

## The Functional Status Examination in Mild Traumatic Brain Injury: A TRACK-TBI Sub-Study

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### Abstract

**Objective:** The Functional Status Examination (FSE) is a comprehensive measure of functional status post-traumatic brain injury (TBI) that has primarily been used in studies of moderate-to-severe TBI. The present observational study examines functional status using the FSE among patients who sustained mild TBIs (mTBIs; defined as Glasgow Coma Scale [GCS] = 13–15 at admission) seen in a Level 1 trauma center. Study aims included examining the course of functional status following mTBI, as well as exploring relationships of the FSE and other relevant constructs among those with GCS = 13–15.

**Method:** Participants were assessed at 2 weeks ( $n = 112$ ), 3 months ( $n = 113$ ), 6 months ( $n = 106$ ), and 12 months ( $n = 88$ ) post-injury for changes in functional status resulting both (a) from all injuries and (b) from TBI only.

**Results:** Among seven domains of day-to-day functioning, participants generally experienced the greatest disruption in their primary activity (work or school) and in leisure and recreation. Subjects' overall functional status tended to improve over time, with sharpest increases in functionality occurring in the first 3 months post-injury. However, some subjects continued to report functional limitations even at 12 months post-injury. Functional status was largely unrelated to neurocognitive functioning, but related strongly to post-traumatic symptoms, life satisfaction, and emotional well-being, particularly at 3 months post-injury and beyond.

**Conclusion:** Findings indicate that functional impairments related to mTBI may be more likely to persist than widely believed, with those who experience lingering functional deficits at particular risk for emotional health difficulties.

**Keywords:** Brain injuries, Traumatic; Brain concussion; Patient outcome assessment; Neuropsychology; Mental health; Glasgow Coma Scale

### Introduction

In assessing recovery from traumatic brain injury (TBI), a key domain to consider is functional status, or a person's capacity to operate within the roles, tasks, or activities that are considered by society to be valuable or important (Dikmen, Machamer, Miller, Doctor, & Temkin, 2001). Functional status is a sub-component of the broader picture of one's health-related quality of life, and is composed of functioning across psychological, social, and physical domains. This construct represents a key aspect of well-being, adjustment, and recovery following brain injury, and is an important dimension for consideration in planning treatment and conducting clinical trials.

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As functional status has received increasing attention in the literature, an area of emphasis has been to identify effective measurement methods (Dikmen et al., 2001; Hudak et al., 2005; Nichol et al., 2010; Shukla, Devi, & Agrawal, 2011). The Glasgow Outcome Scale (GOS; Jennett & Bond, 1975) and its extended version (Glasgow Outcome Scale-Extended [GOS-E]; Wilson, Pettigrew, & Teasdale, 1998) have been most commonly used in TBI research (Nichol et al., 2010; Shukla et al., 2011), along with other measures such as the Disability Rating Scale (DRS; Rappaport, Hall, Hopkins, Belleza, & Cope, 1982), Functional Independence Measure (FIM; Granger, Deutsch, & Linn, 1998; Granger, Hamilton, Keith, Zielezny, & Sherwin, 1986), Community Integration Questionnaire (CIQ; Willer, Rosenthal, Kreutzer, Gordon, & Rempel, 1993), and Sickness Impact Profile (SIP; Bergner, Bobbit, Pollard, Martin, & Gilson, 1976). However, limitations across these measures such as ceiling effects (DRS, FIM, CIQ; Hall et al., 1996), reliability and validity concerns (CIQ; Dijkers, 1997), lack of detail in examining specific domains of functioning (GOS-E; Dikmen et al., 2001; Wilson et al., 1998), difficulty of administration (DRS; Shukla et al., 2011), and difficulty of use with patients who cannot respond on their own behalf (SIP; Dikmen et al., 2001) have posed challenges for many studies of functional status to date. Additionally, these measures largely were developed for use with moderate-to-severe TBI populations, without detailed exploration of their utility following mild traumatic brain injury (mTBI).

To address these shortcomings among extant measures of functional status, the Functional Status Examination (FSE; Dikmen et al., 2001) was developed with the goal of providing a reliable, sensitive, and valid instrument that would assess multiple domains of functioning following TBI, cover a full range of outcomes, minimize ceiling effects, and provide relative ease of administration via structured interview. Subsequent studies of the FSE among samples of primarily moderately- to severely-brain injured patients have evidenced strong psychometric properties such as reliability, consistency in patient and proxy reporting, sensitivity to injury severity and changes over time, and criterion validity (Dikmen et al., 2001; Dikmen, Machamer, Powell, & Temkin, 2003; Hudak et al., 2005; Machamer, Temkin, & Dikmen, 2013; Temkin, Machamer, & Dikmen, 2003). However, descriptive and prospective studies utilizing the FSE focused specifically on patients with mTBI (defined as GCS = 13–15) are largely lacking. The present study targets this gap in the literature, focusing on three main goals: (a) to describe the impairments in various domains of functional status observed among mTBI patients, (b) to explore the course of post-mTBI recovery in functional status over the first 12 months following injury, and (c) to assess relationships of functional status as assessed by the FSE to neuropsychological test performance, measures of psychological well-being, and other measures of day-to-day functioning in the context of mTBI.

## Methods

### *Subjects and Study Design*

This observational study was conducted in compliance with institutional research standards and in accordance with the Helsinki Declaration. Participants were drawn from the larger subject pool of the Transforming Research and Clinical Knowledge in Traumatic Brain Injury (TRACK-TBI) study, a large-scale longitudinal observational multi-center research effort assessing outcomes related to closed TBIs of all severities (for further information, please see the study website at <http://tracktbi.ucsf.edu/>; complete details of primary study inclusion and exclusion criteria can be found in supplemental materials accompanying the online publication version of this report). The present study included patients admitted to the emergency department (ED) at Harborview Medical Center, a TRACK-TBI site and Level 1 Trauma Center serving several states in the Northwest Region of the United States, between May 2014 and September 2017. We included subjects who, upon admission to the ED, (a) were diagnosed with TBI (i.e., reported sustaining a head injury resulting in disturbance of consciousness and/or post-traumatic amnesia) and (b) received Glasgow Coma Scale (GCS) scores of 13–15, resulting in initial enrollment of 141 individuals ( $M_{\text{age}} = 41.4$  [ $SD = 17.71$ ; range = 18–88]; 33.3% female; 65.2% White, 29.1% minority, 5.7% did not identify racial/ethnic background; 77.3% GCS = 15).

Participants were assessed via interview for functional status and related factors at 2 weeks, 3 months (via phone only due to parent study cost constraints), 6 months, and 12 months following the injury. Of the 141 participants enrolled, 112 provided complete FSE data at 2 weeks following injury; reasons for initial subject loss included inability to contact subject ( $n = 15$ ; 11.3%) or incomplete assessment wherein the FSE, a site-specific measure included at the end of the evaluation, was not administered ( $n = 13$ , 9.2%). Complete FSE data were also collected from 113, 106, and 88 participants at 3-, 6-, and 12-month follow-up, respectively. The smaller  $N$  at 12-month follow-up was due in part to the ongoing course of TRACK-TBI data collection, such that 12.1% of active participants ( $n = 17$ ) were not yet eligible for 12-month follow-up at the time of this report (i.e., had been enrolled in the ongoing TRACK-TBI study for fewer than 12 months). At 12-month follow-up, 97.7% of subjects ( $n = 86$ ) provided data regarding current involvement in litigation, with the large majority (84.9%,  $n = 73$ )

indicating no involvement (thus, 13 subjects indicated current involvement with litigation at 12 months post-injury). Likewise, of 78 subjects who provided responses to a query regarding future plans, most (84.6%,  $n = 66$ ) indicated that they had no plans for future litigation relating to their traumatic injuries (with the remaining 12 subjects indicating they had plans to become involved in injury-related litigation in the future).

### Measures

*Functional status: FSE.* The Functional Status Examination (FSE; [Dikmen et al., 2001](#)) measures change from pre-injury to post-injury in functional status due to traumatic injury, yielding two separate scores representing (a) changes due to all system injuries including TBI (termed “FSE-all”) and (b) changes due to TBI alone (“FSE-TBI”). The measure assesses functioning in seven domains: personal care, ambulation, travel, major activity (work or school), home management, leisure/recreation, and social integration. In its originally published form, the FSE featured an additional three subscales (standard of living, cognitive competency, and behavioral competency) that have since been eliminated from the measure by its authors, resulting in the structure of the measure as described here. Administered via structured interview, the FSE asks participants to rate their functioning in each of these seven areas from 0 (same as before the injury) to 3 (nonperformance, inability to perform, or complete reliance on others for domain-specific activities), with respect to all traumatic injuries sustained (i.e., FSE-all). FSE subscale scores relating to all injuries (FSE-all) are summed across the seven domains, resulting in FSE-all total scores that can range from 0 (entirely back to normal) to 21 (totally dependent on others or can no longer perform any activities across domains). Pro-rated FSE-all total scores are generated for subjects missing just one of seven subscale scores based on the mean of responses across the six non-missing subscales. Participants who die are assigned FSE-all total scores of 22.

Participants who indicate some level of impairment (i.e., scores from 1 to 3) in any domain are also asked what their level of impairment would be in that same domain if all peripheral systems injuries (i.e., all other injuries not including the TBI) were not present, thus providing a TBI-only rating for each domain (FSE-TBI). Participants who indicate that they are back to normal in any area (i.e., FSE-all = 0) are automatically assigned FSE-TBI ratings of 0 for that domain. Thus, a separate FSE-all and FSE-TBI rating is generated for each of the seven subscales assessed by the FSE. Resulting FSE-TBI subscale ratings are summed to create a distinct FSE-TBI total score, reflecting TBI-specific impairments, that also ranges from 0 to 21. Missing subscale scores and deaths are treated following the same procedure as for FSE-all. The FSE was administered at all four time points.

*Functional status: GOS-E.* The Glasgow Outcome Scale-Extended (GOS-E; [Wilson et al., 1998](#)), a widely-used measure of global outcome following TBI, was also administered to study participants. This measure classifies patients’ functional status using an eight-category scale that ranges from 1 (“dead”) to 8 (“upper good recovery”). In this study, this measure also provided ratings for functional status both in relation to all traumatic injuries (including TBI; GOS-E-all) and in relation to the TBI alone (GOS-E-TBI), resulting in separate scores for each similar to those provided by the FSE as described above. The GOS-E was administered at all four time points.

*Post-traumatic symptoms.* The Rivermead Post-Concussion Symptoms Questionnaire (RPQ; [King, Crawford, Wenden, Moss, & Wade, 1995](#)) was used to assess a range of common symptoms reported post-head injury. In responding to this measure, subjects indicate the extent to which they have been bothered by a series of 16 symptoms utilizing a scale from 0 (not experienced) to 4 (severe problem), with total scores ranging from 0 to 64. Past study has evidenced strong reliability and other psychometric properties for the RPQ ([King et al., 1995](#); [Potter, Leigh, Wade, & Fleminger, 2006](#)). This measure was administered at all time points.

*Verbal learning and memory.* Learning and memory for verbal content was assessed via the Rey Auditory Verbal Learning Test (RAVLT; [Strauss, Sherman, & Spreen, 2006](#)). This measure requires subjects to attempt to learn a list of 15 semantically unrelated words over five trials. Total learning is represented by the sum of correct responses across all five trials, which is then transformed into a standardized score representing learning and memory performance as compared with an age-matched normative population. The RAVLT was administered at all time points with the exception of 3-month follow-up, which occurred exclusively via phone and thus precluded face-to-face neuropsychological testing. Different versions of this measure (i.e., featuring distinct stimuli) were administered at each of these follow-up points so as to minimize possible practice effects.

*Processing speed.* Speed of cognitive processing was assessed via the Wechsler Adult Intelligence Scale-Fourth Edition (WAIS-IV; [Wechsler, 2008](#)) Processing Speed Index (PSI). Scores on this measure are Index Scores composed of the Symbol

Search and Coding subtests of the WAIS-IV, and are normed such that their age- and education-adjusted population mean and standard deviation are 100 and 15, respectively. The WAIS-IV PSI testing was conducted at all time points with the exception of 3-month follow-up.

*Life satisfaction.* The Satisfaction with Life Scale (SWLS; Diener, Emmons, Larsen, & Griffin, 1985) is a brief measure designed to assess the extent to which respondents experience overall life satisfaction. Five statements about one's life are endorsed on a scale from 1 (strongly disagree) to 7 (strongly agree); thus, total scores can range from 5 to 35. This scale has demonstrated excellent internal consistency in past research (Pavot & Diener, 2008). The SWLS was administered at all time points.

*Global psychiatric symptoms.* The Brief Symptom Inventory–18-item version (BSI-18; Derogatis, 2000), which was adapted from the longer Brief Symptom Inventory (BSI; Derogatis & Melisaratos, 1983) in order to provide a brief self-report measure of psychological dysfunction in the domains of depression, anxiety, and somatization, was administered as part of the present study. The scale includes three subscales of six items each corresponding to these three domains. Respondents endorse the extent to which they have been bothered by various psychiatric symptoms using a scale ranging from 0 (not at all) to 4 (extremely). Item-responses corresponding to each symptom area are summed to create subscale scores for depression, anxiety, and somatization, which are in turn summed to generate a Global Symptom Inventory (GSI) total score ranging from 0 to 72. This GSI total score was used as the measure of global psychiatric symptoms in the present study. Past studies have demonstrated adequate psychometric properties, including reliability and validity, for the BSI-18 (Derogatis, 2000; Recklitis, Parsons, Shih, Mertens, & Robison, 2006). The BSI-18 was administered at all time points.

*Depression.* The Patient Health Questionnaire (PHQ-9; Kroenke, Spitzer, & Williams, 2001) is a well-validated and commonly used brief diagnostic measure of depression. Respondents indicate the frequency with which they have experienced nine common symptoms of depression over the past two weeks using a scale from 0 (not at all) to 3 (nearly every day). Item responses are summed to generate a total depression score ranging from 0 to 27. The PHQ-9 has demonstrated strong reliability and validity in past research (Kroenke et al., 2001). The PHQ-9 was administered at all time points.

*Post-traumatic stress.* The Posttraumatic Stress Disorder Checklist for DSM-5 (PCL-5; Blevins, Weathers, Davis, Witte, & Domino, 2015) is a 20-item self-report measure of PTSD symptoms adjusted from its previous version to reflect changes to PTSD criteria in the most recent edition of the DSM. Respondents indicate the extent to which they experienced each symptom in the previous month on a scale from 0 (not at all) to 4 (extremely); item responses are summed to create a total PTSD symptom score that can range from 0 to 80. Psychometric evaluation of the PCL-5 has evidenced strong reliability and validity of the scale (Blevins et al., 2015). The PCL-5 was administered at all time points.

### Data Analysis

Participants were included in each of the following analyses who provided responses for the included measures (i.e., who completed the patient interview at included time points). Paired-samples *t*-tests were used to test for change over time in functional status attributed both to all systems injuries (FSE-all) and TBI only (FSE-TBI). In each of these instances, analyses included six cross-time comparisons: (a) 2 weeks versus 3 months, (b) 2 weeks versus 6 months, (c) 2 weeks versus 12 months, (d) 3 months versus 6 months, (e) 3 months versus 12 months, and (f) 6 months versus 12 months. In order to statistically adjust for increased family-wise error rate across six comparisons each for FSE-all and FSE-TBI, Bonferroni corrections were implemented in which the *p*-value required to constitute statistical significance was adjusted from .05 to .05/6, or .008. This pair-wise approach was selected over multivariate alternatives (e.g., multivariate analysis of variance [MANOVA]) due to the differing sample sizes across the four time points, as an omnibus multivariate analysis would have permitted use of data from only the 70 subjects for whom data were present at all four time points.

Pearson product-moment correlations were used to assess relationships among FSE total scores (FSE-all and FSE-TBI) and other continuous variables (including GOS-E functional status ratings, post-concussion symptom levels, verbal learning and memory, processing speed, life satisfaction, global psychiatric symptoms, depressive symptoms, and post-traumatic stress). As a statistical adjustment for increased family-wise error rate across the nine correlations evaluated at each time point, Bonferroni corrections were implemented wherein the *p*-value necessary for statistical significance was adjusted from .05 to .05/9, or .006.

## Results

### Descriptive Results and Course of Functional Status over Time

Descriptive statistics for FSE subscales and total scores including both FSE-all and FSE-TBI ratings are presented in Table 1. For both the FSE-all and FSE-TBI ratings and at all four time points, participants tended to report the greatest impairment (i.e., in terms of average raw score on the FSE's 0–3 scale) in the areas of primary activity and leisure/recreation. Some relatively high limitations were also indicated in the domain of mobility/travel at 2-week follow-up, particularly specific to TBI. Impairment ratings in all seven domains of functioning tended to decrease across time. FSE-all and FSE-TBI total scores were strongly correlated, with  $r_s = .60$  at 2 weeks post-injury,  $.78$  at 3 months,  $.89$  at 6 months, and  $.91$  at 12 months (all  $p_s < .001$ ).

The proportions of participants reporting some degree of functional impairment (i.e., FSE-all total  $>0$ ) were 92.0% at 2-week follow-up, 72.6% at 3 months, 55.7% at 6 months, and 52.3% at 12 months post-injury. In terms of TBI-specific impairments, 69.6%, 56.4%, 47.2%, and 38.1% of subjects reported some functional impairment (i.e., FSE-TBI total  $>0$ ) at 2 weeks, 3 months, 6 months, and 12 months post-injury, respectively. Marginally smaller proportions of subjects reported more substantial functional impairment (i.e., FSE-all total scores  $\geq 4$ ; a cut-off chosen as it reflected overall limitations greater than would be caused by severe impairment in just one domain), including 83.0% of subjects at 2-week follow-up, 51.4% at 3 months, 36.8% at 6 months, and 27.3% at 12 months post-injury. Likewise, the proportions of subjects reporting more substantial functional impairment specific to TBI (i.e., FSE-TBI total scores  $\geq 4$ ) were somewhat smaller across the four time points (50.9%, 35.5%, 27.4%, and 20.2% of subjects).

Results of statistical tests of absolute changes in FSE-all and FSE-TBI total scores are presented in Table 2. FSE-all and FSE-TBI total scores evidenced a general trend of improving functional status over time, both in terms of all injuries and specific to TBI. For FSE-all total ratings, subjects tended to show sizable improvements in functional status over the first three months following injury (i.e., from 2-week to 3-month follow-up); this pattern was consistent for FSE-TBI impairments as well. For both FSE-all and FSE-TBI ratings, participants also showed statistically significant improvements from 3 months to 12 months post-injury, although these changes tended to slow over time. For FSE-all ratings, overall improvements from 2 weeks to 12 months post-injury constituted effects that were quite large on average; improvements in TBI-specific functional status from 2-week to 12-month follow-up constituted medium-large effects according to standard effect size guidelines (Cohen, 1988).

### Relationships of the Functional Status Examination to Other Constructs

Correlations of FSE-all and FSE-TBI with other study variables at all four time points are presented in Table 3. (Descriptive statistics for measures other than the FSE can be found in supplemental materials accompanying the online

**Table 1.** Subscale and total means and standard deviations: FSE-all and FSE-TBI

	Time Point			
	2 weeks <i>M (SD)</i>	3 months <i>M (SD)</i>	6 months <i>M (SD)</i>	12 months <i>M (SD)</i>
(A) FSE-all	<i>N</i> = 112	<i>N</i> = 113	<i>N</i> = 106	<i>N</i> = 88
Personal care	1.26 (0.92)	0.49 (0.77)	0.28 (0.60)	0.20 (0.48)
Mobility/ambulation	1.31 (1.00)	0.44 (0.73)	0.43 (0.73)	0.21 (0.53)
Mobility/travel	1.87 (1.24)	0.72 (1.03)	0.47 (0.88)	0.32 (0.71)
Primary activity (work or school)	1.92 (1.27)	1.18 (1.22)	0.61 (1.00)	0.52 (0.90)
Home management	1.78 (1.29)	0.73 (1.05)	0.54 (0.94)	0.28 (0.68)
Leisure and recreation	1.96 (1.20)	1.30 (1.20)	0.96 (1.18)	0.80 (1.02)
Social integration	1.16 (1.16)	0.83 (1.06)	0.53 (0.91)	0.40 (0.84)
Total score	11.29 (6.40)	5.74 (5.77)	4.03 (5.19)	2.94 (4.35)
(B) FSE-TBI	<i>N</i> = 111	<i>N</i> = 110	<i>N</i> = 106	<i>N</i> = 84
Personal care	0.61 (0.89)	0.30 (0.67)	0.18 (0.49)	0.11 (0.35)
Mobility/ambulation	0.76 (0.96)	0.20 (0.53)	0.31 (0.67)	0.10 (0.40)
Mobility/travel	1.15 (1.29)	0.56 (0.93)	0.44 (0.87)	0.30 (0.69)
Primary activity (work or school)	1.13 (1.35)	0.67 (1.00)	0.47 (0.88)	0.34 (0.74)
Home management	1.02 (1.29)	0.39 (0.79)	0.34 (0.81)	0.14 (0.49)
Leisure and recreation	1.20 (1.37)	0.87 (1.15)	0.71 (1.08)	0.59 (0.95)
Social integration	0.73 (1.09)	0.66 (0.98)	0.49 (0.87)	0.33 (0.77)
Total score	6.71 (6.81)	3.73 (4.92)	3.15 (4.80)	2.13 (4.05)

**Table 2.** Tests for change over time: FSE-all and FSE-TBI

	<i>N</i>	(a) <i>M (SD)</i>	(b) <i>M (SD)</i>	<i>t</i>	<i>df</i>	<i>p</i>	Cohen's <i>d</i>
(A) FSE-all cross-time comparisons							
(a) 2 weeks vs. (b) 3 months	98	10.93 (6.43)	5.52 (5.49)	10.45*	97	<.001	−1.07
(a) 2 weeks vs. (b) 6 months	91	10.85 (6.50)	3.73 (5.15)	12.46*	90	<.001	−1.33
(a) 2 weeks vs. (b) 12 months	76	10.86 (6.54)	3.01 (4.56)	11.25*	75	<.001	−1.32
(a) 3 months vs. (b) 6 months	100	5.55 (5.84)	3.83 (5.13)	4.46*	99	<.001	−0.45
(a) 3 months vs. (b) 12 months	82	5.84 (5.68)	3.00 (4.45)	5.97*	81	<.001	−0.68
(a) 6 months vs. (b) 12 months	82	3.96 (5.12)	3.04 (4.48)	2.79*	81	.007	−0.31
(B) FSE-TBI cross-time comparisons							
(a) 2 weeks vs. (b) 3 months	95	6.42 (6.61)	3.56 (4.65)	5.32*	94	<.001	−0.57
(a) 2 weeks vs. (b) 6 months	91	6.38 (6.70)	2.88 (4.66)	6.40*	90	<.001	−0.71
(a) 2 weeks vs. (b) 12 months	73	6.17 (6.68)	2.19 (4.26)	6.04*	72	<.001	−0.75
(a) 3 months vs. (b) 6 months	98	3.52 (4.87)	2.96 (4.75)	1.90	97	.061	−0.19
(a) 3 months vs. (b) 12 months	78	3.42 (4.72)	2.22 (4.14)	3.31*	77	.001	−0.38
(a) 6 months vs. (b) 12 months	79	2.97 (4.71)	2.23 (4.15)	2.29	78	.025	−0.26

\**p* < .008, the adjusted *p*-value derived via Bonferroni correction for multiple comparisons.

**Table 3.** Correlations of FSE-all and FSE-TBI total scores with other study variables across time points

	FSE-all (2 weeks)	FSE-all (3 months)	FSE-all (6 months)	FSE-all (12 months)	FSE-TBI (2 weeks)	FSE-TBI (3 months)	FSE-TBI (6 months)	FSE-TBI (12 months)
GOS-E-all	−.80*	−.70*	−.75*	−.78*	−.43*	−.60*	−.68*	−.75*
GOS-E-TBI	−.52*	−.58*	−.62*	−.78*	−.77*	−.75*	−.67*	−.81*
RPQ	.50*	.58*	.73*	.75*	.70*	.74*	.77*	.66*
PSI	−.22	—	−.16	−.18	−.16	—	−.21	−.09
RAVLT	−.02	—	−.13	−.17	.08	—	−.14	−.12
SWLS	−.22	−.51*	−.47*	−.59*	−.18	−.49*	−.51*	−.53*
BSI-GSI	.34*	.51*	.53*	.58*	.51*	.58*	.58*	.47*
PHQ-9	.42*	.51*	.53*	.62*	.61*	.61*	.59*	.64*
PCL-5	.18	.51*	.46*	.50*	.41*	.65*	.53*	.42*

Note: All correlations represent associations between FSE scores and other variables at corresponding time points. Correlations with PSI & RAVLT not present at 3 months as neuropsychological measures were not administered at this follow-up point.

\**p* < .006, the adjusted *p*-value derived via Bonferroni correction for multiple comparisons.

publication version of this report.) The FSE evidenced excellent criterion validity among this post-mTBI sample, such that FSE-all and FSE-TBI total scores correlated very strongly (absolute *r*-values >.67) with their corresponding GOS-E scores (i.e., GOS-E-all or GOS-E-TBI) across all four time points. FSE-all and FSE-TBI scores were highly correlated with self-reported post-traumatic symptoms (*r*s ranging from .50 to .77). However, after implementing a correction for family-wise error rate, neither FSE-all nor FSE-TBI ratings correlated with formal neuropsychological measures of learning and memory or processing speed. At 2 weeks post-injury, FSE-all and FSE-TBI scores tended to be moderately associated with life satisfaction, global psychiatric symptoms, depression, and post-traumatic stress. This pattern solidified at later time points, such that greater functional impairment in terms of both FSE-all and FSE-TBI was associated with less life satisfaction and higher levels of global psychiatric symptoms, depression, and post-traumatic stress across 3-, 6-, and 12-month follow-ups. The associations at these later time points tended to be in the strong range, according to standard effect size conventions (Cohen, 1988).

## Discussion

In this study of functional status following mTBI, descriptive results demonstrated that functional limitations tended to decrease over time within each of the seven domains of functioning assessed by the FSE. Of these seven domains, participants tended to report the greatest impairment in primary activity (either work or school) and leisure/recreation across all four time points assessed (2 weeks, 3 months, 6 months, and 12 months post-injury). This finding is consistent with past studies of functional status following TBIs of a range of severities, wherein work and leisure/recreation have been identified as areas of particular concern (Pagulayan, Temkin, Machamer, & Dikmen, 2006; Wise et al., 2010). Total FSE scores reflecting limitations due to all system injuries and to TBI alone also tended to decrease over time. This trajectory of recovery was

characterized by steep initial improvements and slower continuing progress over time, which is also consistent with past study of traumatic brain injury (e.g., Pagulayan et al., 2006).

Importantly, results evidenced increasingly strong correlations between FSE-all and FSE-TBI scores over time, such that the two scores were nearly convergent by 12-month follow-up ( $r = .91$ ). These findings indicate that TBI-specific impairments may constitute the driving force behind reports of functional impairments at later follow-ups, suggesting that limitations related to TBI may be less likely to resolve over time as compared with injuries to other body systems. This notion is supported by other findings identified here, as approximately one-fifth (20.2%) of subjects reported substantial TBI-specific functional limitations (i.e., FSE-TBI scores  $\geq 4$ ) that had not resolved by 12 months post-injury, with this proportion increasing only marginally (27.3%) when accounting for all system injuries at 12-month follow-up. Thus, the preponderance of functional impairment persisting at a year post-injury appeared to be specific to TBI. Although follow-up with the subjects included in the present study did not continue past 12 months post-injury, we might expect that some impairments would continue even 3–5 years following injury, as has been found in other longitudinal studies of TBI outcomes across injuries of a range of severity (Hiploylee et al., 2017; Pagulayan et al., 2006). These results are at odds with the widely held belief that post-concussive symptoms and functional deficits relating to mTBI should be expected to have largely abated within a few months of injury (e.g., Carroll et al., 2004).

These findings have important implications for future clinical trials focused on outcome related to mTBI, particularly among subjects who have also sustained injuries to other body systems. Chief among these is the necessity for choosing an appropriate interval post-injury at which to test for level of—or improvements in—functional status over time. Past studies have noted the uniform failure of clinical trials in TBI research to detect beneficial effects, citing the insensitivity of outcome measures as one likely cause of this trend (Menon & Maas, 2015). Researchers conducting clinical trials specific to mTBI may be at risk of the opposite problem if they select too short a post-injury interval at which to measure mTBI outcome, finding apparent rapid improvement in functioning within the first 3 months that is primarily due to abating injuries to other body systems. Clinical trials in mTBI would be well advised to select 6 months or later post-injury as an appropriate interval at which to assess for changes in functioning related to TBI, as the present results indicate that functional impairments due to non-TBI injuries have largely faded by this time, and that TBI-specific deficits seem to account for nearly 80% of remaining functional impairment.

Several other findings also merit further discussion. One unsurprising result was the consistently strong association between functional limitations and post-traumatic symptoms: results indicated that greater report of symptoms tended to be accompanied by decreased functional status, and vice versa, although our findings do not indicate a causal direction to this relationship. In contrast to these findings, however, functional impairments due to mTBI reported across time points did not appear to be associated with neuropsychological functioning either in terms of memory (RAVLT) or processing speed (WAIS-IV Processing Speed Index). This was in contrast to previous studies examining neuropsychological functioning among patients who had sustained moderate-to-severe TBIs, wherein deficits in functional status were associated with poorer neuropsychological performance (Chaytor, Temkin, Machamer, & Dikmen, 2007). One possible explanation for this result is that participants may largely have experienced recovery of their neuropsychological functioning by the time of the first follow-up evaluation. This would be consistent with past research focused on sport concussion (i.e., mTBI without associated structural abnormalities sustained while participating in athletics), which has demonstrated that neuropsychological deficits observed immediately post-concussion tend to be alleviated within days of the injury for most athletes (McCrea et al., 2003, 2005). Alternatively, this finding may have resulted due to differences in the domains of cognitive functioning assessed by this study versus those included in the (2007) report by Chaytor and colleagues (which featured a greater emphasis on executive functioning and did not include memory measures), or because Chaytor and colleagues (2007) utilized an older version of the FSE that included cognition as an aspect of functional status. Future research is needed to conclusively explain our finding that functional status was consistently unrelated to neuropsychological performance following mTBI.

Also of note, and consistent with prior research in moderate-severe cohorts (Chaytor et al., 2007; Hudak, Hynan, Harper & Diaz-Arrastia, 2013; Temkin et al., 2003), our analyses evidenced a stable pattern of relationships between the FSE and measures of emotional and psychological functioning. Greater functional impairment was largely associated with report of greater global psychiatric symptoms, depression, and post-traumatic stress, as well as poorer life satisfaction; this pattern of results was particularly clear at 3-month follow-up and beyond. Importantly, the results of the present study are correlational, leaving open the question of whether symptoms of mental health concerns arise as a result of persistent functional impairment, or whether the opposite is true. Past research has identified pre-morbid psychological history as an important predictor of recovery post mTBI (e.g., Silverberg et al., 2015), perhaps suggesting that psychological dysfunction subsequent to injury might also contribute to poorer functional outcome. Though additional research is needed to elucidate the direction of this relationship, the present results are sufficient to indicate that individuals who experience lingering functional impairments due to mTBI may also be at increased risk for mental health concerns such as depression and post-traumatic stress. Past studies

focused primarily on moderate-severe TBI have explored the temporal direction of this relationship utilizing cross-lagged designs, concluding that it is functional limitations that precede emotional dysfunction, and not the other way around (Pagulayan, Hoffman, Temkin, Machamer, & Dikmen, 2008; Schönberger, Ponsford, Gould, & Johnston, 2011). Studies using similar designs but among those with mild brain injury are needed in order to see if this pattern remains similar among mTBI populations.

In understanding and interpreting the findings of the present study, we recognize several important limitations. First, the TRACK-TBI study, while a large-scale national study of outcomes associated with traumatic brain injury, is not an epidemiological study and, thus, its sample should not be taken as necessarily representative of the larger population of those who sustain TBIs in the United States. Further, the sample for the present study was drawn from only one of the centers involved in this project, thus limiting the subjects included to those treated within the northwest region of the United States. One reason for this is the site-specific nature of the FSE, which was administered only to subjects recruited at the particular medical center at which the present study's sample was evaluated. Future research is needed utilizing the FSE in samples of TBI patients distributed more broadly across the United States, which will continue to build generalizability of results.

Another limitation that merits consideration is the lack of trauma control subjects in the present study, a common comparison group utilized in TBI research in order to isolate the impacts of brain injury as compared with other traumatic injuries (e.g., Dikmen, Machamer, & Temkin, 2017; Hiploylee et al., 2017; Korley et al., 2017). This limitation is somewhat mitigated by the design of the FSE itself, a strength of which is that it asks subjects to rate their functioning as compared with their pre-injury baseline, thus seeking to identify the impacts of injury on functional status for each individual. Nonetheless, the measure relies on self-report of functional limitations due to TBI and other traumatic injuries. Future research directly comparing mTBI patients with trauma controls is needed to further support the utility of the FSE in this population.

Additionally, a methodological limitation of this study is its repeated administration of the WAIS-IV PSI subtests at intervals of only a few months. As alternate forms of this measure were not administered, our subjects may have experienced improved processing speed performance over time that was at least partially secondary to practice effects. Given that processing speed was not associated with functional status at any time point, this is not likely to have significantly impacted the central findings of this study; nonetheless, this limitation merits mention. (We also note that alternate forms of the RAVLT were administered at each follow-up point, thus limiting the possible impacts of practice effects on memory performance.)

Finally, it is worth noting that this study does not include measures of symptom validity or performance validity. This limitation resulted from the design of the larger TRACK-TBI parent study, which does not include such measures. Without any such indicators, we were unable to assess for the possibility of invalid reporting of functional limitations by the present study's subjects. This is an important factor to note, as validity concerns have been observed with some frequency among TBI patients (Sherer et al., 2015). Importantly, our sample was predominantly composed of patients who were not currently involved or planning to be involved in litigation relating to their injuries, suggesting that one frequent incentive for invalid symptom reporting was largely absent among our sample. Still, future research with the FSE in mTBI should directly address this question by including indicators of symptom and performance validity.

Despite the limitations discussed above, the present study provides additional support for the validity and utility of the FSE, a measure designed to offer a comprehensive and detailed assessment of functional status following TBI. Given its ability to detect changes in functional status over time and its consistent associations with post-concussive symptoms and psychological well-being, the FSE represents a promising measure of functional status for use in mTBI clinical trials and beyond.

## Supplementary Material

Supplementary material is available at *Archives of Clinical Neuropsychology* online.

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## Conflict of Interest

None declared.



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