COGNITION AND MILD TBI HISTORY:

RECENT FINDINGS FROM THE LIMBIC-CENC PROSPECTIVE STUDY ALONG WITH CLINICAL TRANSLATION

William C. Walker, MD

Objectives:

- Understand the relationship between remote mTBIs and cognitive performance in the LIMBIC-CENC cohort
- Understand the relationship that aerobic exercise/activities has with cognition and well-being in those with positive mTBI histories
- Assimilate these recent findings into the research literature
- Learn clinical strategies to address cognitive concerns among patients with prior mTBI

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Branches of LIMBIC-CENC Research

- Retrospective Database study (PI: Yaffe)
- Phenotyping study (PI: Pugh)
- Health Economics study (PI: Dismuke)
- Prospective Longitudinal Study (PI: Walker)
- PLS Biomarker study (PI: Kenney)
- PLS Imaging Study (PI: Wilde)

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Purpose of LIMBIC PLS

Background: The CENC PLS established a multicenter cohort of combat-exposed SM/Vs who underwent comprehensive 360^0 evaluation of brain and neurologic health and function. The LIMBIC-CENC PLS continues to expand and serially assess the cohort.

Overall Goal: Answer critical questions about:

- the long-term effects of mild traumatic brain injury (mTBI), including any evidence of neurodegeneration
- the contribution of other factors on long-term post-deployment brain health

that will lead to **improved patient care and life outcomes**

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Methods Synopsis

- Comprehensive, holistic, 360 degree **assessment of brain and neurologic health and functioning**
- **Prospective follow-up (longitudinal) evaluations**
  - Annual brief (< 1 hr) telephonic
  - Comprehensive full-day at least once every 5 years
  - Merging of retrospective (administrative) data
- **Scientific analyses**
  - LIMBIC internal analyses of prospective data, longitudinal and cross-sectional
  - Collaborations with other scientific stakeholders
  - Sharing of datasets directly from external requests and through the FITBIR
- **Leveraging cohort** for
  - Dual study enrollment
  - Additional funding opportunities with added research aims

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Protocol Content Highlights

- Establishing lifetime mild TBI history
  - Highly standardized and quality-controlled process
  - Mapping of **all potential concussive events (PCEs)** during lifetime
    - Modification of OSU TBI-ID Interview
  - Determining **mTBI diagnosis for each PCE**
    - VCU retrospective Concussion Diagnostic Interview (VCU rCDI)

- Full assessment battery summary
  - **Neurocognition emphasis** (primary outcome)
  - Advance neuroimaging and biomarkers
  - Co-factors and confounders
  - Sensory impairments
  - Converging symptom, structural, physiologic, and functional outcomes

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PLS Eligibility Criteria

- Prior Military Combat Deployment
  - Under CENC Post-911 deployment was required; Under LIMBIC: any era permitted
- Combat Exposure (CE)
  - Deployment Related Risk Inventory (DRRI-2) combat CE module of at least 1 point
- Absence of TBI severity > mild (e.g. moderate or severe TBI)
  - Both mild TBI and TBI negative (controls) are permitted
- Absence of Major Neurologic d/o (e.g. SCI) or Psychiatric d/o (e.g. schizophrenia)
  - Most neuro or psych disorders are permitted (e.g. PTSD, mini-stroke)

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LIMBIC-CENC Prospective Longitudinal Study Enrollment & Testing Sites

#	Location	Name	PI
01	Richmond, VA	Hunter Holmes McGuire VA Medical Center	William Walker, MD David Glazier, MD
02	Houston, TX	Michael E. DeBakey VA Medical Center Baylor College of Medicine	Randall Scheibel, PhD Maya Troyanskaya, MD
03	Tampa, FL	James A. Haley Veterans' Hospital	Risa Richardson, PhD Shannon Miles, PhD
04	San Antonio, TX	South Texas Veterans' Health Care System	Carlos A. Jaramillo, MD, PhD
05	Ft. Belvoir, VA	Fort Belvoir Community Hospital Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc.	Melissa Guerra, MD
06	Portland, OR	VA Portland Health Care System	Kathleen Carlson, PhD
07	Minneapolis, MN	University of Minnesota	Scott Sponheim, PhD Nicholas Davenport, PhD
08	Boston, MA	VA Boston Healthcare System	Terri Pagoda, PhD
09	Salisbury, NC	W.G. (Bill) Hefner VA Medical Center	Sarah Martindale, PhD Jared Rowland, PhD
10	San Diego, CA	VA San Diego Healthcare System/Camp Pendleton	Amy Jak, PhD Jason Bailie, PhD
11	Fort Gordon, GA	Dwight D. Eisenhower Army Medical Center	John Rigg, MD Scott Mooney, PhD

Sites added under LIMBIC in red font

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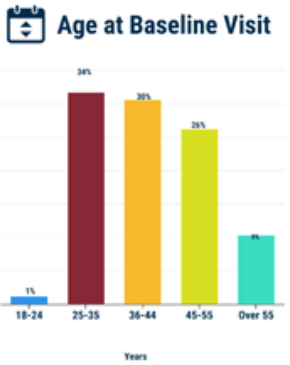
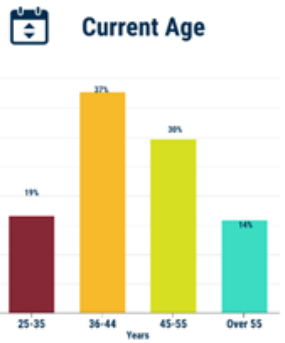
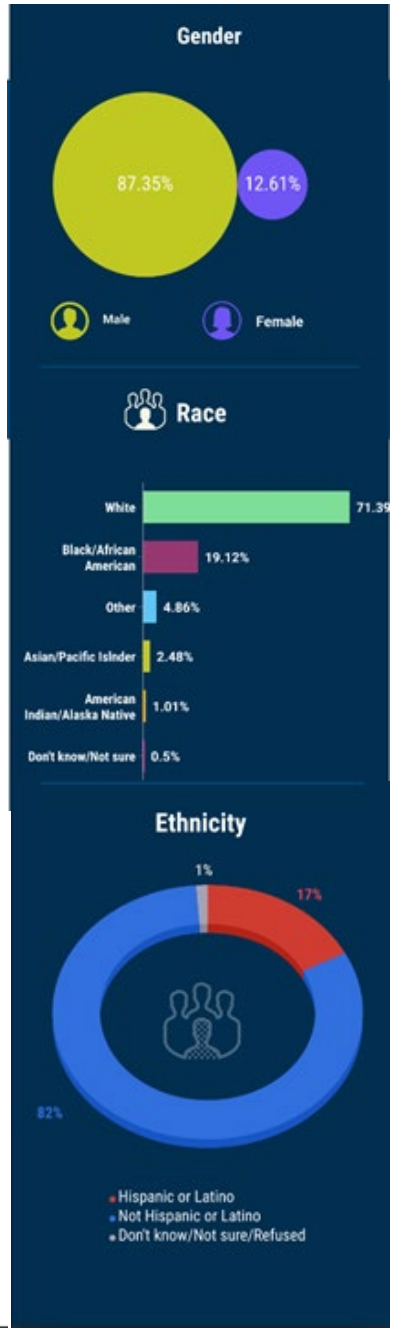
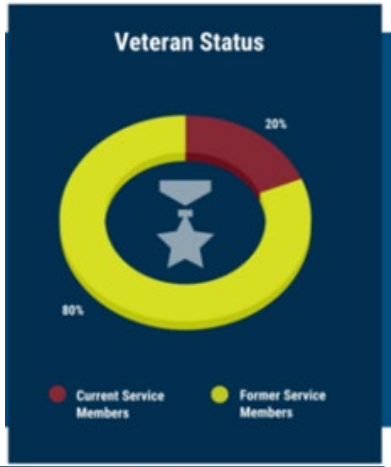
Enrollment
2308 Enrolled Participants
2181 Fully Assessed Participants
Richmond 378 367
Houston 306 299
Tampa 388 348
San Antonio 281 267
Ft. Belvoir 172 164
Portland 236 236
Minneapolis 215 188
Boston 141 132
Salisbury 114 114
Fort Gordon 51 41
San Diego 26 25

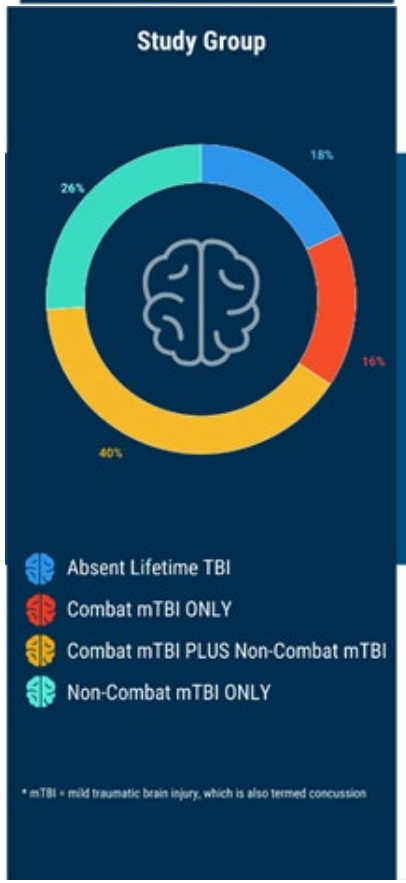

Age at Baseline Visit
18-24
25-35
36-44
45-55
Over 55
Years

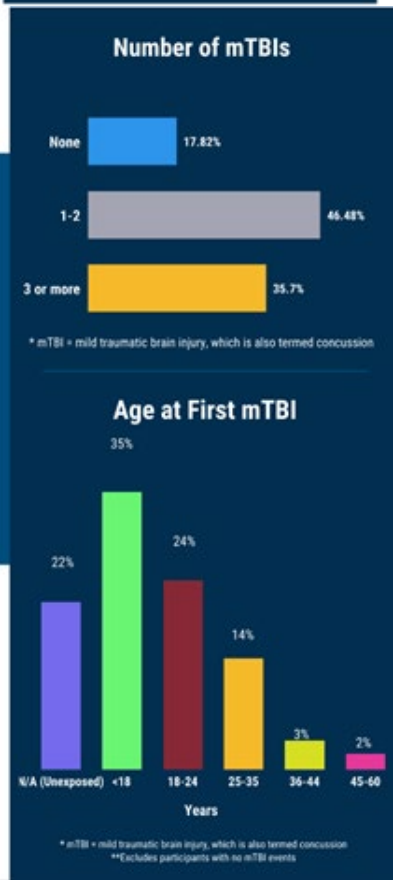

Current Age
25-35
36-44
45-55
Over 55
Years

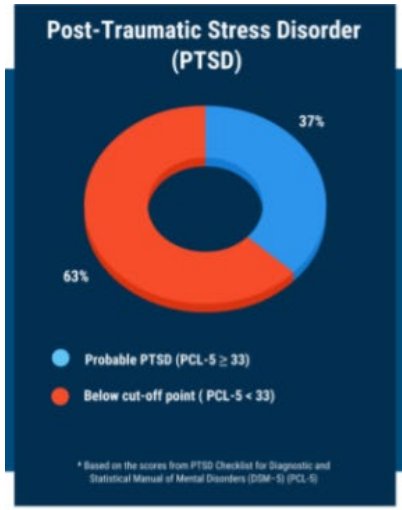

Gender
87.35%
12.61%
Male
Female
Race
White 71.39
Black/African American 19.12%
Other 4.86%
Asian/Pacific Islnder 2.48%
American Indian/Alaska Native 1.01%
Don't know/Not sure 0.5%
Ethnicity
1%
17%
82%
Hispanic or Latino
Not Hispanic or Latino
Don't know/Not sure/Refused

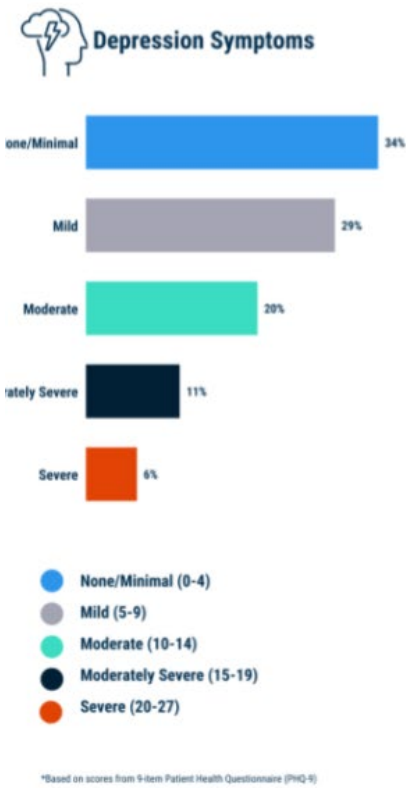

Veteran Status
20%
80%
Current Service Members
Former Service Members

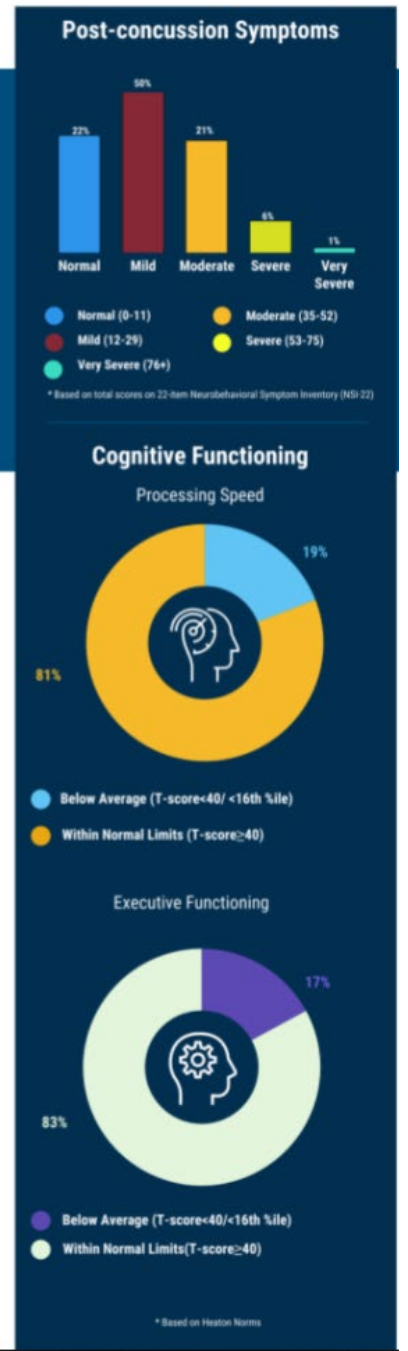

Rank
17%
83%
Enlisted
Officer
* Based on the last rank for former service members and current rank for current service members


Study Group
18%
26%
16%
40%
Absent Lifetime TBI
Combat mTBI ONLY
Combat mTBI PLUS Non-Combat mTBI
Non-Combat mTBI ONLY
* mTBI = mild traumatic brain injury, which is also termed concussion


Number of mTBIs
None 17.82%
1-2 46.48%
3 or more 35.7%
* mTBI = mild traumatic brain injury, which is also termed concussion
Age at First mTBI
35%
22%
24%
14%
3%
2%
N/A (Unexposed)
<18
18-24
25-35
36-44
45-60
Years
* mTBI = mild traumatic brain injury, which is also termed concussion
**Excludes participants with no mTBI events


Post-Traumatic Stress Disorder (PTSD)
37%
63%
Probable PTSD (PCL-5 ≥ 33)
Below cut-off point (PCL-5 < 33)
* Based on the scores from PTSD Checklist for Diagnostic and Statistical Manual of Mental Disorders (DSM-5) (PCL-5)


Depression Symptoms
one/Minimal 34%
Mild 29%
Moderate 20%
ately Severe 11%
Severe 6%
None/Minimal (0-4)
Mild (5-9)
Moderate (10-14)
Moderately Severe (15-19)
Severe (20-27)
*Based on scores from 9-item Patient Health Questionnaire (PHQ-9)


Post-concussion Symptoms
22%
58%
21%
6%
1%
Normal
Mild
Moderate
Severe
Very Severe
Normal (0-11)
Mild (12-29)
Very Severe (76+)
Moderate (35-52)
Severe (53-75)
* Based on total scores on 22-item Neurobehavioral Symptom Inventory (NSI-22)
Cognitive Functioning
Processing Speed
19%
81%
Below Average (T-score<40/ <16th %ile)
Within Normal Limits (T-score≥40)
Executive Functioning
17%
83%
Below Average (T-score<40/<16th %ile)
Within Normal Limits(T-score≥40)
* Based on Heaton Norms

Walker WC, O'Neil ME, Ou Z, Pogoda TK, Belanger HG, Scheibel RS, Presson AP, Miles SR, Wilde EA, Tate DF, Troyanskaya M, Pugh MJ, Jak A, Cifu DX.

CAN MILD TBI ALTER COGNITION CHRONICALLY? A LIMBIC-CENC MULTICENTER STUDY

Neuropsychology. 2022 Sep 29. doi: 10.1037/neu0000855. Online ahead of print. PMID: 36174184.

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Background

- Severe TBI: well-demonstrated long-term effects and considered a chronic disease
  - The signature long-term impairments are neurocognitive and neurobehavioral
- Outcome from mild traumatic brain injury (mTBI) is generally favorable

HOWEVER:

- Poor subjective outcomes after mTBI are common (i.e., PPCS)
- Concern remains over other potential negative long-term effects of mTBI
  - A leading candidate, and arguably most critical, is altered cognition.
  - Demonstrating objective deficits has been elusive with inconsistencies in literature

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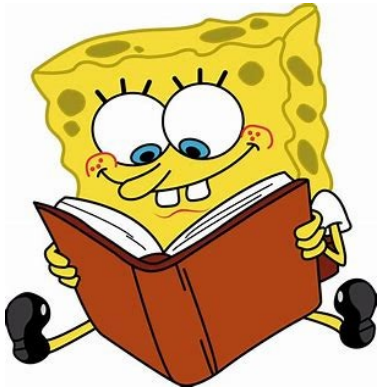
Study Objective

- Objective: Examine the link between cognitive performance and remote mTBI history within the LIMBIC-CENC PLS cohort of U.S. Veterans and SMs with combat exposure.

- Aim: Determine the amount of unique versus shared variance for mTBI history, comorbidities, and other potential contributing factors on current, objective, cognitive performance.



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Study Hypothesis

Potential mechanisms for altered cognition attributable to remote mTBI(s)

unresolved early cognitive effect

and/or

product of increased neurodegeneration risk

- Main Hypothesis: >= 3 lifetime mTBIs (repetitive mTBI) is associated with lower cognition as compared to those with no mTBIs (TBI negative controls).
  - Associated hypothesis: 1-2 mTBIs will also have lower cognition vs controls

- Other aspects of mTBI history examined:
  - total number of mTBIs,
  - mechanism (blast versus blunt), and
  - elapsed time between mTBI event(s) and time of testing

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Study Methods

- Design: Cross Sectional using baseline (enrollment) assessments only (n = 1,551)
- Primary outcomes: preselected multi-dimensional set of cognitive tests
- Exclusions: performance validity failure (MSVT, CVLT or WAIS-IV; n = 241))
- TBI positive groups, non-repetitive (1-2) and repetitive (3+), were compared to TBI negative controls on each of the seven cognitive domains (n = 1,310).
  - Multivariable regression models (n = 1,129) that adjusted for covariates
  - P-values were adjusted for multiple comparisons.

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Domains	Component Test Scores
Episodic memory	CVLT-II: Trials 1-5 total; Long Delay Free Recall BVMT-R: Total Recall NIH-TB-CB Picture Sequence
Attention	TMT Part A
Processing speed	WAIS-IV Processing Speed Index NIH-TB-CB Pattern Comparison
Working Memory	WAIS-IV Working Memory Index NIH-TB-CB List Sorting
Executive functioning	TMT Part B WAIS-IV Visual Puzzles NIH-TB-CB Dimensional change card sort test NIH-TB-CB Flanker Inhibitory control
Verbal Fluency	D-KEFS VFT: Letter fluency; Category fluency
Fine Motor & Dexterity	Grooved Pegboard: Dominant; Non-dominant

Domain scores were computed by averaging Z-scores of component tests.

Abbreviations: CVLT-II = California Verbal Learning Test-II; BVMT-R = Brief Visuospatial Memory Test-Revised; NIH TB-CB = NIH Toolbox Cognition Battery; TMT = Trail Making Test; WAIS-IV = Wechsler Adult Intelligence Scale 4th Edition; DKEFS = the Delis–Kaplan Executive Function System

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Multivariable (adjusted) linear regression models; 3+ and 1-2 mTBIs vs TBI negative controls

	Episodic Memory			Attention			Processing Speed			Working Memory		
Variable	Coefficient (95% CI)	p-value		Coefficient (95% CI)	p-value		Coefficient (95% CI)	p-value		Coefficient (95% CI)	p-value	
		Raw	Adjust		Raw	Adjust		Raw	Adjust		Raw	Adjust
mTBI Positive Groups versus TBI Negative Controls												
1-2 mTBIs	-0.06 (-0.17, 0.05)	0.26	1	-0.09 (-0.24, 0.07)	0.26	1	-0.01 (-0.12, 0.10)	0.90	1	0.02 (-0.08, 0.13)	0.70	1
3+ mTBIs	-0.03 (-0.16, 0.09)	0.60	1	0.04 (-0.14, 0.22)	0.65	1	-0.04 (-0.17, 0.09)	0.54	1	0.02 (-0.10, 0.14)	0.76	1

	Executive Function			Verbal Fluency			Fine Motor & Dexterity		
variable	Coefficient (95% CI)	p-value		Coefficient (95% CI)	p-value		Coefficient (95% CI)	p-value	
		Raw	Adjust		Raw	Adjust		Raw	Adjust
mTBI Positive Groups versus TBI Negative Controls									
1-2 mTBIs	-0.08 (-0.16, 0.00)	0.06	0.42	0.05 (-0.08, 0.18)	0.42	1	-0.02 (-0.16, 0.12)	0.77	1
3+ mTBIs	-0.04 (-0.14, 0.05)	0.39	1	0.17 (0.03, 0.32)	**0.022**	0.15	0.01 (-0.15, 0.16)	0.95	1

- **Summary of Findings:** adjusted p values were > 0.05 on all seven prespecified cognitive domain scores

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Covariate findings & Sensitivity analyses

- **Covariates with effects**:
  - largest and most consistent: Age, Education, Estimated Pre-morbid intelligence
  - Others: Gender, Race, Vestibular symptoms (Grooved Pegboard)

- **Sensitivity Analyses** (separate multivariable models with other TBI history variables)
  - Continuous number of mTBIs
  - Number of blast-related mTBIs
  - Time since first and last mTBI (excluded mTBI positive only)
  - For every TBI history variable, adjusted p values were also > 0.05 on all seven prespecified cognitive domain scores

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Conclusions

- Among combat-exposed Veterans and SMs, mTBI history was not associated with performance on any cognitive testing domain when adjusting for other factors.

- More evidence that in unselected samples, lower cognitive performance from mTBI(s) alone does not chronically persist relative to controls

- Also no evidence that Blast-related mTBI has a unique deleterious chronic effect on cognition.

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Take-home for research and clinical care

- **Key Evidence:** Remote mTBI(s) alone, even if repetitive, is not associated with objective cognitive problems in the average combat-exposed Veteran or SM
- **Assimilation:** This is consistent with the weight of the pre-existing research literature
- **Clinical Translation:** A holistic healthcare approach including comorbidity assessment is indicated for patients reporting chronic cognitive difficulties after mTBI(s), and strategies for addressing misattribution may be beneficial.
- **Research Translation:** Future study is recommended to assess phenotypes (e.g. cognitive impaired) and longitudinal decline from potential neurodegeneration.

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Relation of aerobic activity to cognition and well-being in chronic mild traumatic brain injury; A LIMBIC-CENC study

Wright B, Zhong C, Fisher R, Karmarkar A, Bjork JM, Pugh MJ, Hodges CB, Martindale SL, Wilde EA, Kenney K, McDonald SD, Scheibel RS, Newsome MR, Cook LJ, Walker WC.

Question: *Do SMs & Vs with remote mild TBI(s) who perform more aerobic physical activity have better cognition?*

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Background/Objectives/Methods

- Background:
  - Cognitive complaints are common in chronic stage of mild TBI
  - Regular aerobic exercise shown to improve cognition in healthy persons and neurologic conditions, but data is lacking on benefit for persons with chronic mTBI including SMs and Vs
- Objective:
  - Determine the relationship between self-reported aerobic physical activity and objective cognitive test performance in SMs/Vs with remote history of mTBI.
- Methods
  - Participants: Positive mTBI histories and passed performance and symptom validity tests
  - physical activity data from CDC BRFSS; categorized into 4 aerobic activity level groups
  - 2-step multivariable regression adjusting first for fixed factors (e.g. age) and then adding state factors (e.g., pain).

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Results Summary

- Final analytic sample (n=1087)
  - classified as ‘inactive’ (23%), ‘insufficiently active’ (46%), ‘active’ (19%), or ‘highly active’ (13%) based on level of reported aerobic activity.
- Primary Outcome Analysis
  - Prespecified/preregistered: 7 tests of memory, learning and executive function (CVLT LDFR and Total Recall, BVMT-R Total Recall, TMT-B, and NIHTB-CB Picture Sequence Memory, Flanker, and DCCS).
  - **Adjusted p-values were > 0.05 for all group comparisons on all seven primary outcome measures**

- Secondary Outcomes
  - **Better Life Satisfaction and Perceived Health Status with higher Aerobic Exercise levels**
- Exploratory Outcomes
  - Better working memory (WAIS-IV) and verbal fluency (DKEF) with higher Aerobic Exercise levels

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Abbreviated Regression Model Findings; Secondary Outcomes

Outcome	Variables	Coefficient[1] (95% CI)	Raw P-value	Coefficient[2] (95% CI)	Adjusted P-value
Euro Qol Heath Status Today 0-100 scale	Insufficiently Active	0.30 (0.14,0.45)	**<0.001**	0.15 (0.01,0.29)	0.032
	Active	0.53 (0.35,0.72)	**<0.001**	0.32 (0.15,0.49)	**<0.001**
	Highly Active	0.36 (0.15,0.57)	**<0.001**	0.19 (0.01,0.38	0.044
		Reference Group: Inactive			
Satisfaction With Life Scale total score	Insufficiently Active	0.30 (0.16,0.45)	**<0.001**	0.19 (0.05,0.33)	**0.009**
	Active	0.30 (0.12,0.47)	**<0.001**	0.13 (-0.04,0.30)	0.12
	Highly Active	0.21 (0.01,0.41)	0.037	0.09 (-0.10,0.28)	0.36

Multivariable Regression Models

[1]First step regression [2]Second step regression

Bolded p-values significant at Alpha = 0.05 with Bonferroni-Holmes correction factor (p<0.0125).

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Take-home for Research & Clinical Care

- **Conclusion:** Although cognitive performance on prespecified primary outcomes were similar, subjective well-being was better among SMs/Vs with remote mTBI who reported regular aerobic exercise.
- **Assimilation:** Regular aerobic exercise has well demonstrated positive effects in the general population including an association with lower dementia risk.
- **Clinical Translation: Regular aerobic exercise is recommended for SMs and Veterans with chronic mild TBI.**
- **Research Needed:** Longitudinal analyses of the exercise-cognition relationship in chronic mTBI populations; objective measures of exercise dose would increase level of evidence.

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Comorbidities and Lifestyle factors impacting key outcomes

LIMBIC-CENC prospective study findings to date

- Sleep apnea
- Pain
- PTSD
- Depression
- Aerobic physical activity & exercise
- Alcohol misuse
- Others under active investigation

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CLINICAL CARE IMPLICATIONS AND RECOMMENDATIONS FOR TREATING COGNITIVE PROBLEMS AND CONCERNS IN CHRONIC MILD TBI

- psycho-education
- lifestyle factors including exercise
- role of meds
- cognitive compensatory strategies
- cognitive rehabilitation

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Maximize Cognition with Holistic Care

Provide Holistic Care via:

- ✓**Empathy**
- ✓**Common goal setting**
- ✓**Education**
- ✓**Counseling on lifestyle factors**
- ✓**Progressive physical exercise**
- ✓**Symptom based approach**
- ✓**Address comorbidities (PTSD, chronic pain)**

What to Avoid:

- × Prolonged passive therapies
- × Medications with cognitive or other significant side effects (e.g. benzodiazepines, gabapentin)
- × PolyPharmacy
- × Inferring patient's condition is not 'real'
- × Inferring you will 'fix' patient's condition (instead, let them know that you will help them to better manage their lives)

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Treatment of cognitive problems in chronic mTBI:

Psycho-education

- Goal: increase insight (consider neuropsych testing to guide*)
  - Favorable prognosis
  - Acceptance of possible over-attribution to mTBI history
  - Acceptance of role of comorbidities and other factors

- Goal: Actuate self-management
  - Cognitive compensatory strategies
  - Lifestyle factors; actively changing
    - Engagement in treating non-TBI factors, especially stress reduction, sleep hygiene, SUD, and physical conditioning

*Objective findings often have little to no relation to either mTBI history or subjective cognitive functioning

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Education Touchstones

- Movement throughout day (aim for 4,000+ steps/day)
- Structured physical exercise
  - encourage aerobic component
  - consider formal physical therapy for focal difficulties
- Sleep hygiene (aim for 7 hours/night of sleep)
- Stress (mental/emotional) reduction
  - encourage use of relaxation training program
- Nutrition (aim wt. control and healthy choices)
- EtOH, tobacco and illicit substance use
- Social interaction & cognitively active leisure pursuits
- Role of Medications; discuss options and why you are advising for or against
  - When using: Counsel on goals, when to take, what good and bad may result; at f/u confirm usage
- Cognitive & Communication compensatory strategies
- Address misattribution to mTBI?

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Physical Exercise with Emphasis on Aerobics and Daily Movement

Aerobic ('cardio') Exercise Dosing Recommendations

- ≥150 minutes low-moderate intensity aerobic activity per week
- OR ≥ 75 minutes high-intensity activity per week
- OR equivalent combination
- Caveat: There is no magic threshold

Advise to promote more movement during daily life activities

- Take stairs instead of elevators
- Skip the moving walk-way in airport
- Park further from destination
- Do gardening or yard-work yourself
- Some may benefit from step tracker to set goals

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Addressing mTBI related Misattribution

- Beliefs, attributions and expectations **may adversely impact outcomes** (Ozen & Fernandes, 2011).
- **Contributors of Misattribution** include:
  - Proliferation of info in media on negative consequences of concussion(s)
  - Secondary gain (e.g. litigation, disability compensation)
  - Personality factors and 'Good-Old Days' syndrome
- **Attributional styles are mutable** and can be successfully addressed (Peters et al., 2011)
- **Traditional model of assess and feedback is often ineffective in individuals with tightly held beliefs/attributions about concussion**
- **Cross-disciplinary, behavioral approaches** that draw upon elements of treatment for other chronic conditions **might be needed** (Belanger et al., 2020)

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Cognitive Compensatory Strategies

Memory Problems

- Maintain a schedule and routine
  - Unless PRN, take meds at same time(s) of day every day.
  - Make a 'to do' list every night and review every morning.
  - Keep commonly-used important items in consistent spot.
  - Place a large display where you often see it to keep important information such as appointments.
- Use proven strategies to aid memory and avoid confusion or mistakes
  - Allow time for memory consolidation after learning new info
  - Keep info simple and repeat it to yourself frequently.
  - Use repeat back method for verifying verbal communication
  - Break activities in the simple steps
  - Always check written work in the same order such as left to right, up and down

Attention and Concentration Problems

- Avoid multitasking
- When pausing from task, write down what was done and what still remained
- Use self-coaching techniques such as talking yourself through a task.
- Consistently check over your work very carefully.
- Schedule frequent breaks during the day.
- Try to avoid interruptions.

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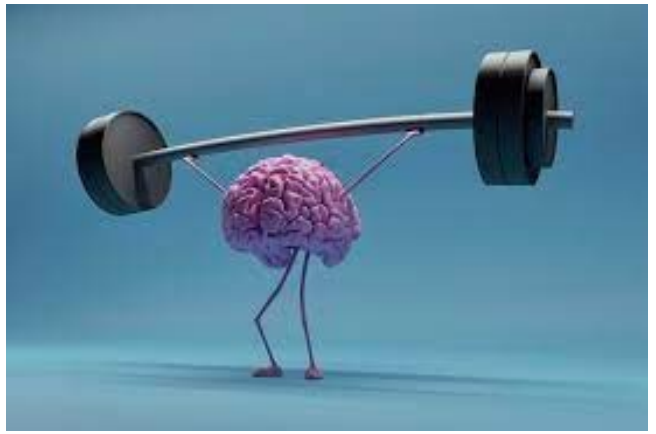
Cognitive Rehabilitation



- Standard TBI cognitive rehab
  - Typically with SLP
  - Compensatory strategy training to integrate into daily life
  - Other individualized psychoeducation
  - Remediation training to improve executive function, memory, attention, and verbal fluency
- Patients with comorbid PTSD
  - Also need Cognitive Behavioral therapy (CBT) and psychoeducation with psychotherapist
  - Could be integrated with TBI cognitive rehab

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Poll Question #1

Which is required for eligibility into the LIMBIC-CENC Multicenter Prospective Longitudinal study (PLS) ? [choose the best answer]

A. Combat Exposure
B. Mild Traumatic Brain Injury
C. Cognitive impairment
D. Absence of PTSD

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Poll Question #2

What group differences were found on cognitive performance? [choose the best answer]

A. History of any mild TBI(s) did poorer than controls
B. Repetitive mild TBI did poorer than controls
C. Blast-related mild TBI did poorer than controls
D. All mild TBI groups performed similarly

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Poll Question #3

What differences were found between the groups endorsing aerobic exercise and the totally inactive group? [choose the best answer]

A. Better cognition for all levels (insufficient, active, highly active)
B. Better cognition only for the highly active group
C. Better perceived quality of life for most levels
D. Perceived quality of life was similar for all groups

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Poll Question #4:

What treatment is least helpful for patients with mTBI and persistent cognitive complaints or problems?

A. Cognitive compensatory strategies
B. Psychoeducation
C. Cognitive Rehabilitation
D. Memantine (Namenda™)

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The End

Questions?

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