

II Congreso Anual de Ictus - RICORS

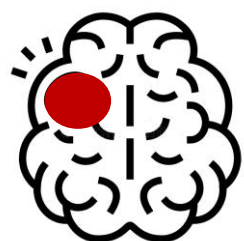
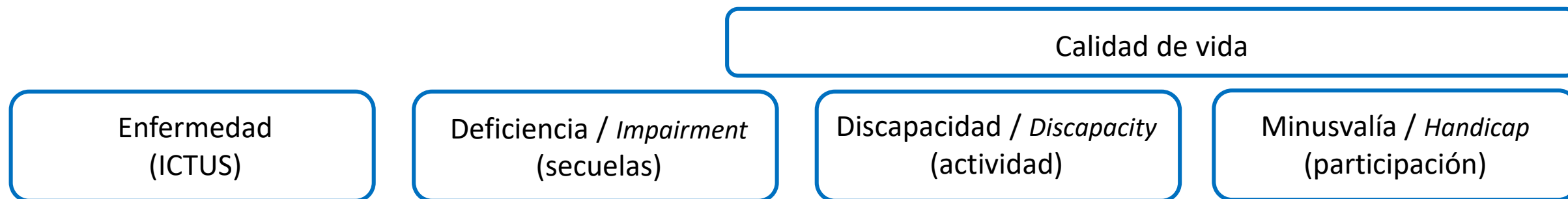


¿Cómo se debe medir la eficacia clínica en terapias de reperfusión?

Variables clínicas: ¿las escalas funcionales son adecuadas?

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Hospital Germans Trias i Pujol, Badalona*

World Health Organization
International Classification of **Function**
(WHO-ICF)

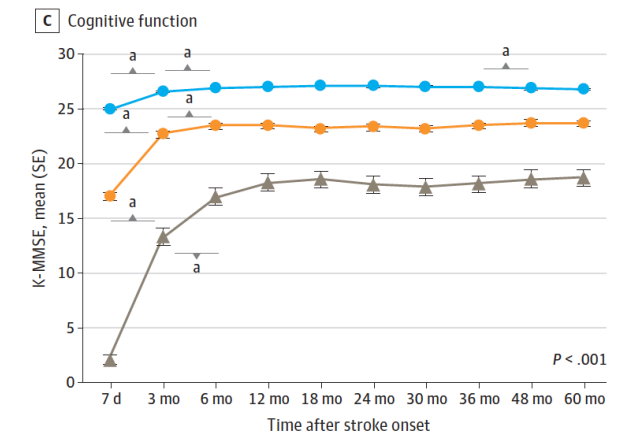
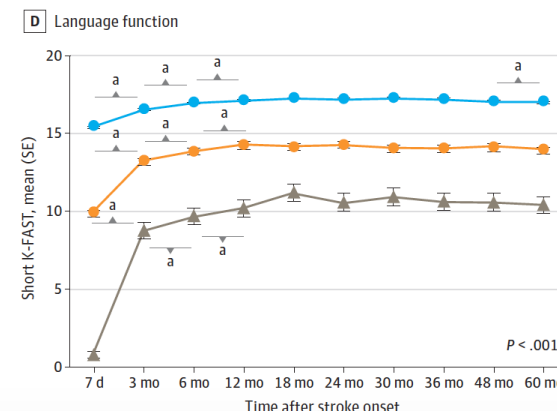
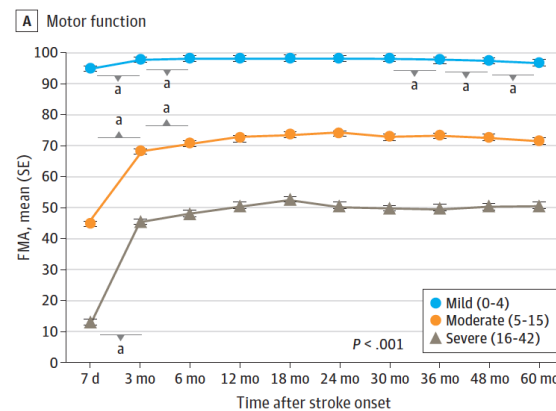
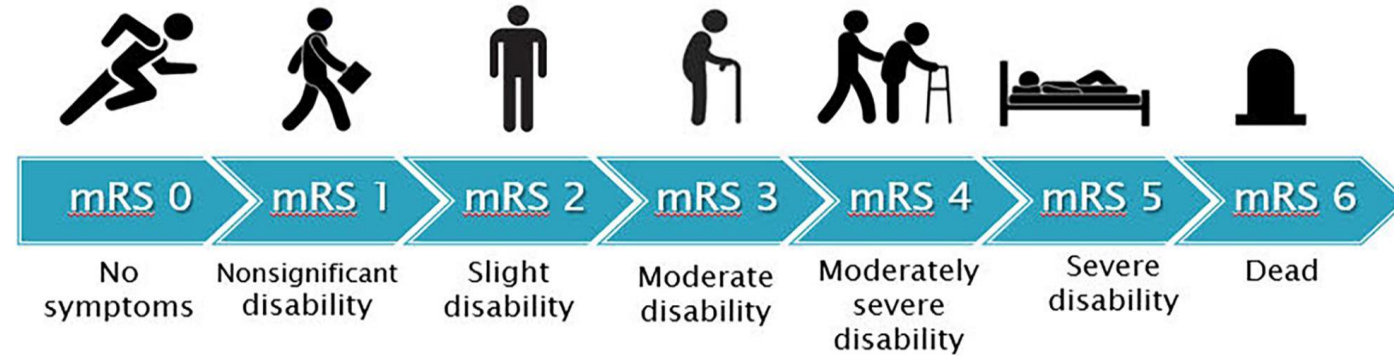


Motor
Afasia
Cognitivo





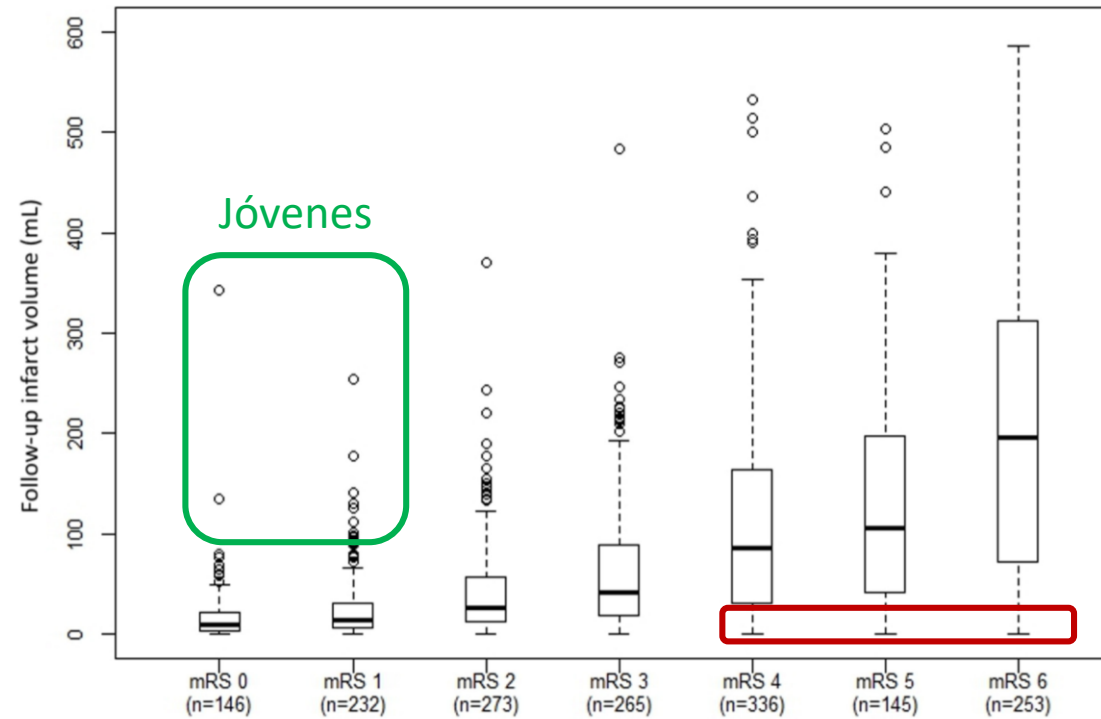
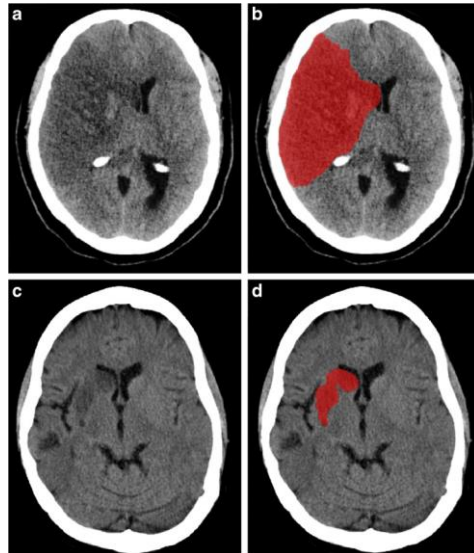
John Rankin (1923-1981)



90 días post-ictus

Trombectomía <6h (HERMES)

Spearman's ρ correlation coefficient 0.58



SAES
Neumonía
Recurrencias
Insuficiencia Cardiaca

El tamaño final del infarto explica el 14% del efecto clínico de la trombectomía en el pronóstico funcional.

Deficiencia
(secuelas)



NIHSS 1

Discapacidad
(actividad)



mRS 1

Calidad de vida



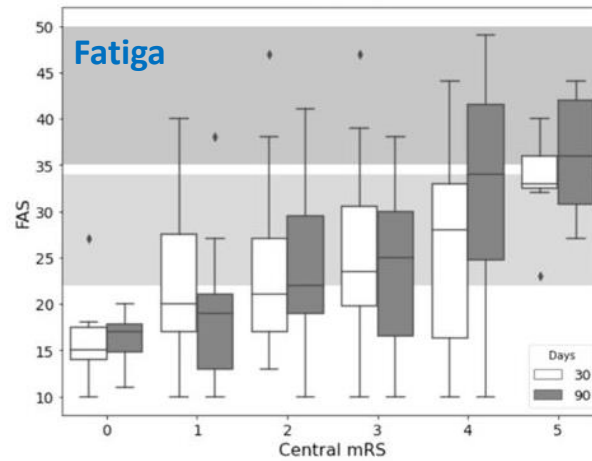
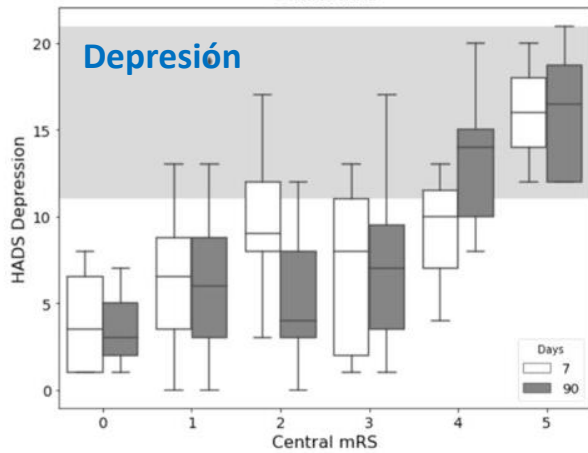
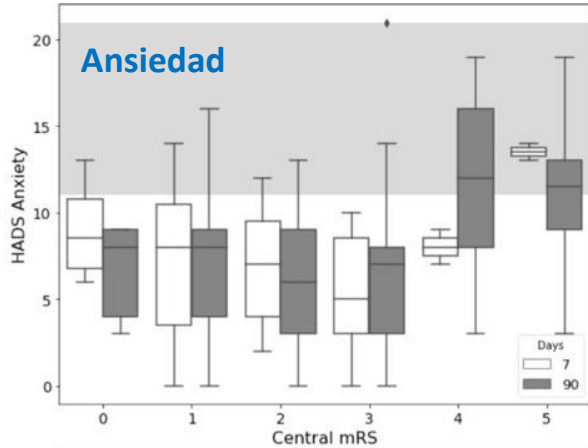
NIHSS 1



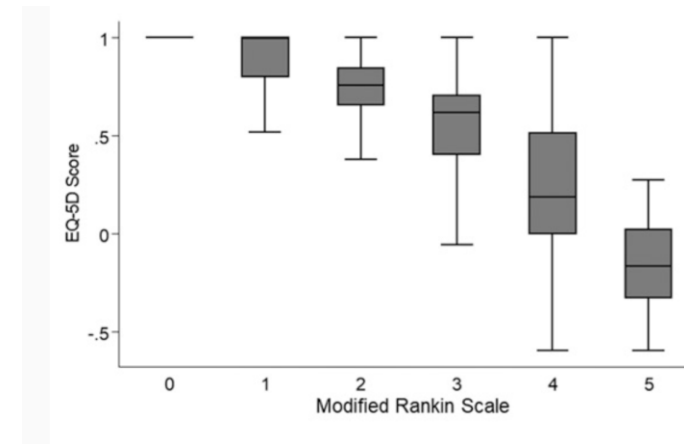
mRS 2



PROMs (Patient-Reported Outcome Measures)



Calidad de vida



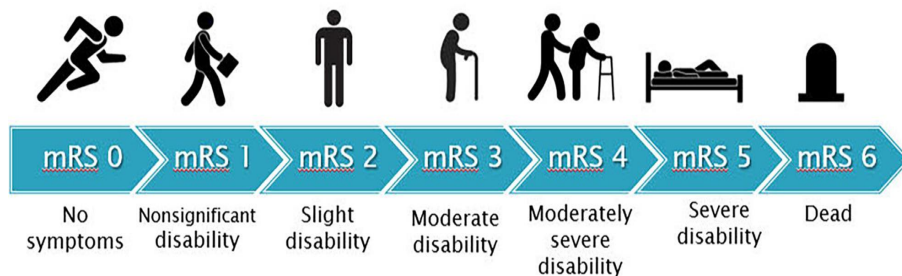
- Tiempo largo de evaluación largo (tecnologías, Apps)
- Dificultad en pacientes con problemas de comunicación
- Limitada experiencia como outcomes en ensayos clínicos

| | Intervention group (n=103) | Control group (n=103) | Effect measure | Unadjusted value (95% CI) | Adjusted value* (95% CI) |
|--|----------------------------|-----------------------|-------------------|---------------------------|--------------------------|
| Modified Rankin Scale score at 12 months | | | Common odds ratio | 1.69 (1.03 to 2.76) | 1.80 (1.09 to 2.99) |
| Modified Rankin Scale score 0-2 at 12 months | 45 (44%) | 31 (30%) | Odds ratio | 1.81 (1.02 to 3.20) | 1.86 (1.01 to 3.44) |
| EQ-5D utility index score† | | | Beta‡ | | |
| At 3 months | 0.44 (0.36) | 0.34 (0.34) | | 0.09 (-0.01 to 0.18) | 0.08 (-0.01 to 0.17) |
| At 6 months | 0.45 (0.36) | 0.34 (0.34) | | 0.11 (0.01 to 0.20) | 0.10 (0.01 to 0.19) |
| At 12 months | 0.46 (0.38) | 0.33 (0.33) | | 0.12 (0.03 to 0.22) | 0.12 (0.03 to 0.22) |
| EQ-5D visual analogue scale†§ | | | Beta‡ | | |
| At 3 months | 60.0 (22.0) | 52.2 (23.8) | | 7.81 (0.65 to 14.97) | 7.73 (0.59 to 14.88) |
| At 6 months | 59.9 (22.8) | 52.3 (24.1) | | 7.58 (0.17 to 14.98) | 8.23 (0.75 to 15.70) |
| At 12 months | 63.0 (23.9) | 57.0 (23.8) | | 5.99 (-1.69 to 13.67) | 6.27 (-1.32 to 13.86) |
| Barthel index, 95-100 at 12 months†§ | 49 (48%) | 29 (28%) | Odds ratio | 2.31 (1.30 to 4.42) | 2.47 (1.33 to 4.62) |

Data are n (%) or mean (SD) unless otherwise stated. EQ-5D=EuroQol five dimensions questionnaire. *Adjusted for minimisation factors and alteplase use. †The zero value was imputed to dead patients; p values for repeated measures analysis **p=0.023** for treatment effect on EQ-5D utility index and p=0.035 for treatment effect on EQ-5D visual analogue scale. ‡Beta estimates the difference of means between treatment groups. §Analyses were not prespecified.

Table 2: Secondary clinical outcomes and other follow-up assessments up to 12 months post randomisation

mRS: Ventajas



Aceptación Experiencia

Utilizada en la mayoría de EC

Agencias reguladoras

Grupos consenso

Estructurada Certificada

Evaluación rápida y sencilla

Difícilmente sustituible

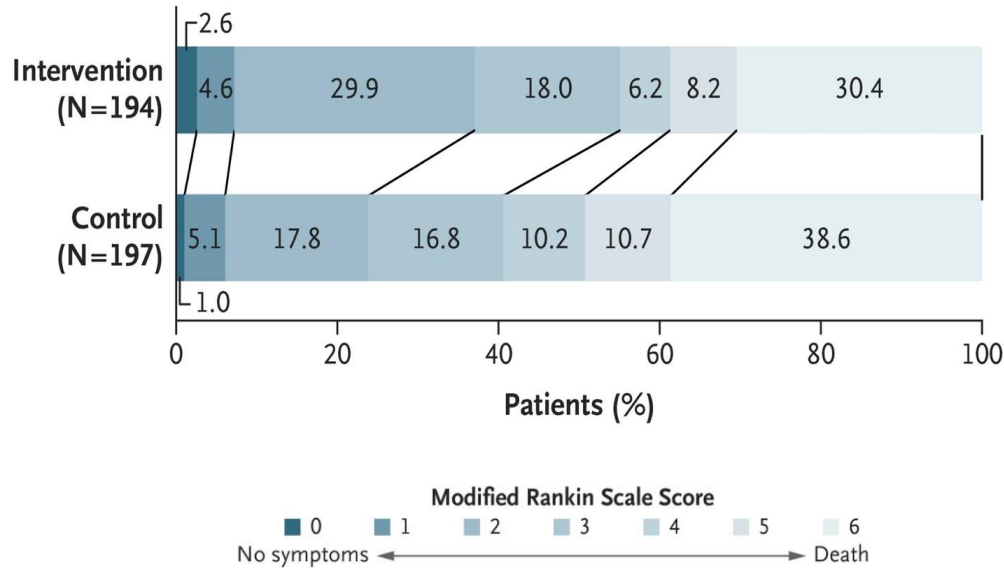
Buena concordancia (estructurada
o incluso centralizada)

Tratamiento estadístico

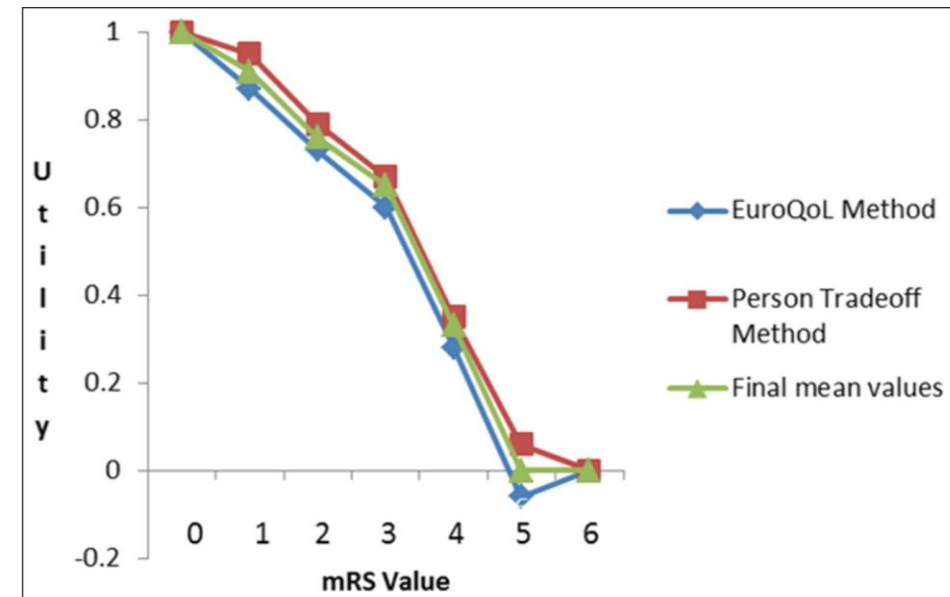
Incluye todos los rangos de
discapacidad (incluye mortalidad)

Diversos métodos de análisis
Fácilmente interpretable

mRS: dicotómico vs. ordinal vs. utility weighted



| Modified Rankin Scale Vs Utility Weighted Modified Rankin Scale | | | | | | | |
|---|-------|-------------------|-------------------|---------------------|------------------------|-------------------|------|
| mRS Description | No SX | SX w/o disability | Slight disability | Moderate disability | Mod. Severe disability | Severe disability | Dead |
| mRS-value | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| UW-mRS | 10 | 9.1 | 7.6 | 6.5 | 3.3 | 0 | 0 |



Dicotómico: (% y OR)

mRS 0-1 vs. 2-6

mRS 0-2 vs. 3-6

mRS 0-3 vs. 4-6

Ordinal:

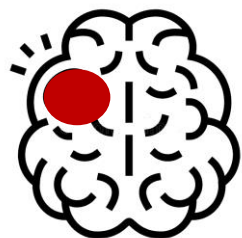
Shift analysis - cOR

Chaisinanunkul et al, Stroke 2015

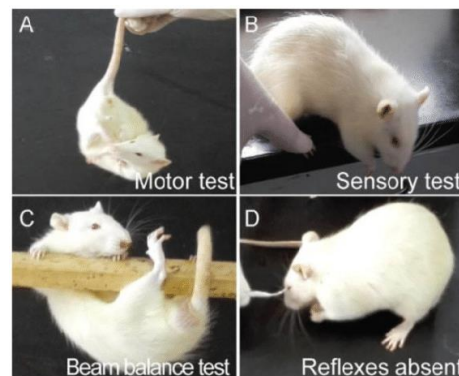
Wang et al, Stroke 2020

Calidad de vida

Enfermedad
(ICTUS)



Deficiencia / *Impairment*
(secuelas)



Discapacidad / *Discapacity*
(actividad)



Minusvalía / *Handicap*
(participación)



SPECIAL REPORT

Standardized Nomenclature for Modified Rankin Scale Global Disability Outcomes

Consensus Recommendations From Stroke Therapy Academic Industry Roundtable XI

Jeffrey L. Saver¹, MD*; Napasri Chaisinanunkul², MD*; Bruce C.V. Campbell, MBBS, BMedSc, PhD;
James C. Grotta, MD; Michael D. Hill, MD, MSc; Pooja Khatri, MD, MS; Jaren Landen, PhD; Maarten G. Lansberg, MD;
Chitra Venkatasubramanian, MD; Gregory W. Albers, MD; on behalf of the XIth Stroke Treatment Academic Industry Roundtable

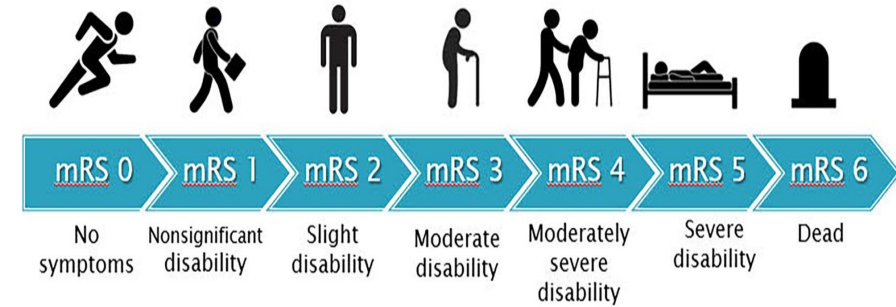


Table 3. Recommended Health State Terms for mRS Ranges

| Cut point | Key feature | Better outcome | Worse outcome |
|------------|--|--|---|
| 0 vs 1–6 | Symptoms | Normal | Symptomatic or dead |
| 0–1 vs 2–6 | Able to do work/leisure/school activities fulltime | Nondisabled | Disabled or dead |
| 0–2 vs 3–6 | Able to live alone for >1 wk | Independent | Dependent or dead |
| 0–3 vs 4–6 | Able to walk | Ambulatory or bodily needs-capable or better | Not ambulatory nor bodily needs-capable or dead |
| 0–4 vs 5–6 | Constant care | Not requiring constant care or better | Requires constant care or dead |
| 0–5 vs 6 | Survival | Alive | Dead |

mRS indicates modified Rankin Scale.

Table 6. Recommended Health State Terms for mRS Multilevel Outcomes

| Outcome | Health state term | Better outcome | Worse outcome |
|----------------------|--------------------------------|---|--|
| Ordinal shift | Level of disability | Reduced disability | Increased disability |
| Utility-weighted mRS | Health-related quality of life | Improved health-related quality of life | Reduced health-related quality of life |

| Level | Can | ...But | Valence |
|-------|--|---|-----------|
| mRS 0 | No symptoms | ... | Ideal |
| mRS 1 | Do work/leisure/school activities fulltime | ...has symptoms | Excellent |
| mRS 2 | Live alone for >1 wk | ...can't do work/leisure/school activities fulltime | Good |
| mRS 3 | Walk* | ...can't live alone for >1 wk | Fair |
| mRS 4 | Not require constant nursing care | ...can't walk* nor do body self-care | Poor |
| mRS 5 | Alive | ...requires constant care | Very poor |
| mRS 6 | ... | Not alive | ... |