Disability assessment: can we combine responsiveness and clinical relevance?

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Disclosures

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Bottom line

Functional assessments are promising tools for measuring disability in multiple sclerosis (MS) trials.

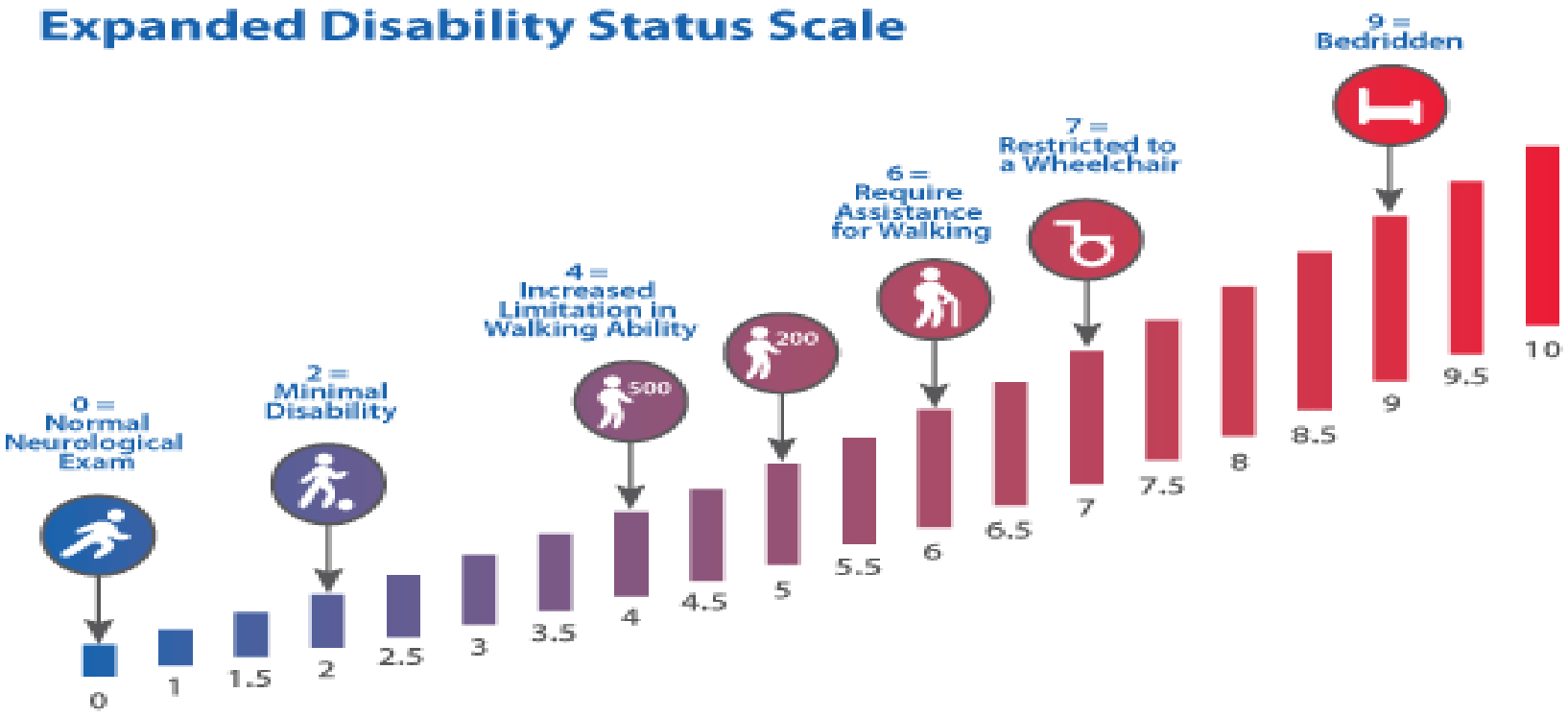
* multidimensional
* reliable
* meaningful to the patient
* valid
* responsive

MS is a multidimensional disease

- Mobility
- Manual dexterity
- Vision
- Cognition
- Bladder problems
- etc

- Motor function
- Sensory function
- Coordination
- Brain stem function
- Visual function
- Higher cortical functions
- etc

EDSS


Expanded Disability Status Scale
0 = Normal Neurological Exam
2 = Minimal Disability
4 = Increased Limitation in Walking Ability
6 = Require Assistance for Walking
7 = Restricted to a Wheelchair
9 = Bedridden
500
200
0
1
1.5
2
2.5
3
3.5
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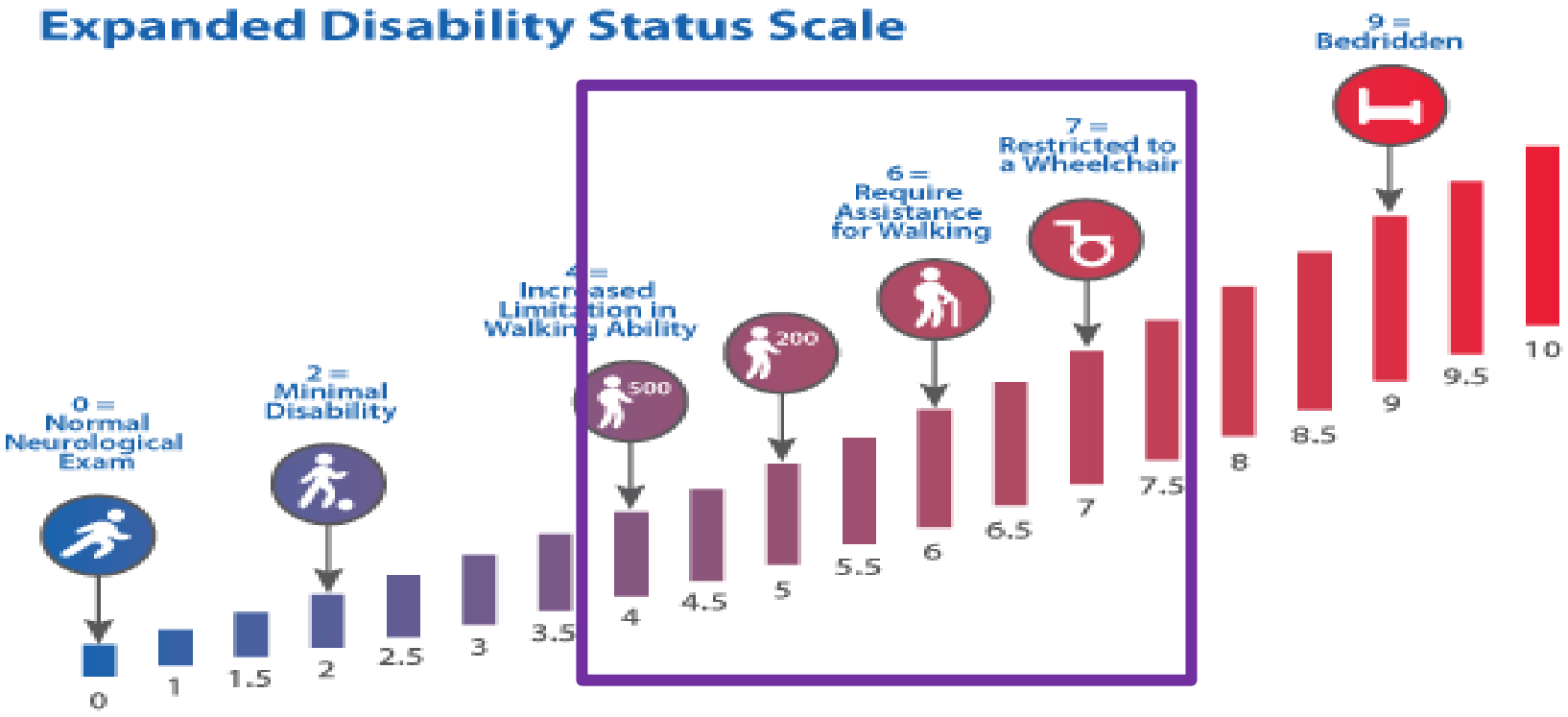
10

EDSS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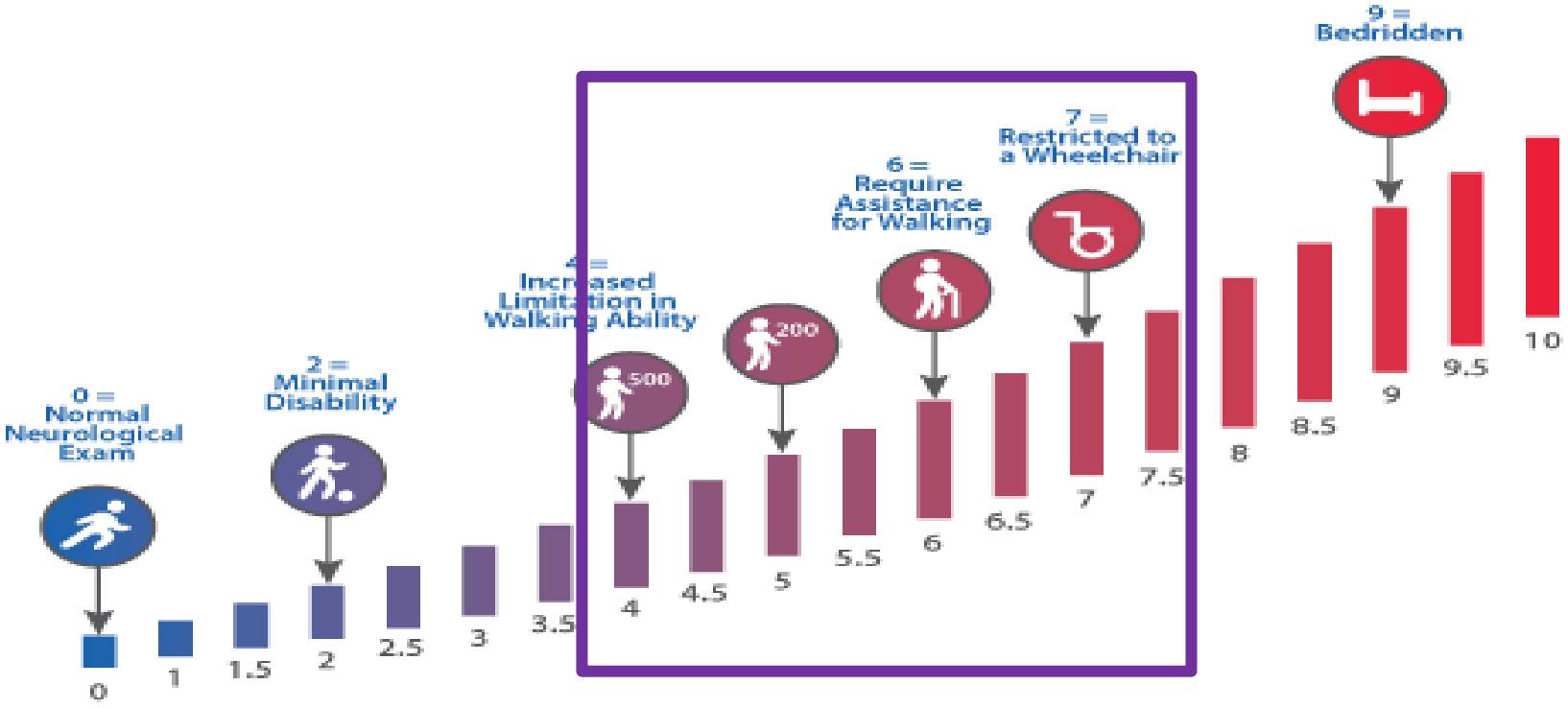
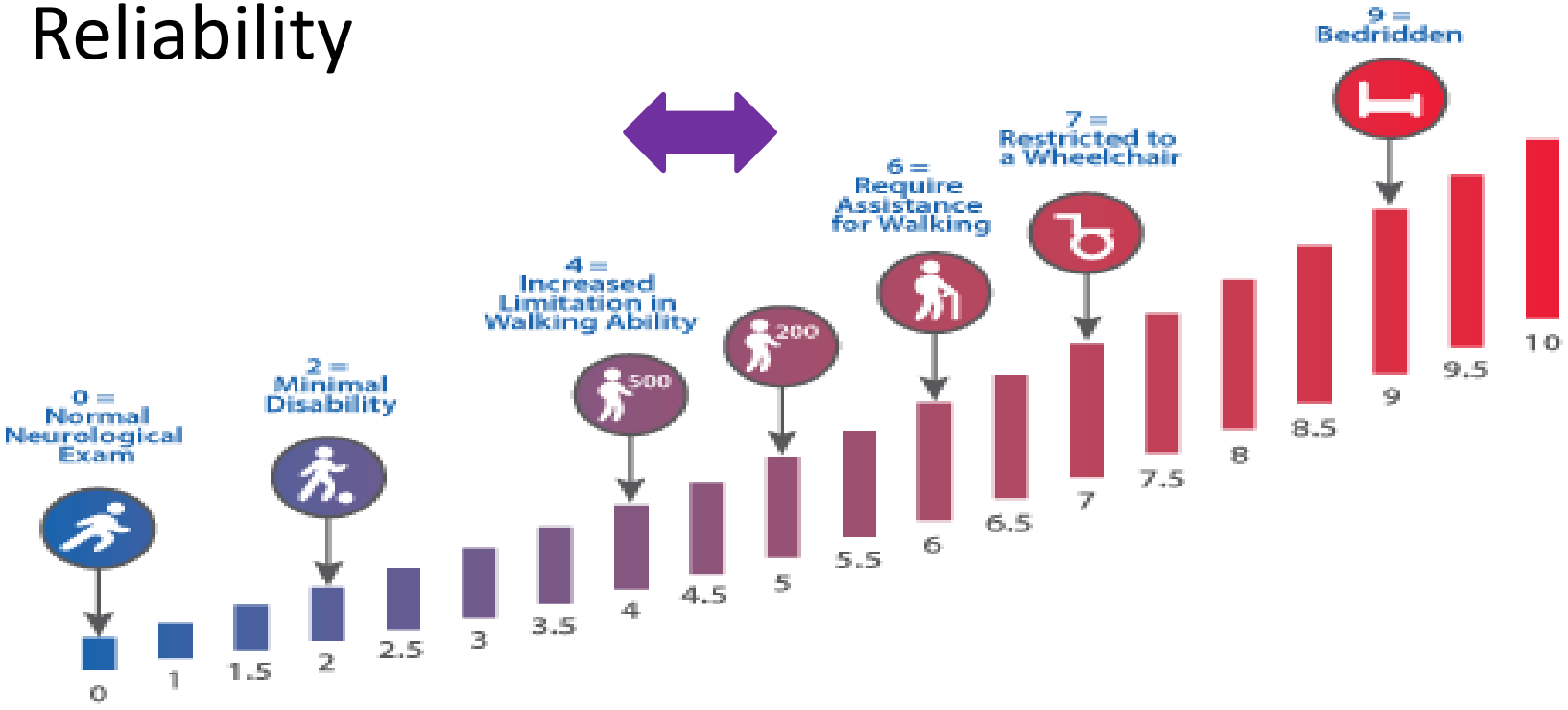
EDSS

- Dimensionality



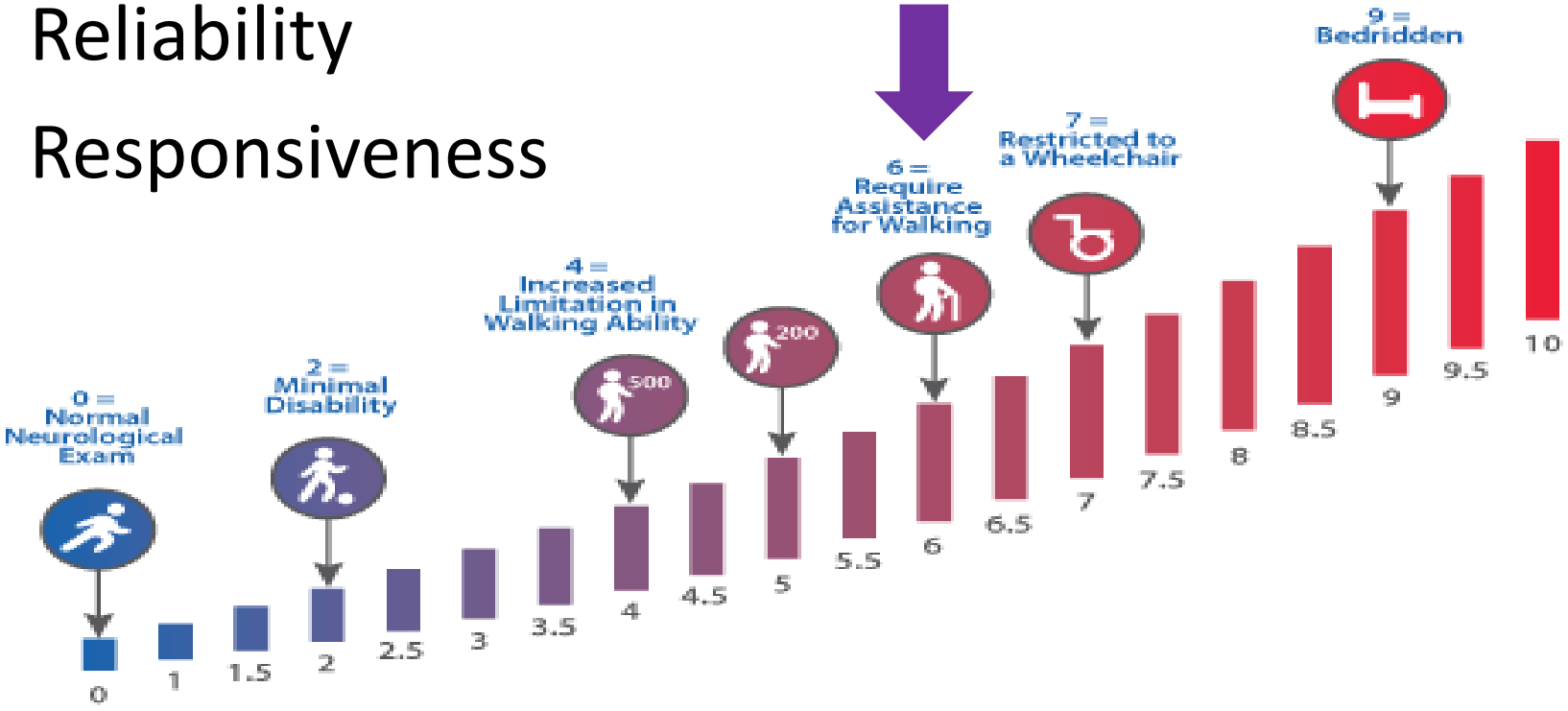
EDSS

- Dimensionality
- Reliability



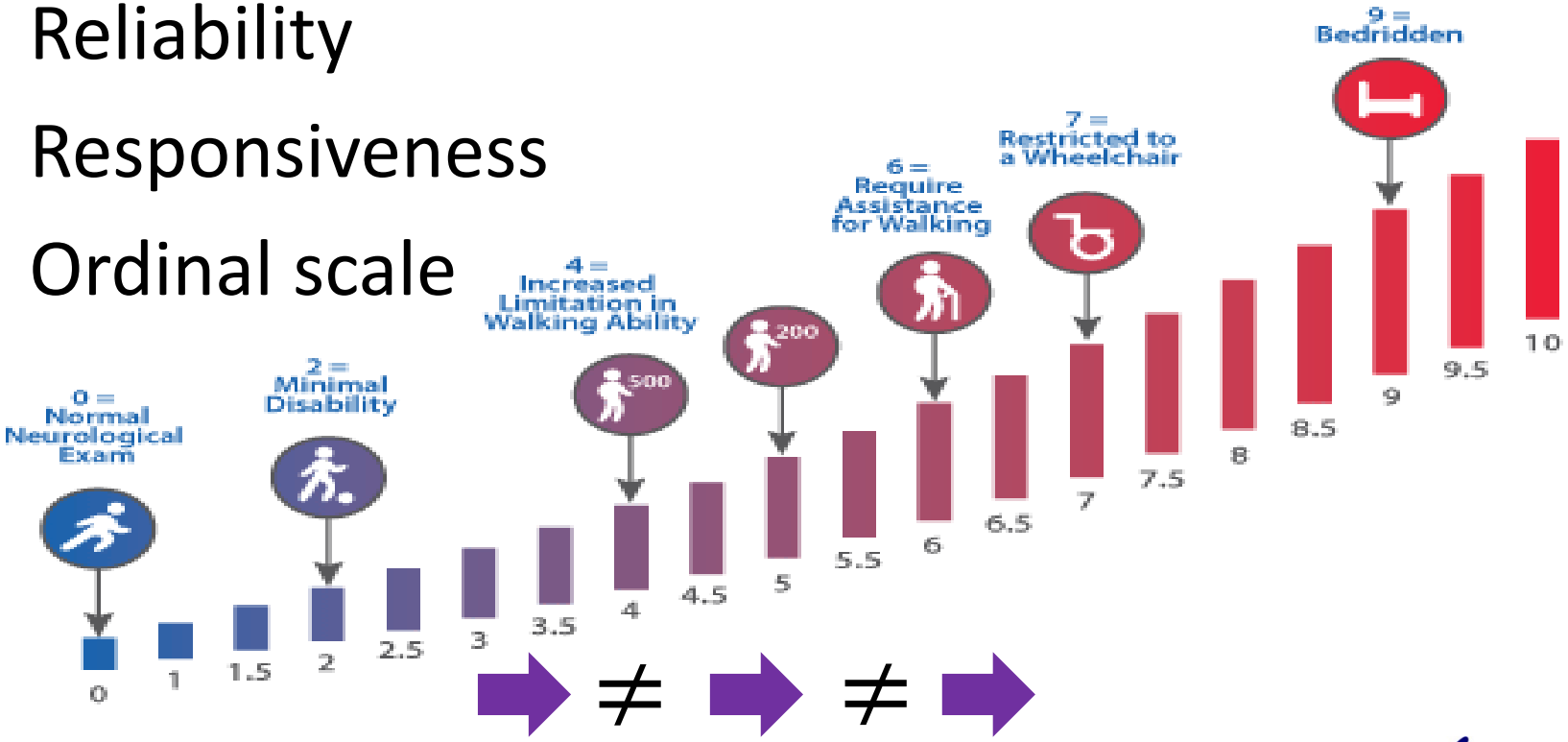
EDSS

- Dimensionality
- Reliability
- Responsiveness

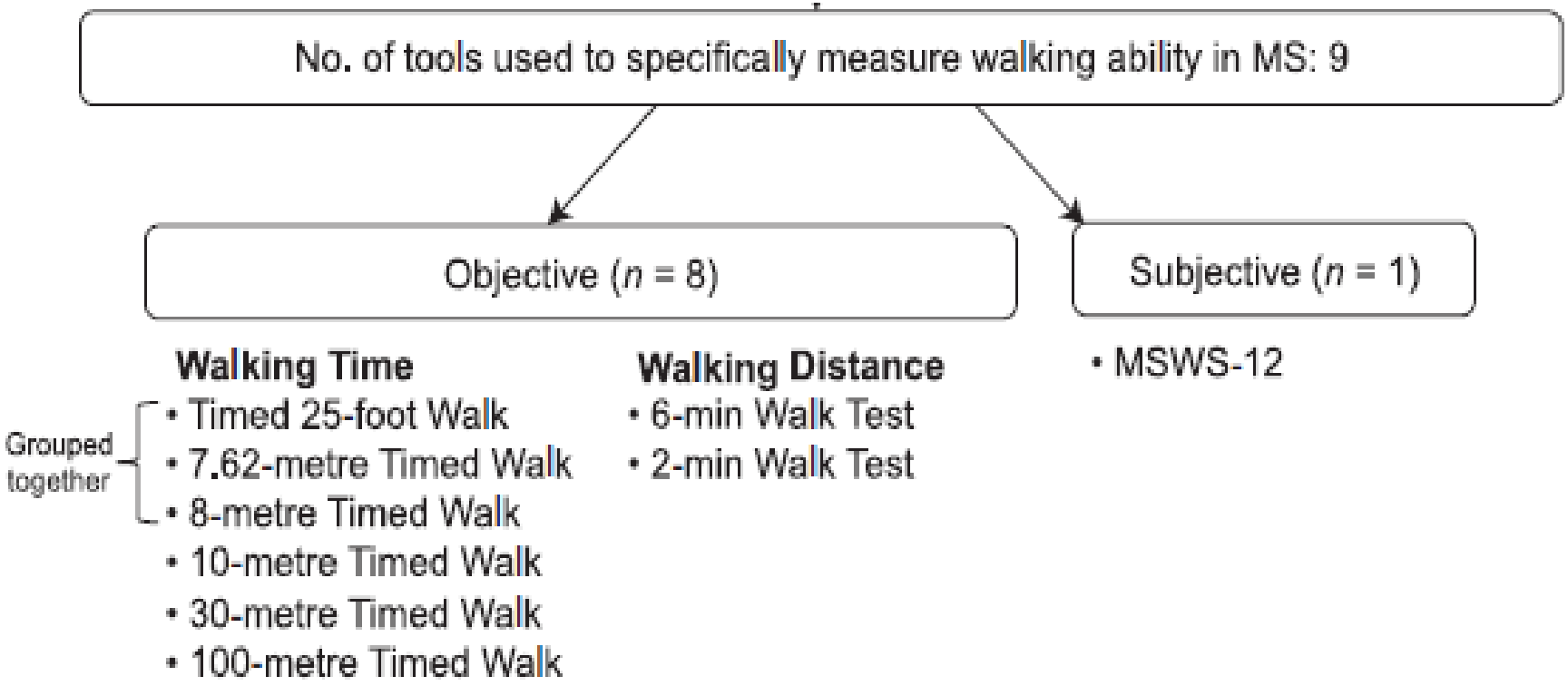


EDSS

- Dimensionality
- Reliability
- Responsiveness
- Ordinal scale



Functional walking test

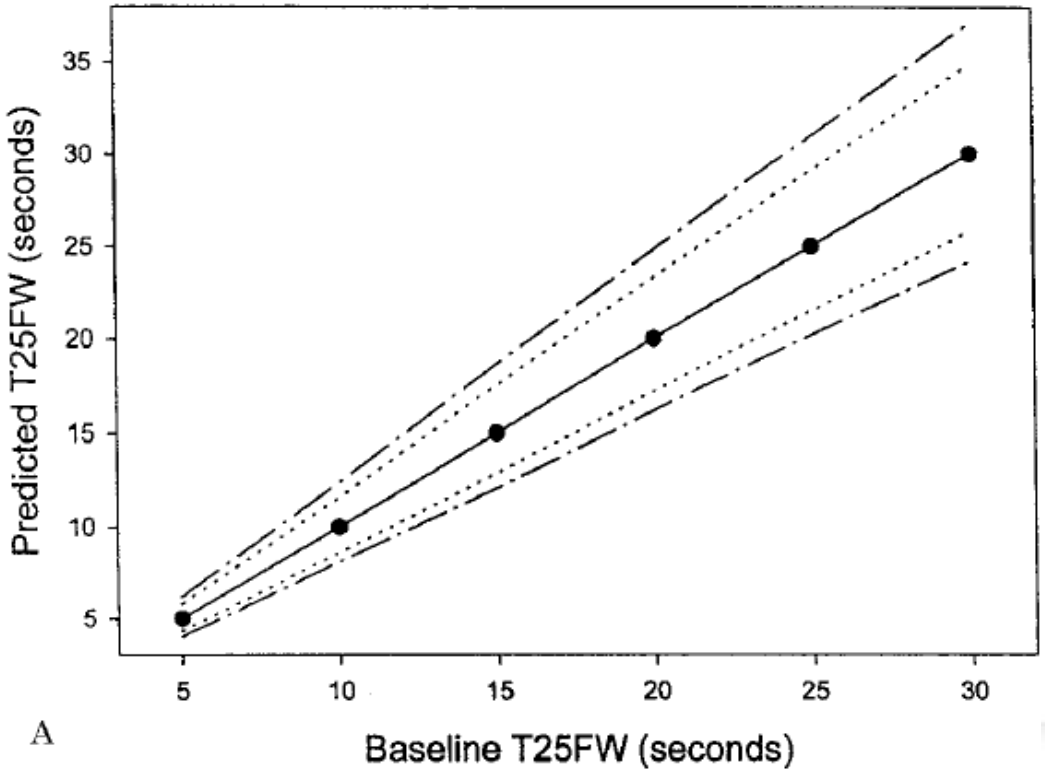


Kieseier and Pozzilli MSJ 2012

Timed 25 foot walk test (TWT)

TWT - reliability

Repeated TWT assessment in stable patients
n=63 (single center: n = 27, multicenter: n = 36)



variability
single center: 16%
multicenter: 24%

Schwid et al. Neurology 2002

TWT - reliability

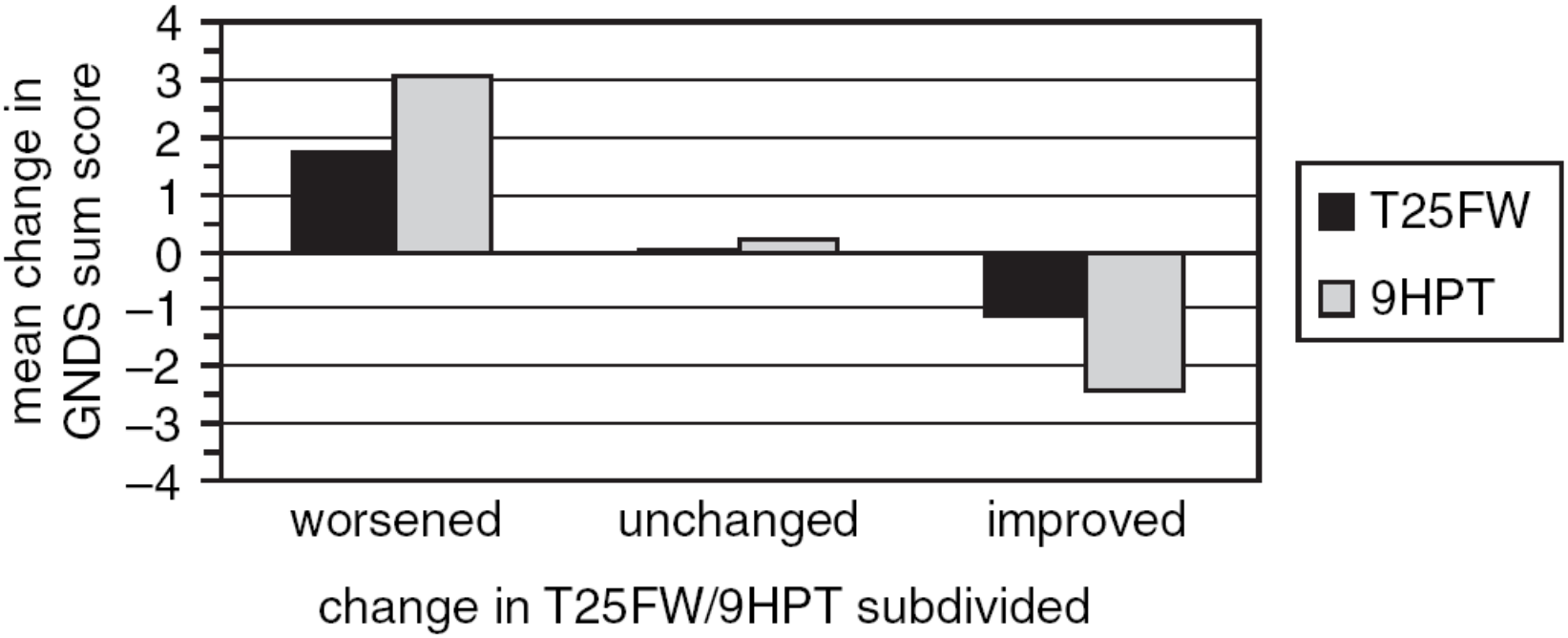
Table 2. Reliability of objective walking measures in multiple sclerosis.

Assessment	Inter-rater	Intra-rater	Test-retest
Walking time			
T25FW[a]	• Same day ICC: 1.0 (95% CI, 0.99–1.0)[16] • Same day ICC: 0.942[18]	• 1 week interval ICC: 0.99 (95% CI, 0.98–1.0)[16]	• Same day ICC: 0.96[15]

Kieseier and Pozzilli MSJ 2012

TWT - validity

vs Guy's Neurological Disability Scale (GNDS); n=527



Kragt et al. Mult. Scler. 2006

TWT - validity

Perceived changes in walking during exacerbation; n=49

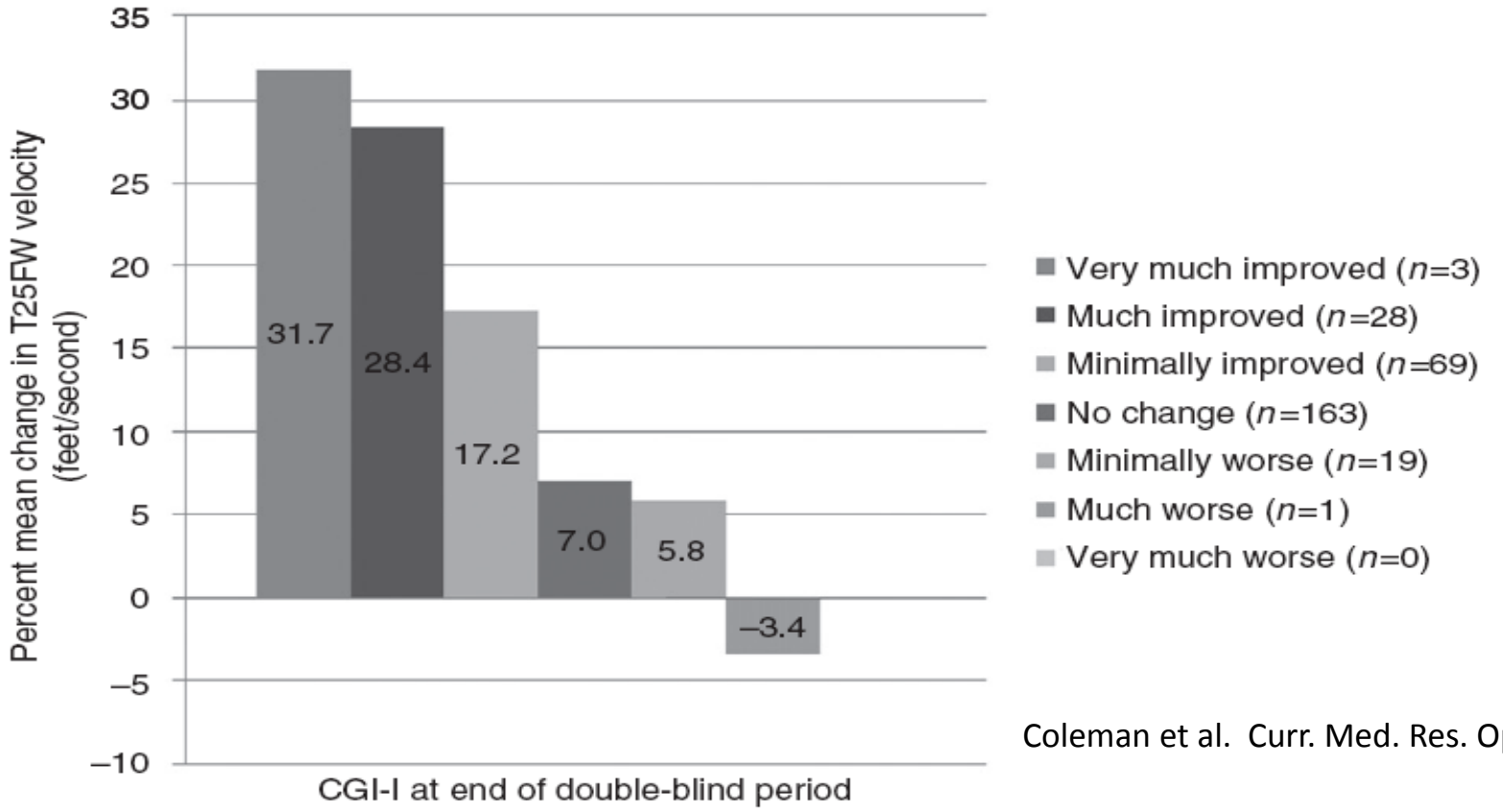
Perceived changes in walking	*With changes in the standard neurological examination*	
	T25FW Δ>20%	*T25DW Δ>3 s*
Subjective trouble	14 of 19	7 of 19
No subjective trouble	0 of 17	0 of 17

Perceived changes in walking	*Without changes in the standard neurological examination*	
	T25FW Δ>20%	*T25FW Δ>3 s*
Subjective trouble	2 of 7	0 of 8
No subjective trouble	0 of 6	0 of 6

Kaufman et al. Mult. Scler. 2000

TWT - validity

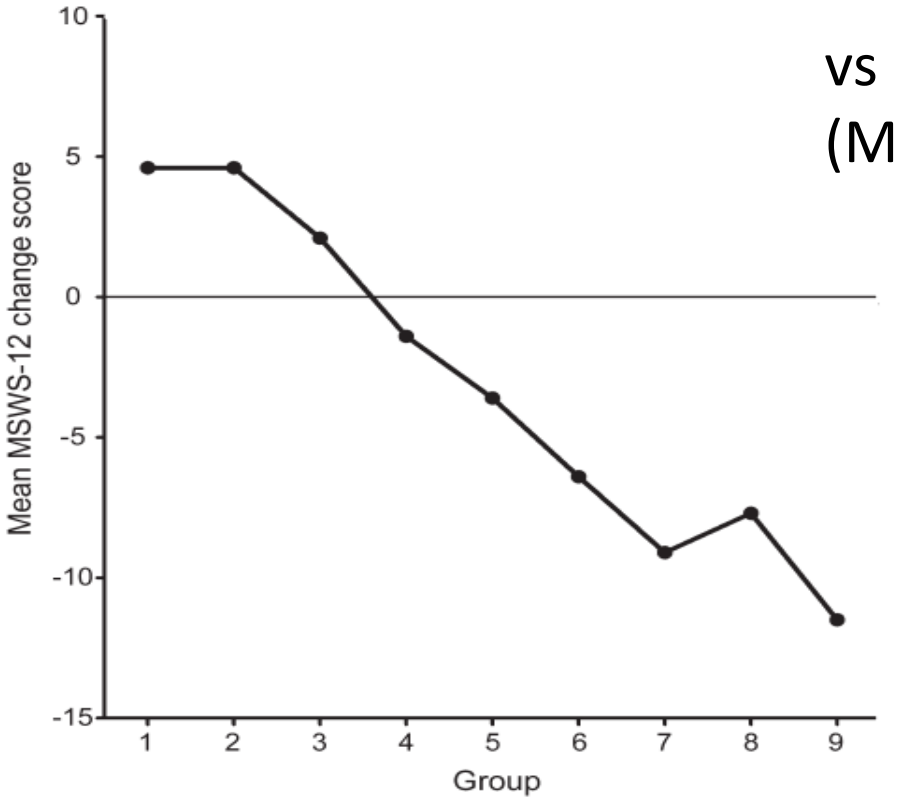
vs Clinician Global Impression (CGI); n=296



Coleman et al. Curr. Med. Res. Opin. 2012

TWT - validity

Figure 1 Change in MSWS-12 score for 9 groups defined by their change in T25FW speed



vs MS Walking Scale-12 (MSWS-12); n=533

1 = > 20% slower
2 = 10-20% slower
3 = -10 - + 10 change
4 = 10-15% faster
5 = 15-20% faster
6 = 20-15% faster

Hobart et al. Neurology 2013

Timed 25 foot walk test (TWT)

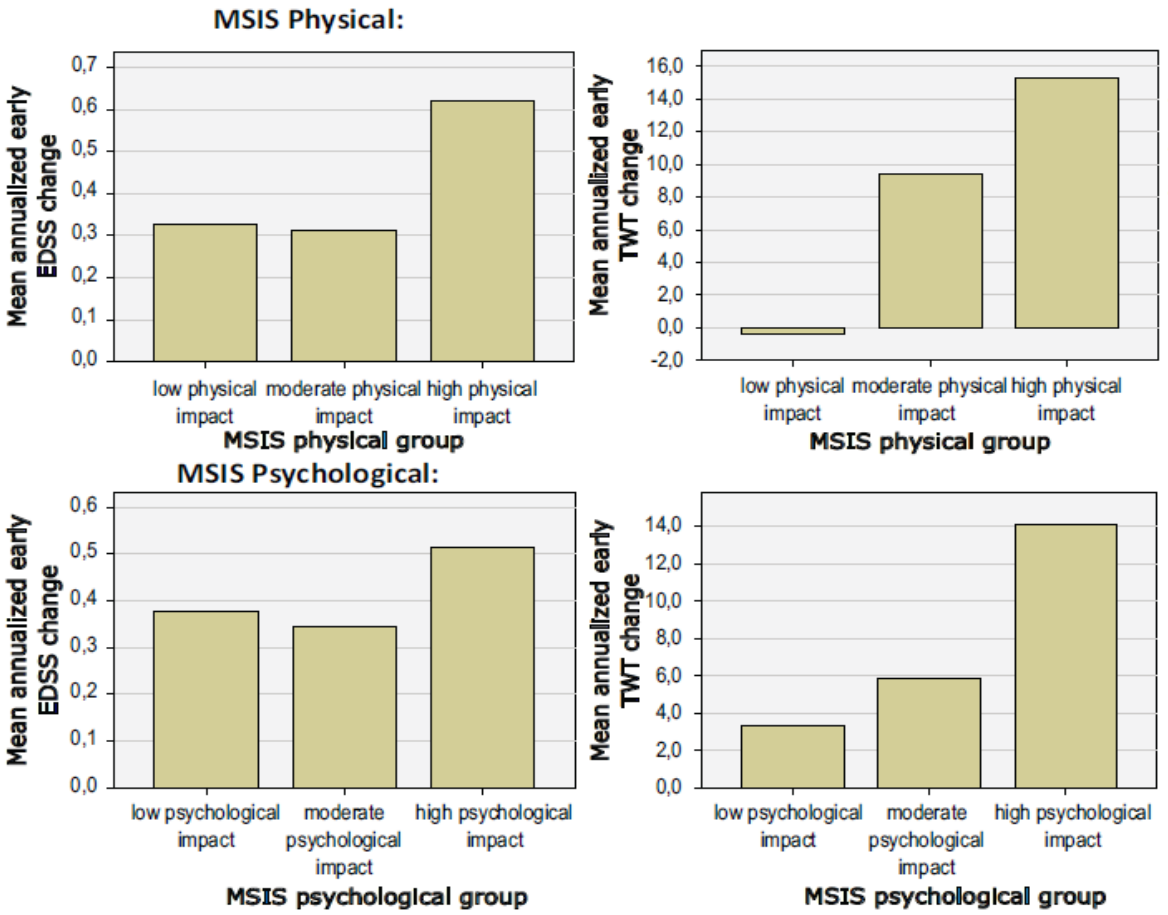
Predicting PRO's in progressive MS; n=134

EDSS: Expanded Disability Status Scale, 9HPT: 9-Hole Peg Test, MSIS-29: Multiple Sclerosis Impact Scale, MSWS-12: Multiple Sclerosis Walking Scale, T25FW: Timed 25-Foot Walk, yr: years, Δ: delta (change)

Figure 1. MS patient visit scheme.

Bosma et al. MSJ 2012

Timed 25 foot walk test (TWT)



Bosma et al. MSJ 2012

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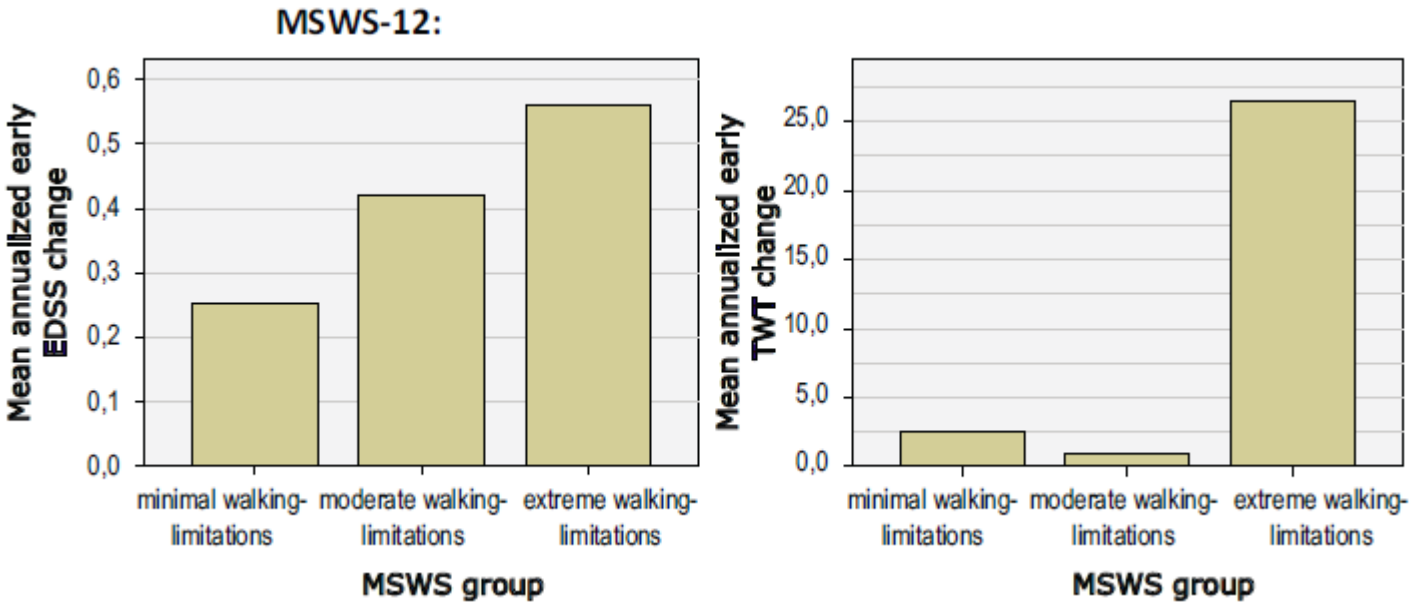

Bosma et al. MSJ 2012

TWT

- Reliable
- Responsive
- Clinically meaningful
  - Concurrent validity
  - Predictive validity

TWT

- Seconds or speed
- Group vs individuals
- Worsening vs improvement

TWT

- Functional assessment tool for mobility
- Part of a spectrum to cover multidimensionality
- Easy to perform, well accepted

Bottom line

Functional assessments are promising tools for measuring disability in multiple sclerosis (MS) trials.