Athena GTX, Inc., in cooperation with Athena Telemedicine Partners.

Not only will Men of Science have to grapple with the sciences that deal with man, but…

and this is a far more difficult matter…

they will have to persuade the world to listen to what they have discovered.

If they cannot succeed in this difficult enterprise,

man will destroy himself

by his halfway cleverness.

— B. Russell 1872–1970

This Press Release summarizes the results of the Watchdawg® *Pilot Study* recently completed. The details of the program, objectives and expectations, and a market summary have been described previously. In review, ten (10) military veteran participants, were recruited for the study and upon acceptance provided the pharmaceuticals (LDX) and nutraceuticals in addition to 24/07 access to therapies consisting of mental health expertise, yoga and meditation via Yogani/Exalted Warrior Foundation and a wearable recording and acquisition system of vital signs consisting of either a Garmin or Samsung wearable wrist monitor (shown as an example in Figure 1) and mobile phone for cloud-based upload of data via the FDA cleared Athena Device Management Suite (ADMS).

Figure 1. Representative custom GUI with color coding on the wearable Garmin platform.

Participants were provided contact information for troubleshooting and participated voluntarily in a weekly physician Zoom call to discuss any issues, problems and anecdotal evidence concerning the system's efficacy and safety.

A summary of results (just a dozen for now) is presented below:

1. Validated the wearable and acquisition system as functionally sound and gathered data on the two potential wearables data sets as to relevance to the program.
2. A subset of the participants had functionality issues with the system provided and required more interface for troubleshooting for a variety of reasons.
3. Some participants "forgot" to put on their wearable after charging.
4. One participant took off their system when they felt a stress episode coming on (exactly the opposite of what we hoped for.
5. One participant bailed after starting treatment, opting to enter an alternative drug trial that was paid.
6. Upgrades to the wearables, and the cloud-based system were identified and are now in development for the upcoming 100 participant trial on safety and efficacy
7. New participant requests to participate based on word-of-mouth were significant.
8. Data was acquired pre-LDX as a baseline for about a week, and then post therapies to determine a preliminary efficacy score of the program. Overall pilots compiled 4-6 weeks of data.
9. Overall stability of vital sign data pre-therapy was significantly greater and a nominal reduction in volatility and stress of nearly 60% with therapy.
10. Some participants showed a fairly-stable pre-therapy statistical relationship computed to be linear (best fit regression), some showed extreme volatility in pre-therapy data, but all showed trends to the more positive as follows:
    a. Decrease in heart rates on average by 18 =/- 10 bpm
    b. Increase in HRV/HRC by 10 to 30%
    c. Increased trend to higher SpO2 during treatment, which may indicate a potential improvement in cognition (or a reversal of cognitive decline)
    d. Decrease in RR by 5 =/-4 bpm
    e. Decrease in stress score by 20-60%
    f. Improved recovery rates of stress reaction (cause of stress was not documented in the pilot)

11. Nearly 100% of the participants reported positive outcomes early and consistently with WatchDawg in the 4-6 week study, followed by a desire to continue treatment after the pilot ended.
    a. A significant number of testimonials have been received by both pilot study participants and other civilians paralleling the results of the pilot.
    b. The volume of nutraceuticals consumed/used was significantly underestimated. The volume of these needed averaged 3 times more per week.
    c. The LDX/CBN combo appears to be working better anecdotally than LDN+ when supported by autonomic nervous system (ANS) regulation achieved via yoga, exercise, or meditation.
12. Identified a long-term (weeks vs hours or days) treatment pattern of stress mediation that has little to no precursor data published.

The pilot met or exceeded the Objectives identified by the study team.

Objective 1 Met. This was the most important Objective! Success criteria was clearly achieved with a trans-therapeutic, sustainable, low-impact health and wellness management solution. LDX modulation appeared to be extended or increased by CBN, physiological indications of sympathovagal balance were observed with specialized yoga and meditation. The data acquisition system performed adequately to support participants who were unsure if positive changes were just "in their heads." We are ready to fix a few issues, incorporate valuable user feedback, and move to Phase 1 clinical through the IRB.

Objective 2 Met. The team created a *patented approach that successfully* summarized mathematically what we do know at any moment in time from the participants and what data trending we can identify (a scaling factor)- derived from trauma care (seriously injured)- that is currently referred to as Summary State.

- Psychology may manifest in physiological data. Critical but stable versus critical and failing versus highly volatile inputs (unstable) are totally different.
- Relevance- a participant with critical vitals and dysregulated data trending versus one with critical vitals but regulated/stable (i.e., he/she is perhaps exercising/working hard).
- Validated by Athena against US Army Trauma Vitals Data Base under CRADA- now plans on validating in Watchdawg® in Phase 1. As an example:

Vital Sign	Green (0-1)	Yellow (2-3)	Red (4-5)	ROC (1 min)
SpO2	SpO2 ≥ 94%	87% < SpO2 < 94%	SpO2 ≤ 87%	Decreases by 4%
Heart Rate	50 ≤ HR ≤ 80	35 ≤ HR < 50 80 < HR ≤ 120	HR < 35 HR > 120	± 6 bpm
Skin Temp	N/A	N/A	T < 80°F T > 99°F	
Respiration Rate	6 ≤ RR < 18	18 ≤ RR < 25 3 < RR < 6	RR ≥ 25 RR ≤ 3	TBD
Cognitive State	1 ≤ CS ≤2	CS = 3	4 ≤ CS ≤ 5	TBD
HR Fatigue	70 ≤ HR FTG ≤ 100	30 < HR FTG < 70	HR FTG ≤ 30	TBD

Summary State	0 ≤ State ≤ 1	2 ≤ State ≤ 3	4 ≤ State ≤ 5	

Figure 2. Summary State Watchdawg parameters tracked in pilot study

As an example, the participant's heart rate alone is not the whole picture. A stress response would perhaps vary from an exercised response and recovery. See below.

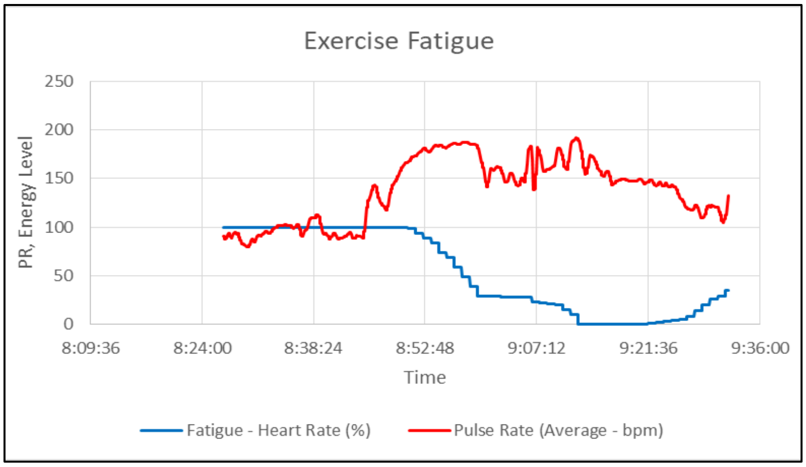

Figure 3. An examplke of heart rate changes and the participant fatigues and recovers. This would be a normal reactive process.

In this example the WatchDawg algorithm can predict the rate of HR fatigue and recovery to "tease" the stressor response out of the data for workload increases. This work was leveraged from US Navy work on aircrew monitoring in flight and ground forces exercising.

In addition to recording data inputs, we also used calculated inputs in its final summary state calculations on the participants successfully. This will become the trigger in our new military proposal on PAWS (discussed in the last PR). CSSI (Cardiac Stress Index) was key in helping to better understand the whole-body psychophysiological profile. Rate of change compares past and present values to evaluate if the participant's health is improving or deteriorating. The slight irregular pattern of heart rate is described by heart rate variability and heart rate complexity, which is controlled by the autonomic nervous system. In the next study we will add Pulse Wave Transit Time, Respiratory Sinus Arrythmia, and Pulse Integrity, to more definitely track the changes in blood pressure and respiration. Useful when a blood pressure monitor or capnography module is not available, or between measurements.

How vital sign data changes can be more important than the values to which they change. In a study of sudden death patients, a majority had a sudden deterioration in vitals, frequently blood pressure (Boyle, 2008). It is common practice to track the improvement or deterioration of a patient's vitals that is suffering from a *traumatic brain injury (TBI)* (The Merck Manual for Healthcar Professionals, 2007). Any sudden deterioration of a patient with a TBI requires prompt attention and treatment (The Merck Manual for Healthcar Professionals, 2007). Vitals tracking of acutely ill patients is usually not as rigorous. Patients, who seem fine, may not be examined in such great detail (Luettel, Beaumont, & Healey, 2007). For this reason, a rate of change parameter was added that will be able to incorporate information on how vitals change in the summary alarm. A medic or other care giver can then be summarily informed when a patient is deteriorating, and which vitals are indicating deterioration.

Why is this important? The National Patient Safety Agency (NPSA) reported that 11% of deaths were a result of sudden deterioration, which was not acted upon and/or recognized (Luettel, Beaumont, & Healey, 2007). The military's CSSI code, developed by Athena, aims to eliminate this error through recording vital signs and evaluating rate of change. We have taken steps towards adaption for WatchDawg with evidence-based inputs. Each vital has an associated amount it can increase or decrease within a set time frame before notifying a medical professional. Each allowed variance is specific to the vital. For example, if the blood pressure dropped 10 mmHg it could be caused by something as small as a change in position, whereas if the oxygen saturation were to decrease by 10% that would indicate that patient is in a serious condition and needs immediate attention. More on this in the next section.

Objective 3 Met. SpO_2 (oxygen saturation) data was acquired, but the data alone does not tell the acute nor chronic story of body oxygenation. We successfully expanded the value of this measurement. We know long term, even mild hypoxia can impair cognition, which may be a key parameter of functional ability to complete mental tasking effectively. In fact, with the preliminary pilot data, we may have insight into tracking cognitive decline in the elderly as well as military veterans using LDX. This model was leveraged from prior Athena GTX, Inc contract work for the US Navy.

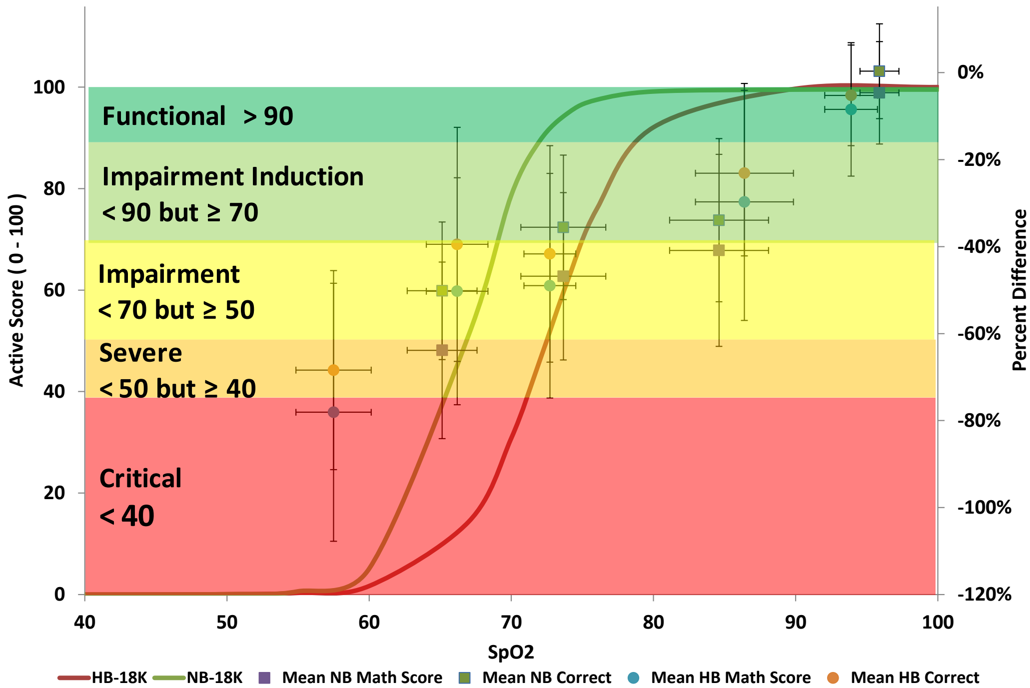

Figure 4. Decreased cognition model adapted from the prior works of Athena.

The "SpO_2 min" is the minimum value for an altitude exposure while the Model Score (0 – 100) is the active score calculated by the neurological model. A very similar approach was used in the FDA cleared miniMedic® medical assessment code dome by Athena GTX previously as in when bad is medically and clinically relevant; "how bad" is not really as much of an issue. We also looked at a math task score ratio which would bring large reductions asymptotically toward zero, but that approach had poor dynamic range, as the values were mostly low.

Active Score	State	Interpretation
> 90	1	Functional
< 90 but >= 70	2	Impairment Induction
< 70 but >= 50	3	Mild Impairment
< 50 but >= 40	4	Severe Impairment
< 40	5	Critical

Figure 5. Summary State of the participants in terms of SpO2.

Every living tissue in the body needs oxygen and nutrients to function. These essentials are distributed through the body via the circulatory system. Hypoxia occurs when tissues lack sufficient oxygen or are unable to utilize it effectively (Furgang). Hypoxia can occur because of posture, low hemoglobin, carbon monoxide (CO) poisoning, and altitude (Furgang). Normal oxygen saturation is between 90-99%, depending on altitude (Furgang), but for most, healthy is between 95-98% (Lawrence & Simpson, 2006), and 91-94% is considered mild hypoxia (Normal Vital Signs Guidelines for EMS). Oxygen saturation under 90% cannot provide sufficient oxygen for all the cells of the body, and oxygen saturation under 85% cannot provide enough oxygen for the vital organs (Lawrence & Simpson, 2006).

Hypoxia is present in numerous types of shock and stress responses. Hypovolemic and cardiogenic shock cause hypoxia through an insufficient amount of blood being able to reach body parts. Neurogenic, septic, and psychogenic shock dilate blood vessels, decreasing blood pressure, therefore slowing transportation of oxygen rich blood. Also, respiratory shock causes hypoxia, by not presenting sufficient oxygen to the hemoglobin at the lungs (Doherty).

Objective 4 Met. Consistent HR data was acquired. Heart rate, change, and volatility are key to participant status. Moreover, heart rate is one of the most commonly measured vital signs. It can be found on your own body, or someone else, with a finger and a watch. Even though it may seem very simple, it is one of the most essential vitals of the body. The normal adult resting heart rate is between 60-100 beats per minute (bpm), though a trained athlete may have a resting heart rate as low as 40 bpm (Laskowski, 2008). When the heart beats too fast or too slow, blood does not effectively travel through the body's circulation, creating a hypoxic condition (Kongo, Yamamoto, Kobayashi, & Nosaka, 1999). Once this condition affects the body's vital organs, they will begin to fail (Kongo, Yamamoto, Kobayashi, & Nosaka, 1999).

The heart may become tachycardic (abnormally high) during stress as it does during a hemorrhage, hypoglycemia, sepsis, dehydration, shock, or snake bites, attempting to move more blood and nutrients through our the body (Low Heart Rate/High Heart Rate, n.d.). At some point, the increased rate of pumping, does not allow sufficient time for adequate ventricular preload for the heart, and therefore less blood is pumped from the heart (Cardiology and Arrhythmia Consultants P.C., 2005). In addition to the decreased blood flow and blood pressure, the heart, which is now working harder to pump more often, requires more oxygen for metabolism of ATP, which reduces the blood flow to other areas of the body, increasing the risk of ischemia that may result in an infection (Cardiology and Arrhythmia Consultants P.C., 2005). Bradycardia, on the other hand, which is a heart rate that is significantly slower than normal, causes an inefficient amount of oxygenated blood to be present in the circulatory system. It is most often identified as heart failure (Nursing Times, 2008). As opposed to tachycardia, when the filling time is shortened, during bradycardia the long ventricular preloads may lead to an overextension of the ventricles (Nursing Times, 2008). Some causes of bradycardia include intercerebral hemorrhage, heart attack, dilated cardiomyopathy, and marine animal stings or bites (Low Heart Rate/High Heart Rate, n.d.).

Objective 5 Met. Skin temperature was acquired from the watch. This is a common vital used to determine if someone is sick (typically a febrile episode). The normal core body temperature is approximately 37^{o}C (98.6^{o}F), varying slightly person to person, as well as time of day (Elert, 2005). In many cases, the *skin temperature* will be used in the watches because of its ease of access. Normal skin temperature is slightly lower around 32-34^{o}C (89.6-93.2^{o}F). When the body temperature is lower or higher than normal it is described as hypothermia and hyperthermia, respectively.

Hyperthermia is very serious because high body temperatures cause increased metabolism expenditure, exhausting the patient's energy (Thomas, Tkacs, Saataman, Raghupathi, & McIntosh, 2003). It usually occurs in the form of a heat stroke or heat exhaustion. This can precipitate out of stress reactions. Heat exhaustion usually occurs while exercising in a hot environment, as it is caused by the inability to cool the body. Symptoms are commonly heavy sweating, paleness, muscle cramps, tiredness, weakness, vomiting, or fainting (Hyperthermia and Heat Related Illness, 2008). A heat stroke is similar, but also *involves symptoms of confusion, seizures, or unconsciousness* (Hyperthermia and Heat Related Illness, 2008).

Hyperthermia has also been associated with post traumatic cerebral inflammation, hypothalamic damage or infection (Thomas, Tkacs, Saataman, Raghupathi, & McIntosh, 2003). During a fever, the body increases body temperature in order to attempt to denature viral proteins (Sanford, 2010). Unfortunately, most proteins, including those in the human body, denature at 40^{o} C (104^{o} F) (Sanford, 2010). Hyperpyrexia is especially dangerous to the cells of the brain and heart, as they cannot rejuvenate.

Hypothermia occurs when the body temperature is colder than normal, which occurs in cold environments, shock, alcohol or drug use, and some metabolic disorders (Body Temperature, 2009). It causes shivering, lethargy, confusion, and coma (Hypothermia, 2009). Hypothermia slows all physiological conditions including heart rate, respiration, nerve conduction, mental acuity, neuromuscular reaction time, and metabolic rate (Hypothermia, 2009). This slow metabolism allows cells to survive longer without oxygen (Lowering Body Temperature Shows Promise for Trauma Treatment, 2006). One study on the effects of shock on rats, found that rats with a lower tissue temperature had significantly less brain damage from the induced shock, than those high tissue temperature (Lowering Body Temperature Shows Promise for Trauma Treatment, 2006). Though hypothermia has detrimental effects, such as increased susceptibility to infection because of the depressed immune system, "the risk of mild cooling appears minimal, especially when the outlook is grim" (Lowering Body Temperature Shows Promise for Trauma Treatment, 2006).

Objective 6 Met. We acquired reasonable indirect RR from the watch pulse ox sensor as well. Breathing is essential for oxygenation of blood and can significantly change with anger and anxiety. Normal breathing rate is 12-20 breaths/min (Normal Vital Signs Guidelines for EMS). Breathing brings in oxygen for the blood and releases carbon dioxide waste from the body. The body contains chemoreceptors to regulate the amount of oxygen and carbon dioxide in the blood (Cretikos, et al., 2007). When the body is hypocarbia or hypoxaemia it will increase tidal volume, respiratory rate, and alveolar ventilation (Cretikos, et al., 2007). This is directed by the autonomic nervous system (ANS) and can be monitored by the HRV/HRC. If the body begins to hyperventilation, breathing too deep or too fast, CO_2 levels decrease in the body, which reduces blood flow to the brain (Hyperventilation, 2010). Though the overall cause of hyperventilation is unknown, it is common during an infection, bleeding, and heart attacks (Hyperventilation, 2010). Hyperventilating patients may be dizzy, confused, agitated, hallucinate, or faint (Hyperventilation, 2010). Hyperventilation also causes a drop in calcium which can cause numbness or tingling of arms and mouth, and muscle twitching, spasms or cramps of feet or hands (Hyperventilation, 2010).

One study found that respiration rate was a good indicator of the stableness of a patient. They found that relative changes in respiration rates were higher than heart rate and systolic blood pressure between patients of varying health conditions (Cretikos, et al., 2007). From the study, the authors recommended that patients with a respiration rate higher than 24 breaths/min should be monitored, and patients with a respiration rate higher than 27 breaths/min should receive immediate attention.

Below please find some participant representative data files obtained and plotted for consideration and comment. Names are removed for HIPPA compliance and summaries are presented on each which ties back to the pilot result summaries and the six (6) Objectives Met.

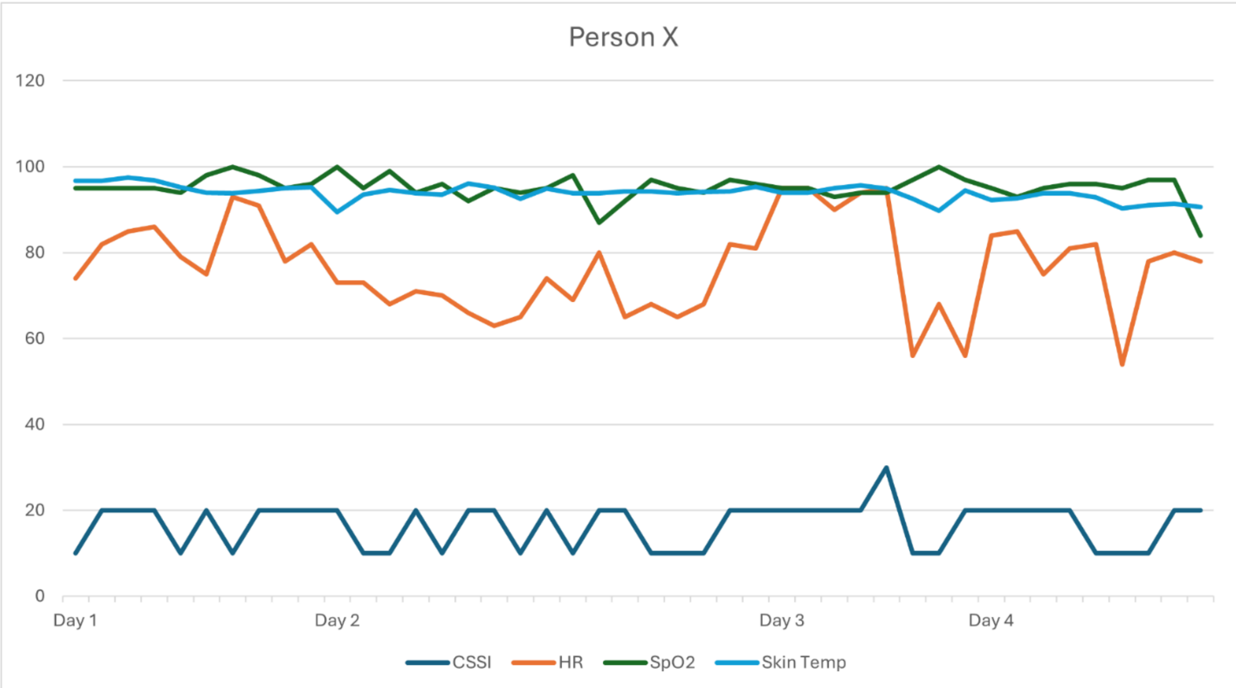

Figure 6. Participant representative data plot of stability prior to trial initiation.

In this study, the first few days in the pilot were used as a stability and data acquisition check. We see the participants data is linear and stable even though there were, as expected, some volatility, especially on heart rate shown in Orange (totally expected and normal).

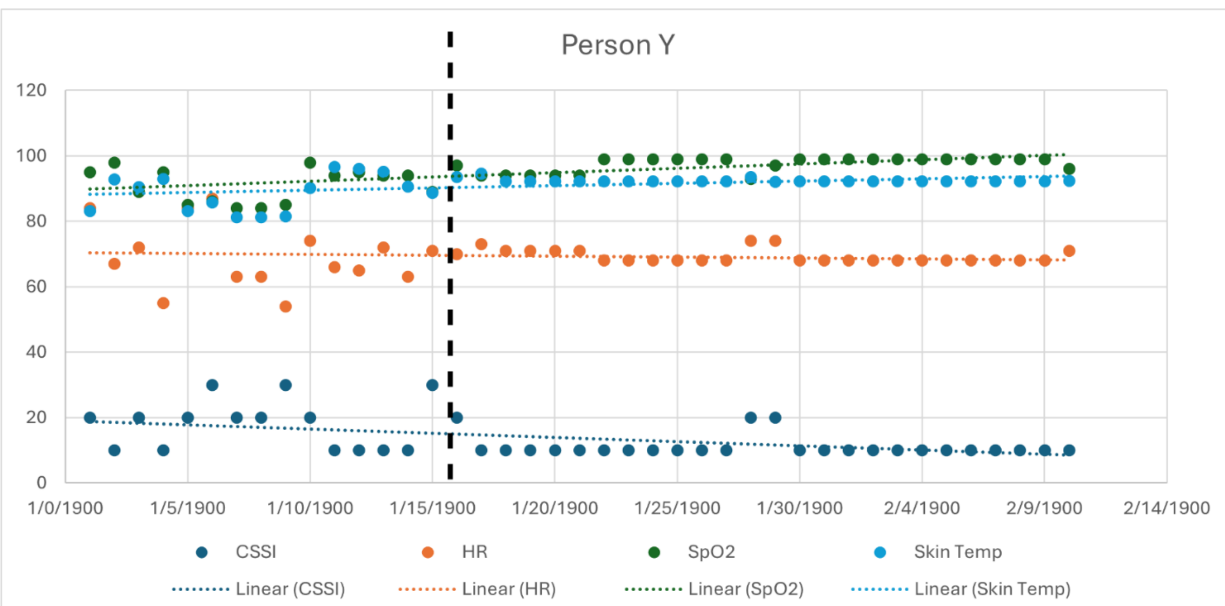

Figure 7. Participant data file pre and post therapy consistent with acquisition pre- and post-therapy starting as noted by black vertical dashed line.

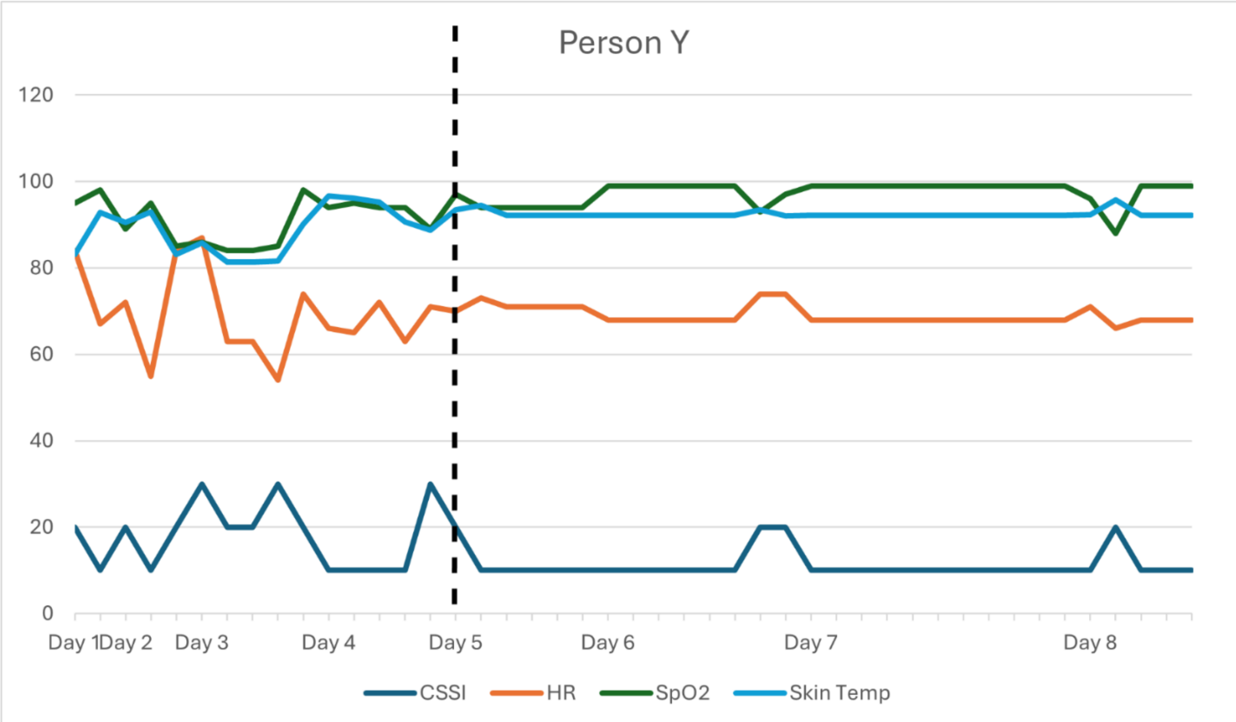

Figure 8. Same participant, Participant Y, showing a volatility abrupt change in data files after treatment starts depicted by the vertical black dotted line on Day 5.

Figures 7 and 8 show a consistent impact of the comprehensive treatment. As depicted herein, the volatility on each parameter in this participant is markedly obvious pre and post LDX. Exactly a compelling and typical participant result. In addition, the reduction in CSSI trends shows the participant is overall better off than pre-treatment.

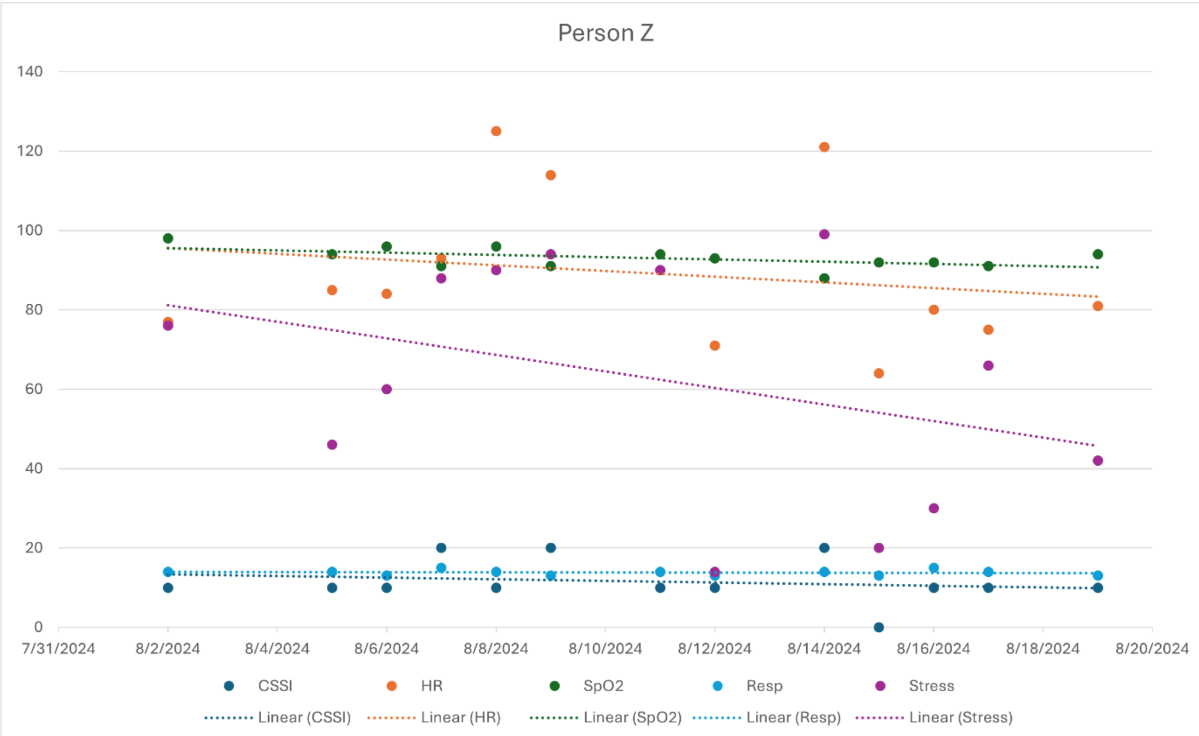

Figure 9 Sample participant trial with trending lines statistically inserted. Note the trend to reduction in HR and stress.

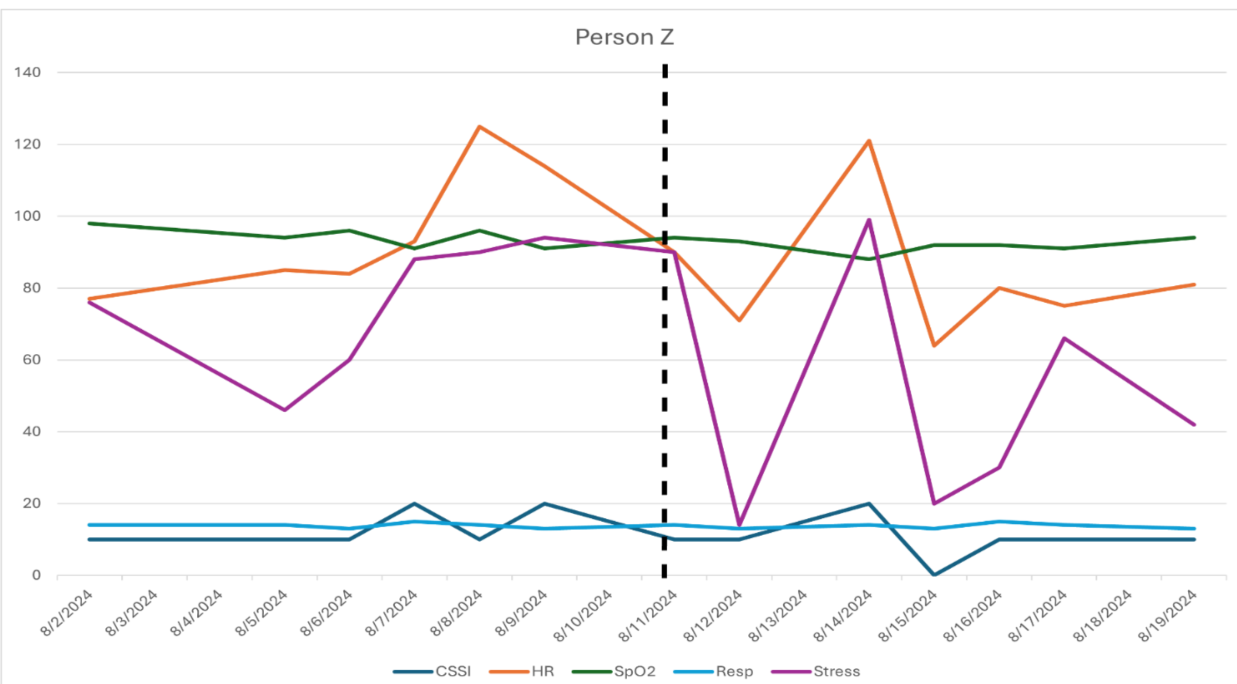

Figure 10. Volatility in a participants data file, focused in on stress which in also manifested in tachycardia (124 bpm)

This was an initial pilot study and analysis on WatchDawg; therefore, no industry standard statistics were compiled/created except best fit trend analysis. The Six (6) Objectives all met or exceeded success criteria, and it appears that based on the participant data, the therapy surpassed expectations of mental/physical health management and whole-body wellness. Therefore, we are please to announce our intentions to confidently move ahead to the next phase featuring a one hundred (100) participant study in preparation for FDA clearance. However, that does not prevent entering the market with the compounded formulation under current protocols that have allowed us to proceed thus far.

As we enter the next programmed step, we wanted to remind any interested parties to consider enrolling in or supporting Phase 1 trials. There is an open invitation to witness first-hand the value and ease of the therapy and its impact.

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