



unyte

Evidence Summary

August 2023

An Integrated Approach

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

Clinical Trials

Best for developing safety and efficacy evidence, often with specific populations and environments that are different from the realities of the clinic or home; undergoes ethics board review and peer-review publication process.

Led by independent researchers, Unyte supports clinical trials development through connection to clinical partners, complimentary product access, and research support services (i.e. data analysis, coordination, and protocol design).

Real World Evidence

Real world evidence is derived from sources outside clinical research settings, including electronic health records, product registries, personal devices and health applications.

Real world evidence includes data collected through Unyte Assessments results, demographic information, provider profiles, case consultations, case studies, provider surveys, and other information systems.



Clinical Trials



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

3, 5, 8, 10



Autonomic State Regulation

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

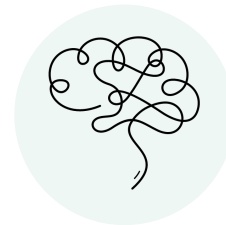
5, 6, 8, 10



Sensory Processing

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

2, 5, 8



Mental Health

- Stress
- Depression
- Anxiety

1, 8

Reducing auditory hypersensitivities in autistic spectrum disorder: preliminary findings evaluating the listening project protocol

BACKGROUND

*Safe and Sound Protocol (SSP)

- Designed to reduce auditory hypersensitivities by applying computer altered vocal music (i.e., filtered music) to exaggerate the features of human prosody
- Metaphorical “treadmill” to exercise the middle ear muscles and promote social engagement system/parasympathetic nervous system activity

Guiding principles

1. The role of the neural network associated with listening in extracting the frequencies of human voice from background noise
2. Evolution of the brainstem influence neural regulation of the striated muscles of the face, head, and middle ear muscles (Polyvagal Theory)

*Previously the Listening Project Protocol (LPP)

METHOD

Design

Two sequential randomized controlled trials with parallel control groups

Participants (N=156)

Children with ASD or who met criteria on subscales of the ADI-R/DSM-IV

Conditions

- Supportive play,
- 45-minutes, 5 consecutive days
- Parents blind to the intervention
- Circumaural headphones

Trial I

Filtered Music (n=36)

Headphones only (n=28)

Trial II

Filtered music (n=50)

Unfiltered music (n=32)

Assessments

Structured Behavioral Questionnaire

Parents report changes on hearing sensitivity, affect, eye contact, behavioral organization, emotional control, spontaneous speech, receptive speech, listening, spontaneity, relatedness

Play-based assessment (video-taped)

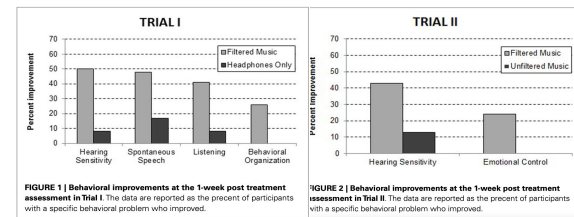
Social interaction coding scale (SICS)

RESULTS

Play-based assessment (video-taped)

Participants with improvement on hearing sensitivity following the intervention (n = 14) also demonstrated increase in sharing behaviors

Structured Behavioral Questionnaire



Trial I: Significant improvements in **hearing sensitivity, spontaneous speech, listening, and behavioral organization**

Trial II: Significant improvements in **hearing sensitivity and emotional control**

Respiratory sinus arrhythmia and auditory processing in autism: modifiable deficits of an integrated social engagement system?

BACKGROUND

Features of the Social Engagement System commonly impaired in ASD:

- Eye contact
- facial expression/gestures
- vocal prosody
- Sensory processing differences

Difficulty with state regulation and auditory processing is observed in other conditions:

- fragile X syndrome
- attention deficit disorder (ADD)
- post-traumatic stress disorder (PTSD)
- anxiety disorders

What is the common neural mechanism?

Respiratory Sinus Arrhythmia (RSA)



HIGH resting RSA

- Adaptive autonomic response
- **Parasympathetic activation (vagal brake)**

LOW resting RSA

- Maladaptive autonomic response
- **Sympathetic activation**

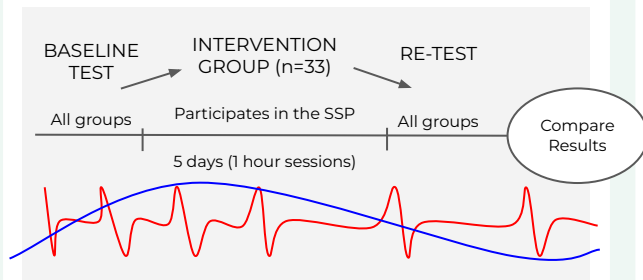
METHOD

Participants

- **Intervention group (n=33)** children with ASD ages 6 - 21 (8 female)
- **Control group (n=49)** children ages 6 - 21 (9 female)

Assessments

- **SCAN test** — receptive language; Ability to decipher human voice from background sounds
Dichotic listening (both ears)
- **Heart Period and RSA** — Measure of autonomic state using Electrocardiogram (ECG)



RESULTS

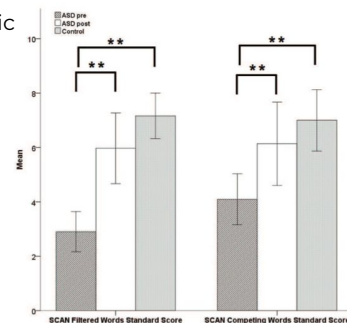
SCAN test

- Significant improvements in the ASD intervention group, pre-post
- ASD intervention group post intervention: scores not longer different from the control group

Heart Rate and RSA

Resting RSA **lower at baseline** in the ASD Group
Resting RSA **increased** in the ASD group after the SSP

Adaptive autonomic response:
Parasympathetic/SES (vagal brake engaged)



Social Outcomes of a Child with Autism Spectrum Disorder (ASD) Following a Listening Protocol

BACKGROUND

Children with ASD who present with sensory processing disturbances may present with impairments in self-regulation which are manifested in maladaptive responses to various sensory inputs.

METHODS

Single-subject ABAB design examining the effectiveness of the SSP© integrated listening program on a child diagnosed with autism spectrum disorder.

CASE HISTORY

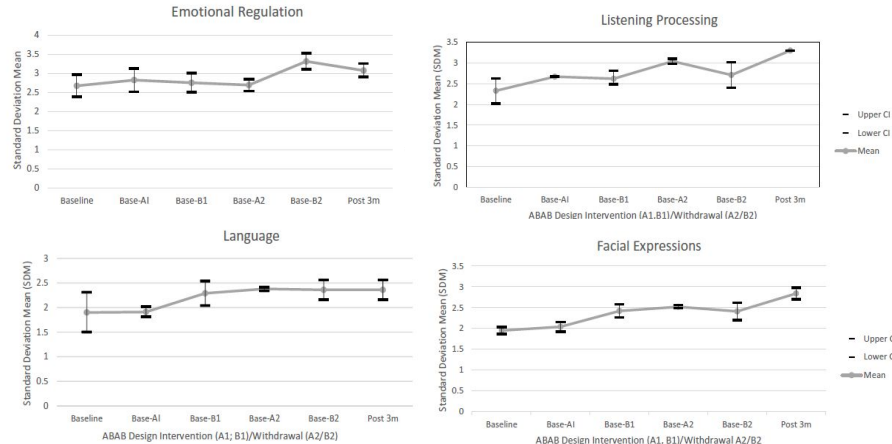
Case: Sydney, a **20-month-old girl with moderate ASD**, presenting with limited social engagement, overactivity, hypersensitivities, and decreased state regulation resulting in behavioral reactivity to certain stimulations, and sensory seeking behaviors.

INTERVENTION

Following the initial screening, the OT visited Sydney to fit her with the SSP© headphones, complete an environmental evaluation. The parent was instructed to **deliver the SSP for 10 days for 30 min per day**. Sydney was situated in a specific quiet room. The parent was permitted to comfort the child by allowing the child to sit on their lap or engage in simple activities that make the child happy and comfortable, and provide reassurance through touch and facial expressions as needed.

RESULTS

The results of this study show a range of significant differences within the categories of **language, facial expression, listening and processing, emotional regulation, and behavior**. Strong associations between the intervention and responses were found within all categories and phases of the study using the Cramer's V method. During the post-three-month phase, the mother of the child reported that her child was demonstrating better listening, social referencing, and turning and smiling in response to her name.



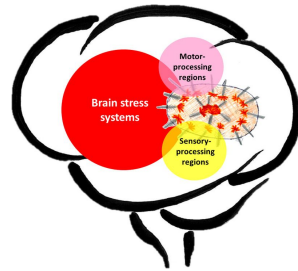
Neuromodulation Using Computer-Altered Music to Treat a Ten-Year-Old Child Unresponsive to Standard Interventions for Functional Neurological Disorder

CASE HISTORY

Case: MT, a **10-year-old girl with Functional Neurological Disorder (FND)**: a neurological-somatic condition with an unknown cause. There is disconnection between the brain and body due to disruption in the sending and receiving of signals related to memory, concentration, emotions, cognition and motor functions. FND is often triggered by bio-psycho-social factors, including childhood trauma, interpersonal stress or illness (NINDS, 2022).

Symptom Presentation:

- unsteady gait
- blurry vision
- periods of confusion
- a persisting headache
- back pain
- nausea
- difficulty swallowing



Following a formal diagnosis of FND, she was admitted to the intensive Mind-Body Program at the hospital, which included physical, psychological, pharmacological and family therapy.

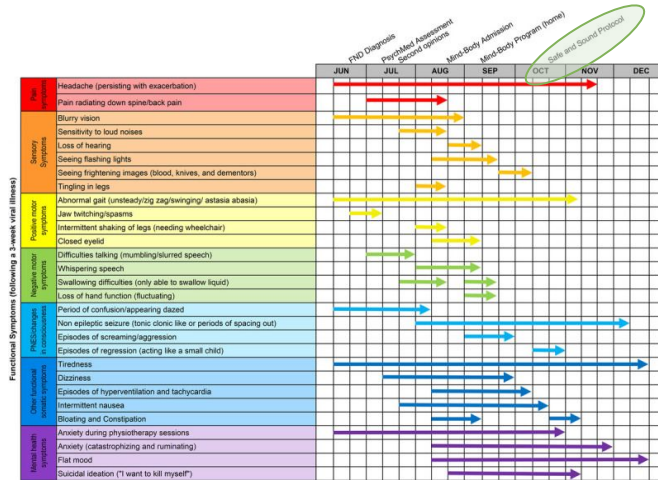
MT struggled to participate in the program, and rumination on her pain grew to catastrophizing and suicidal ideation. MT particularly struggled with cognitive, or “top-down” therapies, which directed the team to prioritize physiological, “bottom-up” and passive regulatory therapies — including the SSP.

INTERVENTION

The SSP was delivered in nine listening sessions over six weeks, starting with 15-minute sessions and building up to 30 minutes.

RESULTS

As she participated in the SSP, her capacity for communication, social behaviors and physical movement improved significantly, returning to walking, climbing and play. Her breathing slowed and catastrophic thoughts settled.



Assessment scores on **anxiety, depression, stress** and the Body Perception Questionnaire (BPQ) returned to “normal” levels.

In follow-ups two months, then a year and a half later, **MT had retained these benefits and her sense of well-being.**

Effects of the Safe and Sound Protocol™ (SSP) on Sensory Processing, Digestive Function and Selective Eating in Children and Adults with Autism: A Prospective Single-Arm Study

BACKGROUND

Because of the interaction between sensory experiences, autonomic state and GI function, this study aimed to assess the effectiveness of the SSP on improving **sensory sensitivities, digestive problems** and **selective eating** across various age groups.



METHOD

Design

Effectiveness study, prospective, single-arm

Participants (N=37)

Children and Adults with Autism Spectrum Disorder (ASD);
7 - 39 years

INTERVENTION

Delivery Model

In-person (clinic, school) and Remotely (home)

- 60-minutes, 5 consecutive days
- Gentle motivation by therapist, caregivers present
- Soft floor play, colouring opportunities, puzzles, quiet games, tactile sensory tools, clay, cards and space to move

Assessment

Brain Body Center Sensory Scales (BBCSS)

Baseline, 1-week and 4-week

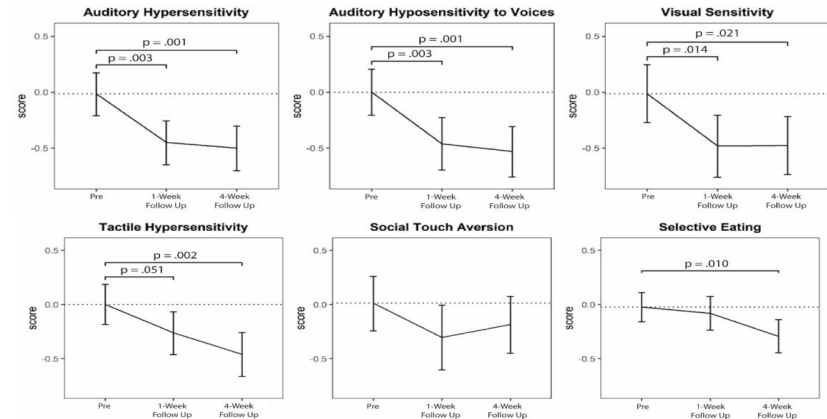
Subscales for Auditory Processing, Visual Processing, Tactile Processing (Touch), Ingestion and Digestion

RESULTS

Brain Body Center Sensory Scales (BBCSS)

Auditory hypersensitivities, auditory hypo-sensitivities to voices, visual sensitivity, and digestive problems all declined at the 1-week and 4-week follow-up assessments,

Tactile hypersensitivities and selective eating showed a significant decline at the 4-week follow-up assessment.



Initial Outcomes of the Safe and Sound Protocol on patients with adult autism Spectrum Disorder: Exploratory Pilot Study

BACKGROUND

Several studies on the SSP have found improvements in auditory function and social communication in children with ASD. This study evaluates the efficacy of **SSP in adults with ASD**, as well as its safety, feasibility, and applicability.

METHOD

Design

Exploratory Pilot Study

Participants (N=6)

Adults with Autism Spectrum Disorder (ASD);
21 – 44 years old

INTERVENTION

Delivery Model

In-person (clinic) and Remotely (home)

- 60-minutes, 5 consecutive days
- Day 1 and 5 in the outpatient clinic; Days 2 - 4 at home
- The participants were instructed on how to use SSP equipment.
- The practitioner helped the client feel safe and comfortable.

Assessment

Effects: **SRS-2 Family-Report**

Secondary outcomes:

Studies Depression Scale (CES-D)
State-Trait Anxiety Inventory (STAI)
WHO Quality of Life 26 (WHOQOL-BREF)
Adolescent/Adult Sensory Profile (A/ASP)

RESULTS

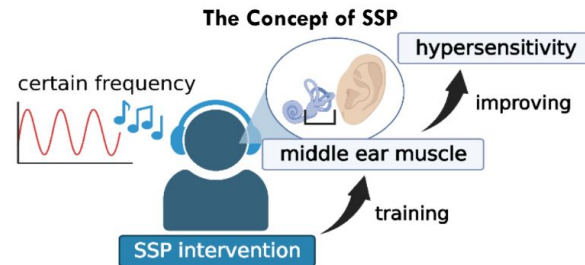
SRS-2 Family-Report

Social Awareness scale of the SRS-2 Family-Report showed a **significant improvement** after the SSP intervention.

SRS-2 Family Report	df	p Value	
		Before and After	Before and Endpoint
Social Awareness	16	0.596	0.027 *

Narrative reports from participants and family members:

- Emotional release leading to improvements in daily life
- Improved responsiveness
- Better sleep
- Increase in awareness and self-regulation of hypersensitivity
- Improved self control of vocal volume



The results of data collected on the Integrating Listening System (ILS) have found improvements in the following areas: ^{11, 12, 13}



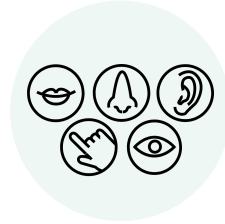
Social Engagement

- 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

A Pilot Study of Integrated Listening Systems for Children With Sensory Processing Problems

BACKGROUND

This study explores the effects of ILS on individualized parent goals for children with sensory processing impairments.

METHOD

Design

single-subject, nonconcurrent, multiple-baseline, repeated-measures across-subjects, AB design

Participants (N=7)

Four males and three females ranging in age from 5 to 12 years with significant sensory processing challenges.

INTERVENTION

Sensory Motor Program (40-sessions), delivered 5 days a week for 60 min (1 day per week in-clinic, and 4-days per week at home).

Participation in visual motor activities during the first 15 to 20 minutes of each session, followed by child-selected motor activities; creative and/or relaxing activities.

RESULTS

Significant improvements in progress toward GOALS, AROUSAL, and BEHAVIOR.



Individual Goals (VAS): 23 of 28 goals demonstrated a positive change, which was sustained or improved.



Arousal (EDA): Three of seven participants had a reduction in EDA to 2 to 4 of the sensory challenges, both of which involved the two sound stimuli. Four of the seven participants had a reduction in EDA, and two had an increase.



Adaptive Behavior Assessment System (ABAS): Improvement across all scores and subtests, with statistically significant changes in 'Communication' and 'Self-care'.

Behavior Assessment System for Children (BASC): Significant changes in Externalizing, Internalizing, Behavioral Symptoms Index, and Adaptive Skills and 7 of 13 subtests, including Hyperactivity, Aggression, Anxiety, Depression, Atypicality, Adaptability, and Activities of Daily Living.

Gains reported by parents:

- “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”;
- and
- “His behavior in school is better.”

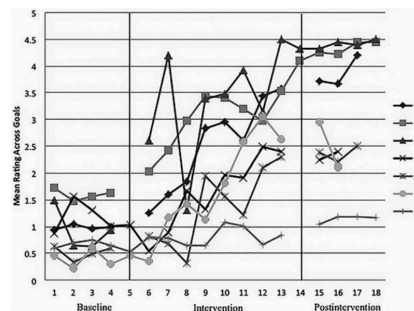


Figure 1. Individual mean goal performance across time.

Effectively addressing attention and auditory processing in school-age children

BACKGROUND

This study explores the effects of ILS on individualized parent goals for children with sensory processing impairments.

DESIGN

Participants (N=29)

Children with Auditory Processing Disorder (APD)

Combined therapy of sound and SI Occupational Therapy at the Therapeeds clinic in Florida.

The sound component was the receptive and expressive programs of ILS; The movement program was the H.O.P.E. sensory motor program developed by Julia Harper, OT, founder of Therapeeds.



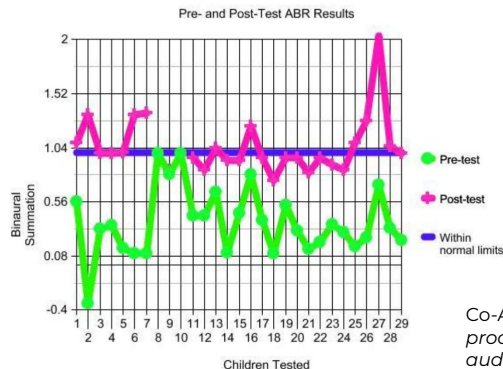
Parents and teachers reported improvements in social skills, language, improved grades in reading and math, with most of the kids showing definite improvement in reading comprehension.

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 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 29 children began this therapy on medication for attentional concerns. Post-testing, the medications for all 7 had all been discontinued.



Auditory Brainstem Response (ABR) is an electrophysiological test, similar to an EEG, which measures neural integrity, which 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.

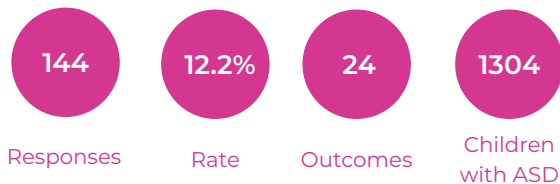
Co-Author Dr. Weiner's Comments: "I have been looking at auditory processing disorders now for 28 years, and until recently, I have never seen auditory processing skills really get better...I've watched children come in with auditory processing problems and leave without them."

Practitioner Survey on the Effectiveness of iLs Programs with Children with Autism Spectrum Disorder

BACKGROUND

This 19-question survey examined the perceived effectiveness of ILS for children 2 to 18 years with Autism Spectrum Disorder (ASD).

RESPONSES



Responses ranged from Never (1) to Always (5)

Three functional areas:

- Sensory motor/ behavioral skills
- Social-emotional skills and functioning
- Language/ academic skills.

RESULTS

All 24 outcomes had mean scores between 3.2 – 4.5 ('Sometimes' and 'Often' range).

Median scores were mostly 4's; Sensory integration/sensory processing were 5's; Digestion and self injurious behaviors were 3's;

There were very few 'Never' responses across the 24 outcome areas. In general **70-80% of responses were in the 'Often' and 'Always' range.**

The **most frequent changes** were seen in

- Motor coordination
- Sensory integration/sensory processing,
- Auditory processing
- Self-regulation
- Ability to make transitions

Notes on ILS Program Delivery:

- Most Providers deliver the iLs program in-clinic, or a combination of clinic and home programming.
- In-clinic delivery is often 3 times per week, up to 90 minutes of listening per session.
- In-home delivery is often 5-7 days per week, for 60-min sessions.
- Additional listening beyond an initial program often needed to see strong gains in higher level outcomes such as reading or writing.



*Respondents were overwhelmingly happy with the iLs program and were **very likely to recommend it to colleagues.***

How does this evidence translate?

Autism Spectrum Disorder (ASD) is a model condition for assessing the impact of the Unyte programs because features of the **Social Engagement System** are well represented, including:

- Social communication
- Eye contact, facial expression and gestures
- Vocal prosody and verbal communication
- Sensory processing differences (auditory sensitivity)
- Challenges with autonomic state regulation

These features are observed in many other conditions:

- Attention and learning differences
- Neurodevelopmental conditions and sensory processing differences
- Mental health conditions, like depression and anxiety
- Developmental and other trauma conditions
- Chronic pain, fatigue, and immunological conditions

Further research is underway to better understand the link between autonomic regulation and the impact of the SSP across various presentations.



Pilot Studies and Data Collection Projects

Medication and its Effect on
Safe & Sound Protocol
Therapy Outcomes in a
Pediatric Population

published

Cook, Victoria & Hunt, Doreen & Kolacz, Jacek. (2021). Medication and its Effect on Safe & Sound Protocol Therapy Outcomes in a Pediatric Population. Proceedings of IMPRS. 4. 10.18060/25904.

Effectiveness of the Safe and
Sound Protocol in Pediatric
Occupational Therapy
Patients

published

Alison Turner, M.A.
Applied Health Research
Eastern Health, T: 709-777-2945

Cindy Whitten, Ph.D.
Applied Health Research
Eastern Health, T: 709-777-7614

www.easternhealth.ca

Impact of a mentorship
program on self-reported
autonomic capacity and
implementation of the Safe
and Sound Protocol (SSP)

In-progress

Alecia Smith, LISW, tCADAC, PhD
Chief Program Officer
ASMITH@pamhc.org

A partnership with the National Council for Mental Health (NCMH) and Substance Abuse and Mental Health Services Administration (SAMHSA)

Developing Research



Adults with chronic pain

Single group design

Impact of the SSP on improving medically unexplained pain

Developing



Adults with Long-haul Covid

Data collection project

Impact of the SSP on body awareness and autonomic reactivity

Data collection



Adults with self-reported voice, throat, and breathing complaints

Single group design

Effects of SSP on self-reported autonomic function, anxiety, and depression

Under Review



Adults with depression and anxiety

Randomized Controlled Trial (RCT)

Impact of the SSP on reducing anxiety and depression symptoms

IRB Review



Adults with PTSD and anxiety

Experimental, non-randomized design

Impact of the SSP on improving symptoms of PTSD and anxiety, and physiological measures (HRV)

Data analysis

Developing Research



Older adults with Parkinson's Disease

Randomized Controlled Trial (RCT)

Comparing the effect of singing groups and the SSP on neuropsychological functioning, ADL, quality of life, body awareness and autonomic reactivity

Data collection



Young adults and adolescents with Ehler Danlos Syndrome (EDS)

Randomized Controlled Trial (RCT)

Impact of the SSP on improving autonomic regulation and gastrointestinal symptoms

Data collection



Children with trauma history

Non-randomized, parallel assignment

Impact of the SSP on auditory hypersensitivity, autonomic state regulation, auditory processing, social behavior, and middle ear muscle transfer function

Data analysis



Students with special needs in early intervention (0-5 years)

Multiple Case Study Design

Impact of the SSP on developmental function

Pending publication

Clinical Research Partnerships



Kids deserve the best.



**Brain Imaging and Neurostimulation
University of Mainz - GroppaLAB**





Real World Evidence

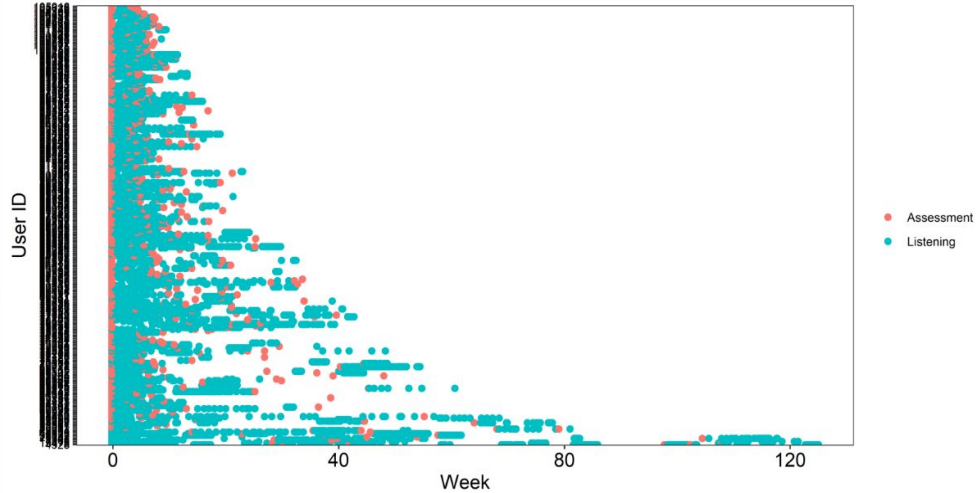
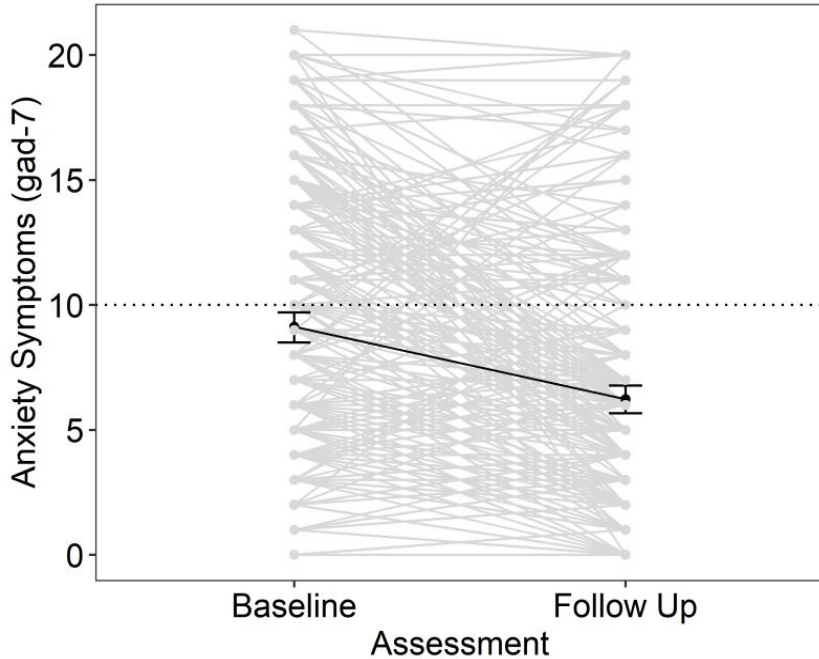


Real World Evidence: Preliminary Results

Preliminary results from Unyte Assessment results demonstrate **statistically significant** improvement across group averages in each assessment following completion of SSP Core.

BBC Child	140 Clients (each a pre/post program assessment, a total of 280 assessments) Average auditory hypersensitivity score has decreased from 2.10 to 1.79 (14.4%)
BBC Adult	283 Clients (each a pre/post program assessment, a total of 566 assessments) Average auditory hypersensitivity score has decreased from 2.24 to 2 (11%)
PHQ-9	207 Clients (each a pre/post program assessment, a total of 414 assessments) Average PHQ score has decreased from 8.78 to 6.82 (22.3%)
GAD-7	282 Clients (each a pre/post program assessment, a total of 564 assessments) Average GAD7 score has decreased from 9.13 to 6.23 (31.7%)
BPQ (AR)	219 Clients (each a pre/post program assessment, a total of 438 assessments) Average BPQ (AR) CRT score has decreased from 54 to 51.36 (5%)
PCL-5	90 Clients (each a pre/post program assessment, a total of 180 assessments) Average PCL total severity score has decreased from 28.73 to 19.51 (32%)

Real World Evidence: GAD-7, Preliminary Results

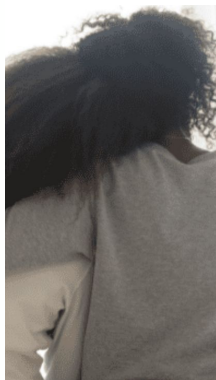


N = 282 Clients

Average score decrease from 9.13 to 6.23 **(31.7% symptom improvement)**

SSP Case Studies

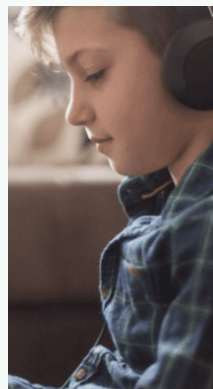
A full list of Case Studies can be found [here](#).



Discovering the Bonds of Connection

"AB has been demonstrating **less reactivity, fewer angry outbursts, more bids for connection with Mom, and better acceptance of co-regulation from parents.**

Mom is pleased with the results of the SSP and has stated that this is **better connection than she has experienced with AB throughout her life.**"



SSP and co-regulation from family helps 1st grader increase awareness and emotional regulation

"Two weeks after completing the five hours of SSP Core, Matthew's mother reported that his **handwriting had become much more legible**, and he could take his time to erase and form his letters more legibly. He began to seek out coloring on his own at home, an activity that he would previously avoid or show no interest in. He showed **improved frustration tolerance**; he was able to **remain calm and social with a peer.**"



Safe and Sound Protocol (SSP) reduces autistic boy's rigidity and chronic fight-or-flight

"Watching my client change has been special. Seeing **more curiosity and engagement** has brought joy to our OT sessions and a wider capacity for challenging skill areas and building resilience through tricky tasks. His family is so pleased that their son appears **less agitated and able to participate in his life with more pleasure.** His school has also noted an increase in participation in activities, even those that were once avoided."



SSP and OT intervention help eliminate teen's panic attacks at school

Alyssa responded immediately to the SSP Core. On the third day of the half-hour sessions, her panic attacks dropped to once per day. By the sixth session, the duration of her panic attacks had reduced in intensity and would last about one to two minutes — from 15 minutes previously.

Within one month of completing the SSP, **Alyssa was completely free of panic attacks at school.**

ILS Case Studies

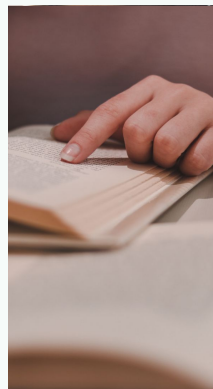
A full list of Case Studies can be found [here](#).



Brain Stem Injury

In addition to the **objective changes on the SCAN-A**, client is now able to attend church, go to restaurants and attend meetings. **Balance has improved enormously** and client has been taking a Zumba class and notes that her coordination has also improved. At her most recent optometry exam she needed new glasses because her vision had improved.

“The response of this 60-yr old women 18 years post-TBI exemplifies the resiliency of the brain in mature adults. It is also a **great example of the neuroplasticity of the brain stem**, as well as the brain.”



Stroke

At the onset of therapy, the client was able to read single words with 44% accuracy, [and]...read basic sentences with 20% accuracy.

At post-testing, the client was able to read single words with about **80% accuracy** and simple sentences with **55% accuracy**. Initially, the client would read only the nouns in the sentences, but **now the client is able to read the full sentence word for word, in order**. The client also improved his Aphasia Quotient Score on the Western Aphasia Battery from 78 to 84.



Mild Traumatic Brain Injury

Significant, and sustained, improvements in cognitive performance after both ILS programs, the first of which began 11 years post-injury.

Improvement in temper at home; Recognizing others are around and being more considerate of others; **Feels his brain is getting clearer – not overwhelmed as much**; Can prioritize what is important to do now and what can wait; “I know when to ask for help now, and when to stop.”



NLD, ADHD, Anxiety Disorder

Improvement on standardized test scores, able to get a job and received promotion, improvement in relationships, no depression or anxiety reported.

“GD seems less defensive.”

“A new feeling of self, constant happiness, almost energized.”

The Impact: Client and Caregiver Testimony



“Our client and her family have attempted many different therapeutic interventions over the developmental years and unfortunately were discouraged with the outcomes. The positive results of the SSP have provided this family with encouragement and hope.”

- Dalcyce Wilson-Podesky and Julie Campbell, Therapists



“There are few modalities out there that intervene at the brainstem level and can impact and support physiological shifts, and it is an incredibly efficient and effective way to move someone to a place where they’re able to receive connection and be in the here and now.”

— Deirdre Stewart, LPC, SEP, BCN, Vice President of Trauma Resolution Services at The Meadows



“[The SSP] has allowed me to work with clients, children and adults, through a very short period of time and achieve results that normally would take me six months or more in a regular therapeutic process.

— Ana do Valle, OTR, SEP



“We have tried so many other things with minimal help – we just never got to the core of the issue – the SSP got to the core.”

- Amy R., Parent.



“Thankful to be able to offer such a powerful treatment for our kiddos and their families!”

- Julie Kurrasch, Therapist

SSP Provider Survey: Context and Objectives

Context

In 2020, Unyte conducted a community-wide survey in collaboration with Jacek Kolacz, Phd and Evan Nix at Ohio State University.

497 responses were collected.

Objectives

- Provider demographics and composition;
- The symptoms/features SSP Providers treat in their practice and their perceived impact (benefits/efficacy) of the SSP on these symptoms/features;
- How providers deliver the SSP in their practices;
- The impact of various 'interfering factors' in SSP delivery and efficacy;
- Providers' frequency of use of other modalities, pairing with the SSP, and perceived benefits of pairing with the SSP.

Provider Survey: Key Takeaways

The data supports the broader notion that the nervous system is at the center of both mental and physical health, and that the SSP is a powerful tool to support nervous system health.

- Demonstrated by the breadth of features impacted, and the consistency/degree of impact.

Clearer areas of future research focus/investment are emerging.

- In addition to the observed impact on social-emotional, sensory, speech-language and behavioral features, the results indicate strong impact in certain psychiatric (namely anxiety, phobias and depression) and bodily features (namely sleep/fatigue, pain and GI).

The data validates the notion that the SSP is supportive to a wide range of modalities, and drives meaningful benefits when paired.

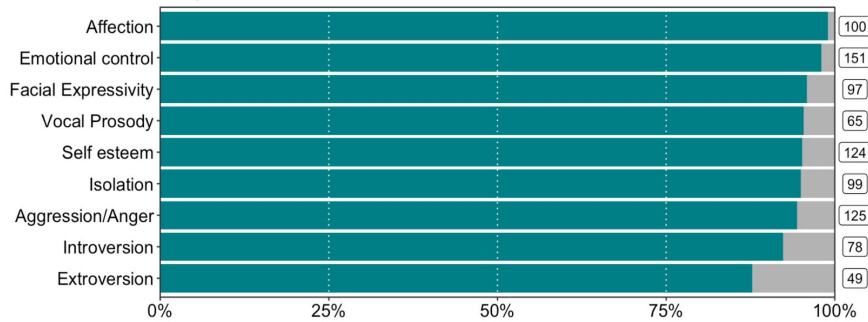
- This is true for both adult/trauma-focused modalities (e.g. SE, EMDR, etc.) and pediatric modalities (SI, DIR Floortime, Play, etc.)

The research supports the hypothesis that a client's trauma history, autonomic patterns, access to support and psychoeducation are the most important factors affecting approach to, and pace of, delivery.

Provider Survey: Key Takeaways

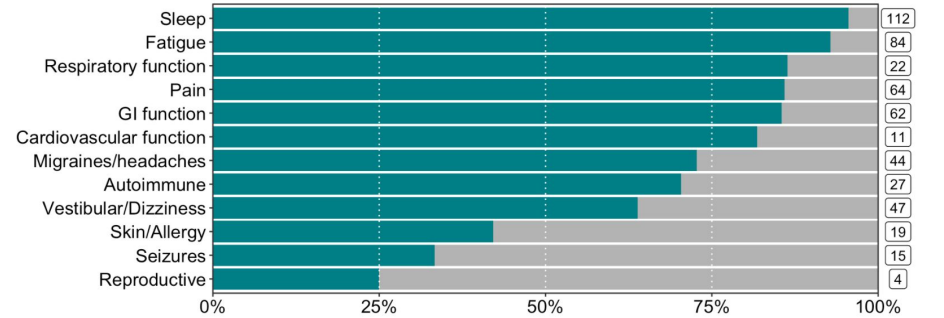
When you use SSP with clients, how often do you see benefits in this domain?
(Social - Emotional Features)

n Respondents = 168



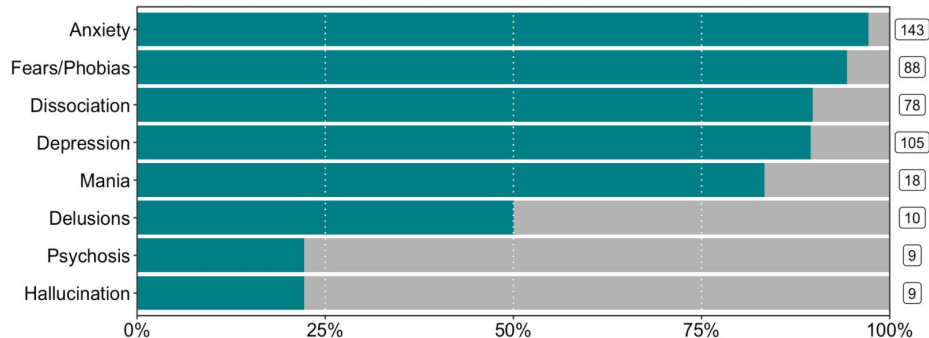
When you use SSP with clients, how often do you see benefits in this domain?
(Bodily Features)

n Respondents = 128



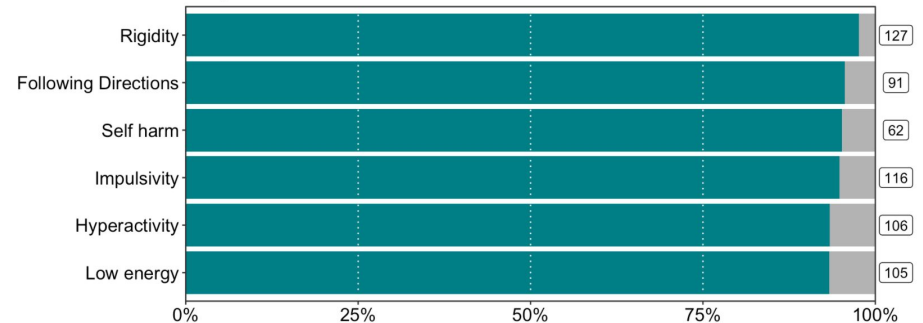
When you use SSP with clients, how often do you see benefits in this domain?
(Psychiatric Features)

n Respondents = 154



When you use SSP with clients, how often do you see benefits in this domain?
(Behavioral Features)

n Respondents = 155





Resources

INSTRUCTIONS

For more information, visit [www.irs.gov/efile](#)

FILE

STATUS

DATE

TIME

STEPS

1. Start your return with a new return or an amended return.
2. Check the e-file status.
 - Accepted: You have successfully e-filed your return.
 - Rejected: Your return was not accepted for e-filing. You may need to make corrections and re-file.
 - Pending: Your return is being processed.
 - Failed: Your return was not e-filed successfully.
3. Now you are ready to print your return. You can print your return and mail it to the IRS, or you can print it and take it to a tax professional for e-filing.
4. Print the tax return and mail it to the IRS, or you can print it and take it to a tax professional for e-filing.
5. With one final step, you are ready to e-file your return. You can e-file your return directly to the IRS, or you can e-file your return through a tax professional.
6. After the e-file process is complete, you will receive a confirmation message from the IRS. You can check the status of your return at any time.
7. Check the status of your return. You can check the status of your return at any time.
8. **DO NOT** send your return to the IRS by mail. You should e-file your return.
9. For more information, visit [www.irs.gov/efile](#).

What Is the Safe and Sound Protocol (SSP)?

The Safe & Sound Protocol (SSP) is an evidenced-based listening therapy and practical application of Polyvagal Theory, that supports autonomic state regulation, social engagement, sensory processing, and mental health.



Specially-filtered,
therapeutic music



Delivered by a certified
SSP Provider



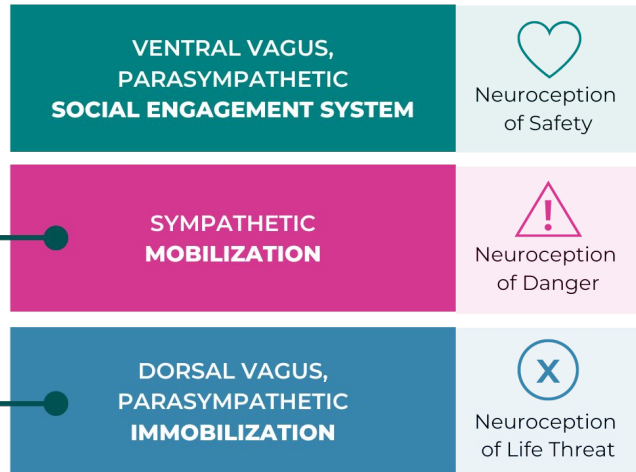
Helps to regulate the
nervous system

An Introduction to the SSP



How Does It Work?

The SSP helps to regulate the autonomic nervous system by sending cues of safety through the auditory portal.



Based on hierarchical recruitment of the ANS, the SSP trains the auditory processing system tune-in to cues of safety signaled by the frequencies of human voice, which stimulates the social engagement system.

When our nervous system is in a state of defense, all of our resources are spent on survival.

When we feel safe, we are better able to adapt and respond to life's challenges.



Developed by Stephen Porges, PhD, evidence for the SSP is informed by decades of research on Polyvagal Theory, clinical trials, and a growing base of real world evidence and case reports.

Polyvagal Theory

BOOKS

Clinical Applications of the Polyvagal Theory: The Emergence of Polyvagal-Informed Therapies, with Deb Dana (Norton)

Porges SW (2021). **Polyvagal Safety: Attachment, Communication and Self-Regulation.** New York: WW Norton.

More can be found at:
stephenporges.com/articles

KEY PUBLICATIONS

Conceptualization of neuroception.

Porges, S.W. (2003). Social engagement and attachment: a phylogenetic perspective. *Annals of the New York Academy of Sciences*, 1008(1), 31-47.

Conceptualization of vagal brake as an indicator of social engagement.

Porges, S.W., Doussard-Roosevelt, J.A., Portales, A. L., & Greenspan, S. I. (1996). Infant regulation of the vagal “brake” predicts child behavior problems: A psychobiological model of social behavior. *Developmental Psychology*, 29(8), 697-712.

First publication describing Polyvagal Theory.

Porges, S. W. (1995). Orienting in a defensive world: Mammalian modifications of our evolutionary heritage. A polyvagal theory. *Psychophysiology*, 32(4), 301-318.

Key Supporting Publications

Reference

Kolacz, J., daSilva, E. B., Lewis, G. F., Bertenthal, B. I., & Porges, S. W. (2022). [Associations between acoustic features of maternal speech and infants' emotion regulation following a social stressor](#). *Infancy: the official journal of the International Society on Infant Studies*, 27(1), 135–158.

Cattaneo, L. A., Franquillo, A. C., Grecucci, A., Beccia, L., Caretti, V., & Dadomo, H. (2021). [Is Low Heart Rate Variability Associated with Emotional Dysregulation, Psychopathological Dimensions, and Prefrontal Dysfunctions?](#) An Integrative View. *Journal of personalized medicine*, 11(9), 872.

Kovacic, K., Kolacz, J., Lewis, G. F., & Porges, S. W. (2020). [Impaired Vagal Efficiency Predicts Auricular Neurostimulation Response in Adolescent Functional Abdominal Pain Disorders](#). *The American journal of gastroenterology*, 115(9), 1534–1538.

Results & application:

This study recorded mothers' voices as they interacted with their infant to examine what vocal features predicted infant calming. Mother's voices that had safety cues which included strong middle frequencies, reduced high frequencies, and fluctuations in intonation predicted decreases in infant distress and improvement in infants' autonomic regulation (as measured by heart rate slowing and increases in ventral vagal activation in infants who had low VVC activity).

The features that were measured in this study are based on the same principles as the music filtering in the Safe and Sound Protocol, which amplifies the way that sound is modulated around middle frequency bands associated with safety. These findings provide real-world evidence that the filtering of the SSP targets acoustic features that are important for autonomic state regulation in children.

This study supports the importance of considering the heart-brain relationship, and its effect on emotions, mental health, and cognitive functioning. This is consistent with the integrative process of SSP delivery - beyond the music itself.

Low HRV is associated with emotional dysregulation, worse cognitive performance, and transversal psychopathological conditions.

This study is a 4-week randomized, double-blinded, sham-controlled experiment using non-invasive stimulation to the vagus nerve through the auricular branch, with adolescents with functional abdominal pain disorders. It found that impaired cardiac vagal regulation measured by vagal efficiency predicted pain improvement with auricular neurostimulation.

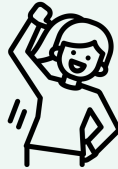
Similar to the SSP, this study identifies the impact of non-invasive vagus nerve stimulation on functional pain outcomes.

What Is the Integrating Listening System (ILS)?

The Integrated Listening System (ILS) is a therapeutic tool using specially-treated music, bone conduction, and movement activities to improve brain function through multisensory input.



Specially-filtered,
therapeutic music,
delivered through air
and bone conduction



Combined with
movement activities,
Delivered by a certified
Provider



Promotes regulation and
skill-building through
neuroplasticity

How Does It Work?

The ILS combines movement and sound to activate the vestibular system and the postural network, linking sensory, autonomic, and central nervous systems for neural integration.



Based in decades of auditory research by Dr. Alfred A. Tomatis (1920-2001)

Emphasizes subcortical (bottom-up) processing from the brainstem and cerebellum.

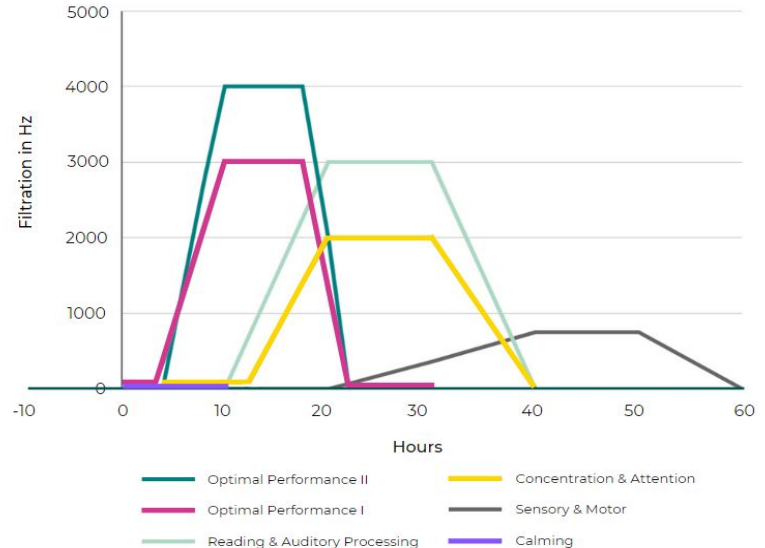
The simultaneous, synchronous firing of neurons in different areas of the brain as a result of multisensory activity promotes increased neural connectivity between these areas (Hebb's Law).

Evidence for the SSP is informed by decades of research on therapeutic sound, clinical trials, and a growing base of real world evidence and case reports.

ILS Programs

The ILS dynamically adjusts the frequency presentation of the music in each program to optimize functional skills, and can be delivered in-person or at-home.

- **Calming**
- **Sensory & Motor**
- **Concentration & Attention**
- **Reading & Auditory Processing**
- **Optimal Performance I**
- **Optimal Performance II**





Thank you!



The logo for Unyte features a stylized teal leaf icon above the word "unyte" in a bold, lowercase, teal sans-serif font. The leaf icon consists of three leaves of varying sizes arranged in a fan shape, with the largest leaf at the top and two smaller ones below it.

unyte

Reference

1. Burns, S. (2022). HRV measurement not predictive of depression symptoms or improvement: a case report. *Cogent Psychology*, 9(1). <https://doi.org/10.1080/23311908.2022.2080318>
2. Heilman, K. J., Heinrich, S., Achermann, M., Nix, E., Kyuchukov, H. (2023). Effects of the Safe and Sound Protocol (SSP) on sensory processing, digestive function and selective eating in children and adults with autism: a prospective single-arm study. *Journal on Developmental Disabilities*, 20(1).
3. Kawai, H., Kishimoto, M., Okahisa, Y., Sakamoto, S., Terada, S., & Takaki, M. (2023). Initial Outcomes of the Safe and Sound Protocol on patients with adult autism Spectrum Disorder: Exploratory Pilot Study. *International Journal of Environmental Research and Public Health*, 20(6), 4862. <https://doi.org/10.3390/ijerph20064862>
4. National Institute of Mental Health. (n.d.). NIMH guidance on risk-based monitoring. *U.S. Department of Health and Human Services, National Institutes of Health*. Retrieved June 6, 2023, from <https://www.nimh.nih.gov/funding/clinical-research/nimh-guidance-on-risk-based-monitoring>

Reference

5. Porges, S. W., Bazhenova, O. V., Bal, E., Carlson, N., Sorokin, Y., Heilman, K. J., Cook, E. H., & Lewis, G. F. (2014). Reducing auditory hypersensitivities in autistic spectrum disorder: preliminary findings evaluating the listening project protocol. *Frontiers in pediatrics*, 2, 80. <https://doi.org/10.3389/fped.2014.00080>
6. Porges, S. W., Macellaio, M., Stanfill, S. D., McCue, K., Lewis, G. F., Harden, E. R., Handelman, M., Denver, J., Bazhenova, O. V., & Heilman, K. J. (2013). Respiratory sinus arrhythmia and auditory processing in autism: modifiable deficits of an integrated social engagement system?. *International journal of psychophysiology: official journal of the International Organization of Psychophysiology*, 88(3), 261–270. <https://doi.org/10.1016/j.ijpsycho.2012.11.009>
7. Porges, S. W. (1995). Orienting in a defensive world: mammalian modifications of our evolutionary heritage. A Polyvagal Theory. *Psychophysiology*, 32(4), 301–318. <https://doi.org/10.1111/j.1469-8986.1995.tb01213.x>
8. Rajabalee, N., Kozłowska, K., Lee, S. Y., Savage, B., Hawkes, C., Siciliano, D., Porges, S. W., Pick, S., & Torbey, S. (2022). Neuromodulation using computer-altered music to treat a ten-year-old child unresponsive to standard interventions for functional neurological disorder. *Harvard Review of Psychiatry*, 30(5), 303–316. <https://doi.org/10.1097/HRP.0000000000000341>

Reference

9. Sherman, R. E., Anderson, S. A., Dal Pan, G. J., Gray, G. W., Gross, T., Hunter, N. L., LaVange, L., Marinac-Dabic, D., Marks, P. W., Robb, M. A., Shuren, J., Temple, R., Woodcock, J., Yue, L. Q., & Califf, R. M. (2016). Real-World Evidence - What Is It and What Can It Tell Us?. *The New England journal of medicine*, 375(23), 2293–2297. <https://doi.org/10.1056/NEJMsb1609216>
10. Squillace, M., Lopez, A., & Cohn, K. (2022). Social outcomes of a child with autism spectrum disorder following a listening protocol. *Journal of Occupational Therapy, Schools, & Early Intervention*. <https://doi.org/10.1080/19411243.2022.2156425>
11. Schoen, S. A., Miller, L. J., & Sullivan, J. (2015). A pilot study of integrated listening systems for children with sensory processing problems. *Journal of Occupational Therapy, Schools, & Early Intervention*, 8(3), 256–276. <https://doi.org/10.1080/19411243.2015.1055418>
12. Harper, J., and Weiner, A., L. (2010). Effectively addressing attention and auditory processing in school-age children. *Advance OT (Occupational therapy) Magazine* – January 4, 2010.
13. Practitioner Survey on the Effectiveness of iLs Programs with Children with Autism Spectrum Disorder; Conducted by Teresa May-Benson, ScD, OTR/L and Alison Teasdale at ‘The Spiral Foundation’ on March 15, 2012