REPORT TO THE NORTH CAROLINA LEGISLATURE ON THE FY 2021: MILITARY VETERAN HYPERBARIC OXYGEN THERAPY (HBOT) PROGRAM







Prepared For: Community Foundation of North Carolina East

By:

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REPORT TO THE NORTH CAROLINA LEGISLATURE

ON THE USE OF FY 2021 FUNDING FOR

MILITARY VETERAN HYPERBARIC OXYGEN THERAPY (HBOT) PROGRAM

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NC Veteran Suicide Prevention Funding Results

North Carolina is leading the nation by treating our veterans with Hyperbaric Oxygen Therapy (HBOT). HBOT is a non-invasive therapy, combining oxygen and pressure, that heals much of the invisible wounds caused by war. Many veterans experience debilitating neurological damage resulting from their service to our nation.

The details contained in this report provides proof that the rate of suicide among our veterans, resulting in tragic losses for families, has a solution and path moving forward. North Carolina is now recognized as a leader in providing solutions for these enormously tragic suicides that effects dozens of veterans a day. The state has shown how its legislature along with corporate sponsors can step up in a big way to stop veteran suicide.

Beyond the details reported herein, what you won't see are the personal lives and journeys of our constituents. Thanks to this life saving program, we have witnessed veterans finally breaking free from the torture of TBI and PTSD. Tears of joy are often shed by our heroes and their families because of the healing experience of Hyperbaric Oxygen Therapy.

The challenge moving forward now is how best to expand the program and reach all our wounded warriors - to allow them a promising future and the hope they deserve.

Although it's important, our success it is not just determined by the state budget funding this program. It is equally important to educate the veterans in your district who are suffering. Most veterans are unaware of the benefits of Hyperbaric Oxygen Therapy and North Carolina's support.

If every member of the legislature - directed at least 5 veterans to the program from their district, working together with HBOT for Veterans, the leadership of NC will continue to shine like no other.

Moreover, we recommend following - the progress of veterans in your area, over the course of the 8-week treatment program. We trust that by seeing the healing and success firsthand, it will be an eye opener, and something for our North Carolinian constituents to cherish and feel honored to be a part of.

Please step-up and direct your veterans to the program. The future of our injured heroes and their families is now in NC legislator's hands.



Melissa Q. Spain, Chief Executive Officer Community Foundation of NC East 625 Lynndale Court, Suite A Greenville, NC 27858

January 15, 2023

RE: 2023 Contribution in Support of Hyperbaric Oxygen Therapy for Vets

Dear Ms. Spain,

We are grateful for your efforts supporting the HBOT for Vets program funded by the North Carolina legislature. Without the efforts of your staff, Jim Hooker, and Michael Weeks, the 25 Veterans completing the program would not have benefited from lifesaving HBOT.

We are pleased to inform you that TSN is committed to continue its matching contribution at Extivita-RTP for the HBOT for Vets 2023 program. In 2022, TSN contributed ninety-four thousand five hundred dollars (\$94,500) to fund treatments for Veterans. After witnessing the success from the 2022 program, TSN will increase the 2023 budget to two-hundred-fifty thousand dollars (\$250,000). Our goal is to commit additional resources towards the outreach effort and increase the number of veterans treated in this program.

In 2022, your program proved that HBOT was a game changer for treating NC vets and improving their mental health. This year, we hope to reach thousands of vets in our state suffering from TBI/PTSD. It is a continued honor to help your team educate our veterans that a safe and effective treatment is available to end their suffering. We intend to focus all our efforts to uncover the real need and hidden suffering we can help alleviate.

I believe the NC legislature working alongside companies like The Steel Network, a veteran owned steel manufacturer, speaks volumes to how we as patriots, prioritize and value our nation's heroes. In addition to TSN's contribution to the effort, we will be reaching out to our customer and vendor base to ask for additional support for the program.

May God bless you and keep you safe,

Edward di Girolamo, PE Chief Executive Officer The Steel Network, Inc.



The Steel Network, Inc. ~ www.steelnetwork.com PO Box 13887, Durham, NC 27709 Toll Free (888) 474-4TSN (4876) Fax (919) 845-1028

<u>TAB - A</u>

HOUSE BILL 50 AUTHORIZING VETERANS HBOT

AN ACT AUTHORIZING CERTAIN MEDICAL PROFESSIONALS TO PRESCRIBE HYPERBARIC THERAPY FOR VETERANS WITH TRAUMATIC BRAIN INJURY AND POSTRAUMATIC STRESS DISORDER



To all whom these presents shall come, Greeting:

I, Elaine F. Marshall, Secretary of State of the State of North Carolina, do hereby certify the following and hereto two (2) sheets to be a true copy of Session Law 2019-175, House Bill 50, of the 2019 Legislative Session, entitled

AN ACT AUTHORIZING CERTAIN MEDICAL PROFESSIONALS TO PRESCRIBE HYPERBARIC OXYGEN THERAPY FOR VETERANS WITH TRAUMATIC BRAIN INJURY AND POSTTRAUMATIC STRESS DISORDER.

ratified on the 18th day of July, 2019, by

The General Assembly of North Carolina

the original of which is now on file and a matter of record in this office.

In Witness Whereof, I have hereunto set my hand and affixed my official seal.

Done in This Office, at Raleigh, this the 134 day of August, 2019.



Claime F. Marshall Secretary of State

GENERAL ASSEMBLY OF NORTH CAROLINA SESSION 2019

HOUSE BILL 50 RATIFIED BILL

RECEIVED JUL 19 2019 2:37 pm

AN ACT AUTHORIZING CERTAIN MEDICAL PROFESSIONALS TO PRESCRIBE HYPERBARIC OXYGEN THERAPY FOR VETERANS WITH TRAUMATIC BRAIN INJURY AND POSTTRAUMATIC STRESS DISORDER.

Whereas, hyperbaric oxygen therapy is a recognized and accepted treatment for wound care and inflammation disorders; and

Whereas, traumatic brain injury and posttraumatic stress disorder are recognized to result from brain injuries and subsequent inflammation; Now, therefore,

The General Assembly of North Carolina enacts:

SECTION 1. This act shall be known and may be cited as the "North Carolina Veterans Traumatic Brain Injury and Posttraumatic Stress Disorder Treatment and Recovery Act of 2019."

SECTION 2.(a) G.S. 122C-455 through G.S. 122C-464. Reserved for future codification purposes.

SECTION 2.(b) Article 6 of Chapter 122C of the General Statutes is amended by adding a new Part to read:

"Part 5. Traumatic Brain Injury and Posttraumatic Stress Disorder Services for Veterans.

"<u>§ 122C-465. Definitions.</u>

As used in this Part, the following definitions apply:

- (1) <u>Authorized medical professional. A doctor of medicine, nurse practitioner,</u> physician assistant, or doctor of osteopathy licensed to practice in this State.
- (2) <u>Hyperbaric oxygen therapy treatment. Treatment with a valid prescription</u> from an authorized medical professional in either a hyperbaric chamber approved by the United States Food and Drug Administration (FDA), or a device with an appropriate FDA-approved investigational device exemption.
- (3) Veteran. A person who served on active duty, other than for training, in any component of the Armed Forces of the United States for a period of 180 days or more, unless released earlier because of service-connected disability, and who was discharged or released from the Armed Forces of the United States under other than dishonorable conditions.

"§ 122C-465.1. Hyperbaric oxygen therapy treatment authorized.

(a) No person other than an authorized medical professional shall prescribe hyperbaric oxygen therapy treatment to a veteran for the treatment of traumatic brain injury or posttraumatic stress disorder. Any authorized medical professional who prescribes hyperbaric oxygen therapy treatment to a veteran for traumatic brain injury or posttraumatic stress disorder shall do so in a manner that complies with the standard approved treatment protocols for this therapy.

(b) <u>Any veteran residing in North Carolina who has been diagnosed with a traumatic</u> brain injury or posttraumatic stress disorder by an authorized medical professional may receive hyperbaric oxygen therapy treatment in this State."



SECTION 2.(c) G.S. 122C-465.2 through G.S. 122C-465.5. Reserved for future codification purposes.

SECTION 3. This act becomes effective October 1, 2019.

In the General Assembly read three times and ratified this the 18th day of July, 2019.

Ford Cái

Presiding Officer of the Senate

Tim Moore Speaker of the House of Representatives

Roy Cooper Governor

July Approved 12:12 p.m. this 26 day of _____ 2019

<u>TAB – B:</u>

- NORTH CAROLINA HBOT ASSISTANCE APPLICATION
- APPLICATION AND APPROVAL PROCESS
- HBOT TREATMENT PROTOCOL
- HBOT PRESCRIPTION
- PRE HBOT CONSULTATION:
 - o INTERVIEW RESULTS
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- HBOT TEST BATTERY DESCRIPTIONS
- EXTIVITA CLINIC DESCRIPTION

North Carolina HBOT Assistance Application

- 1. Signed and completed History Form
- 2. A personal biography of your situation (pages provided below)
 - a. Testimony about your situation and why you'd like to be considered for this HBOT assistance program
 - b. A description of your symptoms and the impact they have had on: 1) your life; 2) your work; 3) your family
 - c. A short description of your goals for treatment
 - d. A short biography from your significant other (if applicable) explaining the impact of your injury on him/her and his/ her program goals
- 3. A diagnosis of Traumatic Brain Injury, Post-Concussion Syndrome, and/or Post Traumatic Stress Disorder.
- 4. Signed and dated attached Code of Conduct and Consent form
- 5. A copy of your most recent DD214 or if Active Duty, your ID card or most recent orders
- 6. A copy of your Drivers License and Insurance Card if applicable

*All six parts of the application must be submitted to be considered for the program.

Personal History Form

1.	Name
	Birthdate
3.	Street Address
4.	Mailing Address (if different):
5.	CityStateZip
6.	Email Address:
7.	Phone 1: Phone 2:
8.	Spouse/Caregiver Name
9.	Spouse/Caregiver Phone
10	.Spouse/Caregiver Email
11	.Gender: Circle One Male Female
12	Military Status: Circle One Active Duty Veteran
13	. Did you serve in OIF or OEF: Circle those that apply
14	.Branch of Service:
15	. Are/ were you part of the Special Operations Community? Yes No
16	.How did you hear about this program?
17	.Have you been diagnosed with TBI, PTSD or PCS (Circle those that apply)?
18	. Your annual household gross income:
19	. Your annual household living expenses:

20. Your highest level of education: (Circle highest) GED HS Associate Degree Bachelors Degree Masters PhD

Personal Biography

We want to understand why you'd like to be considered for this HBOT assistance program; please simply explain your situation. You may use the following bullets as a guide.

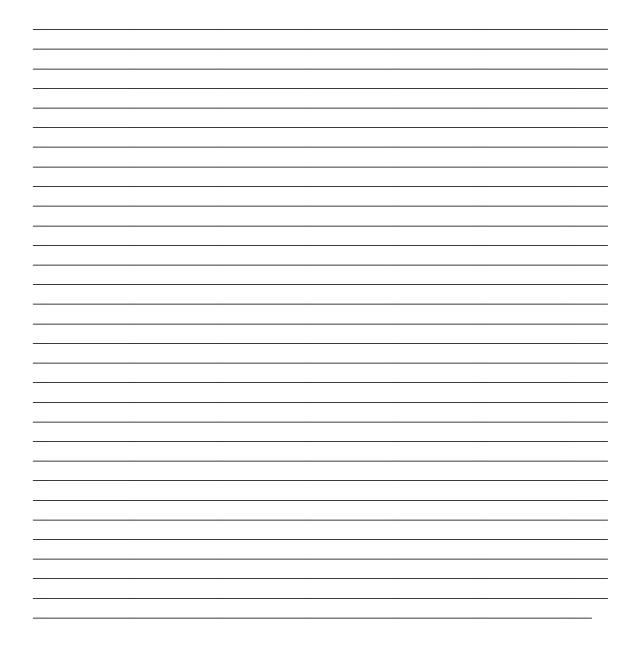
a. Testimony about your situation:



b. Describe your symptoms and the impact they have had on: 1) your life; 2) your work; 3) your family

c. Describe your goals for treatment

d. Provide from the person listed on page 3 as your spouse/caregiver in your life (spouse, fiancé, parent, sibling, close personal friend) the impact the injury has had on this person, and the goals they seek from this therapy. This person person(s) may prefer to submit a separate statement in confidence directly to James Hooker at jameshooker@suddenlink.net.



Code of Conduct and Consent

This HBOT Program was established to address the significant need for safe and effective treatment for TBI, PTSD or PCS of former military or active duty personnel. It is enabled by 2021 funding provided by the North Carolina legislature. The goal in providing this therapy is to successfully treat as many of these heroes as possible. Therefore, it is imperative that each applicant sign and date the following Code of Conduct:

If accepted into this HBOT Program and medically cleared for treatment, I agree to:

- 1. Attend treatment and/or therapy sessions consistently and timely as prescribed by the doctor and the treatment center.
- Notify James Hooker, the treatment coordinator, as soon as possible, if any deviation from prescribed treatment or schedule is necessary, regardless of the reason; <u>jameshooker@suddenlink.net</u>, 703-994-5201.
- 3. Honestly and accurately describe my experiences and results.
- 4. Keep confidential all personal information of others that may be acquire during treatment or interaction while receiving treatment.
- 5. Be courteous and respectful of others in care, as well as the treatment facility staff.
- 6. Abstain from using alcohol, tobacco, or any other non-prescribed medications, marijuana, cbd or illegal drugs, and from abuse of prescription and non-prescription drugs during the entire duration of treatment. (For over-the-counter medications, please consult your HBOT treatment physician.)

By signing below, you agree to each fo the above statements and consent to sharing your information with organizations that assist in the mission to help you; this consent may include providing your HBOT results to substantiate support for others needing this therapy.

Print Name:	[Date:

Signature:

APPLICATION AND APPROVAL PROCESS

Applicants respond to a referral or an advertising campaign which sends them to the program website: HBOTFORVETS.COM. This page contains the application and instructions on preparation and forwarding for consideration. Each veteran is interviewed to determine their basic qualification for the program: honorable military service, and TBI and/or PTSD diagnosis. Veterans initially approved are referred to Extivita. Then in consultation with Extivita's nurse practitioner, relevant medical history is reviewed, and a physical exam is conducted. After the patient is medically cleared, a series of tests are administered to quantify and record symptom severity. At this point, the veteran can begin therapy.



HBOT TREATMENT PROTOCOL

- HBOT is applied in a sealed multi-seat chamber:
 - Hyperbaric oxygen 100 % medical grade is given at 2.0 atmospheres absolute (ATA)
 - Patients spend approximately 90 min in the chamber, 60 min of which is at 100% oxygen and full pressure. A trained attendant is in the chamber at all times.
- Treatment protocol is 40 sessions
- Sessions can be provided as often as 1-2 times per day, 4 hours apart in any 24 hour period
- Patient vital signs are taken prior to each therapy session
- An oral amino acid supplement is provided to support detoxification during HBOT treatments



Mailing: 8311 Brier Creek Parkway, Suite 105, Box 416, Raleigh, NC 27617 Street: 2012-D T.W. Alexander Drive, Durham, NC 27709 Tel: 919-354-3775 Fax: 919-354-3776

Jay Stevens, MD, FAAFP, CAQSM, ABAARM

Elena Schertz, NP

Name:		DOB:			
	Phone Numb	er:			
<u>1</u>					
□ 100% Oxygen					
X 100% Oxygen with	Pressure [ATA]:	□ 1.5			
Air Breaks [*specify below]		□ 1.75			
Breathing Air		X 2.0			
		□ Linear increase from 1.0			
		to 2.0 ATA for duration.			
		Other			
□ 90					
□ Other see below					
	Total # of Treatment	s: 40			
Other					
	100% Oxygen X 100% Oxygen with Air Breaks [*specify below] Breathing Air X 60 75 90 Other see below X _1-2x_Time(s) Per Day Time(s) Per Week Every Other Day	Phone Numb Phone Numb 100% Oxygen X 100% Oxygen with Air Breaks [*specify below] Breathing Air X 60 75 90 Other see below X _1-2x_Time(s) Per Day Time(s) Per Week Every Other Day			

TREATMENT PROTOCOL:

FiO2 21% @1.0 ATA to 1.25 ATA then FiO2 100% from 1.25 ATA to 2 ATA over 10 min (total compression time) then FiO2 100% @ 2.0 ATA x 60 minutes then FiO2 100% @2.0 ATA to 1.25 ATA then FiO2 21% from 1.25 ATA to 1 ATA over 10 min (total decompression time). Give 5-minute air break x 1 after 30 minutes at bottom . Total dive time 85 minutes. Notes:

Signature:

Date: _____



PRE HBOT CONSULTATION INTERVIEW RESULTS

Jane Doe is a 64-year-old female marine here for health and wellness via NCHBOT program.

History of multiple TBIs from blast exposures and direct impact with + LOC. Presenting complaints include- exhaustion 8/10, MCS, anxiety, agoraphobia, easily overwhelmed, IBS, migraines, photo and noise sensitivities, joint pain, MCS, tinnitus L>R, sleep issues.

PMH- Chronic fatigue, Military sexual trauma, HMT, hypothyroidism, TMJ, vertigo, PTSD

Neuro- migraines triggered by stress and chemical exposures, frequency- once a month; duration- up to la 1-2 weeks. Medications ineffective. GSH and magnesium helped. Dizziness -Triggers worse with sinus issues, going from sitting to standing, and/or with certain chem exposures. Severe intolerance to light and sound/noise. Brain "can't shut off". Neuropathy+

MSK- arthritis joint pain-, denies ROM limitations, occasional + balance problems from joint pain. Difficulty opening lids, bending over and walking upstairs and downstairs ("feels like knee will give way"; down worse than up) Getting up off floor is difficult Joints to ankle and knees worse R>L

Sleep- Takes sleep aids, L theanine, valerian root, which help. Takes 2-3 hours to fall asleep, interrupted, sometimes easy resleep but usually not. Nightmares, pain turning over interrupts sleep. Not rested when waking. Sleeps 5 hours on a good night. Rests but not naps.

Exercise- Does PBS Tai chi, yoga, Pilates, 22 minutes 5 days a week, Stationary bike tries to do daily at least 15 min (cumulative) a day. Energy level- 2/10

Diet- GF, minimal sugar (only in fruit), occasional dairy (loves cheese). + animal proteins and veggies. ETOH- occasionally drinks wine. Coffee- 1-3 a day -36 oz max a day.

GI-fairly regular BM's. + IBS, D>C, can be explosive

Psych- Stress level 9/10.

Social-lives alone which she loves. Family nearby, not as supportive as her friends. Spouse died 2018

Other therapies- acupuncture

Goal- Achieve normal life functions including sleep improvement, pain reduction, and increased energy

Assessment scores: ANAM: various, PCS= 94, PHQ -9= 24, PCL- M= 75





Name: _____ Date of Birth: _____ Date: _____

PATIENT MEDICAL HISTORY & CONTRAINDICATIONS:

1) Review the patient's medical history to ensure for accuracy and completion.

2) Identify any contraindications this patient may have [listed below].

Absolute Contraindications	Absolute Drug Contraindications
Untreated [tension] pneumothorax	 Bleomycin (<6 mos) (interstitial pneumonitis)
	Cisplatin/Cis-platinum (impair wound healing)
	Disulfiram [Antabuse] (blocks SOD)
	Doxorubicin [Adriamycin] (cardiotoxicity)
	Mafenide acetate [Sulfamylon] (cause local carbon dioxide
	production and acidosis)

Relative	Relative Contraindications				
□ Asymptomatic lesions, air cysts or blebs in lungs	Known atherosclerotic disease and/or other risk factors				
[seen on chest x-ray]	for heart disease				
Claustrophobia OR anxiety due to confinement	Large skull defects following surgery				
Compromised tympanic membrane integrity	Latex allergy				
Congenital spherocytosis	Image: Malignant disease [ex. cancer]				
Emphysema, COPD (hypercarbia), asthma (pulm	Pneumonia and/or any air-trapping evidenced by air				
baro/air trap)	bronchogram [i.e. due to asthma or emphysema]				
Diabetes insulin dependent	Pregnancy (unknown side effects on fetus)				
 History of ear surgery [ex. surgery for otosclerosis] 	Psychiatric/psychological/behavior disorders				
History of lung disease	 Seizure disorders [including epilepsy & convulsions due to vitamin E deficiency] 				
□ History of optic neuritis or eye surgery	Smoking				
 History of spontaneous pneumothorax or pneumo-mediastinum [even if treated] 	Uncontrolled high fever (decreases seizure threshold)				
 History of thoracic surgery (pneumo/ atelectasis) 	 Upper respiratory infection [URI], colds, flu, sinus infections/chronic sinusitis, allergies [i.e. anything that causes excessive mucus, congestion, and/or cough] 				
□ Inability to "clear ears" [i.e. equalize middle ear	Perilymph fistulas (vertigo and other vestibular				
pressure] during chamber pressurization	symptoms				

Adverse Device/Object Interactions			
	Implanted devices affected by INCREASED PRESSURE		
Dentures	[pacemakers, deep brain stimulators, pain/intrathecal		
	pumps, defibrillators, glucose pumps, etc.]		
	Transdermal medication patches [*including nicotine		
Hearing aids	patches] $ ightarrow$ must be removed PRIOR to treatment, but can		
	be replaced AFTER treatment		



Name: _____ Date of Birth: _____ Date: _____

PATIENT MEDICAL HISTORY & CONTRAINDICATIONS [continued]:

Drugs with Potential for Adverse Reactions/Oxygen Toxicity Enhancement			
Acetazolamide	🗆 Heparin		
Adrenomimetic, adrenolytic, and ganglion-	🗆 Insulin		
blocking agents			
Ammonium chloride [NH ₄ Cl]	Narcotic analgesics		
Antianginal drugs	Perfluorocarbon [PFC]		
🗆 Aspirin	Recent drug abuse and/or other intoxications		
CNS stimulants [ex. dextroamphetamine]	Reserpine		
Digitalis/Digoxin	Scopolamine		
🗆 Ethanol	Thyroid extract		
Guanethidine			

Factors that Enhance Oxygen Toxicity				
Gases	Physiological States of Increased Metabolism			
Carbon dioxide	Scuba diving			
Nitrous oxide	High humidity			
Hormones	Hyperthermia			
Thyroid hormones	Physical exercise			
Adrenocortical hormones	Trace Metals			
Neurotransmitters	Iron			
Epinephrine	Copper			
Norepinephrine				

PHYSICAL EXAM

Vital Signs					
Blood Glucose Level	O ₂ Saturation				
Blood Pressure	Respiratory Rate				
Lungs	Temperature				
Pulse Rate	TM Integrity				
Notes:					



POST-HBOT CONSULTATION

Jane Doe is a 64-year-old female here for health and wellness. She is a retired marine who initially came to Extivita via NCHBOT program. She has completed 40 HBOT treatments and 5 nutrient IV's since starting treatments about a month ago. Presenting complaints: exhaustion, sleep issues, migraines, MCS, anxiety, agoraphobia, easily overwhelmed, IBS, migraines, photo and noise sensitivities, joint pain throughout, nerve pain, tinnitus. Her goal was to achieve normal life functions including sleep improvement, pain reduction, and increased energy.

Med History: multiple TBI's with +LOC, C- PTSD, chronic fatigue, military sexual trauma, hypothyroidism, and vertigo.

Today, upon completion of 40 sessions, she reports:

- Neuro-
 - Migraines- immediate resolution after the first week of starting HBOT. Reported only having had 2 minor headaches since starting treatments
 - Tinnitus: L ear- decreased intensity. Resolved in R ear.
 - Light Sensitivity- decreased: is 5/10 (was 10/10).
 - Noise Sensitivity- decreased and is now 5/10 (was 10/10)
- Immune
 - Decreased multiple chemical sensitivities (MCS)
- Energy
 - Continues to feel improvement in energy
 - Chronic Fatigue: has not noticed since starting treatments.
- Pain-
 - Pain is still present but overall pain has improved by 80%. Patient rates pain 2/10 now.
 - Fibromyalgia and nerve pain: improved by 75%
- Sleep-
 - Quality: improved. Falls asleep easier and in shorter amt of time (20 min vs 2-3 hrs) Sleeping 6 7 hours per night uninterrupted (was 5 hours), only wakes up to use restroom with easy resleep. Rested when waking. Has stated she has started dreaming, versus nightmares patient was experiencing prior to treatment.
- MSK-
 - Increase mobility and flexibility. Joints not as swollen and painful. Able to walk up and down stairs without pain and difficulty. Continues to use treadmill daily.

Assesment and scores	Initial:PCS94		Post 40:	% Change	
PCS	94	26	13	86% improvement	
PHQ-9	24	9	8	67% improvement	
PCL-M	75	54	42	44% improvement	

ANAM: please see attached report

In summary, she has improved in test scores post 40 sessions, now performing within expected range of functioning compared to her normative group. This includes improvement in reaction time, processing speed, attention span, and memory. Per mood scale, she has less anxiety, depression, fatigue, and restlessness. She is happier and has increased vigor. During her pre HBOT ANAM test, she appeared to have high level of anxiety, which resulted in comprehension issues, trouble following directions, fidgeting, needed reassurance, frustrated and tearful. She did not exemplify any of these qualities during her post 40 ANAM testing, and where she performed much better, reflected in her scores.

Jane has been a pleasure having around. She is cheerful and interacts with other patients and staff appropriately. She is more relaxed. She reports that she is finally feeling as if she is getting her life back. She would likely benefit from another 20 HBOT sessions given the severities of her symptoms as per assessment forms.

Thank you,

Elena Schertz, NP

HBOT TEST BATTERY DESCRIPTIONS

Neuropsychological and self-assessment tests:

These tests are administered to determine the effects of hyperbaric oxygen therapy (HBOT) on symptoms and quality of life among veteran military personnel with persistent post-concussion symptoms. These tests measure the number and severity of the veteran's symptoms prior to the beginning of therapy, after 20 and after 40 HBOT treatments. Tests include neurocognitive testing (ANAM) and three additional self-reported questionnaires: the three self-reported questionnaires are Post Concussion Symptom Checklist (PCSS), Posttraumatic Stress Disorder Checklist (PCL-M), and the Patient Health Questionnaire-9 (PHQ-9).

- 1. **ANAM-** Automated Neuropsychological Assessment Metrics- is an FDA cleared computer-based neurocognitive assessment tool patented by the U.S. Army. ANAM is used by DOD to establish the brain baseline capability of all military personal prior to deployment. ANAM has a three-decade long history of use in basic and applied research as well as in clinical practice. Over 350 peer-reviewed publications demonstrate its effectiveness in assessing cognition and measuring cognitive change. ANAM is used to measure the cognitive effects of stressful, extreme, or hazardous conditions; to quantify the effects and progression of neurological and other medical disorders; and to measure the effects of mild traumatic brain injury and sports concussion on cognitive function. In this application, a Core battery set was used, comprising 8 neurocognitive performance-based tests, as well as subtests reflecting mood scores. ANAM was used to assess the likelihood that a change in symptom reporting is reliable and clinically meaningful compared to military personnel sample as well as their own the pre-treatment baseline.
- 2. Post-concussion syndrome (PCS) is a collection of symptoms that can include cognitive, physical, and psychosocial complaints. It has been estimated that 10-15% complain of persistent post concussive symptoms which can last from months to years after injury and result in sometimes progressive, long term debilitating effects. <u>The Post-Concussion Symptom Scale (PCSS)</u> is a self-reported questionnaire widely used by health care professionals to document the intensity, and impact of symptoms after a concussion. It consists of a list of 22 symptoms for which the veterans rate the intensity from 0 (none) to 6 (severe). A total score was then calculated, with a maximum of 132 points.

Research has shown that the PCSS questionnaire can accurately detect meaningful changes in a patient's condition (responsiveness) and used by clinicians and researchers to evaluate change over time in patients with persistent symptoms after concussion1. Normative data, test-retest reliability (intraclass correlation coefficient [ICC], 0.62-0.69),23,29 internal consistency (r = 0.93), and minimal detectable change (MDC; total score of 12.3 points) of the PCSS have already been established (1).

3. It has been increasingly recognized that there is a frequent association of mTBI and PTSD in modern warfare. **The PTSD Check List military version (PCL-M)** is a 17 item self-report instrument developed by staff at the Veterans Administration National Center for PTSD, to measure symptom severity, symptoms in response to "stressful

military experiences" within the past month. A total symptom severity score (range = 17-85) can be obtained by summing the scores from each of the items that have response options ranging from 1 "Not at all" to 5 "Extremely." It can be self-administered and completed in approximately 5-10 minutes. Its 17 items are based on criteria from the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV). It can be used to screen individuals for PTSD and make provisional diagnosis. For this purpose, this checklist is used to monitor change in PTSD symptoms during and after HBOT treatment. Evidence suggests that a 5–10-point change represents reliable change (i.e., change not due to chance) and a 10–20-point change represents clinically significant change (2). According to studies, The PCL-M is "psychometrically sound, is valid and reliable, useful in quantifying PTSD symptom severity, and sensitive to change over time in military service members".

- 4. PHQ-9- Patient Health Questionnaire-9 is a reliable, valid, rapid and effective tool for detection as well as for monitoring the severity of depression (4). It has been widely used in community-based settings, in the general population, and among people with physical diseases. A study of 6000 subjects found that PHQ-9 is more than a screening tool for depression; it is also a reliable and effective tool for monitoring the severity of depression (3).
 - a. PHQ-9 is self-administered, which scores each of the 9 items/criteria (for depression) from 0 (not at all) to 3 (nearly every day.) PHQ-9 scores of 5, 10, 15, and 20 represented mild, moderate, moderately severe, and severe depression, respectively.

References

- Kroenke, K et al. "The PHQ-9: validity of a brief depression severity measure." Journal of general internal medicine vol. 16,9 (2001): 606-13. doi:10.1046/j.1525-1497.2001.016009606.x
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- Sun, Y., Fu, Z., Bo, Q. et al. The reliability and validity of PHQ-9 in patients with major depressive disorder in psychiatric hospital. BMC Psychiatry 20, 474 (2020). <u>https://doi.org/10.1186/s12888-020-02885-6</u>

https://www.ptsd.va.gov/professional/assessment/documents/PCL_handoutDSM4.pdf



EXTIVITA

State of the Art Hyperbaric Oxygen Therapy Clinic







Extivita- RTP is a medical clinic which operates one of the largest, private, hyperbaric oxygen therapy centers in the United States. The clinic is located in Durham, NC on the edge of Research Triangle Park. The Extivita team is dedicated to extending and improving patients' quality of life by providing science-based integrative therapies. The outpatient clinic houses two state-of-the-art multi-seat Hyperbaric Oxygen Chambers, a Nutritional IV Clinic, Infrared Sauna, Pulsed Electromagnetic Field Therapy, and Neurofeedback Therapy. A medical director oversees Extivita's operations, and the team is committed to treating patients successfully. The therapy used has effectively demonstrated reduction in inflammation and detoxification throughout the body.



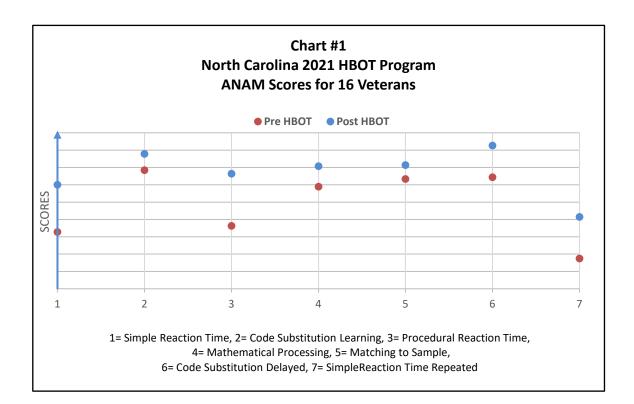


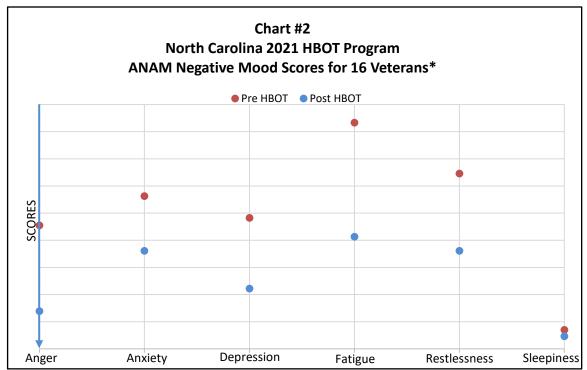
<u>TAB – C:</u>

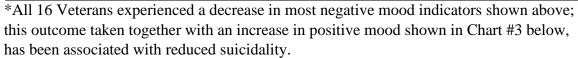
- ANAM RESULTS
- PCS, PCL-M, PHQ-9 RESULTS
- VETERAN VIDEO TESTIMONIALS

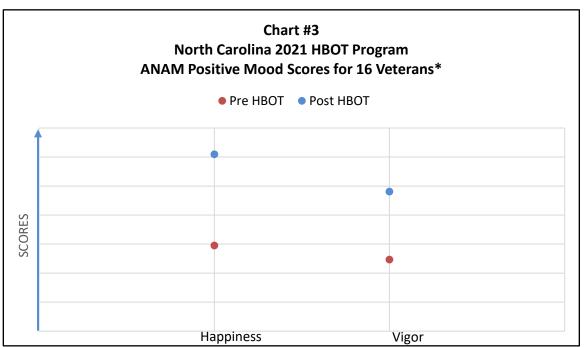
ANAM RESULTS

There were 16 individuals in the NC 2021 HBOT program who were treated with HBOT, who had a pre-assessment prior to beginning the HBOT treatment and a post-assessment after HBOT. The tests and mood scales that are given in the ANAM are listed in charts 1, 2, and 3 below. Examining chart 1 shows that there was improvement in scores from pre to post assessments. In chart 2, improvement in depression and anger scores is noted. Lower scores indicate less depression and anger. This is significant given the work of Stanley, Joiner, Bryan (2017), who showed that there was a relationship between the presence of depression and anger and suicide. They found that a higher presence of depression and anger with a history of TBI was associated with more suicidal thoughts and attempts. The pre and post assessment showed reduced suicidality indicators with improved positive mood (happiness and vigor) and less negative mood (anger, anxiety, depression, restlessness and fatigue).









*All 16 Veterans experienced an increase in positive mood as shown; this outcome taken together with a decrease in negative mood indicators as shown in Chart #3 above, has been associated with reduced suicidality.

A paired samples test was conducted, and the results are presented in table 1. This test measures the significance of the difference of the individual test items between the two assessments. Items that are bolded showed a significant difference from the pre assessment. Ten of fifteen test scores (Table 1) were significantly improved between pre and post, 10/15 = 67% improvement from the pre assessment. A repeated measures analysis showed that the Simple Reaction Time, Procedural Reaction Time and Code Substitution Delayed were the most noted improvements between the two assessments. This indicates an improvement in sustained attention, which suggests improvement in cognition.

Table	1
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ANAM Throughput Scores (d	f=15) and M	ood Scale	s				
		Pairec	l Differe	nces			
		95% Confidence				Sig.	
		Std.	Std.		al of the		(2-
		Deviat	Error	Diffe	erence		tailed
	Mean	ion	Mean	Lower	Upper	t)
Simple Reaction Time				-		-	
	-13.625	22	5.5	25.348	-1.902	2.477	0.026
Code Substitution Learning	4 75	10 7 40	2 (9)	-	0.074	-	0.007
	-4.75	10.742	2.686	10.474	0.974	1.769	0.097
Procedural Reaction Time	-15.063	25.637	6.409	- 28.724	-1.401	-2.35	0.033
Mathematical Processing				_		_	
	-5.938	23.408	5.852	18.411	6.536	1.015	0.326
Matching to Sample				-		-	
0	-4	15.345	3.836	12.177	4.177	1.043	0.314
Code Substitution Delayed				-			
	-9.125	10.112	2.528	14.513	-3.737	-3.61	0.003
Simple Reaction Time							
Repeated	-12	24.489	6.122	-25.05	1.05	-1.96	0.069
Anger		24.188	6.047	2.9103	28.688		
	15.79938	2	0	7	38	2.613	0.02
Anxiety		23.895	5.973	-	22.800		
	10.06812	0	7	2.6646	9	1.685	0.113
Depression		22.353	5.588	1.1079	24.930		
	13.01938	6	4	7	78	2.33	0.034
Fatigue		23.742	5.935	8.3550	33.657		
	21.00625	0	5	1	49	3.539	0.003
Happiness					-		
		24.124	6.031	-	18.568		<0.00
	-31.4238	5	1	44.278	7	-5.21	1
Restlessness	14 0075	22.540	5.635	2.2266	26.248	0.507	0.000
* 7'	14.2375	1	0	9	31	2.527	0.023
Vigor		22 5 47	5.005		-		
	22 4260	23.547	5.886	-	10.889	-	0 001
Sleeninges	-23.4369	4	8	35.984	4	3.981	0.001
Sleepiness	1.188	1.377	0.344	0.454	1.921	3.45	0.004

References

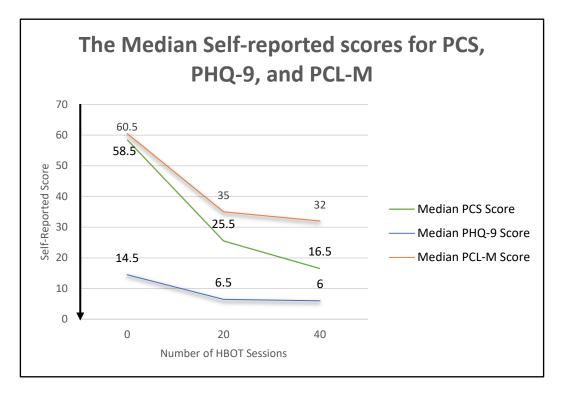
Stanley I.H, Joiner T.E, Bryan C.J. (2017). Mild traumatic brain injury and suicide risk among a clinical sample of deployed military personnel: Evidence for a serial mediation model of anger and depression. J Psychiatr Res. 84:161-168. doi:

10.1016/j.jpsychires.2016.10.004. Epub 2016 Oct 7. PMID: 27743528.

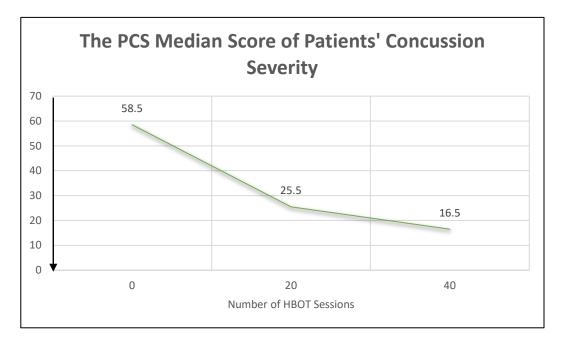
PCS, PCL-M, & PHQ-9 RESULTS

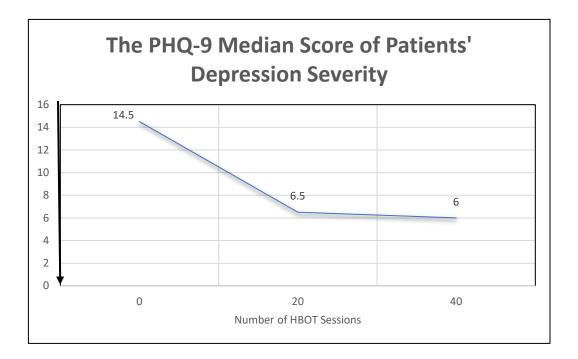
The US Dept of Veterans Affairs, and research from Kennedy, J. et al (2019), Borinuoluwa, R. (2022) and Loignon, A. et al (2020), among others, report chronically elevated rates of comorbid PTSD and depressive disorders among service members with a history of traumatic brain injury (mTBI). mTBI-related PTSD and depression are linked with impaired executive function, mood disorders, psychological impairments poor functional outcomes, and increased risk of suicide (Nichter, B. et al 2019).

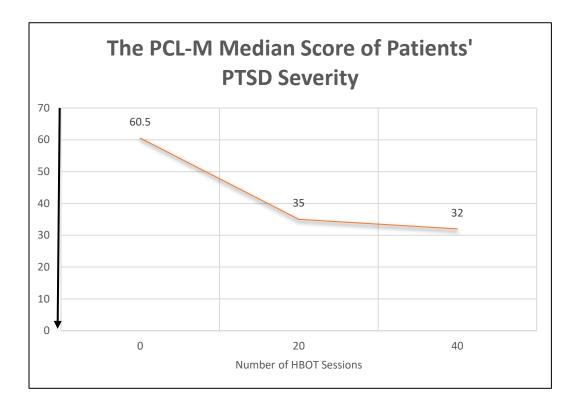
Patients with persistent symptoms after mTBI (N = 16) were evaluated with questionnaires at baseline, post-20, and post-40 hyperbaric oxygen treatments. These questionnaires, used with confidence by clinicians and researchers to monitor changes in such patients, included the Post-Concussion Symptom Scale (PCSS), Posttraumatic Stress Disorder Checklist (PCL-M), and Patient Health Questionnaire (PHQ- 9). All three assessments showed clinically significant decreases in the number of symptoms and their severity scores between baseline (pre-hyperbaric oxygen therapy) and post-40 hyperbaric oxygen therapy.



PCS







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- Borinuoluwa R, Ahmed Z. Does Blast Mild Traumatic Brain Injury Have an Impact on PTSD Severity? A Systematic Review and Meta-Analysis. Trauma Care. 2023; 3(1):9-21. https://doi.org/10.3390/traumacare3010002
- Bryan CJ, Clemans TA. Repetitive Traumatic Brain Injury, Psychological Symptoms, and
 Suicide Risk in a Clinical Sample of Deployed Military Personnel. JAMA Psychiatry.
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- Jan E Kennedy, Lisa H Lu, Matthew W Reid, Felix O Leal, Douglas B Cooper, Correlates of Depression in U.S. Military Service Members With a History of Mild Traumatic Brain Injury, Military Medicine, Volume 184, Issue Supplement_1, March-April 2019, Pages 148–154, https://doi.org/10.1093/milmed/usy321
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VETERAN VIDEO TESTIMONY



Watch Now: https://vimeo.com/742425082

"For the Vets that have TBI, so many of them don't know about this and story needs to be told and they need to learn."

"Once I started the treatment and got to that position, it really gave me an opportunity to see my life and get it back as a whole."

"Since I have been doing HBOT therapy, the bipolar medication they had me on, I haven't taken since I started treatments here."

"My short-term memory has improved."



Sergeant Dan Campbell, USA, Retired

A 76 year old Vietnam Veteran recovered from TBI/PTSD with HBOT



Watch Video: https://vimeo.com/731784760

"I just completed what I think was the best thing that I've ever done in my life. With PTSD, you don't have clarity of mind. I can't tell you how great that feels when you didn't have it all your life and all of a sudden you just your whole mind, everything improves. When I left there, I just seem to be a new person. I don't have the rage anymore."

"Hyperbaric oxygen therapy is a wonderful thing. It's noninvasive. They put you in a chamber you breathe in 100% Oxygen kind of changes your life. It did me."

"So many Vets that have TBI don't know about this and the story needs to be told and instead of some doctor giving you a pill, to confusion you even more. They need to start recommending this and I hope they do!"



Staff Sergeant Robert Dawson, USMC, Retired

Gulf War, Iraq War, Afghanistan War.



Watch Video: https://vimeo.com/734378418

"Prior to the treatment I'd be very explosive, very agitated, very sluggish. After the first 5 treatments I already noticed a change; and that explosive, agitated, easily triggered mindset has definitely diminished."

"On my last ANAM, one of the portions where you have to hit the X and then not hit the circle; I could feel the communication. Where in the ANAM prior to my treatment I had hit maybe eight or nine circles, after HBOT I only hit one circle. But I could feel the tingling in my finger, the communication that I had not had when it comes to reflexes between my finger and my brain, and I sense that now with everyday things."

"It's improved and enhanced my way of life. I've been able to hone in on certain prioritized tasks. Rather than stress out, lose my mind, run around. It's just enhanced my whole way of life; my thought process and it's just been phenomenal."



Master Gunnery Sergeant Malvin Haubenstein, USMC, Retired Gulf War, Iraq War, Afghanistan War.



Watch Video: https://vimeo.com/748159060

"In 2013 my deployments were to include Iwakuni, Japan four to five times. And I did Kosovo. I did Desert Storm. Did three tours in Iraq. And a couple months in Afghanistan. In 2013, I had a knee replaced then I had my neck surgery and then I had esophageal cancer which I spent a long time recovering from that and that really put me into a depression."

"After coming to the HBOT program, I noticed energy burst and then it was like my head just cleared after the second week and as it went on, things got just clearer. Like a fog had just lifted, my joints, my range of motion, and everything."

" I have more energy. I wasn't as fatigued all the time. I was able to get up and go do stuff instead of just sitting around. It's just been a wonderful program."

<u>TAB – D</u>

NC HBOT PROGRAM TEAM RESUMES AVAILABLE BY REQUEST

- MELISSA SPAIN, CEO COMMUNITY FOUNDATION OF NC EAST
- EDWARD DI GIROLAMO, PE, CEO, THE STEEL NETWORK
- MICHAEL WEEKS, MEDIA CONSULTANT
- COMMANDER JAMES HOOKER, USN, RETIRED
- JOHN MEYERS, ANAM CONSLUTANT
- SERGEANT MAJOR SIMON LEMAY, USMC, RETIRED
- CAPTAIN GREGORY GREEN, USA, RETIRED
- JAMES STEVENS, MD, MEDICAL DIRECTOR, EXTIVITA-RTP
- ELENA SCHERTZ, NP, CLINIC MANAGER, EXTIVITA-RTP