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THE GEORGE WASHINGTON UNIVERSITY

WASHINGTON, DC

Comparing Indices Of Responsiveness For the Coma Near-**Coma Scale With and Without Pain Items** Vera Pertsovskaya,¹ Jennifer A. Weaver,² Jasmine Tran,² Allan J. Kozlowski,³ Trudy Mallinson¹

INTRODUCTION

- Recovery of consciousness must be monitored using validated assessments to determine treatment effectiveness and patient response to treatment.¹
- Indices of responsiveness such as the distribution-based minimal clinically important difference (MCID), minimal detectable change (MDC), and conditional MDC (cMDC) indicate whether an individual or group has made a change that is greater than measurement error or a clinical standard.
- Painful stimuli are common in these assessments but raise ethical concerns.
- The Coma Near Coma (CNC) Scale is a short assessment (10-items)* to evaluate the neurobehavioral function (NBF) of patients with Disorders of Consciousness (DoC).²
 - Recent psychometric analyses indicate the assessment is unidimensional when the two pain items are removed.³
- The 10 item Wright's Person Separation Reliability is 0.89 indicating the assessment is reliable for group-level decisions.⁴

*CNC has 11 items; the olfactory item was not administered in this study due to difficulty controlling the substance across clinical settings.

Purpose: To compare indices of responsiveness for the CNC 10-item and 8-item scales. A secondary purpose is to identify proportions of improvers and non-improvers making change \geq MCID, MDC, and cMDC.

METHODS

Participants: 32 adults with severe brain injury who have been in a DoC state for at least 28 consecutive days.

Table 1: Sample Characteristics								
Characteristic	Total (N= 32)							
Sex, n (%)								
Men	28 (88)							
Women	4 (12)							
Veteran status, n (%)								
Veteran	6 (19)							
Civilian	26 (81)							
Time from onset to enrollment, n (%)								
<90 d	19 (60)							
91-180 d	11 (34)							
>180 d	2 (6)							
Etiology of BI, n (%)								
Traumatic	28 (88)							
Non-Traumatic	4 (12)							
State of consciousness at baseline, n (%)								
MCS	15 (47)							
VS	14 (44)							
Missing	3 (9)							
Tracheostomy at baseline, n (%)								
Present	27 (84)							
Absent	0 (0)							
Missing	5 (16)							
Source								
PACS	18 (56)							
FAMV	14 (44)							

Coma Near Coma Scale (CNC):

- 3-point rating scale (0, 2, and 4) rescored so that a higher score indicated more neurobehavioral function:
- 0 = no response; 1 = partially responsive state; 2 = consistent responsive state
- 10-item CNC total raw score: 0 to 40; 8-item CNC total raw score: 0 to 32
- Raw scores were transformed to equal-interval Rasch measures for analyses **Data Analysis:**
- Participants were evaluated twice, 12-16 days apart
- Analyses conducted with (10-items) and without (8-items) pain items
- Participants were classified either as improvers (CNC change > 0) or nonimprovers (CNC change ≤ 0)
- Indices of responsiveness (MCID, MDC, and cMDC) were calculated for all participants, improvers, and non-improvers

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RESULTS

The CNC is an imprecise measure resulting in an MDC that is larger than the MCID. **CNC MCID** should not be used to evaluate clinical change in individual patients.

Baseline, Followitems Status mean (using up, pooled (SD) mean SD) (SD) Non 0.22 -1.31 0.89 -0.44-0.93 0.67 improvers (n=11) Non 0.87 0.31 0.86 -1.05 -1.07 improvers -0.16 (n=12) Improvers 0.89 0.64 1.18 -0.43 -1.36 (n=21) Improvers 0.48 0.87 -1.45 -0.33 1.34 0.83 (n=20) 0.61 0.27 participants -0.91-0.600.89 1.13 (n=32) 0.46 0.87 0.28 1.28 -0.96 -0.60 participants (n=32)

Table 2: Responsiveness Indices for the CNC for Non-Improvers, Improvers, and All Participants Abbr: SD=standard deviation; r=Wright's reliability coefficient, SEM=standard error of measurement; ES=effect size; CI=confidence interval; SRM=standardized response mean

cMDC for the 8-item CNC

Raw Score		Time 2	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
	Rasch Measure		-3.81	-2.59	-1.86	-1.4	-1.04	-0.74	-0.47	-0.21	0.03	0.28	0.54	0.83	1.16	1.57	2.14	3.08	4.52
Time 1		SE	1.83	1.01	0.74	0.63	0.57	0.53	0.51	0.5	0.5	0.5	0.52	0.55	0.6	0.69	0.83	1.14	1.92
0	-3.81	1.83		3.94	3.56	3.41	3.33	3.27	3.24	3.23	3.23	3.23	3.26	3.30	3.37	3.49	3.69	4.12	5.20
1	-2.59	1.01	3.94		2.43	2.27	2.19	2.13	2.11	2.09	2.09	2.09	2.12	2.16	2.23	2.36	2.55	2.98	4.06
2	-1.86	0.74	3.56	2.43		1.90	1.82	1.76	1.73	1.72	1.72	1.72	1.75	1.79	1.86	1.98	2.18	2.61	3.69
3	-1.4	0.63	3.41	2.27	1.90		1.66	1.61	1.58	1.57	1.57	1.57	1.59	1.64	1.70	1.83	2.02	2.45	3.53
4	-1.04	0.57	3.33	2.19	1.82	1.66		1.52	1.50	1.48	1.48	1.48	1.51	1.55	1.62	1.75	1.94	2.37	3.45
5	-0.74	0.53	3.27	2.13	1.76	1.61	1.52		1.44	1.43	1.43	1.43	1.46	1.50	1.57	1.69	1.88	2.31	3.40
6	-0.47	0.51	3.24	2.11	1.73	1.58	1.50	1.44		1.40	1.40	1.40	1.43	1.47	1.54	1.66	1.86	2.29	3.37
7	-0.21	0.5	3.23	2.09	1.72	1.57	1.48	1.43	1.40		1.39	1.39	1.41	1.46	1.52	1.65	1.84	2.27	3.35
8	0.03	0.5	3.23	2.09	1.72	1.57	1.48	1.43	1.40	1.39		1.39	1.41	1.46	1.52	1.65	1.84	2.27	3.35
9	0.28	0.5	3.23	2.09	1.72	1.57	1.48	1.43	1.40	1.39	1.39		1.41	1.46	1.52	1.65	1.84	2.27	3.35
10	0.54	0.52	3.26	2.12	1.75	1.59	1.51	1.46	1.43	1.41	1.41	1.41		1.48	1.55	1.68	1.87	2.30	3.38
11	0.83	0.55	3.30	2.16	1.79	1.64	1.55	1.50	1.47	1.46	1.46	1.46	1.48		1.59	1.72	1.91	2.34	3.42
12	1.16	0.6	3.37	2.23	1.86	1.70	1.62	1.57	1.54	1.52	1.52	1.52	1.55	1.59		1.79	1.98	2.41	3.49
13	1.57	0.69	3.49	2.36	1.98	1.83	1.75	1.69	1.66	1.65	1.65	1.65	1.68	1.72	1.79		2.11	2.54	3.62
14	2.14	0.83	3.69	2.55	2.18	2.02	1.94	1.88	1.86	1.84	1.84	1.84	1.87	1.91	1.98	2.11		2.73	3.81
15	3.08	1.14	4.12	2.98	2.61	2.45	2.37	2.31	2.29	2.27	2.27	2.27	2.30	2.34	2.41	2.54	2.73		4.24
16	4.52	1.92	5.20	4.06	3.69	3.53	3.45	3.40	3.37	3.35	3.35	3.35	3.38	3.42	3.49	3.62	3.81	4.24	

Figure 1: The pair of raw scores can be matched and if the pair lands in: 1) a green cell - the patient has made an improvement beyond measurement error; 2) a red cell - the patient has made a decline beyond measurement error; 3) a gray cell - the patient has not made a change beyond measurement error; or 4) a black cell - the patient has made no change.

The shorter 8-item CNC detects similar number of patients making change beyond measurement error and without inflicting pain.

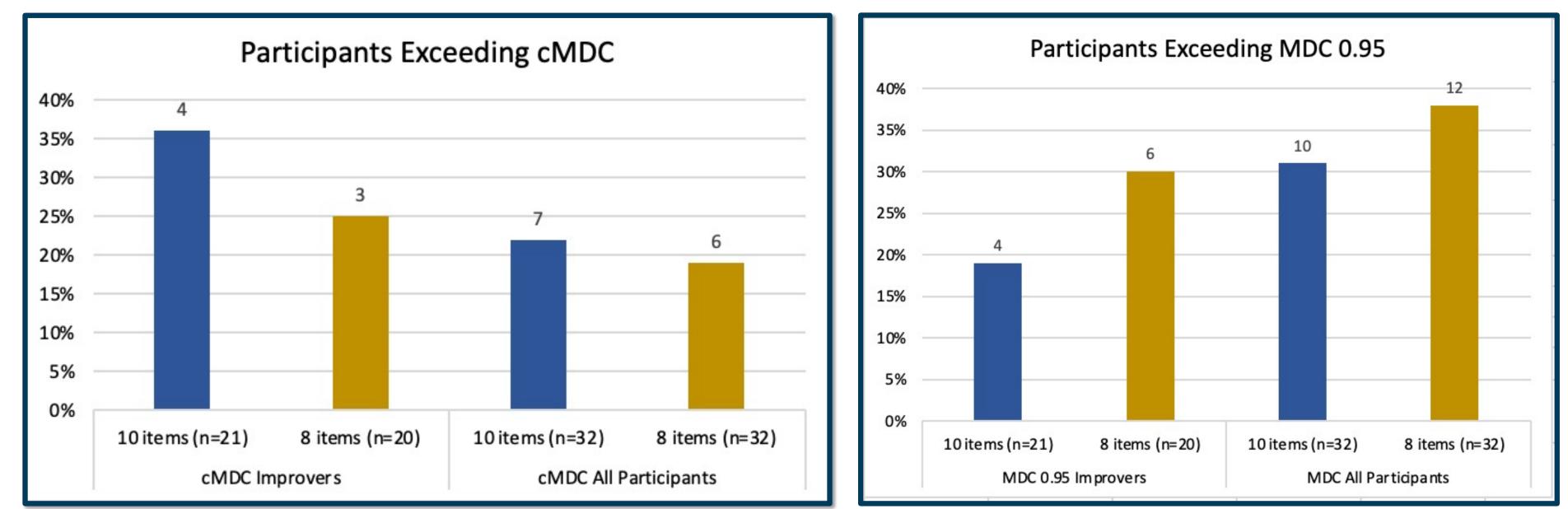


Figure 2: Number of Improvers and All Participants that made a change beyond measurement error using the cMDC or MDC on the 10-item and 8-item CNC.

Lower 95% CI	Upper 95% CI	SRM	MDC .95	MCID .2SD	MCID .33SD	MCID .50SD
-2.18	-0.61	-0.99	0.61	0.13	0.22	0.34
-1.78	-0.56	-1.30	0.86	0.17	0.28	0.43
0.52	1.16	1.16	1.77	0.24	0.39	0.59
0.58	1.18	1.35	1.33	0.27	0.44	0.67
-0.17	-0.62	0.26	1.69	0.23	0.37	0.57
-0.08	0.62	0.29	1.28	0.26	0.42	0.64

- 8-item CNC detected greater variability in this sample with less measurement error (better reliability).
 - Removing pain items resulted in a larger SDpooled and SRM. Larger SDpooled resulted in larger MDC and MCIDs for both improvers and non-improvers.
 - This apparent contradiction of the Spearman-Brown prophecy formula⁵ supports previous work suggesting pain response is a concept distinct from NBF.
- SRM and MCIDs were larger for the group of patients classified as improvers compared to non-improvers.
- How much change in NBF is relevant depends on whether a group of patients is improving or declining.
- cMDC should be used when making decisions based on changes in NBF for an individual.
- cMDC is based on standard errors around specific pairs of patient measures so it is more precise than group-level standard error.
- CNC may not be sensitive enough for determining group level change in NBF.
- MDC for the CNC was larger than any of the MCIDs, suggesting that even large group-level change in NBF as measured by the CNC is within the range of measurement error.

Clinical Relevance: Preliminary evidence supports the 8-item CNC group and patient level indices of responsiveness being as precise as the 10-item version; this suggests NBF can be tracked without administering painful stimuli.

- Larger group of participants is needed to substantiate findings for
- responsiveness
- Determine whether using the cMDC presents an added burden for practitioners

ACKNOWLEDGMENTS

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DISCUSSION

FUTURE RESEARCH

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