of (A) Patient Health Questionnaire-9, PHQ-9 (B) Stroke Impact Scale (SIS) Mood & Emotion subscale, and (C) SIS Perceived Recovery scale. On the horizontal axis, the left side in each figure (*Treatment*) indicates changes (improvements) from baseline assessment to the end-of-treatment time point while the right side (*Follow-up*) reflects end-of-treatment to end-of-study change. Solid blue line (Accelerated Skill Acquisition Program, A), dashed orange line (Dose-equivalent Usual and Customary Care, D), dotted green line (monitoring-only Usual and Customary Care, U). Means and standard error of the means are represented. Group differences at time points are denoted above the data lines; group x time trajectory differences are denoted below the data lines. * $P < .05$, ** $P < .01$.

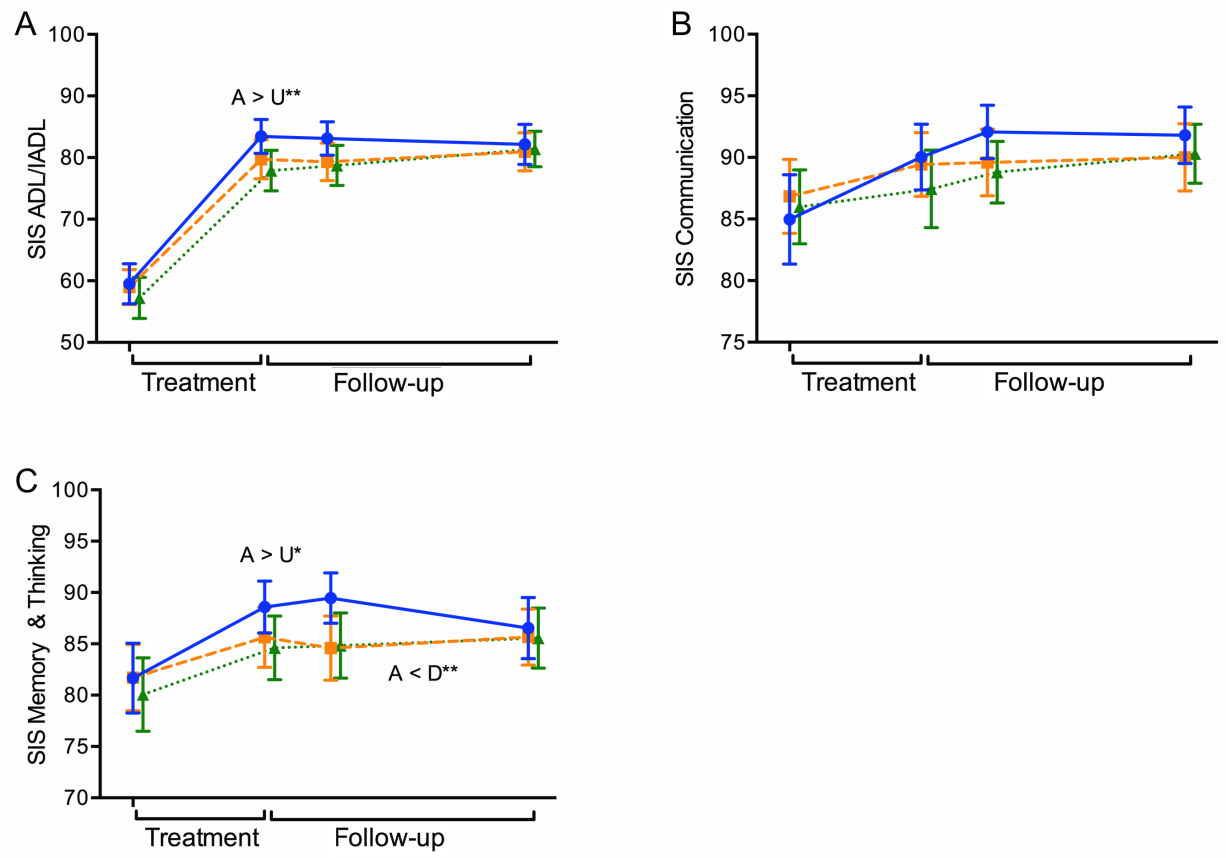


Figure S2. Activity. Longitudinal plots across treatment and follow-up phases of (A) SIS Activities of Daily Living/Instrumental Activities of Daily Living, SIS ADL/IADL, (B) SIS Communication, and (C) SIS Memory & Thinking. On the horizontal axis, the left side in each figure (*Treatment*) indicates changes (improvements) from baseline assessment to the end-of-treatment time point while the right side (*Follow-up*) reflects end-of-treatment to end-of-study change. Solid blue line (Accelerated Skill Acquisition Program, A), dashed orange line (Dose-equivalent Usual and Customary Care, D), dotted green line (monitoring-only Usual and Customary Care, U). Means and standard error of the means are represented. Group differences at time points are denoted above the data lines; group x time trajectory differences are denoted below the data lines. * $P < .05$, ** $P < .01$.

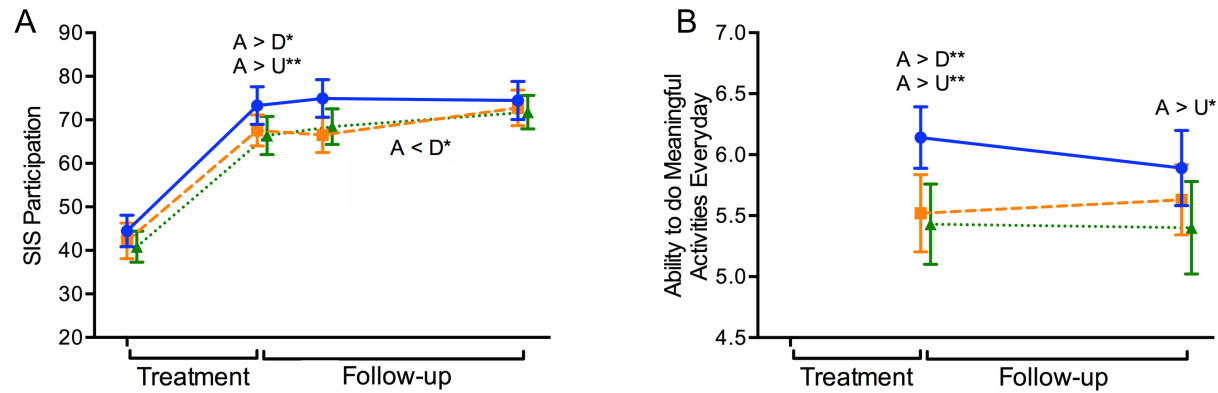


Figure S3. Participation and Quality of Life. Longitudinal plots across treatment and follow-up phases of (A) SIS Participation and (B) Ability to do meaningful activities everyday. On the horizontal axis, the left side in each figure (*Treatment*) indicates changes (improvements) from baseline assessment to the end-of-treatment time point while the right side (*Follow-up*) reflects end-of-treatment to end-of-study change. Solid blue line (Accelerated Skill Acquisition Program, A), dashed orange line (Dose-equivalent Usual and Customary Care, D), dotted green line (monitoring-only Usual and Customary Care, U). Means and standard error of the means are represented. Group differences at time points are denoted above the data lines; group x time trajectory differences are denoted below the data lines. * $P < .05$, ** $P < .01$.