

## BRIEF REPORT

# Comparing indices of responsiveness for the Coma Near-Coma Scale with and without pain items: An Exploratory study

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## Abstract

**Introduction:** This study aimed to establish the indices of responsiveness for the Coma/Near-Coma (CNC) scale without (8 items) and with (10 items) pain test stimuli. A secondary purpose was to examine whether the CNC 8 items and 10 items differ when detecting change in neurobehavioral function.

**Methods:** We analyzed CNC data from three studies of participants with disorders of consciousness: one observational study and two intervention studies. We generated Rasch person measures using the CNC 8 items and CNC 10 items for each participant at two time points  $14 \pm 2$  days apart using Rasch Measurement Theory. We calculated the distribution-based minimal clinically important difference (MCID) and minimal detectable change using 95% confidence intervals ( $MDC_{95}$ ).

**Results:** We used the Rasch transformed equal-interval scale person measures in logits. For the CNC 8 items: Distribution-based MCID 0.33 SD = 0.41 logits and  $MDC_{95} = 1.25$  logits. For the CNC 10 items: Distribution-based MCID 0.33 SD = 0.37 logits and  $MDC_{95} = 1.03$  logits. Twelve and 13 participants made a change beyond measurement error ( $MDC_{95}$ ) using the CNC 8-item and 10-item scales, respectively.

**Conclusion:** Our preliminary evidence supports the clinical and research utility of the CNC 8-item scale for measuring the responsiveness of neurobehavioral function, and that it demonstrates comparable responsiveness to the CNC 10-item scale without administering the two pain items. The distribution-based MCID can be used to evaluate group-level changes while the  $MDC_{95}$  can support clinical, data-driven decisions about an individual patient.

## KEYWORDS

brain injuries, consciousness disorders, pain, rehabilitation

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Clinicians and researchers rely on standardized assessment data to interpret whether patients in disorders of consciousness are making a change in neurobehavioral function (i.e., recovery of consciousness). Evidence of psychometric properties for standardized, bedside observational assessments has grown in recent years (Pape et al., 2014; Weaver et al., 2022; 2020; Williams & Smith, 2017). A systematic review of assessments for disorders of consciousness identified there is a need for reliable and valid assessments to examine a critical gap in measurement, the assessment's ability to detect change (Seel et al., 2010). Only one neurobehavioral function assessment, the Disorders of Consciousness Scale-25, has quantified meaningful change by reporting indices of responsiveness (Mallinson et al., 2016).

Indices of neurobehavioral responsiveness can include the anchor-based and distribution-based minimal clinically important difference (MCID) and minimal detectable change based on a 95% confidence interval ( $MDC_{95}$ ). Anchor-based MCIDs map patient change on an assessment to an external criterion that is considered important to family, care partners, patients, or clinicians (Crosby et al., 2003; Guyatt et al., 2002). To the best of our knowledge, there is currently no assessment of neurobehavioral function for which care partners' or clinicians' perceptions of change is the external criterion for an anchor-based MCID. The distribution-based MCID indicates whether the difference between scores from two time points are likely to represent a group-level change that exceeds a clinical standard. The distribution-based MCID represents the smallest amount of change in an outcome that might be considered important and provides an estimate of treatment effectiveness in research. The  $MDC_{95}$  indicates whether the difference between scores from two time points are likely to represent an individual-level change that exceeds measurement error. Establishing indices of responsiveness, such as the  $MDC_{95}$ , is important because clinicians must monitor neurobehavioral recovery of consciousness using validated measures to determine whether rehabilitation treatment is effective (Giacino et al., 2020). Furthermore, measuring a decline, that is beyond measurement error, in neurobehavioral recovery may signal the need to determine the presence of a new or previously undetected debilitating condition (e.g., subclinical seizures or hydrocephalus).

Assessments evaluating the neurobehavioral function for patients with disorders of consciousness often include items with painful stimuli (e.g., Coma/Near-Coma Scale, Coma Recovery Scale-Revised, and Disability Rating Scale) (Zasler et al., 2022). Previous work has identified the need to assess nociception in patients with disorders of consciousness (Schnakers et al., 2010). While localization to noxious stimulation is considered indicative of conscious perception (Giacino et al., 2002), painful stimuli has produced brain activation in the primary somatosensory cortex of patients in a vegetative state (Laureys et al., 2002). Thus, response to painful stimuli occurs when individuals are in the vegetative state, minimally conscious state, and emerged. Identification of nociception may support clinical decisions to adjust the individual's positioning or provide pain medication to increase the comfort of the individual but may not clearly distinguish different levels of consciousness. Prior research on the Coma/Near-Coma (CNC) scale found that responses to painful stimuli and neurobehavioral function are two dis-

tinct concepts (Weaver et al., 2020). This earlier work indicates the CNC scale is a unidimensional assessment of neurobehavioral function only when painful test stimuli/items are not included. This finding suggests that when responses to painful stimuli change over time, the changes do not necessarily reflect changes in neurobehavioral function. To advance our understanding of this finding, the purpose of this study is to (i) compute the indices of responsiveness for the CNC scale without (8 items) and with (10 items) painful test stimuli, and (ii) determine whether the CNC 8 items and CNC 10 items differ according to detection of change in neurobehavioral function.

## 1 | METHODS

### 1.1 | Participants

This retrospective cohort study includes 40 adults with severe brain injury. Data were included from three studies: (1) Post-Acute Care Study ( $n = 18$ ), an observational study of patients receiving rehabilitation services (Pape et al., 2014); (2) Familiar Auditory Sensory Training ( $n = 14$ ), a clinical trial examining neurobehavioral function when provided a familiar voice intervention (Bender Pape et al., 2015); and (3) repetitive transcranial magnetic stimulation study ( $n = 8$ ), a clinical trial examining neurobehavioral function in response to a neuromodulatory intervention (Pape, 2015; Zilliox et al., 2022). During study enrollment, participants' demographics and medical history were obtained through review of health records and interviews with family. For each of the three studies, participants were evaluated weekly after study enrollment until recovery of consciousness (Bender Pape et al., 2015; Pape, 2015; Pape et al., 2014; Zilliox et al., 2022). Ethical approval for this secondary data analysis was obtained from the Institutional Review Board at George Washington University. Across studies, eligibility criteria were: (1)  $\geq 18$  years, (2) diagnosed with disorders of consciousness from brain injury, and (3) had two CNC scale assessments  $14 \pm 2$  days apart. Participants were excluded from the study if brain injury was due to cancer, tumor, or encephalopathy.

### 1.2 | Coma/Near-Coma Scale

The CNC scale is a short assessment (11 items) originally designed to capture neurobehavioral responses in persons in lower states of disorders of consciousness (Rappaport, 2005, 1992). The assessment scoring form and training recommendations can be found on the Traumatic Brain Injury Model Systems website (Rappaport, 2000). The olfactory item was not administered in any of the three studies due to difficulty in controlling for consistency and shipping restrictions for ammonia; thus, the scale was administered with 10 items (Bender Pape et al., 2015; Pape, 2015; Pape et al., 2014; Zilliox et al., 2022). Each item is scored using a 3-point rating scale with response options of 0, 2, 4; a lower score indicates better neurobehavioral function (Rappaport, 2000). For example, for the Auditory item a "0" reflects that the patient responds to the bell ringing stimulus with behaviors such as eye

**TABLE 1** Total raw score to Rasch person measure conversion for the 8-item and 10-item Coma Near Coma Scale from least to most neurobehavioral function.

	CNC total raw score	CNC-8 item person measure	CNC-10 item person measure
Less neurobehavioral function	40	-	-4.18
	38	-	-2.97
More neurobehavioral function	36	-	-2.25
	34	-	-1.81
	32	-3.81	-1.48
	30	-2.59	-1.21
	28	-1.86	-0.96
	26	-1.40	-0.74
	24	-1.04	-0.53
	22	-0.74	-0.33
	20	-0.46	-0.14
	18	-0.21	0.06
	16	0.04	0.27
	14	0.29	0.48
	12	0.55	0.72
	10	0.83	0.99
	8	1.17	1.30
	6	1.58	1.70
	4	2.16	2.25
	2	3.12	3.17
	0	4.58	4.59

opening or orientation toward sound and that this occurs  $\geq 3$  times. Whereas, for the Vocalization item a "0" reflects spontaneous words (Rappaport, 2000).

The study reported here compares the CNC scale comprised of the 10 items (excluding the olfactory item) and the CNC scale comprised of 8 items (excludes two pain items) (Weaver et al., 2020). For our analyses, the 3-point rating scale was rescored to 2, 1, 0, so that a higher score indicates better neurobehavioral function. Previous work, identified that the Wright's Person Separation Reliability was 0.87 and 0.89 for the CNC 8 items and CNC 10 items, respectively, indicating the CNC scale is sufficiently precise for group-level decisions (Weaver et al., 2020). These person separation reliability values are close to the 0.90 threshold for making consistently reliable individual decisions (Kerlinger & Lee, 2000; Van de Winckel A et al., 2022).

### 1.3 | Data analyses

For the CNC 8 items and CNC 10 items, we confirmed the Wright's Person Separation Reliability using Winsteps software version 5.3.3.1, because our study includes eight participants that were not in the previous CNC scale psychometric analyses (Weaver et al., 2021). We hypothesized the person separation reliability coefficients would

remain the same because a strength of Rasch Measurement Theory is that the analyses are sample-free and item-free (Bond et al., 2020). We generated Rasch person measures for each participant at both time-points for the CNC 8 items and CNC 10 items and used these data for responsiveness analyses.

We calculated the pooled standard deviation ( $SD_{\text{pooled}}$ ), effect size, and the standardized response mean using MedCalc version 17.6. We interpreted the effect size and standardized response mean at 0.20, 0.50, and 0.80 as a small, moderate, and large responsiveness (Husted et al., 2000). The standard error of measurement (SEM) was calculated using the following formula  $SEM = SD_{\text{pooled}}(\sqrt{1-r})$ , where  $r$  reflected the Wright's Person Separation Reliability value. We used the  $SD_{\text{pooled}}$  to calculate the distribution-based MCIDs at 0.20 (small), 0.33 (minimally important), and 0.50 (medium) standard deviations. The 0.20 SD MCID reflects a small but important group-level change, 0.33 SD MCID reflects a minimally important change relevant for clinical interpretation, and a 0.50 SD MCID reflects a medium sized effect (Crosby et al., 2003; Eton et al., 2004). We calculated the minimal detectable change using a 95% confidence interval ( $MDC_{95} = 1.96 \times SEM \times \sqrt{2}$ ). For both the CNC 8-item and CNC 10-item versions, we determined whether the difference between the baseline and follow-up mean person measures exceeded the distribution-based MCID. For both the CNC 8-item and CNC 10-item versions, we determined the proportion

of participants that exceeded the  $MDC_{95}$  after two consecutive weeks of rehabilitation. To exceed the  $MDC_{95}$ , a participant's change score could indicate either a decline or improvement in neurobehavioral function that was beyond measurement error.

## 2 | RESULTS

### 2.1 | Participants

Participants ( $n = 40$ ) were a mean (SD) age of 35 (12.7) years, mostly males ( $n = 35$ ; 88%), with traumatic brain injuries ( $n = 36$ ; 90%). Participants from the Post-Acute Care study were enrolled within the first 90 days postinjury while the Familiar Auditory Sensory Training and repetitive transcranial magnetic stimulation participants were enrolled between 90 days and 2 years after injury. Most participants were within 90 days of their injury date (19; 47%), with 11 participants between 91 and 180 days and 10 participants were more than 180 days from their injury date at time of CNC administration. At study enrollment, most participants had a tracheostomy (29; 73%) and there was an even distribution of participants in the vegetative state/unresponsive wakefulness syndrome (16; 40%) and minimally conscious state (21; 53%).

### 2.2 | Indices of reliability and responsiveness

The CNC 8-item ordinal total raw scores ranged from 0 to 32 and were transformed to equal-interval Rasch person measures, ranging from  $-3.81$  to  $4.58$  logits. The CNC 10-item ordinal total raw scores ranged from 0 to 40 and were transformed to equal-interval Rasch person measures ranging from  $-4.18$  to  $4.59$  logits. We provide a transformation table for converting ordinal total raw scores to equal-interval Rasch person measures in logits for both CNC 8-item and 10-item versions (Table 1). The Wright's Person Separation Reliability indices for the CNC 8 items and CNC 10 items, remained at 0.87 and 0.89, respectively (Table 2).

The small (0.20) effect sizes and standardized response means produced similar values (0.22–0.25 logits) and indicate that sample size computations, for each version, would not differ when designing clinical trials (Table 3). The small (0.20 SD), minimally important (0.33 SD), and medium (0.50 SD) distribution-based MCIDs are almost equivalent for the Coma Near-Coma-8 item and CNC 10-item versions (Table 3). The CNC 8 items has consistently larger distribution-based MCIDs than the CNC 10 items (Table 3). The mean difference between the baseline and follow-up scores after receiving an intervention (Table 2) was 0.37 and 0.35 for the CNC 8 items and CNC 10 items, respectively, which exceeds the respective small (0.20 SD) distribution-based MCIDs (Table 3).

The  $MDC_{95}$  findings indicate the CNC 10-item version has less measurement error yet both versions identified similar proportions of persons making neurobehavioral change beyond measurement error (Table 3). Specifically, the CNC 8-item version identified 12 (30%) par-

**TABLE 2** Indices of Responsiveness for the Coma Near Coma Scale With and Without Painful Test Stimuli.

Coma Near-Coma version	Baseline mean (SD)	Follow-up mean (SD)	SD <sub>pooled</sub>	Wright's Person Separation Reliability	Standard error of measurement	Effect size (using SD <sub>pooled</sub> )	Lower 95% CI	Upper 95% CI	Standardized response mean
8 items (without pain items)	-0.80 (1.4)	-0.43 (1.1)	1.25	0.87	0.45	0.29	-0.03	0.61	0.29
10 items (with pain items)	-0.72 (1.2)	-0.43 (1.0)	1.12	0.89	0.37	0.26	-0.12	-0.57	0.24

Abbreviations: CI, confidence interval; SD, standard deviation; SD<sub>pooled</sub>, pooled standard deviation of baseline and follow-up measures. Notation: Data calculated using Rasch person measures (logits), a higher number indicates more neurobehavioral function.

**TABLE 3** Minimal detectable change and distribution-based minimal clinically important differences for the Coma Near-Coma Scale with and without painful test stimuli.

Coma Near-Coma Version	MDC <sub>95</sub>	MCID 0.20 SD	MCID 0.33 SD	MCID 0.50 SD
8 items (without pain items)	1.25	0.25	0.41	0.63
10 items (with pain items)	1.03	0.22	0.37	0.56

Abbreviations: MCID, minimal clinically important difference; MDC<sub>95</sub>, minimal detectable change using 95% confidence intervals.

ticipants and the CNC 10-item version identified 13 (33%) participants as making a change beyond measurement error or a “true” change. Of these patients making “true” change, the CNC 8-item version identified 9/12 (75%) participants as improved and 3 as declined (25%); the CNC 10-item version identified 10/13 (77%) participants as improved and 3 as declined (23%).

### 3 | DISCUSSION

The preliminary evidence reported here, addresses the identified need for additional research on the measurement properties of the CNC scale, including responsiveness (Seel et al., 2010). The reported findings suggest that the CNC 8 items (without painful test stimuli) and CNC 10 items (with painful stimuli) have comparable reliability and precision for detecting change in neurobehavioral function. As postulated, the Wright’s Person Separation Reliability values did not change with the addition of 8 participants. The finding that the shorter CNC 8 items has comparable precision for detecting change to the longer CNC 10-item supports previous findings suggesting that pain is a distinct concept from neurobehavioral function (Weaver et al., 2020). The Wright sample-independent person separation reliability indices for both CNC versions remain below the 0.90 threshold for making consistently reliable individual patient treatment decisions.

The minor differences in person separation reliability and MDC<sub>95</sub> between the CNC 10 items and CNC 8 items indicate, that both versions identified comparable proportions of participants making a change beyond measurement error. Participants were identified as improvers if the person measure increased and were identified as decliners if the person measure decreased at the second CNC assessment. It is important to include decliners when identifying participants who made a change using the MDC<sub>95</sub> because it illuminates the need for additional clinical reasoning to determine whether there is something unobservable at the bedside hindering progress (i.e., medication changes, subclinical seizures, or hydrocephalus).

The distribution-based MCID values are sample-dependent because the equation uses the group’s  $SD_{pooled}$  (Altman & Bland, 2005). The standard error of measurement and MDC<sub>95</sub> values, are less sample-dependent because the equation utilizes Wright’s Person Separation Reliability coefficient in addition to  $SD_{pooled}$ . The CNC 8 items and CNC 10 items had comparable reliability coefficients. The CNC 8 items had greater distribution-based MCIDs, standard

error of measurement, and MDC<sub>95</sub> values because of a larger  $SD_{pooled}$  compared to the CNC 10-item version. The MDC<sub>95</sub> was greater than the distribution-based MCID values for both CNC versions indicating that if the distribution-based MCIDs are utilized it is possible an improvement or decline is not “true” but within the range of measurement error. This evidence suggests that the distribution-based MCID values should be used to interpret group-level changes and the MDC<sub>95</sub> should be used to interpret change at the individual patient level.

The standard error of measurement and MDC<sub>95</sub> can be used clinically. When a patient has a score of  $-1.86$  logits (raw score: 28) on the CNC 8-item version, the standard error of measurement indicates that the patient’s range of ability is  $-2.31$  to  $-1.41$  logits (total measure in logits  $\pm$  standard error of measurement). The patient’s progress can be considered “true change” beyond measurement error (MDC<sub>95</sub>) when the same patient achieves a total measure of  $-0.61$  logits or greater (raw score: 20 or lower; a difference of 8 or more). This information can support clinicians to determine whether an applied intervention is supporting the patient’s neurobehavioral recovery.

Our study addresses the need for indices of responsiveness for neurobehavioral function assessments used for patients with disorders of consciousness (Seel et al., 2010; Weaver et al., 2020). This preliminary study supports the clinical and research utility of the CNC 8 items for measuring change in neurobehavioral function with reduced administration burden. Our study further suggests no additional value for determining change in neurobehavioral function is achieved by inflicting pain on patients through administration of the pain items. Indices of responsiveness, such as the CNC 8-item MDC<sub>95</sub>, can support clinicians to make data-driven decisions about patient recovery whereas indices such as the CNC 8-item distribution-based MCID and effect size can inform clinical trials examining treatment effectiveness at the group level.

#### 3.1 | Study limitations

The indices of responsiveness we report should be interpreted cautiously because they were generated from a small sample of adults with disorders of consciousness. Future studies should substantiate our findings using larger samples. For patients with disorders of consciousness, establishing an anchor-based MCID reflecting family, care partner, or clinician perception of change is an important area of future inquiry.

## 4 | CONCLUSION

Our preliminary evidence supports the clinical and research utility of the CNC 8 items, as it demonstrates adequate responsiveness to neurobehavioral change without administering the two pain items. When evaluating change at the group level the CNC 8-item effect size and distribution-based MCIDs should be used. When evaluating change for an individual patient, the CNC 8-item MDC<sub>95</sub> should be used to determine when observed change is beyond measurement error.

## DATA AVAILABILITY STATEMENT

Deidentified data from this study are available upon request.

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## PEER REVIEW

The peer review history for this article is available at <https://publons.com/publon/10.1002/brb3.3120>.

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