

# Nervous System Regulation Through Listening: The Science and Applications





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Dear Reader,

It is with great enthusiasm that we present to you the following white paper, in which we dive into the profound impact of music-based interventions, sound therapies and listening therapies. In an exploration of science, clinical research and real-world evidence, we aim to enrich your familiarity with bottom-up therapies and how they can complement traditional, top-down approaches to create holistic healing strategies grounded in physiological safety and autonomic regulation.

In today's therapy and wellness landscape, the transformative potential of sound and music is increasingly being realized and pursued, as we continue to recognize the limitations of common methods in supporting the needs of individuals presenting with a range of neurodevelopmental and mental health challenges. The information presented here, however, is the culmination thus far of Unyte Health's nearly two decades in this space. Since 2007, we have been committed to empowering therapists, clinicians and healthcare providers — and their clients — with the tools and knowledge to create long-lasting, positive changes, through the pioneering of category-creating therapeutic interventions, such as the Safe and Sound Protocol (SSP) and Integrated Listening System (ILS).

There is an intricate connection between the autonomic nervous system and overall well-being rooted in our biology. In this white paper, you will learn about the mechanisms behind listening therapies and their potential impact on the brain and body, as seen in the many thousands of individuals who reported life-changing results after completing a Unyte Health program. By contributing to a greater collective understanding of neuroplasticity and Polyvagal Theory, we not only strive to facilitate a broader adoption of bottom-up interventions, but also advocate for widespread comprehension of the autonomic nervous system, the vagus nerve, trauma, and more.

As you navigate this information in your pursuit of tools to support your clients, we invite you to join us on our mission to help people become more aware, regulated, and resilient so they can better respond to life's challenges and live happier and healthier lives. With the Unyte Health suite of effective mind-body solutions, it is our goal to continue empowering practitioners to accelerate and improve their clients' experiences and therapeutic outcomes. Together, let us harness the power of music and sound to build the foundation of safety, nurture social connection and engagement, and cultivate overall mental well-being for your clients, yourself and your communities.

Thank you for your dedication to the healing profession, and for considering the insights offered in this publication.

Sincerely,  
Unyte Health



## An Introduction to Listening Therapy

Therapeutic applications in music and sound have expanded tremendously in recent years. Institutions like the National Institutes of Health (NIH) have published [calls to action](#) with ongoing funding opportunities for music and health research. A 2023 virtual conference, “Music as Medicine: The Science and Clinical Practice,” sponsored by the NIH and the National Endowment for the Arts (NEA) featured over 100 speakers and panelists across disciplines highlighting new advancements in scientific research on music and health.

### Terminology

**Music-based interventions** can include a wide range of applications, including playing or singing music, listening to music, and integrating music with a therapeutic process. Music therapy is defined by the American Music Therapy Association (AMTA) as the use of goal-based music interventions within a therapeutic relationship, and recognized as an accredited profession (Bruscia, 2014). While licensed music therapists have a unique professional lens and training, many other disciplines and modalities also use music-based interventions to support healing.

**Sound therapy** or sound-based interventions use audible sound vibration to facilitate changes to allow for therapeutic or healing responses, include the use of specific sounds or instruments that center various cultures or traditional practices, such as drumming, singing bowls and gongs, and may be used in community, spiritual, clinical or other therapeutic contexts.

**Listening therapies** are considered to use specific sound qualities alongside a therapeutic process that centers the client’s participation in the experience. Listening therapies include various programs, technologies and theoretical orientations, including Unyte’s evidence-based programs. They may be applied by practitioners in clinical settings or delivered to support general health and well-being.

The terms “music-based intervention,” “sound” and “listening therapy” will be used throughout this paper to describe the many applications of music across populations and disciplines.

## Why Listening, and Why Now?

Listening is built into our nervous systems, based on a biological imperative to socially engage with others and respond to cues in our environment (Porges, 2001). The ability to create and perceive sounds that support safety, connection and communication have been essential to human life from the earliest days. Fauble (2017) describes the history of music and the human experience, and how specific pitch patterns, cadences and rhythms are embedded in our evolutionary history. As ancient knowledge in music and sound converges with new learnings in neuroscience and clinical practice, the potential for healing and recovery continues to unfold, empowered by modern technology.

There is a tremendous need for better and more effective tools in health care, particularly to support individuals with mental health-related and neurodevelopmental challenges. Despite technological advancements in pharmacology over the past 40 years, we are still experiencing the highest incidences of mental illness in history. The [National Alliance on Mental Health \(NAMI\)](#) reports that 1 in 5 U.S. adults experience mental illness each year, with young adults (18-25 years) being the most prevalent. A growing proportion of adolescents (12-17 years) are similarly challenged, evidenced by a 31% increase in mental health-related emergency department visits in 2020. Globally, the [World Health Organization \(WHO\)](#) estimates that 1 in 8 people, and (14%) of 10-to-19-year-olds, are experiencing a mental health condition. Anxiety and depression are most commonly reported. Prevalence rates of Autism Spectrum Disorder (ASD) have increased from 1 in 150 in 2000, to 1 in 36 in 2020 (Maenner et al., 2023). We need better alternatives and further advancements to address this need.

Neurodevelopmental and mental health-related challenges have a holistic impact on overall function, influencing emotions, thoughts, behavior and physical health. There is a need for solutions that address the root cause of these challenges by

### Benefits of integrative approaches, like listening therapies:

- Low risk
- Low cost\*
- Non-invasive
- Accessible
- Integrative

**\*Economic analysis:** Patient-directed music interventions (music tailored to individual preference by a board-certified music therapist) saved **\$2,322 per patient** and concurrently better managed anxiety with less sedative medication than usual care for ICU patients, supporting the cost effectiveness of including music in therapeutic approach (Chlan et al., 2013; 2018).



shifting the narrative from just treating a condition, to supporting mental wellness through each individual's innate capacity for healing.

Approaches that overly focus on symptoms miss the root cause, limiting growth and restoration. Integrative approaches that combine bottom-up (body-based, feeling) alongside top-down (cognitive, thinking) are rapidly developing to meet this need. Modalities and therapeutic approaches like somatic therapies, sensory processing/integration, EMDR, Internal Family Systems, and sound and music are already helping hundreds of thousands of people unlock their nervous system's innate ability to heal, enabling them to lead more connected, regulated and resilient lives.

These new approaches are still only known by and accessible to a small segment of the population. Broader awareness among health care institutions, providers and payers is essential to make these evidence-based treatments more broadly available to those who are in need, and ultimately to help curb the growing global mental health crisis. This paper is one step toward broadening the awareness of the current and potential future impact of evidence-based integrative therapeutic approaches like listening therapies.



## The Science

Beyond ancient wisdom, emerging clinical needs and practical advantages in the modern world, the science of how music affects the brain and body has accelerated in recent years. We now know that music evokes many brain regions and enhances autonomic regulation, leading to better therapeutic outcomes and well-being. This understanding is evidenced by the work of many researchers and clinicians, spreading across disciplines of neuroscience, music therapy and health care.

### Neuroplasticity

**Bridging theory and practice, neuroplasticity helps us understand how music promotes changes in the brain.**

Neuroplasticity is a dynamic process that occurs on various levels, from individual neurons to entire brain regions. Through functional and structural plasticity and neurochemical changes, neural pathways have the capacity to change the magnitude and direction of their connections, resulting in a reorganization in how the brain responds to stimuli. These changes can manifest in shifts in affect, behaviors, sensory processing, executive, social and other functioning. Neuroplastic change can occur throughout the lifespan, giving therapists a unique opportunity to implement tools to create positive shifts in brain function at any age (Neville & Bavelier, 2002).

Music-based interventions are found to be effective methods to promote neuroplasticity (Stegemoller et al., 2014). At a structural level, music induces neurogenesis, the formation of new neurons, and promotes dendritic spine growth (protrusions on the neurons responsible for receiving input from neighboring neurons) (Pant et al., 2022; Papadakakis et al., 2019). Music-induced plastic changes are also expressed through functional shifts at the synapses, where communication between neurons occurs, and through cortical remapping, by adapting brain region responses to sensory input, such as motor, speech or auditory processing changes (Chatterjee et al., 2021). Finally, neurochemical changes, such as those in the dopaminergic and serotonergic systems, map onto the changes observed in mood regulation, emotional processing, learning, memory and motivation following music exposure (Mavridis, 2015).

In a review of articles addressing the effects of music on PTSD, researchers found that music can stimulate neuroplasticity, enhance brain recovery and normalize the stress response for individuals with PTSD (Pant et al., 2022). These plastic-induced changes were expressed through structural and functional changes in areas involved in emotion and memory, namely the hippocampus, hypothalamus, amygdalae and nucleus accumbens (Koelsch & Skouras, 2014; Koelsch, 2014). Further, music listening has been attributed with modulating the stress response by balancing the hypothalamic-pituitary-adrenal axis, observed through consistent reductions in biological markers of stress, such as lowered cortisol and blood glucose levels following music listening (Finn & Fancourt, 2018).

Music has also been observed to enhance dendritic spine density in pre-clinical trials. Papadakakis and colleagues (2019) exposed animal models to 12 hours a day of Mozart for 55 days following the stressor of maternal separation. The group receiving the music intervention demonstrated significantly increased hypothalamic dendritic spine count, reduced depression and anxiety, and improved sociability compared to the control group.

Music-induced neuroplastic changes are involved in the rewiring of sensory, motor and language areas (Chatterjee et al., 2021). Sihvonen and colleagues (2017) found a large body of evidence in using music for neurological rehabilitation, especially for individuals with stroke and dementia, and pointed to the neural circuits involved in reward, arousal, affect regulation and learning as being prominently involved.



These circuits are governed largely by dopaminergic and serotonergic neurons, underlying the long-standing relationship between music and pleasure. Many of these projections touch base in the key pleasure center in the human brain, the nucleus accumbens, which has shown to have increased extracellular dopamine and serotonin following music exposure (Mavridis, 2015). Dopamine also drives neuroplasticity by playing a vital role in strengthening neural connections between regions through long-term potentiation (Kerr & Wickens, 2001). Menon and Levitin (2005) conducted a brain-imaging study that examined the functional connectivity of reward pathways while participants listened to classical music. The music provoked a linking between responses in the nucleus accumbens with fellow reward center, the ventral tegmental area, as well as brain regions that mediate physiological and cognitive responses to rewarding and emotional stimuli, such as the hypothalamus, insula and orbitofrontal region (Menon & Levitin, 2005).

By strengthening functional connectivity of these pathways that influence motivation, reward and learning, musical stimuli can cultivate an enhanced learning environment for non-music tasks and behaviors (Stegemoller et al., 2014). For example, in a case study with a cerebellar stroke patient, combining music alongside physiotherapy led to improved self-motivation in rehabilitation and promoted therapeutic goals including functional movements, coordination, balance, fluency of speaking and multitasking (Ruotsalainen et al., 2022).

The exploration of neuroplasticity and its intricate connection to music provides insight into the transformative impact of music on the brain. From cellular to global levels, music-induced neuroplastic changes manifest in diverse functional shifts, influencing affect, behavior, sensory processing and cognitive functioning, highlighting music's profound potential to enhance therapeutic outcomes.

## Autonomic Regulation

**Beyond neuroplastic changes, listening therapies can profoundly improve physiological functioning through autonomic mechanisms.**

The autonomic nervous system mediates our essential physiological functions. It integrates the brain and body through an extensive network of nerves, operating beyond our conscious control. Its holistic influence extends to sensory perception (eyes, mouth, skin), the cardiovascular system (heart, lungs), gastrointestinal system (stomach, bowel and bladder), reproductive system, immune system, hormonal regulation and more (McCorry, 2007). Due to its holistic influence, shifts in autonomic state can lead to a cascade of physiological changes, with the potential to enhance healing and restoration in a broad range of mental and physical conditions. One perspective on how music influences health is termed “neurovisceral integration” (NVI). This describes the dynamic

interaction between the central and autonomic nervous systems as self-organizing and nonlinear, explaining how music globally influences physiology, leading to functional changes in health and well-being (Ellis & Thayer, 2010).

The therapeutic impact of improving autonomic regulation through listening is evidenced in several high-quality studies. Listening therapies were found to reduce the stress response in individuals with symptoms of trauma and have a global effect on physiological markers of health, including heart rate, blood pressure, respiratory rate, electrodermal activity and hormone regulation (de Witte et al., 2020; Kulinski et al., 2022; Ellis & Thayer, 2010; Pant et al., 2022). Further, music-based interventions have been found to significantly improve heart rate variability (HRV), a measure of autonomic regulation and indicator of enhanced parasympathetic activity (Mojtabavi et al., 2020; Kulinski et al., 2022).



## Clinical Outcomes

The impact of music-induced neuroplastic and autonomic changes are demonstrated through clinical outcomes across diverse populations.

### Mental Health and Trauma

Ten randomized, controlled trials featuring participants with schizophrenia, insomnia, mood disorders, and dementia showed significant improvements in quality of life, social functioning, mental health, sleep, stress, communication and memory (Gassner et al., 2022). The impact of music-based interventions on supporting individuals with PTSD and trauma-related systems is well evidenced. Integrating music into a trauma focus group therapy program led to reduction of PTSD symptoms, in addition to improvements in dissociation, anxiety and depression (Rudstam et al., 2022). Similar findings were reported in a mixed methods study by Story and Beck (2017), including effective use of classical music in reducing PTSD symptoms, decreasing arousal, and improving emotional regulation, communication and connection. Other forms of non-vocal music seem to have similar impact too, as demonstrated in a reduction of PTSD symptoms following the delivery of soothing music featuring nature sounds to mothers of premature infants hospitalized in a neonatal intensive care unit (NICU), a stressful experience for mother and child (Pourmovahed et al., 2021).

## Bottom-up vs. Top-down

Compared to traditional talk therapies (considered “top-down”), music is a universal language that can increase accessibility in mental health care across cultures. Listening therapies (“bottom-up” or “integrative”) are an evidence-based alternative that are found to achieve powerful results. A trauma-informed, neurobiological music program was found to reduce hyperarousal and increase attention and focus in high-risk forensic patients with PTSD who were unresponsive to or unable to participate in other therapies (Macfarlane et al., 2019). Beck et al. (2021) found music therapy had similar or better outcomes compared to standard therapy with refugees, and with much higher adherence and participation. Similarly, Zergani and Naderi (2016) exposed veterans with PTSD to traditional cultural music, which led to improved quality of life and anxiety symptoms, with effects persisting at a one-month follow-up. This is consistent with findings on the power of music to reduce physiological markers of anxiety (de Witte et al., 2020).

While cognitive behavioral therapy (CBT) is considered an evidence-based psychological intervention, the benefits of CBT may not extend to often hard-to-reach individuals living with symptoms of severe trauma. Participants with PTSD who had previously received CBT without meaningful change reported a significant reduction in PTSD and depression symptoms following a group music therapy program (Carr, et al., 2012).

## Autism

Research on listening therapies to support individuals with autism is equally compelling, validated by a growing evidence base that includes clinical trials on Unyte’s Safe and Sound Protocol (SSP) [formerly known as the Listening Project Protocol (LPP)] (Shahrudin et al., 2022). Music can motivate and inspire while facilitating improvements in motor, speech and executive functions, memory and attention, mental health and well-being, as found across populations including individuals with autism, stroke, dementia, Parkinson’s disease, epilepsy and multiple sclerosis (Särkämö et al. 2013; 2014; 2015; 2016; Sihvonen et al., 2017; Ruotsalainen et al., 2022). Informed by an understanding of neuroplasticity, these changes are often found to be long-lasting, with some studies reporting functional gains that continue six months and beyond (Särkämö et al., 2008; 2010; 2014).

## Neurorehabilitation and Pain

It is clear that music and movement share an intimate relationship in our neural circuitry. Pohl and

colleagues (2013) report that pairing rhythmic movements like clapping or stomping with music improved mobility, recall and quality of life when compared to standard care for patients with Parkinson’s disease. Further, by stimulating the connectivity of auditory and motor brain regions, music has been found to support the learning (and re-learning) of motor patterns, applied in both neurological rehabilitation and sports performance (Schaffert et al., 2019). A systematic review and meta-analysis in the Lancet describes the efficacy of listening to music in enhancing physical recovery, evidenced by lower levels of pain and anxiety, less use of analgesics, and higher patient satisfaction (Hole et al., 2015). Listening to music also lowers stress hormones (cortisol), and improves bonding (oxytocin) and regulation essential for healing, as demonstrated in post-operative patients (Nilsson et al., 2009a; 2009b).

## Seizure

Music seems to penetrate neural activity deep within the brain in mysterious ways. In a 3-year, blinded randomized controlled trial, Bodner and team (2012) found listening to classical music during the night significantly reduced seizure activity in patients with neurological differences. Amazingly, 80% of treatment participants experienced a decrease in seizures, with 24% having a complete absence of seizures during the treatment year. While the exact mechanisms are undetermined, these findings demonstrate the potential of music to restore optimal neurological activity.



## The Applications

The mechanisms behind music-based interventions vary widely and are still being explored. Still, there is an emerging understanding of what and how various qualities of music can be manipulated to elicit desired effects. Unyte Health offers several clinical-grade listening therapies, each with unique features and therapeutic applications to support health and well-being. These include the Safe and Sound Protocol (SSP) and the Integrated Listening System (ILS).

## The Safe and Sound Protocol (SSP)

The Safe and Sound Protocol (SSP) is a non-invasive, acoustic vagal nerve stimulator that helps regulate the autonomic nervous system. The music of the SSP has been filtered through a patented, evidence-based algorithm that highlights specific sound frequencies to engage the social engagement system, helping the listener think, feel and connect better with others. The SSP contains several vocal and non-vocal music playlists, is suitable across the lifespan, and is designed to complement a variety of therapeutic approaches and modalities.

The SSP was developed by Dr. Stephen Porges, the author of the Polyvagal Theory. Dr. Porges continues to serve as Unyte's Chief Scientific Advisor.

To learn more, visit <https://integratedlistening.com/SSP>.



## The Integrated Listening System (ILS)

The Integrated Listening System (ILS) is a program designed to improve brain and body function, combining movement, treated music and bone conduction. As the ILS works to improve brain and body organization, individuals are better able to process information from the environment, sustain attention and build new skills. The activities are fun and can easily be customized for all ages and skill levels. By addressing brain function at this foundational level, we are better able to become more mentally and emotionally resilient, be more effective at school or work, and better function in our modern world.

The ILS was co-developed by Dr. Ron Minson, Kate Minson and Randall Redfield, informed by the Tomatis Method. Dr. Ron Minson studied with Dr. Tomatis, and served as Unyte's Clinical and Medical Director for many years, before his passing in 2023.

Learn more by visiting <https://integratedlistening.com/ILS>.





## The Rest and Restore Protocol (RRP)

The Rest and Restore Protocol™ (RRP) is a new advancement in listening therapies, designed to support healing, restoration and homeostasis. It is used primarily to promote deep relaxation, recovery, balance in the body and mind, and connection to self, cultivating interoception and self-regulation.

Developed by Dr. Stephen Porges and Anthony Gorry, a neuroscientist and a music and audio innovator, RRP is informed by decades of research studying physiological rhythms in the body, including heart rate, respiration, blood pressure, and digestion, alongside deep knowledge of advanced sound technology. This scientifically engineered, acoustic signal and music support deep relaxation and optimal recovery for clients. Using endogenous biological rhythms embedded in unique musical themes, RRP provides a tool to signal the healing functions of the autonomic nervous system to gently move into biobehavioral states of calmness and relaxation.

Learn more by visiting <https://integratedlistening.com/RRP>.



## How Do They Work?

### Auditory Processing

Auditory processing is the receipt, integration and interpretation of acoustic energy, and is closely linked to other sensory, central and autonomic nervous systems.



Accurate and discriminatory perception of sound is dependent on the function of the middle ear muscles, which tighten the tympanic membrane (eardrum) to support the perception and attenuation of certain frequencies. The middle ear transfer function is connected to a network of cranial nerves that contribute to the integration of sound with other sensory inputs in the brainstem, leading to cognitive, behavioral and physiological responses. The auditory processing system is a portal that fundamentally changes the way we experience and respond to the world.

Our sensory systems build the foundation for how we experience the world.

The SSP is uniquely designed to improve auditory processing and reduce sound sensitivities by engaging middle ear muscles to better perceive the sounds of safe human communication. These safety cues influence the central and autonomic nervous systems through the auditory portal, leading to improved regulation and sensory processing across systems.

Our sensory systems build the foundation for how we experience the world and inform higher-level functions like movement and cognition (Williams & Shellenberger, 1996, p. 4). Research has shown that inaccurate perception of auditory cues can influence bodily perception, movement and emotions, and further impact motor behavior (Stanton & Spence, 2020). The ILS uniquely combines auditory processing with several other sensory systems (vestibular, proprioceptive, visual, etc.) to enhance functional skills from a foundation of accurate, discriminatory and well-organized sensory information.

Rest and Restore Protocol (RRP) integrates several acoustic parameters, including frequency, tempo, and musical composition to homeostasis and recovery.

Entrainment is a key component of RRP's impact. Entrainment is a biological phenomenon in which adjacent rhythms gradually fall into synchrony. The ebb and flow of the rhythms embedded in RRP facilitate the process of entrainment by bringing natural and physiological rhythms into homeostatic synchronization.

When we are stressed or ill, these rhythms are expressed with a lower amplitude and may drift into a more chaotic, random pattern. In contrast, when our bodies are in states supporting homeostasis, the endogenous rhythms of the body appear to be expressed with higher amplitude and more structured rhythmicity.

## The Vagus Nerve

The vagus nerve (CN X) is the longest nerve in the human body, often described as the “wandering” nerve due to its extensive reach across bodily systems (Dolphin et al., 2022). The vagus nerve serves a key role in communicating information between the brain and body, with approximately 80% afferent fibers communicating sensory information to the brain (Foley & DuBois, 1937). Because of this communication superhighway, stimulating the vagus nerve can alter autonomic state and physiological functioning.

The vagus nerve serves a key role in communicating information between the brain and body.

There is a strong body of evidence behind the ability of vagus nerve stimulation (VNS) to improve clinical outcomes for seizures (Bauer et al., 2016; Wu et al., 2020) and mental health (Koenig et al., 2019; Kraus et al., 2007; Rong et al., 2016; Wu et al., 2018; Fang et al., 2016; Hasan et al., 2015), among other conditions. Methods include invasive devices surgically embedded and non-invasive options such as transcutaneous (tVNS) electrical stimulation to areas of the body where the vagus nerve is most superficial, like the neck or ear. Emerging evidence suggests that non-invasive methods can reduce sympathetic activity (Clancy et al., 2014), treat cluster headaches and migraines (Gaul et al., 2015; Barbanti et al., 2015), reduce dizziness (Eren et al., 2018), and improve gastrointestinal function (Teckentrup et al., 2020; Krasaelap et al., 2019). More specifically, tVNS through the auricular branch can improve functional pain outcomes (Kovacik et al., 2020; Kutlu et al., 2020), depression symptoms (Hein et al., 2012), and acutely increase heart rate variability (HRV) (Forte et al., 2022; Clancy et al., 2014).

The vagus nerve can also be reached through indirect paths. The SSP functions as a non-invasive, acoustic vagal nerve stimulator, offering a low-risk, accessible alternative to electrical stimulation devices. By sending cues of safety through middle frequencies, the SSP engages the social engagement system — an integrated system of cranial nerves (CN V, VII, IX, X, and XII) and structures of the face and head — that enables social behaviors like facial expressions, head-turning, speaking and listening, alongside coordinating essential functions like swallowing, chewing, nursing (infants), and regulation of the heart and lungs (Porges & Lewis, 2010). This system has a bidirectional relationship with the cortex and brainstem, where sensory information converges, and is processed from the internal and external environment. Through the lens of Polyvagal Theory (Porges, 1995), the social engagement system evolved to enhance the ability to communicate, collaborate and build trusting relationships with others from a neurological foundation of safety. This indirect activation of the vagus nerve (CN X) through the social engagement system can improve autonomic function and well-being.

The calming effects of the ILS similarly activate the healing qualities of the vagus nerve, accessed through the auricular branch, which emerges onto the anterior surface of the eardrum and ear canal. Many individuals with sensory, learning or developmental differences experience stress in home and school environments, leading to sympathetic overactivation. As the parasympathetic nervous system becomes more dominant during ILS listening, the sympathetic system dampens, allowing the individual to be happier, alert, attentive, and available for therapeutic intervention and learning.

Regular use of RRP, through its entrainment of physiological rhythms, may help increase vagal tone, a marker of autonomic flexibility and resilience. Higher vagal tone is associated with better emotional regulation, improved stress recovery and an enhanced ability to adapt to life's demands, fostering a more resilient nervous system.

## Polyvagal Theory

Polyvagal Theory posits that the conditions surrounding human evolution led to unique mammalian adaptations that enhanced our ability to socially engage with others. These included the emergence of two distinct vagal systems, the ventral vagal (originating in the nucleus ambiguus) and dorsal vagal (originating in the dorsal motor nucleus) complexes, that facilitate our neurophysiological response to environmental demands (Porges, 1995). How we respond to stress mirrors our evolutionary and embryological development, and is guided by the subconscious detection of cues of safety, danger or life threat in the internal and external environment, called “neuroception” (Porges, 2004).

When we feel safe, the ventral vagal complex enables us to relax our defenses to support communication, collaboration and restorative homeostatic functions. When we feel in danger, the sympathetic nervous system is our first line of defense, helping us mobilize to “fight or flee” the stressor. When we are unsuccessful, or our internal resources are expended, the dorsal vagal complex of the parasympathetic nervous system immobilizes, or shuts the body down. While this system can have restorative qualities, over time, in response to chronic illness, stress or difficult life events, we may become stuck in a state of defense, limiting our ability to return to safe and healing human connection.



“It is my hope to highlight the important role of feeling safe as an important component of the healing process.”

— Stephen W. Porges

Polyvagal Theory provides a new lens for understanding how listening is linked to autonomic state. Porges and Lewis (2010) explain how mammals developed a unique perceptual advantage in listening, made possible by middle ear structures that improve the perception of human voice against background sounds. Because the neural regulation of the middle ear muscles and heart are linked through the social engagement system, prosodic vocal sounds (and similarly, middle-frequency music) help calm physiological state and prompt social behaviors. This work is informed by Borg and Counter (1989), who describe how the function and pathways of the middle ear muscles support unique mammalian abilities in sound perception and attenuation. The regulating qualities of prosodic human voice were similarly demonstrated in work by Kolacz and colleagues (2021), who found that strong middle frequencies, reduced high frequencies, and fluctuations in intonation predicted decreases in infant distress and improvement in infants' autonomic regulation. Non-vocal music has been shown to have similar effects, including promoting emotional bonding and significantly reducing the severity of PTSD in mothers of premature infants in the NICU (Pourmovahed et al., 2021).

The SSP is a practical application of Polyvagal Theory, which prioritizes the modulation (i.e., prosody) of middle frequencies in the range of human voice, gradually entraining and exercising the associated neural network to better perceive human speech and especial vocal cues of safety. This improved neuroceptive capacity can help reduce auditory hypersensitivity, increase social behaviors and enhance autonomic regulation, especially when paired with co-regulation and regulating activities.

The ILS centers the importance of connection and relationship in facilitating change. The movement activities that pair with ILS listening are designed to incorporate a peer or caregiver, centering the guiding principle of “join with joy” — knowing that play, in the context of a meaningful relationship, supports holistic neural organization and integration, and increases interest, motivation and engagement.

The dynamically modulated tempo patterns in RRP are carefully tuned to entrain physiological rhythms engaging both the dorsal and ventral vagal complexes. By synchronizing sound with the body's natural rhythms (e.g., breathing, blood pressure), RRP enhances parasympathetic activation, helping users move into a more restful state in which the brain and the body form a more coherent state of co-regulation. RRP promotes a sense of safety, relaxation and connection without recruiting the motor behaviors related to social engagement. For users who may be stuck in a state of dorsal vagal activation, characterized by shutdown or immobilization, the subtle rhythmic entrainment of RRP can help guide the system into immobilization without fear, designed to gently re-engage the body's endogenous visceral rhythms, restoring energy and alleviating feelings of dissociation or overwhelm.

## Neuroplasticity

As we have learned through the culminating literature on the brain and nervous system, there are many neural capacities evoked in music-based interventions, including the ability of the brain to change in response to stimulation, known as neuroplasticity.

The ILS is based on this principle, and provides gentle and specific stimulation to activate the neural pathways used in the processing of sensory information. Neural connections in these pathways are strengthened and new connections are established through repeated sessions of multisensory input, allowing the nervous system to adapt and find safety more quickly and easily. Just as with physical activity, specific, simultaneous and repeated multisensory stimulation gradually trains the brain and body to process and respond to multisensory input more effectively through better organization, leading to improved function in the world. The ILS programs are 20-60 hours each, and informed by the qualities of specificity, repetition, intensity, time and salience essential to neuroplastic change (Kleim & Jones, 2008).

The SSP gradually and dynamically re-trains the auditory processing system to better perceive and attend to calming, middle frequencies through dynamic, progressive filtration. While this process is designed to have immediate effects on autonomic state, neuroplastic changes can also occur as the individual integrates their memories and visceral feelings with top-down processes. Each SSP program includes five hours of music and three pathways with varying levels of intensity, which can be used to customize delivery on an ongoing basis for lasting change.

Similarly, RRP is designed to guide the listener through a unique sound journey, enabling their brain and body to passively shift into a healing nervous system state. As the acoustic parameters become more complex across the five hours, RRP cultivates re-attunement and easier access to new neural pathways. Listeners can return to supportive segments at any time, to remind their system how to find ease and rest in homeostasis.

## Therapeutic Relationship and Process

Further research on music-based interventions highlights the importance of therapeutic relationships and the process of delivery beyond the music itself.

Ribeiro et al. (2018) emphasize the importance of the therapeutic process of delivery on outcomes, including thoughtful selection of music, considering preference, quiet reflection and verbal processing, leading to improvements in autonomic regulation, lower anxiety and depression in

mothers of preterm infants. Pohl and colleagues (2013) similarly describe the role of the skilled therapist in promoting change through music. Baker et al., (2018) further attribute significant reductions in symptoms of PTSD to the ongoing presence of a skilled therapist, compared to groups with little involvement or absence of a therapist. Citing Polyvagal Theory and the importance of felt safety, Rudstam et al. (2022) describe a trauma-focused group music program that centered processing and expression. Group members reported increased interpersonal safety and connection with feelings and bodily sensations, in addition to an experience of expansion, relaxation and new energy. These reports were in parallel with significant improvements in PTSD dissociation, anxiety and depression.

Unyte listening therapies center the therapeutic relationship, supported by a thorough and ongoing education process that requires certification for delivery. This ensures that skilled providers are equipped with essential knowledge and training about how music affects the brain and body, alongside development of evidence-based practices for integrating listening therapies across disciplines, modalities, populations and practice settings.



## The Evidence

Together, clinical trials and real-world evidence create a powerful and holistic evidence base for Unyte programs.

### Clinical Trials

Unyte programs are supported by a growing body of evidence, including high-quality clinical trials published in peer-reviewed journals.

### The Safe and Sound Protocol (SSP)

Research on the SSP has demonstrated significant improvements in social engagement and behaviors, autonomic regulation, sensory processing, and mental health, including reduced symptoms of anxiety and depression.



In two sequential, randomized controlled trials with parallel control groups, children with autism demonstrated significant improvements in hearing sensitivity, spontaneous speech, listening and behavioral organization following the SSP, with benefits in hearing sensitivity and emotional control sustaining in the second trial comparing the SSP to unfiltered music (Porges et al., 2014). Another study exploring neural mechanisms of the social engagement system found that children with autism who experienced the SSP demonstrated significant improvements on the filtered words and competing words subscales of the SCAN-3 test, a measure of receptive language, ability to decipher human voice from background sounds, and dichotic listening (both ears). Following the SSP, scores of the group with autism were no longer different from typical peers in the control group. Further, the resting respiratory sinus arrhythmia (RSA) increased in the autism group after the SSP, demonstrating improved autonomic regulation (Porges et al., 2013).

A single-subject case study describing the delivery of the SSP to a 20-month-old girl with autism found significant differences within the categories of language, facial expression, listening and processing, emotional regulation, and behavior. During the post-three-month phase, the mother reported that her child demonstrated better listening, social referencing, and turning and smiling in response to her name (Squillace et al., 2022). Further, an exploratory pilot study delivering the SSP to adults with autism through a hybrid model (at home and within an outpatient clinic) showed significant improvements in social awareness (Kawai et al., 2023).

Another case study, published in the Harvard Review of Psychiatry, found that the SSP led to meaningful improvements in a 10-year-old girl with Functional Neurological Disorder who was unresponsive to standard interventions. The participant presented with significant challenges, including unsteady gait, blurry vision, periods of confusion, headache, back pain, nausea, functional seizures, suicidal ideation and difficulty with swallowing. These symptoms persisted during hospitalization within an intensive Mind-Body Program. As she participated in the SSP, her capacity for communication, social behaviors and physical movement improved significantly, as she returned to walking, climbing and playing. Her breathing slowed and catastrophic thoughts settled, and she was able to return to school. Further, her functional seizures were reduced, and she and her parents were able to identify early warning signs and implement aversion strategies. During follow-ups two months and again a year and a half later, these benefits, alongside her sense of well-being, were sustained (Rajabalee et al., 2022). In a case report of an adult woman with depression, Burns (2023) reported that depression symptoms significantly improved after a combination of body techniques and the SSP.

Improvements in sensory processing functions are further demonstrated in two studies. In a prospective single-arm study, Heilman and colleagues (2023) found significant improvements in auditory, tactile and visual processing, alongside digestive function and selective eating in children and adults with autism following the SSP. Kyuchukov and Ackermann (2023) evaluated whether the

reduction in hypersensitivities observed by Heilman and colleagues (2023) was mediated by the participants' language ability. They categorized participants into groups based on language skills, and analyzed their scores on the Brain-Body Center Sensory Scales (BBCSS) before and after SSP. While language ability was not related to baseline hypersensitivity levels, the effectiveness of the SSP in reducing auditory and tactile hypersensitivities was moderated by language ability. Participants with age-appropriate language skills had the greatest improvements, while those with limited or no verbal skills exhibited a high correlation between pre/post-SSP tactile and auditory hypersensitivity levels, demonstrating a more predictive response dependent on initial pre-SSP levels.

A recent publication by Grooten-Bresser, et al. (2024), found that speech therapy clients with breathing, voice and throat complaints presented with higher scores of autonomic reactivity, associated with lower parasympathetic activity and less nervous system adaptation in response to challenge, compared to control participants. A subgroup of 33 clients with self-reported voice, throat, and/or respiratory complaints demonstrated a significant decrease in anxiety, depression, and autonomic reactivity after completing the SSP. These findings help us understand the neurophysiological mechanisms that may underlie medically unexplained oto-rhino-laryngeal symptoms, and the potential impact of interventions that target the social engagement system.

As a non-invasive listening therapy, the SSP is very low-risk, especially compared to VNS devices or pharmaceutical interventions. Notably, no adverse events have been reported by participants in any of the clinical trials. In one study, SSP participants reported mild, temporary side effects, including headache, sleeplessness and fatigue, which did not limit or disrupt program completion (Kawai et al., 2023).

### Clinical Trials on the Safe and Sound Protocol (SSP) have demonstrated significant improvements in the following areas:



#### Social Engagement

- Spontaneous speech
- Listening skills
- Behavioral organization
- Receptive language
- Social communication
- Social awareness



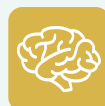
#### Sensory Processing

- Hearing sensitivities
- Visual sensitivities
- Tactile sensitivities
- Selective eating
- Digestion
- Physical movement



#### Autonomic State Regulation

- Vagal tone
- Heart Rate Variability (HRV)
- Emotional regulation
- Emotional control



#### Mental Health

- Stress
- Depression
- Anxiety

## The Integrated Listening System (ILS)

The results of data collected on the ILS have found improvements in social engagement, autonomic regulation, mental health and functional skills.

In a pilot study exploring the effects of the ILS on individualized parent goals for children with sensory processing impairments, Schoen et al. (2015) facilitated a single-subject, nonconcurrent, multiple-baseline, repeated-measures across-subjects AB design with seven children. Following participation in the ILS Sensory Motor Program, alongside visual motor, child-selected, and creative and/or relaxing activities, participants demonstrated significant improvements in progress toward goals, arousal and behavior:

- 23 out of 28 goals demonstrated a positive change, which was sustained or improved;
- 4 of the 7 participants had a reduction in arousal, with 3 of 7 demonstrating changes in arousal in response to sensory challenges;
- Improvement across all scores and subtests of the Adaptive Behavior Assessment System (ABAS) were reported, with statistically significant changes in “Communication” and “Self-care,” and significant changes in Externalizing, Internalizing, Behavioral Symptoms Index;
- Further improvements on the Behavior Assessment System for Children (BASC) were reported, including in Hyperactivity, Aggression, Anxiety, Depression, Atypicality, Adaptability, and Activities of Daily Living.
- Parents reported functional gains, including:
  - “His reading scores came up 4 levels.”
  - “Her face seems more animated.”
  - “She is able to joke with others.”
  - “He sleeps better.”
  - “He picks up on sarcasm more quickly.”
  - “He is happier at school.”
  - “The legibility of her handwriting improved.”
  - “His behavior in school is better.”

Another study exploring the effects of the ILS on individualized parent goals for children with sensory processing impairments found improvements in attention and auditory processing. Children with autism received combined ILS and sensory integration (SI) therapy with the following results:

- Pre-testing, 0 of the 29 children had intact vestibular processing skills; post-testing, all 29 were within normal limits.

- Pre-testing, 28 of the 29 children demonstrated ocular-motor deficits in the areas of visual pursuits, saccades and convergence/divergence skills; post-intervention, 25 of the 29 demonstrated intact ocular motor skills
- Post-intervention, 22 of the 29 children had auditory processing skills within normal limits
- Pre-testing, 7 of the 29 children began this therapy on medication for attentional concerns; post-testing, the medications for all seven had all been discontinued.

Further, the authors administered the Auditory Brainstem Response (ABR), an electrophysiological test similar to an EEG that measures neural integrity and shows if the ears are coordinated well at the brainstem. Pre-intervention, 29 children had little difference between listening with one ear and listening with both ears (binaural summation). Post-intervention, all 29 tested in the normal range. Co-author Dr. Weiner reported, “I have been looking at auditory processing disorders now for 28 years and, until recently, I have never seen auditory processing skills really get better ... I’ve watched children come in with auditory processing problems and leave without them (Harper & Weiner, 2010).”

Practitioners' perspectives on the impact of the ILS on children with autism are well documented in a survey conducted by Teresa May-Benson, ScD, OTR/L, and Alison Teasdale at “The Spiral Foundation” on March 15, 2012. Of 144 responses, 70-80% of responses were in the “Often” and “Always” range regarding the effectiveness of the ILS, with the most frequent changes seen in motor coordination, sensory integration/sensory processing, auditory processing self-regulation, and the ability to make transitions.

### The results of data collected on the Integrating Listening System (ILS) have found improvements in the following areas:



#### Social Engagement

- Social behaviors
- Communication
- Anxiety and depression



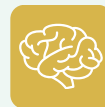
#### Autonomic State Regulation

- Reduction in arousal, measured by electrodermal activity
- Hyperactivity



#### Sensory Processing

- Vestibular processing
- Oculomotor skills
- Auditory processing
- Binaural summation (listening with both ears)



#### Functional Skills

- Self Care
- Internalizing and externalizing behaviors
- Adaptability
- Activities of Daily Living (ADL)
- Language and academic skills

Rest and Restore Protocol (RRP)

As a newly developed listening therapy, research on the impact and efficacy of RRP has just begun. Unyte Health conducted preliminary testing on the RRP with a group of highly skilled and experienced providers between January - October 2024.

A pilot group (n=110) was administered standardized assessments before and after listening to Rest and Restore Protocol™ (RRP). The most prominent effects were observed in measures of anxiety (GAD-7), sleep (AIS), trauma symptoms (PCL-5), and depression (PHQ-9), with the majority of clients reporting improvements on all measures.

In addition, gastrointestinal improvements with RRP were reported consistently by participants, with these findings supported by improvements in the digestive problems subscale on the Brain-Body Center Sensory Scales (BBCSS).

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In the pilot group, 68 clients reported significant symptoms of insomnia on the AIS before starting the RRP program.

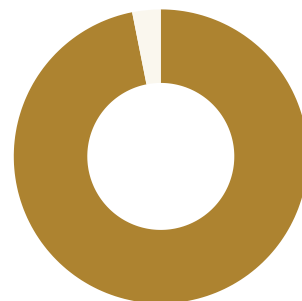
- Following completion of at least 1 hour of RRP:
- 76% experienced an improvement in symptoms.
  - 44% moved from a clinical level to a non-clinical level (score less than 6).
  - The average score on the AIS decreased from 10 to 6; an average decrease of 4 points.



In the pilot group, 27 clients reported significant symptoms of anxiety on the GAD-7 before starting the RRP program.

Following completion of at least 1 hour of RRP:

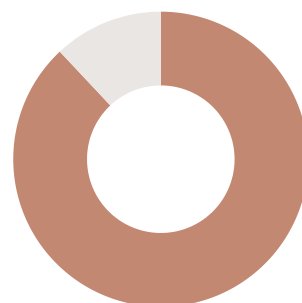
- 93% experienced an improvement in symptoms.
- 67% moved from a clinical level to a non-clinical level (score less than 10).
- The average score on the GAD-7 decreased from 14 to 8; an average decrease of 6 points.



In the pilot group, 25 clients reported significant trauma-related symptoms on the PCL-5 before starting the RRP program.

Following completion of at least 1 hour of RRP:

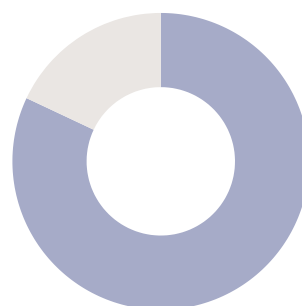
- 88% experienced an improvement in symptoms.
- 72% moved from a clinical level to a non-clinical level (score less than 30).
- The average score on the PCL-5 decreased from 41 to 25; an average decrease of 16 points.



In the pilot group, 22 clients reported significant symptoms of depression on the PHQ-9 before starting the RRP program.

Following completion of at least 1 hour of RRP:

- 82% experienced an improvement in symptoms.
- 68% moved from a clinical level to a non-clinical level (score less than 10).
- The average score on the PHQ-9 decreased from 15 to 9; an average decrease of 6 points.



Stay tuned for more information by visiting <https://learn.unyte.com/restandrestore>.



## Real-World Evidence

Real-world evidence (RWE) relies on health data from sources outside of clinical research settings, including electronic records, registries and technology products, including personal devices and applications. This data can be used to better understand the safety and efficacy of health-related products and services (Sherman et al., 2016).

As compared to traditional clinical trials, real-world evidence has unique benefits and limitations.

### Real-World Evidence

- Settings are more representative of how people behave in the real world
- Limits bias through very large sample sizes, transparency in reporting, and acknowledgment of mediating variables
- Generates larger data sets more quickly
- Easier to generalize to diverse populations
- Can contribute to and/or inform clinical trials and professional use

### Clinical Trials

- Account for natural variation through highly controlled environments and procedures
- Limits bias and chance by controlling variables and narrowing eligibility criteria
- Longer timelines for completion
- More difficult to generalize beyond study population
- Can include and/or be informed by real-world data

The real-world evidence reported by Unyte Health has been collected by providers who administer third-party-developed, standardized assessments to their clients using the Unyte Assessments digital platform. All reported data is de-identified (does not contain PHI) and only reported in aggregate. Consistent with best practices for real-world evidence generation, these reports do not control for other therapies, medications or contextual variables that may influence outcomes. These data are representative of real-world settings.\*

In addition to real-world data from standardized assessment tools, Unyte hosts a database of provider-submitted case studies that describe the context of delivery and related outcomes following the completion of Unyte products across a wide range of disciplines, modalities, client presentations and settings. As the clinical trial evidence for Unyte products continues to grow, case studies provide important insight into the unique factors of delivery across diverse populations, creating a foundation for further research and informing the development of practice guidelines and resources while shedding light on aggregated data reports.

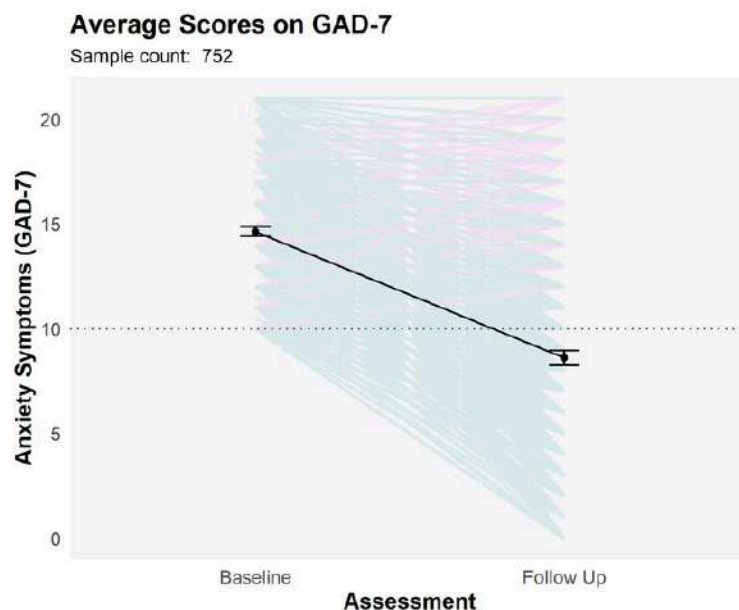
Publication date: 6 Dec 2024

## Many clients who experience the SSP report fewer symptoms of anxiety.

In a real-world data sample, 752 clients reported at least moderate anxiety symptoms on the GAD-7 before starting the SSP Core program.

Following completion of five hours of SSP Core:

- 85% of clients experienced a score improvement.
- 63% of clients moved from clinical to non-clinical level (score less than 10).
- The average score on the GAD-7 decreased from 14.6 (high severity) to 8.6 (mild severity), an average reduction of 6.0 points.



85%

of clients experienced a score improvement

6.0

point improvement in symptoms of anxiety

### **Case study: Client's severe anxiety declines in only a few months with the SSP**

"During the SSP process, it provided me with a safe place. I was constantly looking forward to the next session for the peace and quiet it brought me. After completing the protocol, I had tools to bring myself back into my safe place, and it really helped me with my anxiety issues."

Sophie's score went from a 17/21 (severe anxiety) to a 4/21 (normal range) following the SSP Core.

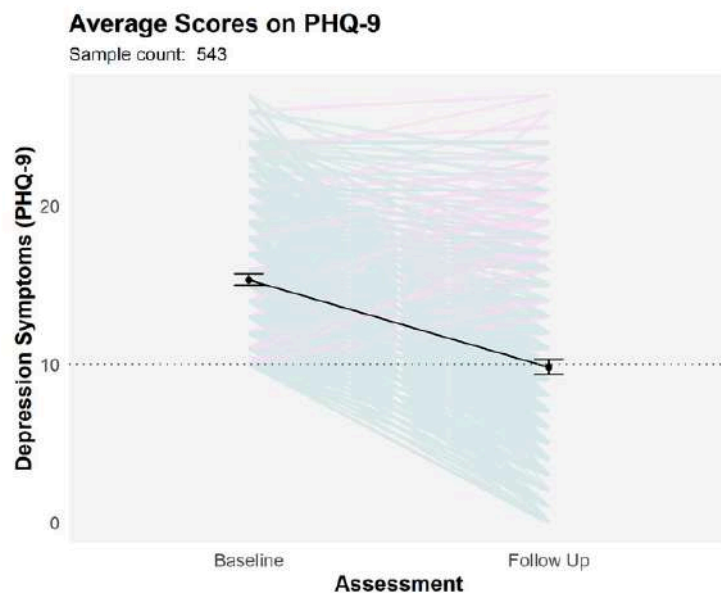
Publication date: 6 Dec 2024

## Many clients who experience the SSP report fewer symptoms of depression.

In a real-world data sample, 543 clients reported at least moderate depression symptoms on the PHQ-9 before starting the SSP Core program.

Following completion of five hours of SSP Core:

- 81% of clients experienced a score improvement.
- 53% of clients moved from clinical to non-clinical level (score less than 10).
- The average score on the PHQ-9 decreased from 15.3 (high severity) to 9.8 (mild severity), an average decrease of 5.5 points.



81%

of clients experienced a score improvement

5.5

point improvement in symptoms of depression

### **Case study: SSP supports woman in achieving a ventral state after 31 years of depression**

At hour two of listening, Jill realized she was waking up without the feeling of dread. She was in tears as she shared this news with her provider, and could not believe how quickly the change happened. During the same time, her motivation to move and accomplish tasks began to increase. Jill has historically been a very poor sleeper, but by the first hour of listening, she began to sleep deeply. Jill explained that her lingering depression just “slid away.” She began to notice and feel that she was in a ventral state for the first time in decades, possibly for the first time in her whole life.

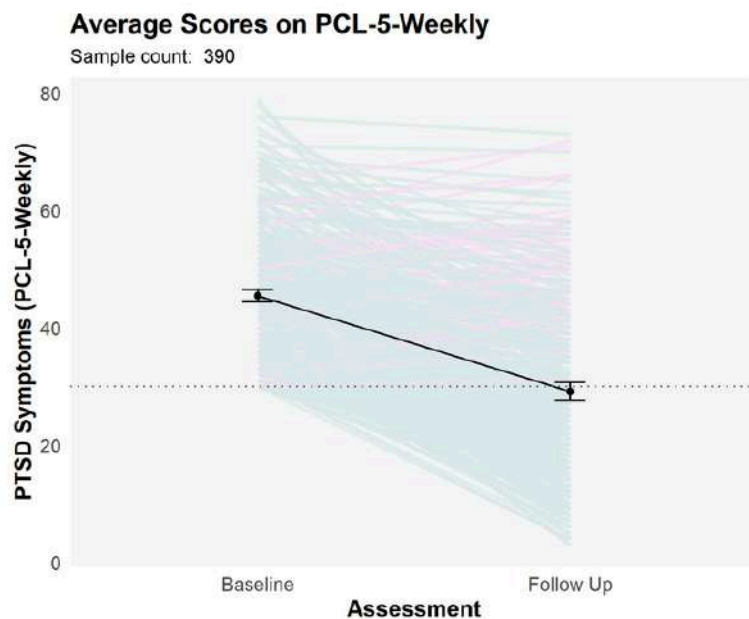
Publication date: 6 Dec 2024

## Many clients who experience the SSP report fewer trauma-related symptoms.

In a real-world data sample, 390 clients reported at least moderate trauma-related symptoms before starting the SSP Core program.

Following completion of five hours of SSP Core:

- 87% of clients experienced a score improvement.
- 57% of clients moved from clinical to non-clinical level (score less than 30).
- The average score on the PCL-5 decreased from 45.4 (severe) to 29.2 (moderate), a 16.3 point improvement in symptoms.



87%

of clients experienced a score improvement

16.3

point improvement in trauma-related symptoms

### **Case study: Using the SSP as part of holistic treatment for childhood trauma**

Lucy was living with her biological parents after years of drug use, homelessness, domestic violence, and having to put a child up for adoption. Following the SSP, Lucy reports feeling able to advocate for herself at work, take walks or meditate in her car instead of working through her breaks. She has purchased a condo and has communicated effectively with her parents about her plans to live on her own, including plans to maintain her sobriety. Lucy also began dating again, after having abstained from romantic relationships since she left her life of drug use. Lucy's PCL-5 scores went from 26 (severe) to 14 (moderate).

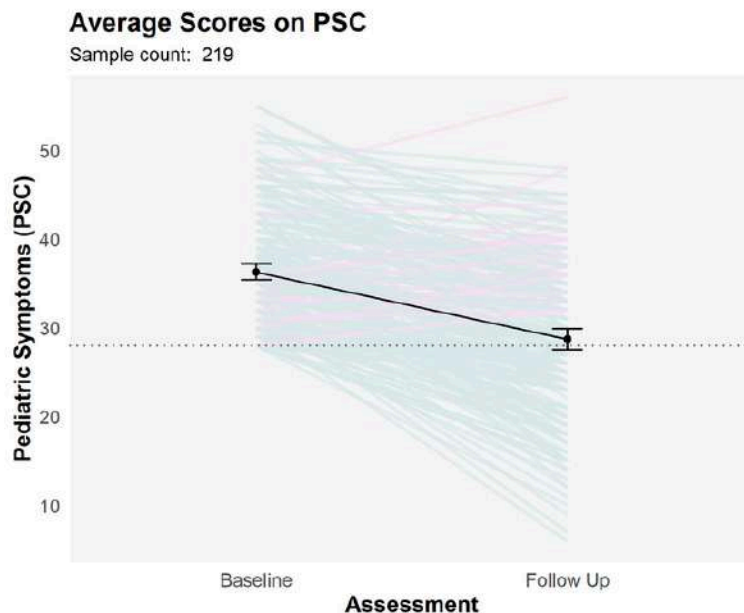
Publication date: 6 Dec 2024

## Caregivers of children who experience the SSP report fewer psychosocial challenges.

In a real-world data sample, caregivers of 219 children reported at least some challenges with psychosocial functioning before starting the SSP Core program.

Following completion of five hours of SSP Core:

- 84% of clients experienced a score improvement.
- 47% of clients moved from “impaired” to “not impaired” category (score less than 28).
- The average score on the PSC decreased from 36.3 to 28.7, a 7.6 point improvement in psychosocial challenges.



84%

of clients experienced a score improvement

7.6

point improvement in psychosocial challenges

**Case study: SSP supports social-emotional learning goals for special education students, ages 6 to 12 (group study consisting of 10 children in a school setting)**

In the case of a 6-year-old boy with autism: He was unable to use an unfamiliar restroom, eat with his peers and was rigid in group play. Post-SSP, [his provider] reports he “became able to eat in proximity [to] peers and use [an] unfamiliar restroom with shaping.” He started reading joke books for fun while eating lunch and improved his peer-to-peer play with negotiation.



Summary

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Paired t-tests were conducted to compare the pre-program and post-program assessment scores. The results indicated a statistically significant improvement in scores after the intervention, with a p-value < 0.001.

Research in Progress

Building upon the foundational evidence on how music affects the brain, body and nervous system, the research on Unyte programs continues to develop and unfold.

There are developing studies on adults with PTSD, chronic pain, breast cancer, ADD, depression and anxiety, older adults with Parkinson’s disease, young adults and adolescents with Ehler-Danlos syndrome (EDS), and children with a history of trauma, anxiety and Autism.

A study measuring the impact of the SSP on auditory hypersensitivity, autonomic state regulation, auditory processing, social behavior and middle ear muscle transfer function in children with trauma history is completing data analysis, with promising early results. Further, a study looking at the impact of the SSP on developmental function in an early intervention setting has completed its initial phase, with plans to publish and expand the study in 2024.

Summary

The potential impact of music and sound in the world of therapy and wellness is quickly gaining traction. Unyte looks forward to contributing to the scientific and clinical expertise of listening therapies as a thought leader and collaborator, ultimately fulfilling our purpose to transform the lives of children and adults every day through empowering therapists, educators, clinicians and health care providers to guide their clients to feel, think and connect better through improved nervous system regulation.



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GAD-7 © Pfizer Inc. all rights reserved; used with permission.

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PHQ9 Copyright © Pfizer Inc. All rights reserved. Reproduced with permission.

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This measure was developed by staff at VA's National Center for PTSD and is in the public domain and not copyrighted.

*\*The reported data have not been evaluated by the FDA, and the products and services are not intended to diagnose, treat, cure, or prevent any disease. Unyte products are not medical devices or medical instruments. It is solely the responsibility of each user (whether a professional user or personal user) to determine whether the products and/or services may be beneficial for their patients/clients or themselves.*

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