Mindstreams® Validity & Reliability

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INTRODUCTION

In the following sections, illustrative examples are given from studies demonstrating the validity and usability of Mindstreams. Excerpts are included from peer-reviewed and internal publications. Sections include: a) discriminant validity, b) construct validity, c) test-retest reliability, d) sensitivity to pharmacologic intervention, and e) usability. Additional information may be requested from NeuroTrax Science (science@neurotrax.com).

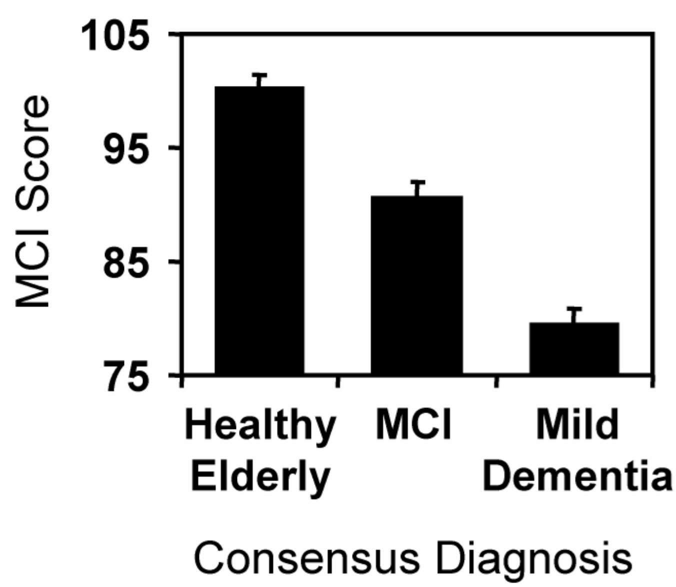
DISCRIMINANT VALIDITY

Discriminant validity refers to the ability to identify patients with a particular cognitive diagnosis. Many of the published studies to date have used Mindstreams to differentiate among cognitively impaired and non-impaired groups. Following are a few illustrative examples.

MCI and Dementia

Mindstreams was initially designed to assist physicians in the diagnosis of mild cognitive impairment (MCI; e.g., Petersen et al., 1999; Petersen & Knopman, 2006), a pre-cursor to dementia. Several studies to date have demonstrated discriminant validity in MCI and early dementia. Indeed the first report on the validity of Mindstreams was in MCI and early dementia, appearing in *BMC Geriatrics* in 2003 (Dwolatzky et al., 2003). A later paper in *Current Alzheimer Research* (Doniger et al., 2005) reported that the 30-minute Early Dementia Battery was as effective as the longer Global Assessment Battery.

Figure 1. Mindstreams discriminates among *N*=161 individuals with expert diagnoses of cognitively healthy, MCI, and mild dementia (*Curr Alzheimer Res,* 2005).



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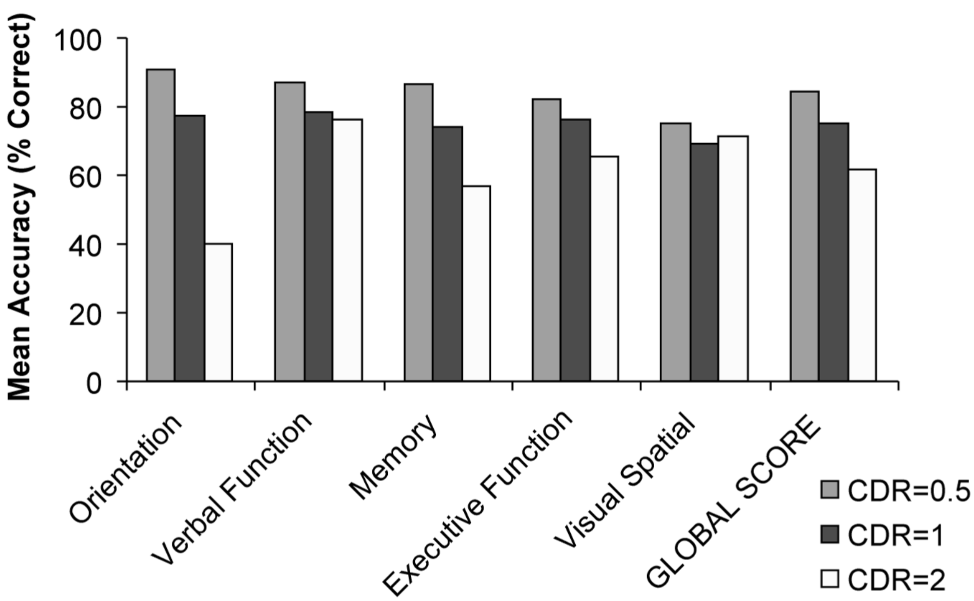
Dementia and depression often co-occur, and there is a concern that cognitive decline apparently attributable to a neurodegenerative condition may be influenced by concurrent depression. To address this issue, a 2006 paper appearing in the *American Journal of Alzheimer's Disease and Other Dementias* found the discriminant validity of Mindstreams to be intact even in the presence of depressive symptoms (Doniger et al., 2006).

A recent analysis in 97 older adults demonstrated the ability of Moderate-Severe Impairment Battery (MSIB) summary measures to distinguish among Clinical Dementia Rating (CDR) stages (Figure 2; unpublished data). Large effect sizes for differences in MSIB Global Score (GS) were obtained for caregiver-reported difficulty managing finances (d=1.25) and medications (d=1.03); medium effect sizes were found for decline over 6 months (d=0.67) and difficulty remembering or finding the right words (d=0.46).

Figure 2. Mindstreams MSIB discriminates among *N*=97 individuals staged with the CDR (unpublished data).



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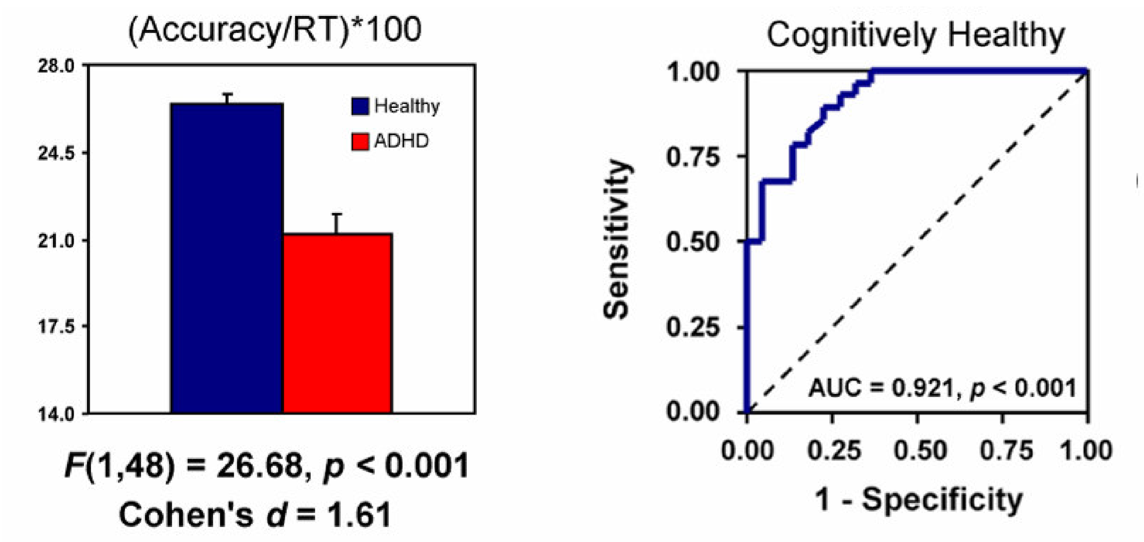
Attention-Deficit Hyperactivity Disorder (ADHD)

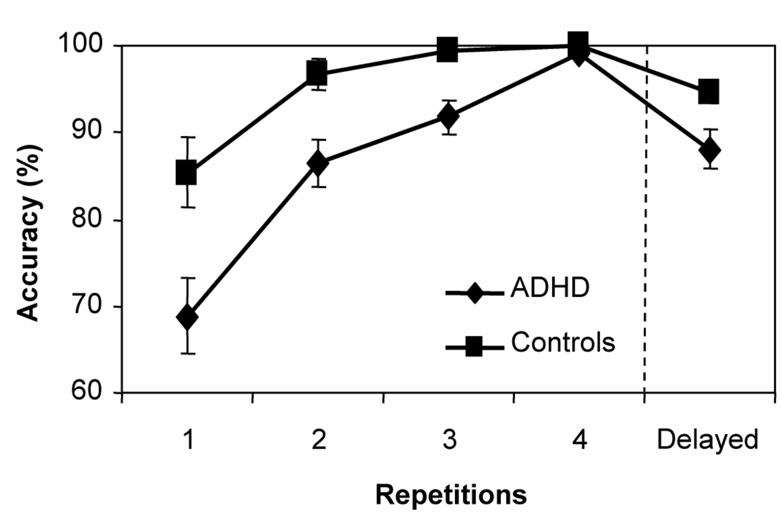
In 2007 a paper appeared in the *Journal of Clinical and Experimental Neuropsychology* (Schweiger et al., 2007) demonstrating the discriminant validity of the Mindstreams ADHD Battery in identifying young adults with ADHD. Discriminant validity of the Mindstreams Expanded Go-NoGo test is shown in Figure 3.

Figure 3. Mindstreams Expanded Go-NoGo test discriminates *N*=29 young adults with ADHD from cognitively healthy young adults (*J Clin Exp Neuropsychol,* 2007).



A forthcoming article in the *Journal of Child Neurology* (Leitner et al., in press) demonstrates the discriminant validity of Mindstreams in children with ADHD (Figure 4).

Figure 4. Mindstreams Verbal Memory test discriminates *N*=15 children with ADHD from cognitively healthy children (*J Child Neurol,* in press).



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Parkinson's Disease (PD) and Gait Disorders

Multiple studies have demonstrated the discriminant validity of Mindstreams in Parkinson's disease and gait disorders. A 2005 study in the *European Journal of Neuroscience* (Yogev et al., 2005) showed the Mindstreams could distinguish among PD and controls (Table 1). A study the following year in *Experimental Aging Research* similarly showed discriminant validity in PD and similarities between the cognitive profile in PD and that in idiopathic fallers (Hausdorff et al., 2006). Another 2006 study showed impaired executive function but not memory in idiopathic fallers (Springer et al., *Movement Disorders,* 2006).

Table 1. Cognitive Function in PD and controls (*Eur J Neurosci,* 2005).

		PD (n=30)	Controls (n=28)	P-value
Executive Function	Stroop Test Accuracy (%)	62.4 (29.5)	80.2 (32.2)	0.036
	Stroop Test Reaction Time (msec)	976.7 (372.5)	715.8 (318.2)	0.007
	Stroop Test Composite Score	8.0 (5.9)	13.2 (6.9)	0.004
	Go-NoGo Accuracy (%)	91.1 (8.0)	93.2 (6.5)	0.282
	Go-NoGo Reaction Time (msec)	542.0 (129.0)	467.8 (76.3)	0.010
	Go-NoGo Composite Score	17.4 (4.0)	20.3 (3.3)	0.004
Memory	First Trial Recall (%)	42.3 (23.1)	56.1 (30.5)	0.223
	Fourth Trial Recall (%)	75.3 (34.4)	77.5 (26.9)	0.785
	Average Recall (%)	64.8 (24.6)	68.5 (32.41)	0.628
	Delayed Recall (after 10 minutes, %)	70.5 (27.9)	71.0 (32.1)	0.957

Entries are mean (SD).

Schizophrenia

A 2006 paper appearing in *Schizophrenia Research* demonstrated the ability of Mindstreams to distinguish among patients with schizophrenia and cognitively healthy individuals (Ritsner et al., 2006; Figure 5).

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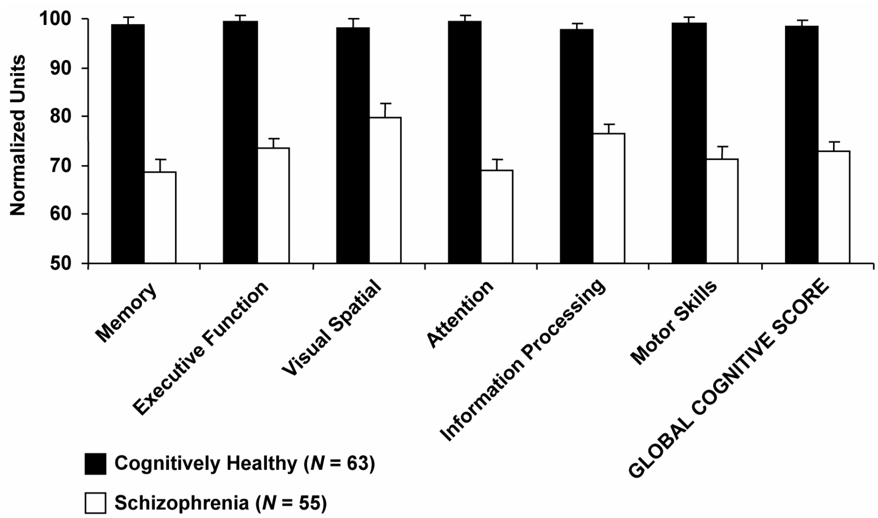
Figure 5. Schizophrenia patients (*N*=55) scored significantly more poorly than healthy subjects on Mindstreams summary measures (*Schizophr Res,* 2006).



CONSTRUCT VALIDITY

C*onstruct validity* refers to the ability of a cognitive measure to measure the intended cognitive domains or functions and can be demonstrated by comparison with well-established traditional measures of those domains or functions. Correlation coefficients are often computed that reflect the degree of relationship between a Mindstreams measure and a corresponding traditional measure. Note that the sign of a correlation coefficient (e.g., Pearson's *r*) is not related to the strength of the correlation; rather a coefficient of 0 indicates no correlation and a coefficient of either 1 or -1 indicates perfect correlation. The construct validity of Mindstreams has been demonstrated in several cohorts; following are a few illustrative examples.

Older Adults

In a cohort of 54 community-based elderly patients comprising healthy and mild cognitive impairment (from Dwolatzky et al., *BMC Geriatrics*, 2003), Mindstreams tests were compared with paper-based tests including subtests of the Weschler Memory Scale, 3rd Edition (WMS-III), the Weschler Adult Intelligence Scale, 3rd Edition (WAIS-III), the Rey Auditory-Verbal Learning Test (RAVLT) and the Stroop test, as well as the Controlled Oral Word Association and Boston Naming tests. Results are shown in Table 2 and demonstrate good comparability between Mindstreams and paper-based tests.

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Table 2. Construct Validity of Mindstreams in Older Adults (*N*=54)

Mindstreams Test (outcome parameter)	Traditional Paper-Based Measures	Correlation r-value[A]
Verbal Memory (accuracy, final repetition, immediate recognition test)	WMS-III Logical Memory II	0.73
	WMS-III Logical Memory I	0.70
	WMS-III Visual Reproduction II	0.70
Non-Verbal Memory (accuracy, final repetition, immediate recognition test)	RAVLT Short Term Retention	0.77
	WMS-III Visual Reproduction II	0.72
	WAIS-III Visual Reproduction II	0.71
	RAVLT Delayed Recall	0.70
	WMS-III Logical Memory I	0.70
	WMS-Logical Memory II	0.70
	WMS-III Visual Reproduction I	0.68
	RAVLT Total Learning	0.61
Go-NoGo (composite score)	Stroop Word Time	-0.81
	Stroop Color Word Time	-0.71
	Controlled Oral Word Association A	0.69
	WAIS-III Digit Symbol	0.68
Stroop Phase III (composite score)	Stroop Color Word Time	-0.52
	Controlled Oral Word Association A	0.50
	WAIS-III Letter-Number Sequencing	0.47
Visual Spatial Imagery (accuracy)	WAIS-III Digit Symbol	0.60
	WMS-III Mental Control	0.57
	WAIS-III Spatial Span	0.57
Verbal Rhyming (weighted accuracy)	Controlled Oral Word Association A	0.64
	Boston Naming Test	0.62
	WMS-III Logical memory I	0.62
	Controlled Oral Word Association FS	0.61
Staged Information Processing (overall composite score)	WMS-III Mental Control	0.76
Problem Solving (accuracy)	WAIS-III Block Depn	0.66
	WAIS-III Similarities	0.61
'Catch' Game (weighted accuracy)	WAIS-III Block Depn	0.60
	WAIS-III Digit Symbol	0.51

[A] $p<0.05$ for all reported correlations

Healthy Children

In a construct validity study of Mindstreams versus paper-based tests in healthy children (*N*=40; age: 11.01±1.27 years; education: 5.12±1.3 years; 22 female), moderate-to-high correlations were generally found between computerized and paper-based measures of comparable cognitive functions (Ohana, masters thesis; Table 3).

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Table 3. Construct Validity of Mindstreams in Healthy Children (*N*=40)

Cognitive Domain	Paper-based Test	Mindstreams Test	*r*-value	*p*-value
Attention	TMT-A (time)	Go-NoGo (performance index)	-.550	<0.001
		Go-NoGo (reaction time)	.575	<0.001
		Go-NoGo (SD of reaction time)	.661	<0.001
		Staged Information Processing low load, medium speed (SD of reaction time)	.501	.001
		Staged Information Processing low load, high speed (SD of reaction time)	.671	<0.001
		Staged Information Processing medium load, high speed (SD of reaction time)	.632	<0.001
	Number Cancellation (592-time)	Stroop (reaction time, non-interference: meaning)	.546	<0.001
		Stroop (composite score, non-interference: meaning)	-.524	.001
Psychomotor Planning	TMT-B (time)	Catch Game (time to first move)	.469	.002
Verbal Function	COWA (5 phases)	Verbal Function (naming, accuracy)	.408	.009
Verbal Memory	RAVLT (trials 1 to 5)	Verbal Memory (accuracy, all repetition trials)	.462	.007
	RAVLT (List A after List B)	Verbal Memory (accuracy, all repetition trials)	.405	.01
	RAVLT (delayed)	Verbal Memory (accuracy, all repetition trials)	.465	.003
	RAVLT (List A after List B)	Verbal Memory (accuracy, delayed recognition)	.404	.01
	RAVLT (delayed)	Verbal Memory (accuracy, delayed recognition)	.490	.002
Non-Verbal Memory	Rey Complex Figure (immediate)	Non-Verbal Memory (accuracy, all repetition trials)	.516	.001

SD: Standard deviation
TMT: Trial Making Test
COWA: Controlled Oral Word Association
RAVLT: Ray Auditory Verbal Learning Test

Movement Disorders Patients

Comparability between Mindstreams and paper-based tests was also evaluated in a cohort of 37 patients (age: 60.3±13.4 years; education: 13.6±2.4 years; 10

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female; MMSE: 28.3±2.3) with a primary movement disorder diagnosis (18 PD; 15 ET; 4 primary dystonia). Results from this study (Doniger et al., *Symposia on the Etiology, Pathogenesis, and Treatment of Parkinson's Disease and Other Movement Disorders*, 2006) are presented in Table 4 and Figures 6 & 7. Mindstreams showed good correspondence with traditional neuropsychological tests.

Table 4. Construct Validity of Mindstreams in Movement Disorders Cohort (*N*=37)

Cognitive Domain	Mindstreams Test	Paper-based Test	Correlation, p-value
MEMORY	Verbal Memory	Hopkins Verbal Learning	r=0.72, p=0.001
		Brief Visuospatial Memory Test-Revised	r=0.66, p=0.003
	Non-Verbal Memory	Brief Visuospatial Memory Test-Revised	r=0.84, p<0.001
		Hopkins Verbal Learning	r=0.71, p<0.001
		Wechsler Memory Scale III (WAIS-3)	r=0.64, p<0.001
EXECUTIVE FUNCTION	Go-NoGo	Trails B	r=0.63, p<0.001
		WAIS-3 Digit Symbol	r=0.63, p<0.001
	Stroop Interference	WAIS-3 Digit Symbol	r=0.63, p<0.001
	Catch Game	Trails B	r=0.70, p<0.001
		WAIS-3 Digit Symbol	r=0.65, p<0.001
VISUAL SPATIAL	Visual Spatial	Judgment of Line Orientation	r=0.70, p<0.001
VERBAL FUNCTION	Verbal Function: Naming	Boston Naming test	r=0.66, p=0.002
		Hopkins Verbal Learning	r=0.69, p=0.001
		Brief Visuospatial Memory Test-Revised	r=0.77, p<0.001
	Verbal Function: Rhyming	Hopkins Verbal Learning	r=0.76, p<0.001
		Brief Visuospatial Memory Test-Revised	r=0.67, p=0.002
ATTENTION	Go-NoGo (RT variability)	Trails B	r=0.74, p<0.001
	Catch Game (RT variability)	Trails B	r=0.65, p<0.001
MOTOR SKILLS	Finger Tapping (inter-tap interval)	Trails A	r=0.60, p<0.001
		Trails B	r=0.60, p<0.001
INFORMATION PROCESSING SPEED	Information Processing: Medium Speed, High Load	Hopkins Verbal Learning	r=0.71, p<0.001
	Information Processing: Fast Speed, Low Load	WAIS-3 Digit Symbol	r=0.70, p<0.001
	Information Processing: Fast Speed, Medium Load	Trails B	r=0.65, p<0.001

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Figure 6. Construct Validity in Memory Domain.

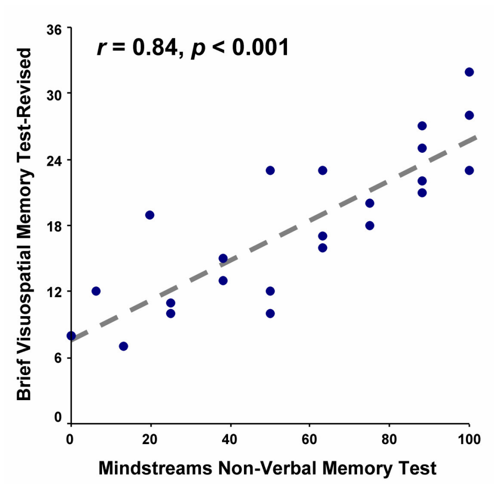
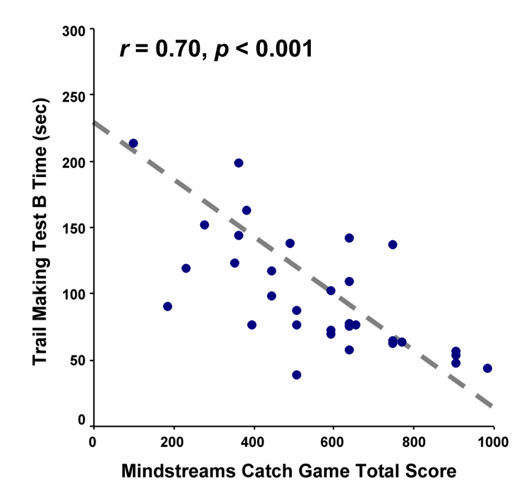


Figure 7. Construct Validity in Executive Function Domain.



Traumatic Brain Injury (TBI)/Post-Concussion Syndrome

32 adults with history of traumatic brain injury (TBI; age: 30.6±9.7 years; 13 female) were tested 0.5 to 5 years post-injury with Mindstreams and with traditional neuropsychological tests (Ben-Harush, masters thesis). Pearson correlations between computerized and paper-based tests are given in Table 5. Good construct validity was demonstrated.

Table 5. Construct Validity of Mindstreams in TBI Cohort (*N*=32)

Mindstreams Test	Outcome Parameter	Paper-Based Test	r-value, p-value
Verbal Memory	Accuracy- delayed memory	RAVLT Immediate Recall 2	r=.611, p=.000
		RAVLT Delayed Recall	r=.581, p=.001
		RAVLT Recognition	r=.528, p=.002
Verbal Function	Accuracy- naming	WAIS III- VIQ	r=.521, p=.003
		WAIS III- Verbal Comprehension Index	r=.545, p=.002
		WAIS III- Information	r=.572, p=.001
		Naming Test	r=.621, p=.003
	Accuracy- rhyming	WAIS III- Verbal Comprehension Index	r=.618, p=.000
		WAIS III- Vocabulary	r=.530, p=.004
		WAIS III- Similarities	r=.567, p=.001
		Naming Test	r=.547, p=.010
Problem Solving	Accuracy	WAIS III- FSIQ	r=.638, p=.000
		WAIS III- VIQ	r=.639, p=.000
		WAIS III- PIQ	r=.459, p=.008

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		WAIS III- Verbal Comprehension Index	r=.603, p=.000
		WAIS III- Perceptual Organization Index	r=.514, p=.003
		WAIS III- Vocabulary	r=.594, p=.001
		WAIS III- Letter- Number Sequencing	r=.546, p=.004
		WAIS III- Matrix Reasoning	r=.648, p=.000
		WAIS III- Symbol Search	r=.608, p=.001
Visual Spatial Processing	Accuracy	WAIS III- FSIQ	r=.525, p=.003
		WAIS III- Similarities	r=.510, p=.004
		WAIS III- Picture Completion	r=.509, p=.004
Staged Information Processing	Composite score- level 1.3	WAIS III- Digit span	r=.586, p=.001
	Composite score- level 2.3	WAIS III- Arithmetic	r=.508, p=.004
	Composite score- level 3.2	WAIS III- Working Memory Index	r=.595, p=.001
		WAIS III- Digit span	r=.566, p=.001
		WAIS III- Block Design	r=.529, p=.002

TEST-RETEST RELIABILITY

Test-retest reliability relates to the similarity of test scores obtained over consecutive test sessions when no change in cognitive status is expected. One way to evaluate test-retest reliability is to compute the correlation coefficient among test scores from consecutive sessions. A high correlation indicates commonality among the measurements and thus good test-retest reliability. This was the approach adopted by Schweiger et al. (2003) in a paper reporting on the test-retest reliability of Mindstreams. Table 6 contains the mean and standard deviation for Mindstreams summary measures from each of two testing sessions as well as the correlation coefficient.

Table 6. Mindstreams tests exhibited good alternate form test-retest reliability in *N*=57 healthy volunteers (median inter-test interval: 4.84 weeks), reflecting their suitability for measuring change (*Acta Neuropsychol,* 2003).

Index Score	Form 1	Form 2	Correlation	
	mean±SD	*mean±SD*	*r*-value	*p*-value
Memory	100.01±10.33	102.96±9.44	0.84	**
Executive Function	99.77±10.07	102.20±11.42	0.80	**
Visual Spatial	101.22±13.28	104.42±11.94	0.64	**
Verbal	99.22±15.96	103.54±8.04	0.40	**
Attention	101.38±8.86	102.49±9.93	0.79	**
Information Processing Speed	97.75±13.78	102.28±14.11	0.68	**
Motor Skills	100.24±11.80	101.11±11.48	0.80	**

*p<0.05 **p<0.01 NS: not significant

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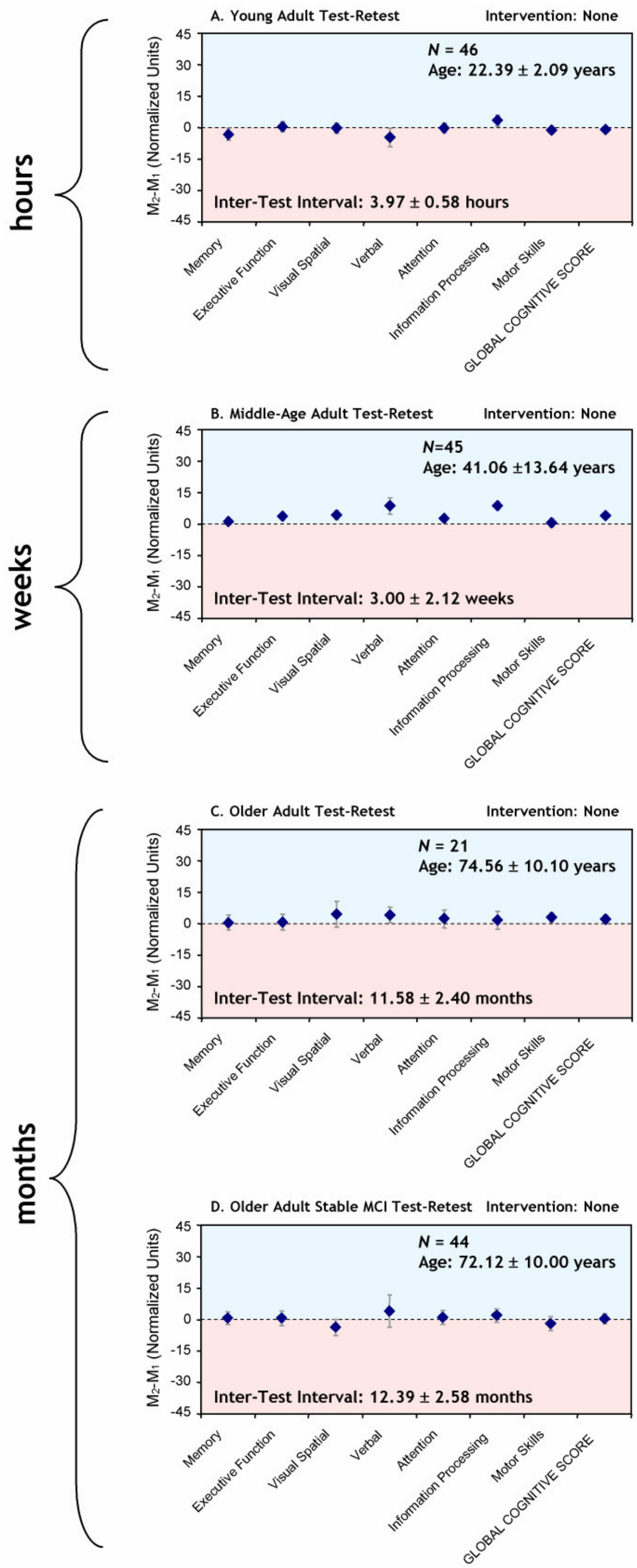

Figure 8. Mean difference (M_2-M_1) in Mindstreams summary measures (normalized units; 1 standard deviation = 15 units) for four test-retest research samples with no expected change in cognitive status. The 95% confidence interval around the difference is indicated.

As mentioned above, Mindstreams includes alternate forms to minimize learning across sessions, which should result in higher test-retest reliability. Thus test-retest reliability coefficients reflect not only comparability across consecutive sessions but also comparability across alternate forms.

Correlation coefficients computed from a cohort of college students tested twice in a few hours (inter-test interval: 3.97±0.58 hours) as part of a research study (Doniger et al., 2006) were relatively high, supporting the earlier results (correlation coefficients: Memory r = 0.52, Executive Function r = 0.68, Visual Spatial r = 0.71, Verbal r = 0.42, Attention r = 0.71, Information Processing r = 0.77, Motor Skills r = 0.83, Global Cognitive Score r = 0.77). Test-retest reliability can also be evaluated by computing the difference in performance between Session 1 and Session 2 for each summary measure. This approach was adopted for several datasets of various ages and retest intervals, and the mean differences are shown in Figure 8.

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The closer the points are to the zero line, the better the comparability between test sessions (i.e., the test-retest reliability). It can be readily appreciated that Mindstreams summary measures show good test-retest reliability both in young and elderly and at inter-test interval ranging from hours to approximately 1 year.

SENSITIVITY TO PHARMACOLOGIC INTERVENTION

High test-retest reliability makes it easier to detect change in cognitive status, whether improvement or decline. Indeed it is important for the clinician or pharmaceutical company to evaluate the effect of treatment upon cognitive function from visit to visit.

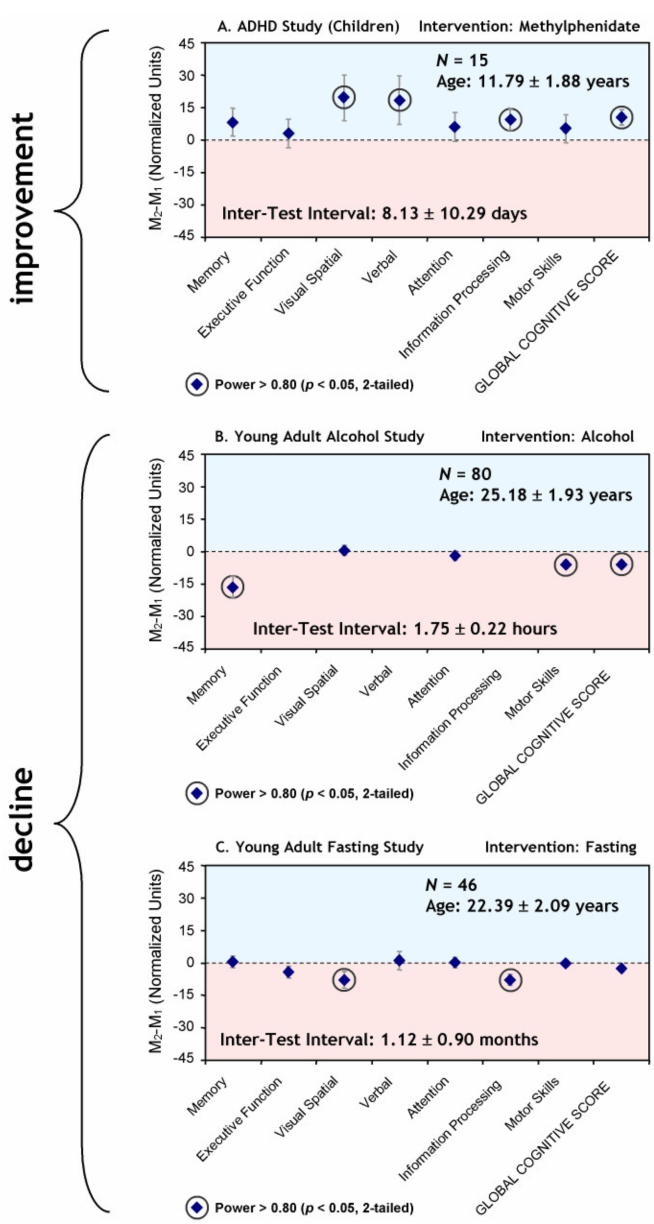

Figure 9. Mean difference (M_2-M_1) in Mindstreams summary measures (normalized units; 1 standard deviation = 15 units) for three study cohorts tested at baseline and following an intervention expected to result in improvement or decline. The 95% confidence interval around the difference is indicated. Mean differences with power exceeding 0.80 ($p < 0.05$, 2-tailed) are indicated on the graphs.

In the case of a pharmaceutical company running a clinical trial, the high test-retest reliability described above indicates that a mean difference of ~10 normalized units in a Mindstreams summary measure would be detectable with only 13 subjects (Cohen's $d = 0.80$, assuming power of 0.80, $p<0.05$, 2-tailed) and a mean difference of ~6 normalized units would be detectable with only 32 subjects (Cohen's $d=0.50$, assuming power of 0.80, $p<0.05$, 2-tailed).

To demonstrate sensitivity to pharmacologic intervention, mean differences were computed for several datasets where there was a

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change in cognitive status as in Figure 9. Panel A demonstrates improvement in children diagnosed with ADHD following administration of methylphenidate in a double-blind controlled trial (Leitner et al., in press). Power exceeded 0.80 for mean differences in Visual Spatial, Verbal Function, and Information Processing index scores and the Global Cognitive Score (GCS). Panel B shows decline in young adults in a study of acute alcohol consumption (Jaffe et al., 2005). Mean differences between baseline and peak alcohol level for Memory and Motor Skills index scores and the GCS exceeded power of 0.80. Panel C shows decline in scores for young adults tested in the afternoon when fasting since the same morning (Doniger et al., 2006). Power exceeded 0.80 for mean differences in Visual Spatial and Information Processing index scores. Thus these results provide good evidence for the sensitivity of Mindstreams scores to change induced by pharmacologic or other intervention.

Several additional publications have demonstrated the sensitivity of Mindstreams for detecting change. A 2006 study by Auriel et al. showed improvement in the Attention index score in 21 Parkinson's disease patients on methylphenidate, but no improvement in Memory or Visual Spatial index scores (Auriel et al., *Clin Neuropharmacol,* 2006). Another more recent study in 19 patients demonstrated sensitivity of Mindstreams to SSRI therapy for depression (Paleacu et al., *Clin Neuropharamcol,* in press). In keeping with expectations, improvement was shown in all cognitive domains other than motor skills following treatment.

A 2005 study by Elstein et al. (*Genet Med,* 2005) using a between-groups design, compared untreated patients with those receiving the traditional treatment for Gaucher disease or a novel treatment. Mindstreams testing consistently showed reduced cognitive function relative to untreated patients in the patients receiving the traditional treatment and improved cognitive function in patient receiving the novel treatment.

USABILITY

In addition to demonstrating the validity of the tests in research studies, it is critical to show that Mindstreams is easy-to-use and practical for clinical settings. As described previously, Mindstreams incorporates many design features to maximize practicality and usability.

To evaluate the usability of Mindstreams, usability questionnaire data was analyzed from the first 2888 consecutive patients to use Mindstreams in a clinical setting (Simon et al., 2006). Patients were from 12 clinical centers including 1 geriatrics practice, 3 primary care practices, and 8 neurology practices. For all patients, 83% rated the tests easy rather than hard to use (p<0.001). 73% of non-computer users, 70% of patients over 75, and 69% of poor performers rated Mindstreams easy rather than hard to use. Ratings from test supervisors were similar (Table 7; Figure 10).

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Table 7. Frequency of responses to "Were the tests easy to use (for the subject)?" categorized as "easy" or "hard" for the entire cohort (*N*=2888) and separately in non-computer users (*N*=1157), patients over 75 years old (*N*=1027), and patients with a Mindstreams Global Cognitive Score ≤ 85 (*N*=854).

Group	Source	Easy	Hard
Entire Cohort	Patient*	1770	356
	Supervisor*	1473	394
Non-Computer Users	Patient*	585	221
	Supervisor*	445	257
Over 75 Years	Patient*	503	211
	Supervisor*	305	220
Global Cognitive Score ≤ 85	Patient*	391	179
	Supervisor*	298	220

*p<0.001, Chi-Square Goodness-of-Fit Test

When test supervisors were queried regarding patient frustration, 76% of supervisor ratings indicated no patient frustration (p<0.001). 78% of ratings for non-computer users, 76% for patients over 75, and 74% for poor performers indicated no frustration (p's<0.001).

The above analyses demonstrate that Mindstreams is practical for typical office-based clinical settings. Indeed even non-computer users, the oldest patients, and those with more severe cognitive impairment found the tests easy to use. In combination with the validity work previously described, this data suggests that Mindstreams can be realistically integrated into a clinical practice to standardize cognitive health care and improve the early detection, assessment and management of cognitive impairment.

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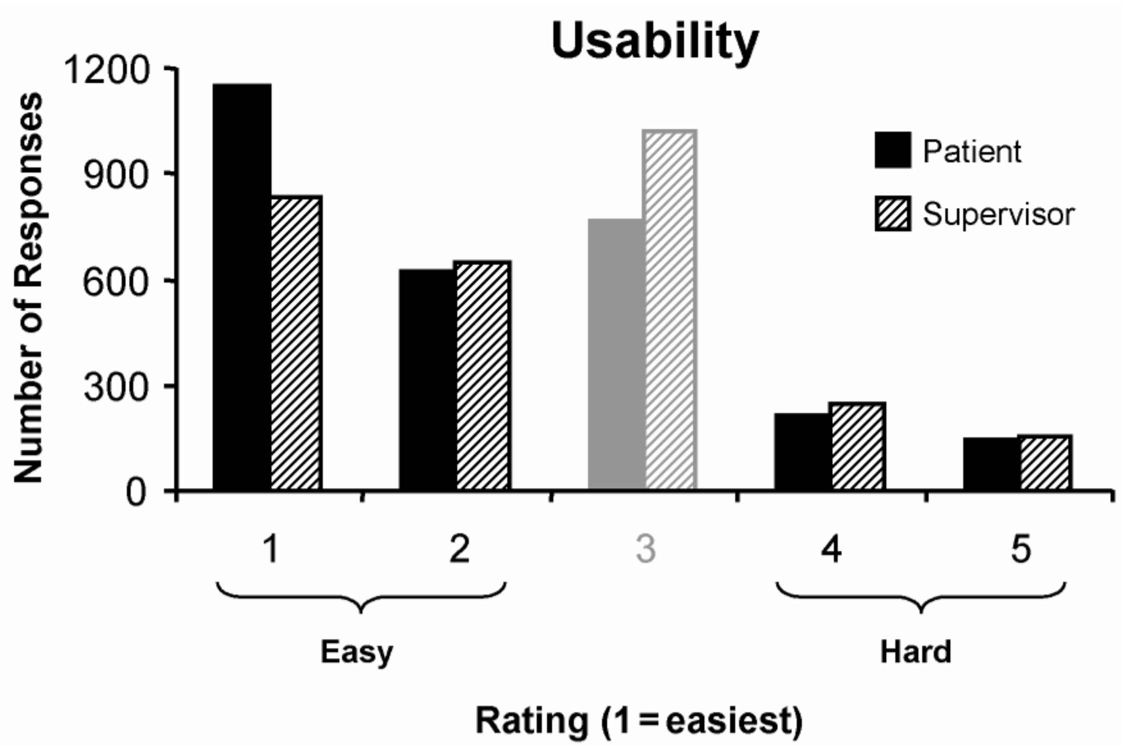
Figure 10. Usability of Mindstreams Tests. Frequency of responses to: "Were the tests easy to use (for the subject)?" for the entire clinical cohort (*N*=2888). There were significantly more "easy" than "hard" ratings (*p*<0.001).



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