



ORIGINAL RESEARCH

# Longitudinal Evaluation of the HABC Monitor Among Trauma Survivors

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**Purpose:** To examine the sensitivity to change of the Healthy Aging Brain Care Monitor (HABC-M) through a longitudinal analytical comparison with reference standards.

Patients and Methods: We used longitudinal data from 120 participants in a multicenter randomized controlled trial evaluating the effectiveness of the Trauma Medical Home (TMH). We used the following reference standards: The depression and anxiety subdomains of the Hospital Anxiety and Depression Scale (HADS), the Patient-Reported Outcomes Measurement Information System Sleep Disturbance Short Form 4a (PROMIS-SF), and the Pain, Enjoyment of Life, and General Activity Scale (PEG). We assessed sensitivity to change using three longitudinal comparative analytical methods. The correlation of the HABC-M score with reference standards' scores over time, the correlation of changes in the HABC-M score with changes in reference standards' scores, and a longitudinal analysis to compare changes in the HABC-M against reference standards' known change categories.

**Results:** Throughout the six-month period, the HABC-M exhibited moderate to high correlations with the HADS (r = 0.66, p<0.001 for the depression subdomain and r = 0.42, p<0.001 for the anxiety subdomain), the PROMIS-SF (r = 0.57, p<0.001), and the PEG (r = 0.47, p<0.001). The changes in HABC-M significantly correlated with changes in reference standards at various time points. HABC-M scores were significantly different across known change categories established by the four reference standards, with standardized response mean (SRM) values ranging from 1.08 to 1.44.

**Conclusion:** The HABC-M is capable of monitoring the recovery of older trauma survivors.

Keywords: sensitivity to change, analytical comparison

### Introduction

Trauma older survivors are facing cognitive, physical, and psychological recovery challenges. <sup>1–5</sup> For example, 29% of trauma survivors develop post-traumatic stress disorder (PTSD) within nine months of injury, <sup>6</sup> and approximately 16% receive a major depression diagnosis within one year. <sup>7</sup> Numerous assessment tools are available to monitor the cognitive, physical, and psychological recovery of trauma survivors. <sup>8–12</sup> Knowledge provided by these tools can be used by clinicians when designing and executing care plans to improve the quality of life of their patients. <sup>7,8,13,14</sup> One of these tools is the Healthy Aging Brain Care Monitor (HABC-M), a patient-reported outcome measure composed of 27 items. <sup>13–16</sup> The HABC-M has shown good psychometric reliability among patients living with mood or cognitive disorders <sup>13</sup> and those who have survived critical illness. <sup>14</sup> A recent study validated the psychometric properties of HABC-M in detecting the cognitive, physical, and psychological recovery states of older trauma survivors. <sup>16</sup> However, the longitudinal evaluation of the HABC-M, including sensitivity to change, was not performed for the purpose of its use as a monitoring tool for the cognitive, physical, and psychological recovery of older trauma survivors. Detecting significant changes over time for patient-reported outcome measures such as the HABC-M is essential for evaluating the efficacy of any care plan. <sup>17,18</sup>

The purpose of the present study is to investigate HABC-M sensitivity to change in older patients recovering from traumatic injuries. We hypothesize that the HABC-M will demonstrate good sensitivity to change when its scores and their changes are compared longitudinally with reference standards. The results will establish the validity of the HABC-M SR to track the progress and effectiveness of various care plans targeting the cognitive, physical, and psychological recovery of older trauma survivors. Confirming the HABC-M's sensitivity to change will also support its use as an outcome measure.

### **Materials and Methods**

# Study Design

Our study used longitudinal data obtained from a multicenter randomized controlled trial that evaluated the efficacy of the Trauma Medical Home (TMH) as a collaborative care model to enhance the recovery of older trauma survivors. <sup>19</sup> In the TMH trial, the HABC-M coupled with four established tools were administered simultaneously at multiple time points to measure the recovery needs of older trauma survivors. The Standards for Reporting of Diagnostic Accuracy Studies (STARD) criteria were followed by the study. <sup>20</sup> The Indiana University Institutional Review Board granted approval for the study (IRB number 1612690852).

# **Participants**

The study included 120 participants aged 50 years or older randomized to the TMH arm who completed the HABC-M and the four reference standards between October 2017 and September 2021. The participating sites were Indiana University Health Methodist Hospital, Sidney & Lois Eskenazi Hospital, St. Vincent Hospital in Indianapolis, IN, and the University of Wisconsin Health University Hospital in Madison, WI. Inclusion criteria were hospital admission due to a traumatic injury, an injury severity score of 9 or higher, and access to a telephone following hospital discharge. Exclusion criteria included significant head injury (indicated by intracranial bleeding on imaging or a Glasgow Coma Scale score below 13), spinal cord injury with a persistent neurological impairment upon hospital release, stroke either on admission or during hospitalization, baseline cognitive impairment (noted by any reference to dementia or Alzheimer's disease in medical records), sensory impairments that hinder active engagement with study evaluations or communications, burns affecting over 10% of total body surface area, recent drug or alcohol use disorder (identified by medical records and/or the Alcohol Use Disorders Screening Test C or Drug Abuse Screening Test within the last 6 months), incarceration, malignancy with a life expectancy of less than 1 year, or residence located more than 50 miles away from the admitting trauma facility. All patients, or their representatives, provided written consent. The participants were informed about the purpose of the study, in accordance with the Declaration of Helsinki.

### HABC-M

The HABC-M is a 27-item patient-reported outcome tool designed to assess cognitive, functional, behavioral, and psychological symptoms. It was originally designed by an interdisciplinary team of dementia experts with the primary goal of measuring and monitoring dementia symptoms.<sup>22</sup> It has demonstrated a high sensitivity to change over time among older adults with mood or cognitive disorders<sup>22</sup> and intensive care unit survivors.<sup>23</sup> Each item prompts patients to report the frequency of a symptom experienced in the past 2 weeks on a 4-point ordinal scale: 0 = None (0–1 days), 1 = Several Days (2–6 days), 2 = More than half the days (7–11 days), and 3 = Almost daily (12–14 days). The HABC-M is composed of 6 cognitive items, 11 functional items, and 10 behavioral and psychological items. Scores for each item are combined to compute a total score. Higher scores reflect greater symptom severity.<sup>16</sup> The Self-Report Version of the HABC-M was selected for this study because the included patients were cognitively intact and did not necessitate input from a care partner or an informal caregiver.

### Reference Standards

The following tools were selected as reference standards. The depression and the anxiety subdomains of the Hospital Anxiety and Depression Scale (HADS), the Patient-Reported Outcomes Measurement Information System Sleep

Disturbance Short Form 4a (PROMIS-SF), and the Pain, Enjoyment of Life, and General Activity Scale (PEG). These measures were selected for their widespread use and established validity in the literature to capture changes in health-related quality of life. The depression and anxiety subdomains of the HADS are used for diagnosing anxiety and depression in non-psychiatric hospital settings.<sup>24</sup> Each of the seven items in the anxiety and depression subdomains has a value ranging from 0 to 3, for a total score ranging from 0 to 21. The PROMIS-SF evaluates sleep quality.<sup>25</sup> It has a maximum raw score of 20 and a minimum score of 4. It measures sleep's depth, quality, and satisfaction that the patient usually obtains during the preceding seven days. The PEG is a short 3-item measure that rates pain intensity on a range of 0–10, along with how the pain is affecting everyday activities and quality of life. A higher score usually corresponds to a larger burden of pain.<sup>26</sup>

# Sensitivity to Change

Although responsiveness is sometimes used synonymously with sensitivity to change, <sup>17</sup> it's useful to distinguish them. Responsiveness is the ability to accurately detect change following therapeutic interventions of known efficacy, but sensitivity to change is a broader concept that does not require a treatment; it assesses how well a tool can provide measurable indicators of a patient's progress by comparing the change in the HABC-M score in relation to changes in a reference standard (eg, global anchor item or, here, between different known change categories of reference standard scale scores). 27,28 The detected change cannot be attributed to random variations that usually occur due to measurement errors or daily fluctuations. <sup>17</sup> To ensure that health status questionnaires are reliable and sensitive regarding these real changes, specific quality criteria need to be established and adhered to.<sup>29</sup> For our purposes, we examined how closely the changes in the HABC-M total score correlated with changes that were observed in established reference standards over time. We conducted three different analytic methods. 22,30,31 First, we used the Spearman correlation coefficient to compare HABC-M scores with the scores of reference standards. Second, we also employed the Spearman correlation coefficient to compare the changes in the HABC-M scores relative to the changes in the scores of reference standards. Finally, we carried out a longitudinal study of change scores, examining how the HABC-M score changed in accordance with the reference standards' "known" or "reliable" change categories. A thorough assessment of the sensitivity to change over a significant period of time was made possible by the four separate intervals at which all three procedures were carried out: baseline assessment and three follow-ups at two, four, and six months following baseline assessment.

# **Analysis**

In addition to calculating the percentage of individuals who had floor and ceiling scores, descriptive data for the total scale included range, median, mean, and standard deviation. We utilized Cronbach's alpha to assess internal consistency.<sup>32</sup> We calculated the minimal clinically important difference (MCID) for the HABC M total score using the distribution-based method,<sup>33</sup> where we employed the most widely used approach that defines MCID as 0.5 SD.<sup>34</sup> Patients with incomplete HABC-M data were not included in this study. Changes in the HABC-M total score were computed using a cumulative change approach in accordance with the following: for each participant, the score at each time point (T2, T4, and T6) was subtracted from the baseline score (T1). The outcome of that computation was the change scores for each time period, which are shown as T1 minus T2 for two months, T1 minus T4 for four months, and T1 minus T6 for six months. For each reference standard, we used the literature to divide participants into declined, stable, and improved known change categories. For the purpose of this analysis, reference standards' change groups were the independent variables, and the change score of the HABC-M total score was the dependent variable. Within-group standardized response mean (SRM) effect size (mean change divided by SD of change) was computed for HABC-M total scores, separately for each of the three known change categories. 35 SRM values of 0.8 and above have been suggested to show high sensitivity to change, 0.5 to 0.79 moderate sensitivity, and 0.2 to 0.49 low sensitivity.<sup>36</sup> An analysis of variance (ANOVA) was used for the statistical comparison of the three known change categories for each reference standard on the HABC-M change scores. Pairwise Tukey-Kramer post hoc tests were used to control the family-wise Type I error rate at 0.05. We conducted all analyses using SAS 9.4 (Cary, NC).

# **Results**

# **Participants**

Out of the 216 patients that were randomized to TMH, data from 120 participants were included in the current study (Table 1) after excluding 96 individuals who did not complete the HABC-M measurements. The bulk of participants (58%) ranged in age from 65 to 79 years. Nearly all participants (99%) identified as non-Hispanic, the majority (91.6%) as white, and just 7.6% as African American. Their median hospital stay was 6.5 days, with a range of 4 to 9 days. The

**Table I** Distributions of Overall Patient Characteristics (n=120)

	N (%) or Median (25–75%)		
Age, n (%)			
50–64	38 (31.7)		
65–79	58 (48.3)		
80+	24 (20.0)		
Female, n (%)	66 (55.0)		
Hispanic, n (%)	0 (0.0)		
Race, n (%)			
White	109 (91.6)		
African-American	9 (7.6)		
Other	I (0.8)		
Hospital Length of Stay	6.5 (4–9)		
Mechanism of Injury, n (%)			
Fall	67 (55.8)		
Motor Vehicle Accident	34 (28.3)		
Other	19 (15.8)		
Injury Severity Score	10 (9–14)		
Charlson Comorbidity Index	0 (0–2)		
Katz ADL	6 (6–6)		
Lawton IADL	8 (8–8)		
Discharge Location, n (%)			
Home	63 (52.5)		
Rehabilitation Facility	35 (29.2)		
	14 (11 7)		
Skilled Nursing Facility	14 (11.7)		

**Abbreviations**: IQR, interquartile range; Katz ADL, Katz Index of Independence in Activities of Daily Living; Lawton IADL, The Lawton Instrumental Activities of Daily Living Scale; PEG, Pain, Enjoyment of Life, and General Activity Scale; HADS, Hospital Anxiety and Depression Scale.

most frequent cause of injuries was falling. They accounted for 55.8% of the cases, with car crashes accounting for 28.3%. The median injury severity score was 10, with an interquartile range of 9 to 14 indicates that study participants, on average, experienced moderate injuries. The Lawton IADL and Katz ADL scales had median scores of 8 and 6, respectively. Meanwhile, the median for the Charlson Comorbidity Index was 0. The majority of cohort participants (52.5%) were discharged home, while 37.6% were discharged to facilities requiring additional care, including rehabilitation centers, skilled nursing facilities, and acute rehabilitation facilities. This suggests that a significant portion of participants experienced symptoms or issues necessitating ongoing medical or rehabilitative support.

# Internal Consistency Reliability, and Score Distributions

As seen in Table 2, HABC-M had good internal consistency at all study time points, ranging from 0.76 to 0.80. During all four time points, the HABC-M score distribution was positively skewed, with minimal floor effects (10%) at baseline and moderate floor effects during follow-up time points (23% to 33%). Additionally, no participant achieved the highest possible score, indicating the absence of a ceiling effect. MCID values for the HABC-M total score ranged from 3.6 at baseline to 2.3 at 4- and 6-months' time points.

Table 3 presents the HABC-M total scores and the reference standards' scores at various time points. The table reveals that the HABC-M total score and the four reference standard scores showed steady improvement over time.

# Comparisons of HABC-M With the Reference Standards

As seen in Table 4, the HABC-M total score had moderate to strong correlations with various health parameters during the six-month period. At the baseline time point, strong correlations were documented with HADS depression (r = 0.60, p < 0.001), and moderate correlations were noted with HADS anxiety (r = 0.43, p < 0.001), the PROMIS SF (r = 0.37, p < 0.001), and the PEG Scale (r = 0.40, p < 0.001). By the two-month mark, the total

Time Point	n	Cronbach's Alpha	# of Possible Levels	Range	Mean	Median	SD	MCID	% Floor	% Ceiling
Baseline	120	0.76	0–81	0–35	9.3	9	7.2	3.6	10	0.0
2 Months	105	0.80	0–81	0-44	4.9	3	5.7	2.9	22.9	0.0
4 Months	92	0.77	0–81	0–31	3.7	2	4.5	2.3	22.8	0.0
6 Months	98	0.80	0–81	0–27	3.3	2	4.5	2.3	32.7	0.0

Table 2 HABC-M Total Score Characteristics at Various Time Points

Abbreviations: HABC-M, Healthy Aging Brain Care Monitor Self-Report; SD, standard deviation; MCID, minimal clinically important difference.

Table 3 Summary Statistics by Time Point

	Baseline (n=120)	2 Months (n=105)	4 Months (n=92)	6 Months (n=98)
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
HABC-M Total	9.3 (7.2)	4.9 (5.7)	3.7 (4.5)	3.3 (4.5)
HADS Anxiety	2.7 (3.1)	1.7 (2.3)	1.7 (2.3)	1.2 (1.8)
HADS Depression	3.3 (3.1)	2.1 (2.8)	1.7 (2.2)	1.5 (2.3)
PEG	4.5 (2.7)	2.1 (2.0)	2.0 (2.1)	1.7 (1.9)
Sleep	9.5 (4.0)	7.5 (3.2)	6.8 (2.7)	6.4 (3.1)

**Abbreviations**: HABC-M, Healthy Aging Brain Care Monitor Self-Report; SD = standard deviation; HADS, Hospital Anxiety and Depression Scale; PEG; Pain, Enjoyment of life, and General activity scale.

Table4Correlation of HABC-MTotalScoreWithReferenceStandards

	НАВС-М
	Total Score
Baseline (n=120)	
HADS Anxiety	0.43 <sup>a</sup>
HADS Depression	0.60 <sup>a</sup>
PEG	0.40 <sup>a</sup>
Sleep	0.37 <sup>a</sup>
2 Months (n=105)	
HADS Anxiety	0.56 <sup>a</sup>
HADS Depression	0.80 <sup>a</sup>
PEG	0.69 <sup>a</sup>
Sleep	0.40 <sup>a</sup>
4 Months (n=92)	
HADS Anxiety	0.62 <sup>a</sup>
HADS Depression	0.58 <sup>a</sup>
PEG	0.31 <sup>b</sup>
Sleep	0.46 <sup>a</sup>
6 Months (n=98)	
HADS Anxiety	0.42 <sup>a</sup>
HADS Depression	0.66ª
PEG	0.47 <sup>a</sup>
Sleep	0.57 <sup>a</sup>

**Notes**:  ${}^{a}p<0.001$ ,  ${}^{b}p<0.01$ .

**Abbreviations**: HABC-M, Healthy Aging Brain Care Monitor Self-Report; HADS, Hospital Anxiety and Depression Scale; PEG; Pain, Enjoyment of life, and General activity scale.

score had a very strong correlation with HADS depression (r = 0.80, p < 0.001), PEG (r = 0.69, p < 0.001), and HADS anxiety (r = 0.56, p < 0.001). Sleep quality maintained a moderate correlation (r = 0.40, p < 0.001). At four months, strong correlations persisted with HADS depression (r = 0.58, p < 0.001) and HADS anxiety (r = 0.62, p < 0.001), while both PEG and sleep scales showed a moderate yet significant correlation with r = 0.31, p < 0.01, and r = 0.46, p < 0.001, respectively. The six-month assessment revealed the presence of strong correlations with HADS depression (r = 0.66, p < 0.001) and sleep quality (r = 0.57, p < 0.001). Moderate correlations were observed for HADS anxiety (r = 0.42, p < 0.001) and PEG (r = 0.47, p < 0.001).

# Comparisons of HABC-M Changes With the Changes in Reference Standards

As seen in Table 5, the total HABC-M was able to detect health changes early, where the change in the HABC-M total score was significantly correlated with changes in reference standards at a two-month time point where moderate correlations were

**Table 5** Correlation of HABC-M Total Score Change With Reference Standard Changes

	HABC-M Total Score
2 Months (n=105)	
HADS Anxiety	0.36 <sup>a</sup>
HADS Depression	0.53 <sup>a</sup>
PEG	0.36 <sup>a</sup>
Sleep	0.38 <sup>a</sup>
4 Months (n=92)	
HADS Anxiety	0.35 <sup>a</sup>
HADS Depression	0.44 <sup>a</sup>
PEG	0.03
Sleep	0.27 <sup>b</sup>
6 Months (n=98)	
HADS Anxiety	0.43 <sup>a</sup>
HADS Depression	0.53 <sup>a</sup>
PEG	0.16
Sleep	0.24 <sup>c</sup>

**Notes**: <sup>a</sup>p<0.001, <sup>b</sup>p<0.01, <sup>c</sup>p<0.05. **Abbreviations**: HABC-M, Healthy Aging Brain Care Monitor Self-Report; HADS, Hospital Anxiety and Depression Scale; PEG; Pain, Enjoyment of life, and General activity scale.

observed with HADS anxiety (r = 0.36, p < 0.001), PEG (r = 0.36, p < 0.001), and sleep quality (r = 0.38, p < 0.001). At the same time, there was a strong correlation with change in HADS depression (r = 0.53, p < 0.001). At the four-months' time point, the total score correlation remained moderate for HADS anxiety (r = 0.35, p < 0.001) and became moderate for HADS depression (r = 0.44, p < 0.001). Meanwhile, sleep quality correlations weakened (r = 0.27, p < 0.01), and PEG scores were no longer significantly correlated (r = 0.03). At six months, the correlations with HADS anxiety increased to a moderate level (r = 0.43, p < 0.001), and HADS depression maintained a strong correlation (r = 0.53, p < 0.001). These correlations indicate the HABC-M's ability to reflect changes in health over time. The correlation with PEG remained non-significant (r = 0.16), while sleep quality persisted with a weak but significant correlation (r = 0.24, p < 0.05).

# Analysis of the Change in HABC-M Total Score by Known Change Categories of the Four Reference Standards

### I) The HADS Anxiety Scale

Table 6 displays the changes in the HABC-M total score according to known change categories of the HADS anxiety scale. The ANOVA omnibus p-value indicates that the HABC-M total score significantly distinguished known change categories of the HADS anxiety scale during 2-, 4-, and 6-month time points. Pairwise tests showed that the HABC-M total score significantly distinguished decline from improved and stable from improved during all time points. The SRM indicates the magnitude of the change in the HABC-M over three time points in a six-month period. A positive effect size indicates a decrease in the HABC-M symptom total score, which represents an improvement in the symptoms of patients.

Table 6 Change in HABC-M Total Score by Known Change Categories of HADS Anxiety Scale

Time Point	Decline in Depression Score	Stable Depression Score	Improved Depression Score	Overall P-value	Decline vs Stable P-value	Decline vs Improved P-value	Stable vs Improved P-value
2 Months	(n=10)	(n=71)	(n=23)	0.001	0.811	0.013	0.001
	1.5 (8.1)	3.0 (7.0)	9.4 (7.6)				
	0.19	0.43	1.24				
4 Months	(n=10)	(n=60)	(n=20)	<0.001	0.130	<0.001	0.003
	-0.2 (11.4)	4.7 (6.1)	11.0 (8.1)				
	-0.02	0.77	1.36				
6 Months	(n=7)	(n=65)	(n=25)	0.001	0.058	0.002	0.031
	-2.0 (12.7)	5.0 (6.3)	9.6 (8.9)				
	-0.16	0.79	1.08				

**Notes**: Values under the decline, stable, improved columns are n, mean change of HABC-M total score (SD of change), and standardized response mean (SRM).

Abbreviations: HABC-M, Healthy Aging Brain Care Monitor; HADS, Hospital Anxiety and Depression Scale.

A negative effect size denotes a worsening of symptoms. The SRM for the HABC-M total score was in the expected negative direction for the group of patients that declined on the HADS anxiety scale and in the positive direction for the group of patients that improved on the HADS anxiety scale. Furthermore, SRM values ranging from 1.08 to 1.36 indicated a very high sensitivity to change among the known improved group.

### 2) The HADS Depression Scale

Table 7 shows the changes in the HABC-M total score by known change categories of the HADS depression scale. The ANOVA omnibus p-value indicates that the HABC-M total score significantly distinguished known HADS depression change categories at all time points. Pairwise tests showed that the HABC-M total score significantly distinguished

Table 7 Change in HABC-M Total Score by Known Change Categories of HADS Depression Scale

Time Point	Decline in Depression Score	Stable Depression Score	Improved Depression Score	Overall P-value	Decline vs Stable P-value	Decline vs Improved P-value	Stable vs Improved P-value
2 Months	(n=15)	(n=62)	(n=27)	<0.001	0.118	<0.001	<0.001
	-0.8 (12.5)	3.2 (4.6)	9.6 (7.1)				
	-0.06	0.70	1.35				
4 Months	(n=9)	(n=52)	(n=29)	<0.001	0.126	<0.001	<0.001
	-1.1 (11.0)	3.9 (4.7)	10.5 (9.0)				
	-0.10	0.83	1.17				
6 Months	(n=10)	(n=56)	(n=31)	<0.001	0.002	<0.001	<0.001
	-4.0 (8.6)	4.2 (5.2)	11.5 (8.0)				
	-0.47	0.81	1.44				

Notes: Values under the decline, stable, improved columns are n, mean change of HABC-M total score (SD of change), and standardized response mean (SRM).

Abbreviations: HABC-M, Healthy Aging Brain Care Monitor; HADS, Hospital Anxiety and Depression Scale.

decline from improved and stable from improved during all time points and decline from stable at 6 months. The SRM for the HABC-M total score was in the expected negative direction for the group of patients that declined on the HADS anxiety scale and in the positive direction for the group of patients that improved on the HADS anxiety scale. Furthermore, SRM values ranging from 1.17 to 1.44 indicated a very high sensitivity to change at all time points for the improved category, and -0.47 showed moderate sensitivity at 6 months for the declined category.

### 3) PEG Scale

Table 8 illustrates the fluctuation in the HABC-M total score according to various levels of change on the PEG scale. Compared to the results from the HADS anxiety and depression scales, the changes that were noted with the PEG scale are less pronounced. However, these changes were significant at the 2-month time point. The ANOVA omnibus p-value demonstrates that the three known change categories of the PEG scale exhibit significantly different mean change scores for the HABC-M total score at the 2-month period. Specifically, the HABC-M total score separated decline from stable and decline from improved at 2 months.

### 3) Sleep Scale

Table 9 compares the changes in the HABC-M total score with the known change categories of the sleep scale. Unlike the HADS anxiety and depression scales, the changes noted on the sleep scale are also less marked. The ANOVA omnibus p-value indicates significant differences in the mean change scores for the HABC-M total score across the three known change categories of the sleep scale at the 2-month and 4-month intervals. The HABC-M total score distinguished between decline and stable, as well as decline from improved known change categories at 2 months.

In summary, the HABC-M showed a very good sensitivity to change across various follow-up time points, as evidenced by high SRM values and significant omnibus and pairwise differences between the known change categories established by four reference standards.

### **Discussion**

Overall, our study found that the HABC-M is effective in detecting changes in the recovery of older trauma survivors over various time intervals. Therefore, the HABC-M can effectively monitor recovery in older adult patients, aligning with the objectives of tools designed for longitudinal symptom monitoring.<sup>37,38</sup> This finding agrees with our previous reports. Those reports showed the practicality of HABC-M by demonstrating its ability to evaluate cognitive,

Time Point	Decline in Depression Score	Stable Depression Score	Improved Depression Score	Overall P-value	Decline vs Stable P-value	Decline vs Improved P-value	Stable vs Improved P-value	
2 Months	(n=7)	(n=25)	(n=73)	0.001	0.009	<0.001	0.462	
	-5.7 (12.8)	3.6 (6.0)	5.5 (6.9)					
	-0.45	0.60	0.80					
4 Months	(n=9)	(n=24)	(n=59)	0.354	0.384	0.764	0.512	
	3.2 (3.8)	7.3 (5.8)	5.2 (8.9)					
	0.84	1.26	0.58					
6 Months	(n=6)	(n=24)	(n=68)	0.652	0.954	0.978	0.626	
	5.5 (3.8)	4.4 (5.8)	6.2 (8.9)					
	1.45	0.76	0.70					

Table 8 Change in HABC-M Total Score by Known Change Categories of PEG Scale

**Notes**: Values under the decline, stable, improved columns are n, mean change of HABC-M total score (SD of change), and standardized response mean (SRM).

Abbreviations: HABC-M, Healthy Aging Brain Care Monitor; PEG, Pain, Enjoyment of Life, and General Activity.

Table 9 Change in HABC-M Total Score by Known Change Categories of Sleep Scale

Time Point	Decline in Depression Score	Stable Depression Score	Improved Depression Score	Overall P-value	Decline vs Stable P-value	Decline vs Improved P-value	Stable vs Improved P-value
2 Months	(n=12)	(n=56)	(n=37)	0.008	0.024	0.009	0.084
	-0.4 (11.1)	3.6 (7.0)	6.9 (6.3)				
	-0.04	0.51	1.10				
4 Months	(n=6)	(n=52)	(n=34)	0.047	0.863	0.229	0.060
	2.5 (3.0)	4.2 (7.7)	8.1 (8.1)				
	0.83	0.55	1.00				
6 Months	(n=5)	(n=55)	(n=38)	0.115	0.911	0.416	0.131
	3.0 (5.5)	4.5 (7.8)	7.8 (8.3)				
	0.55	0.58	0.94				

**Notes**: Values under the decline, stable, improved columns are n, mean change of HABC-M total score (SD of change), and standardized response mean (SRM).

Abbreviation: HABC-M, Healthy Aging Brain Care Monitor.

functional, behavioral, and psychological domains in 5 minutes while minimizing the obstacles that many similar tools have, such as patient burden and narrow scope. <sup>16,23</sup> The HABC-M is user-friendly, patient-reported, standardized, and requires very little training for administration. <sup>14</sup> It can be administered in primary care and subspecialty outpatient care, over the phone, face-to-face, and through the internet. <sup>23</sup> The HABC-M was validated successfully by many international studies following its translation into Spanish, French, Japanese, Persian, and Chinese languages. <sup>41–45</sup>

The Short Form-36 (SF-36) is the most widely used patient-reported health-related quality of life outcome tool in trauma literature. <sup>8,46</sup> It was originally constructed from the most frequently measured concepts in the Medical Outcomes Study. <sup>47</sup> It covers eight domains that are divided into physical component summary (PCS), which includes bodily pain, physical role, physical functioning, and general health, and mental component summary (MCS), which includes emotional role, social functioning, vitality, and mental health. Special algorithms, which are strictly controlled by a private company, are necessary for the accurate computation of SF-36 PCS and MCS summary measures. <sup>48</sup> The SF-36 tool takes about 5–10 minutes to complete, has been translated into many languages, and was used in many populations and settings in many countries. It is a generic tool for health-related quality of life that is used in different diseases to compare health outcomes and evaluate the impact of medical interventions. However, this tool's initial development was aimed at community-dwelling younger adults under the age of 62, <sup>9,49</sup> Moreover, it was not validated longitudinally in studies targeting older trauma survivors.

The second most common tool in trauma-related research studies was developed with support from the National Institutes of Health (NIH): the Patient Reported Outcomes Measurement Information System (PROMIS). PROMIS profiles are a collection of computer adaptive tests (CAT) and short forms composed of a designated number of items covering seven PROMIS domains (anxiety, depression, sleep disturbance, pain interference, physical function, ability to participate in social roles and activities, and fatigue). The PROMIS-29 examines 7 domains with 4 questions each. Pain interference and physical function, the most frequently reported PROMIS domains, have undergone validation and comparison with numerous traditional measures.<sup>50</sup> The CAT is efficient because it enables patients to respond to questions, and the system is designed to choose subsequent questions based on responses to earlier questions, which reduces the burden on the patient while providing clinicians with maximally beneficial information.<sup>51</sup> Its efficacy in orthopedic studies is well-documented and has demonstrated good responsiveness.<sup>52,53</sup> In 2013, the Orthopedic Trauma Association declared it a valuable assessment tool in patient-reported outcome research.<sup>54</sup> Most trauma-related studies concluded that PROMIS has major strengths in terms of seamless integration into electronic health records, quick

administration, and reduced floor and ceiling effects.<sup>55</sup> However, its weaknesses include a lack of specificity for certain anatomical body parts and a lack of validation for mental health outcomes.<sup>56</sup> Furthermore, older trauma survivors were not included in the validation studies involving any of the PROMIS profiles.

Nonetheless, trauma-specific tools such as the Trauma Outcome Profile 17 and the trauma-specific quality-of-life questionnaire 18 are not widely used because of their lack of cognitive domain and they are usually lengthy. The revised, brief version of the trauma-specific quality-of-life questionnaire 19 is more practical because it improved the ability of the original questionnaire to evaluate long-term outcomes more efficiently, although its clinical utility has not been elucidated yet. Also, the average trauma patient age included in its validation study was 58 years.

The findings of the present study that confirmed the longitudinal validity of HABC-M have further demonstrated its potential advantage over other existing tools in guiding patients' treatments over time. 15,39 The importance of longitudinal evaluation with the HABC-M cannot be overstated, particularly for specific patient profiles. Older adults with a history of chronic illnesses, mental health challenges, or those undergoing major life transitions, such as trauma recovery or moving from independent to assisted living, can benefit greatly. Our findings suggest that the HABC-M is particularly effective in detecting changes in mental health symptoms, notably anxiety and depression, across various time points. This capability makes it especially beneficial for patients aged 65 and older, who often face comorbid conditions and psychosocial challenges. The ability to identify early signs of depression allows for quicker access to targeted psychological support. This is very important because psychological conditions are often underdiagnosed in older adults. Furthermore, the HABC-M's high sensitivity suggests its effectiveness in situations where acute health variations are anticipated, such as post-operative recovery or transitions from hospital to home care.

It is important to consider two essential characteristics when evaluating patient self-reported recovery monitoring tools, such as HABC-M. These characteristics include sensitivity to change and the ability to identify clinically meaningful changes. Although in the present study we primarily focused on sensitivity to change, interpreting changes could also be assisted by calculating the MCID. MCID is defined as the smallest change in the assessment's score that significantly impacts patients' lives.<sup>34</sup> MCID is important because it is crucial to differentiate between statistical changes and clinically relevant changes during the monitoring of the recovery of trauma survivors. Health professionals can better evaluate the efficacy of the recovery plans of older trauma survivors when simultaneously considering the sensitivity to change and MCID of patient self-reported recovery monitoring tools.<sup>58</sup> Investigating both sensitivity to change and MCID at the same time is very important because improved sensitivity to change in patient-reported recovery monitoring tools can lower the MCID threshold, leading to the possibility of responding to and detecting smaller clinically significant changes in patients' outcomes.<sup>59</sup> Based on our study the MCID for the HABC-M among older trauma survivors is 4 points at the time of the hospital discharge and 2 points at the 6 months' recovery time.

Our study had several limitations. First, the study was restricted to trauma patients who completed at least one of the three follow-up visits after the baseline evaluation. This criterion could restrict the range of our results and, consequently, the applicability of the results to larger trauma groups or to individuals who do not complete all follow-up visits. Moreover, 89% of participants in our study were Caucasian. This may restrict the extent to which the results may be applied to other demographic groups; however, earlier validation studies of the HABC-M demonstrated its validity across a variety of racial backgrounds. 13,14,22 Another limitation is related to the relatively small size of the anxiety decline group, which resulted in inadequate power to detect moderate effect sizes (eg, 0.50 SD difference between change score means). This limitation may have undermined the significance of findings in pairwise comparisons despite having adequate power for the omnibus test. Therefore, a larger study with an ample size for all three change groups to detect moderate effect sizes may yield even more significant findings than the results obtained here. Finally, a notable limitation is that the MCID results for the HABC-M were derived using only distribution-based methods rather than also anchorbased methods. To enhance the clinical relevance of these findings, we plan to design and implement a future study with an appropriately powered sample size and validated gold-standard anchors. 28 This approach will allow for a more precise determination of the anchor-based MCID for the HABC-M, ensuring its applicability in both research and clinical settings. Furthermore, the original RCT for this sample administered HABC-M in only the intervention arm; therefore, future studies that implement HABC-M in both intervention and control arms can evaluate the responsiveness to treatment for HABC-M.

### **Conclusion**

In summary, the HABC-M showed strong sensitivity to change across all time points during a six-month period compared to reference standards with capability of providing a practical alternative to multiple surveys. The HABC-M's sensitivity to change supports its use as an outcome measure and its ability to track the progress and effectiveness of various recovery care plans targeting the cognitive, physical, and psychological recovery of older trauma survivors.

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### **Disclosure**

Dr Malaz Boustani is the founder of Blue Agilis, Inc, DigiCare Realized, Inc, and Mozyne Health, Inc.; reports speaker and consultant fees from Lilly, Eisai, Biogen, Merck, and Genentech, outside the submitted work. The authors report no other conflicts of interest in this work.

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