

HOPPS: ANAM Reaction Time and Composite Outcome

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Composite score

- FDA did not like that the primary outcome for HOPPS was a symptom questionnaire
- Composite outcome tool requested by FDA
 - Conceived a priori
 - Could be useful for a later phase III trial
- Quantify multidimensional change at baseline and post-chamber sessions
 - Symptoms
 - Neuropsychological testing
 - Functional outcome

Symptom Domain



Neurobehavioral Symptom Questionnaire:

"Rate the following symptoms with regard to how much they have disturbed you in the last 2 weeks."

0 to 4 Likert Scale

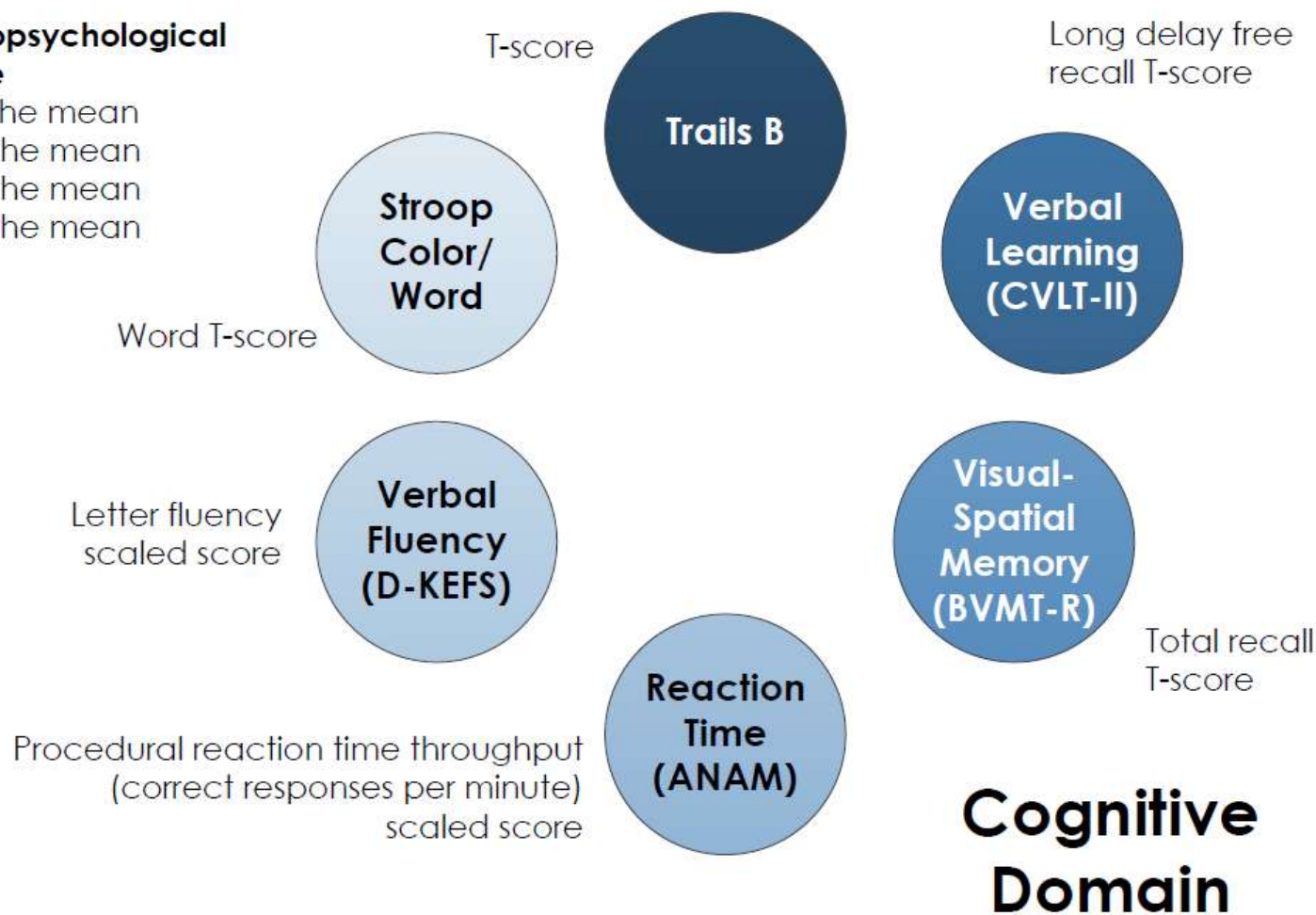
0 – None, rarely if ever present, not a problem at all

4 – Almost always present. Unable to perform at work, school or home due to this problem.

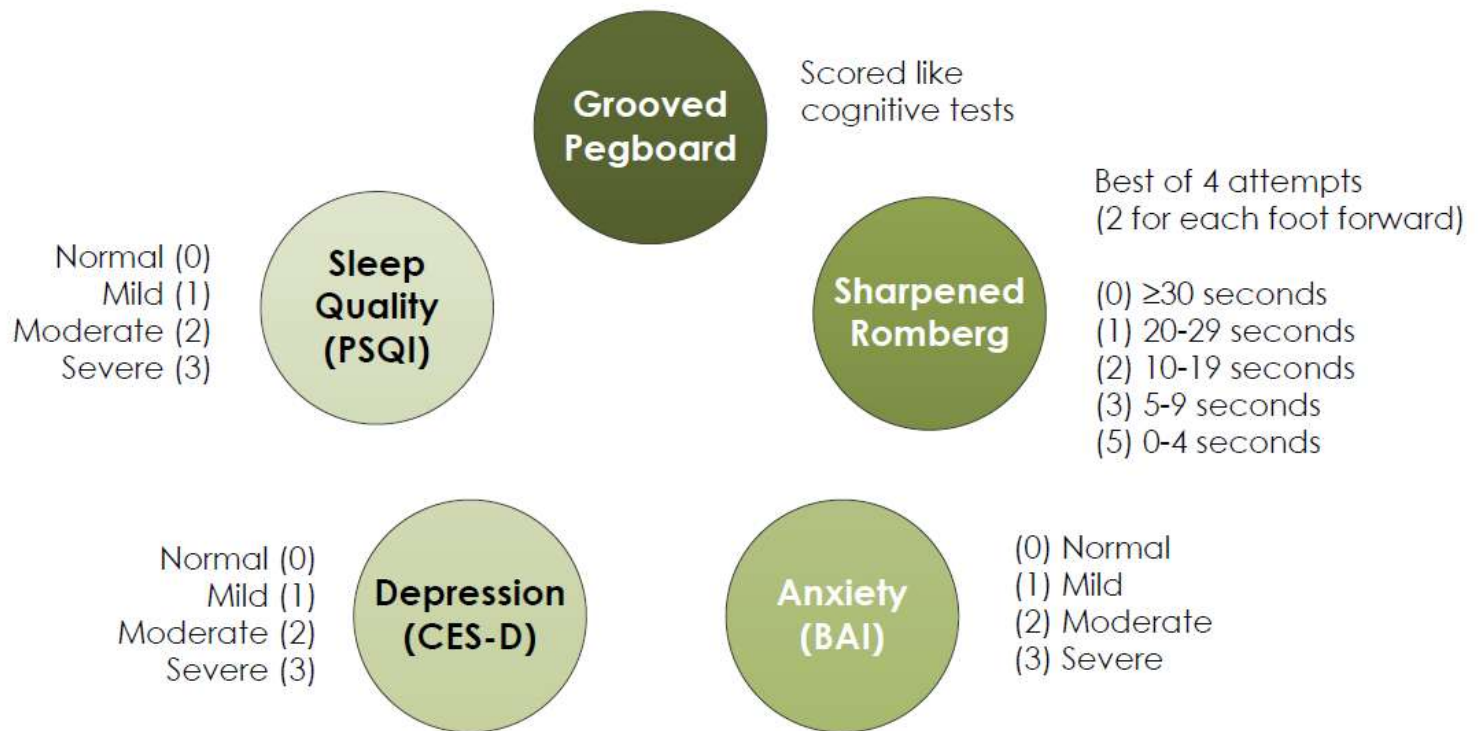
Scores for these items totaled, then divided by 2.

Scoring for Neuropsychological Test Performance

- (0) ≥ 1 SD below the mean
- (1) < 1 SD below the mean
- (2) < 2 SD below the mean
- (3) < 3 SD below the mean



Functional Domain



		Local Care (no chamber) (n=20)	HBO2 (1.5 ATA) (n=23)	Sham (1.2 ATA air) (n=21)
Symptom Domain	Baseline	6±3	7±3	7±3
	Follow-up	6±3	6±3	5±3
Cognitive Domain	Baseline	3±3	4±3	4±3
	Follow-up	3±3	3±4	4±4
Functional Domain	Baseline	6±4	6±4	8±4
	Follow-up	7±4	6±4	5±4
Composite Total (possible range 0-49)	Baseline	16±8	17±9	18±7
	Follow-up	16±8	13±8	14±9
Total NSI Score (possible range 0-88)	Baseline	32±15	33±17	34±17
	Follow-up	33±19	30±16	27±17

Conclusions

- Local care group did not change
- The chamber groups scores on the NSI and composite were similar, do not need this composite
- These data suggest patient reported symptoms may adequately reflect status change after mTBI
- These results confirm what is known about symptoms in mTBI that functional questionnaires remain the gold standard.