unyte

Evidence Summary

2025

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

4, 7, 10, 11, 13

Autonomic State Regulation

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

2, 5, 7, 8, 10, 11, 13

Sensory Processing

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

3, 7, 10

Mental Health

- Stress
- Depression
- Anxiety

1, 2, 10

CLINICAL TRIAL

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)

Trial I	**Trial II**
Filtered Music (n=36)	Filtered music (n=50)
Headphones only (n=28)	Unfiltered music (n=32)

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

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

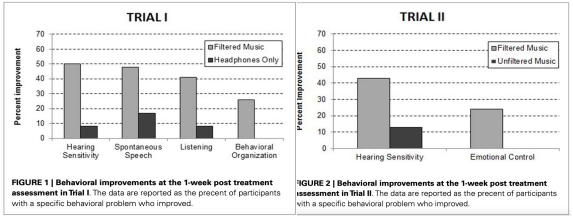


FIGURE 1 | Behavioral improvements at the 1-week post treatment assessment in Trial I. The data are reported as the precent of participants with a specific behavioral problem who improved.

FIGURE 2 | Behavioral improvements at the 1-week post treatment assessment in Trial II. The data are reported as the precent of participants with a specific behavioral problem who improved.

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

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

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.

CLINICAL TRIAL

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**

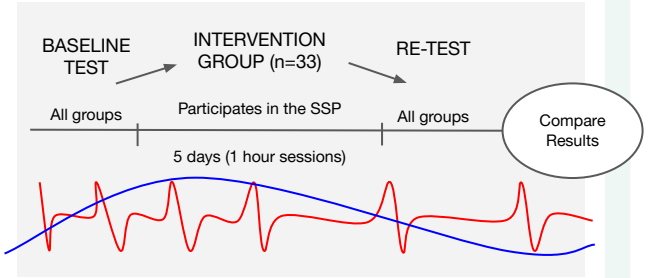
METHOD

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

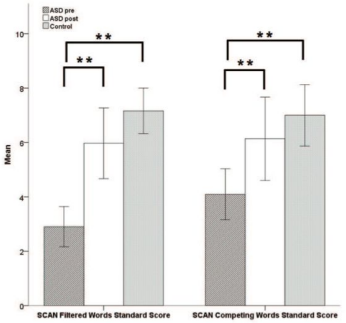
SCAN test

- 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)*



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.

CLINICAL TRIAL

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

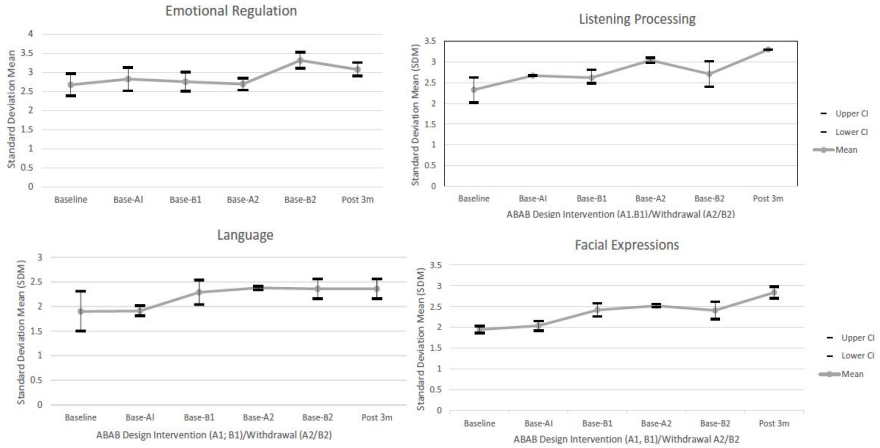
Case: Sydney, a **20-month-old girl with moderate ASD,** presenting with limited social engagement, overactivity, hypersensitivities, and decreased state regulation resulting in behavioral reactivity to certain stimulations, and sensory seeking behaviors.

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.



Mary Squillace, Alex Lopez & Kerri Cohn (2022): Social Outcomes of a Child with Autism Spectrum Disorder Following a Listening Protocol, Journal of Occupational Therapy, Schools, & Early Intervention, DOI: 10.1080/19411243.2022.2156425

CLINICAL TRIAL

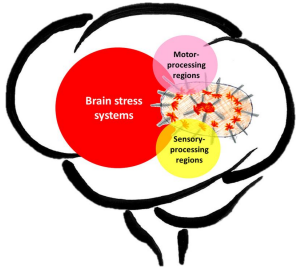
Neuromodulation Using Computer-Altered Music to Treat a Ten-Year-Old Child Unresponsive to Standard Interventions for Functional Neurological Disorder

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.

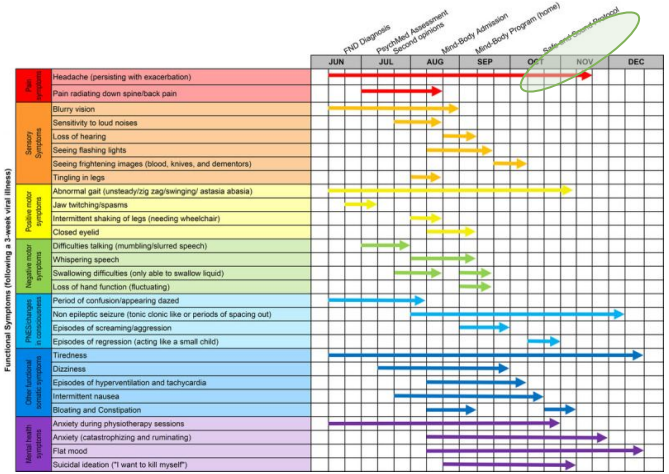
MT struggled to participate in the program, and rumination on her pain grew to catastrophizing and suicidal ideation. MT particularly struggled with cognitive, or "top-down" therapies, which directed the team to prioritize physiological, "bottom-up" and passive regulatory therapies — including the SSP.

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.**

Rajabalee, N., Kozlowska, 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.

CLINICAL TRIAL

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)

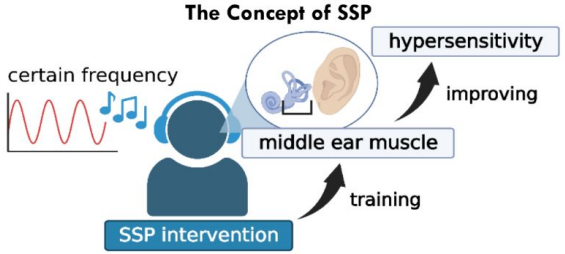
RESULTS

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



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

CLINICAL TRIAL

Effects of the Safe and Sound Protocol TM (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)

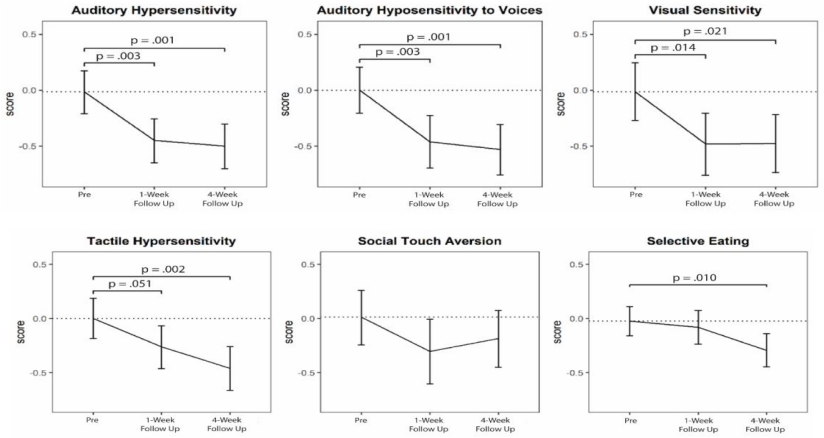
Baseline, 1-week and 4-week

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.



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, 28(1).

CLINICAL TRIAL

Autism, Hypersensitivity and Language Ability

BACKGROUND

The primary aim of this study was to evaluate the effectiveness of the SSP on sensory sensitivities and language development after the SSP.

METHOD

Design
Exploratory Pilot Study

Participants (N=36)
All participants have ASD diagnosis and are counseling clients at a practice in Hamburg, Germany. Participants were split into three age groups:

INTERVENTION

Delivery Model
In-person (clinic or school) and remotely (at home by caregiver, therapist supervision)

- 1 hour per day, 5 consecutive days
- Activities during listening included coloring, building with blocks, and quiet games without screens

Assessment (baseline, 1- and 4-weeks post)

Brain-Body Center Sensory Scales (BBCSS)
50-item questionnaire to assess auditory sensitivity, visual processing, tactile processing and digestive processing.

Language Ability scored as non-verbal, limited verbal or age appropriate.

RESULTS

Participants with age-appropriate language skills had the greatest improvements in the auditory and tactile hypersensitivity subscales.

- Language ability moderated the relationship between pre/post SSP auditory and tactile hypersensitivity scores.
- Participants with limited or no verbal skills had highly correlated pre/post SSP scores.

These findings suggest language ability may optimize the effectiveness of the SSP and provide insight into the link between language abilities and the interoceptive (physiological state) changes in response to SSP.

Perhaps, interoceptive awareness of autonomic state shift following SSP may be a key phenomenon through which the individuals with better language skills benefit more from SSP.

-Stephen Porges, PhD

Kyuchukov, H., & Ackermann, M. (2023). Autism, hypersensitivity and language ability. *East European Journal of Psycholinguistics*, 10(2), 62-72. https://doi.org/10.29038/eejpl.2023.10.2.kyu

CLINICAL TRIAL

Speech therapy clients with voice, throat and respiratory complaints: Self-reported autonomic reactivity, anxiety and depression and effects of Safe and Sound Protocol

BACKGROUND

Evidence suggests that speech therapy clients with oto-rhino-laryngeal symptoms may have challenges with autonomic state regulation. This study explored how the SSP effects anxiety, depression and autonomic reactivity in clients with voice and throat complaints.

METHOD

Design
Feasibility Study

Participants (N=33)
All participants were voice and speech therapy clients referred from the first author's private practice. Participants were between 29-74 years old and had self-reported voice, throat, and/or breathing complaints.

INTERVENTION

Delivery Model
In-person delivery by a therapist. Depending on participant schedules, listening took place in 60-minute intervals over 5 (n=28), 7 (n=1), 8 (n=3), or 10 days (n=1).

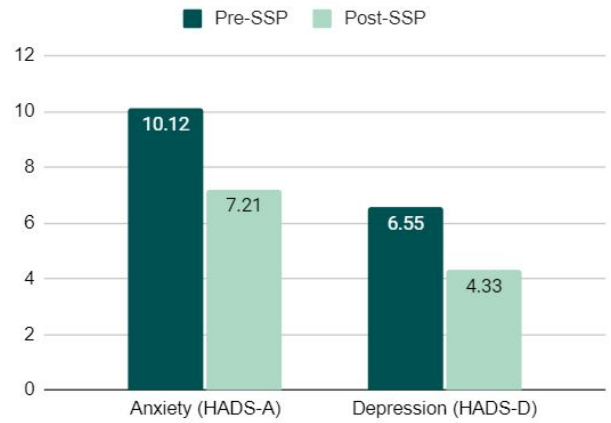
Assessment (completed pre- and post-SSP listening sessions)

Hospital Anxiety and Depression Scale (HADS)
A self-assessment scale for detecting symptoms of anxiety and depression.

Body Perception Questionnaire Short Form (BPQ-SF) A 64-item self-assessment questionnaire assessing body awareness, supra-diaphragmatic autonomic reactivity (e.g. sweat in the armpits), and sub-diaphragmatic autonomic reactivity (e.g. constipation). .

RESULTS

Participants demonstrated a significant decrease in anxiety, depression and autonomic reactivity post-SSP.



Grooten-Bresser, H., Heilman, K. J., Kooijman, P. G. C., Monti, E., Chenault, M. N., Holmes, L. G., & Resto, O. (2024). Speech therapy clients with voice, throat and respiratory complaints: Self-reported autonomic reactivity, anxiety and depression and effects of Safe and Sound Protocol. Music and Medicine, 16 (2) https://doi.org/10.47513/mmd.v16i2.944

CLINICAL TRIAL

An Exploratory Study of the Safe & Sound Protocol in Young Children With Autism

BACKGROUND

Polyvagal theory provides a framework for understanding how the ANS influences behavior, engagement and connection. The SSP works to regulate the ANS, increasing a state of felt safety. This study explores the effects of the SSP on children with ASD receiving early intervention to support regulation and skill development.

METHOD

Design
Mixed-methods, retrospective multiple subject pretest-posttest

Participants (N=5)
2-3 year olds with ASD attending the McCarton Early Intervention Center in Bronx, NY.

INTERVENTION

Delivery Model
The SSP was delivered through speakers during regular OT sessions over 10-12 weeks.

Assessment (completed pre- and post-SSP listening sessions)

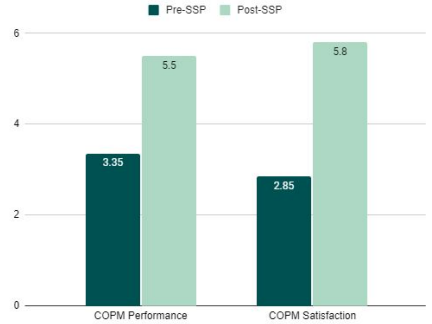
Canadian Occupational Performance Measure (COPM) A goal setting and outcome measure adapted for children, as reported by the participants' teachers, assessed pre/post SSP.

Goal Attainment Scale (GAS): 3 GAS goals per child An individualized outcome measure involving goal selection and scaling, collected via structured session notes by the treating therapist and assessed based on achievement.

RESULTS

All participants met, or exceeded (20%), all of their GAS goals.

COPM means for performance and satisfaction increased over SSP delivery.



Dynamic integration of the following themes emerged in the session notes:

- Attention
- Regulation
- Engagement
- Novelty

Rogowski, M., Damiao, J.A., Cavaliere, C., Rust, N., Lopez, A., Marash, R., & Zdrodowski, A. (2024). An Exploratory Study of the Safe & Sound Protocol in Young Children With Autism. *Am J Occup Ther,* 78(2), 7811500332p1. doi: https://doi.org/10.5014/ajot.2024.78S2-PO332

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

CLINICAL TRIAL

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.”

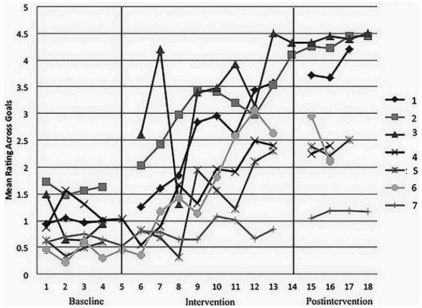


Figure 1. Individual mean goal performance across time.

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

DATA COLLECTION

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.

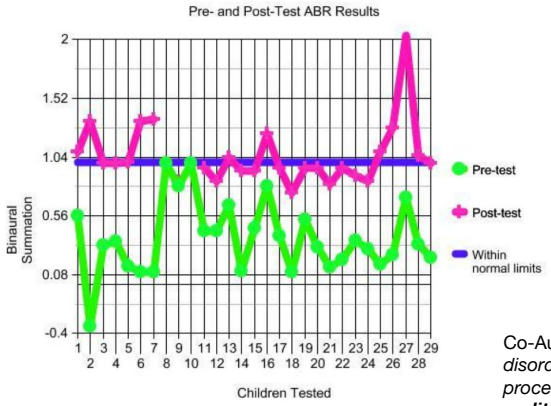
Parents and teachers reported improvements in social skills, language, improved grades in reading and math, with most of the kids showing definite improvement in reading comprehension.

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**.*

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. Original article in Advance OT Magazine: http://occupationaltherapy.advanceweb.com/ebook/magazine.aspx?EBK=OT010410#/26/

PROVIDER SURVEY

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

144	12.2%	24	1304
Responses	Rate	Outcomes	Children with ASD

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 5s;
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.***

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

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

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

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)

Alecia Smith, LISW, tCADC, 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)

An Exploratory Study of the Safe & Sound Protocol in Young Children With Autism

Michelle Rogowski, John A. Damiao, Catherine Cavaliere, Nadia Rust, Alyssa Lopez, Rebecca Marash, Amy Zdrodowski; An Exploratory Study of the Safe & Sound Protocol in Young Children With Autism. Am J Occup Ther August 2024, Vol. 78(Supplement_2), 7811500332p1. doi: https://doi.org/10.5014/ajot.2024.78S2-PO332

The Effect of the Safe and Sound Protocol on the Emotional Regulation of Children: The Caregiver Experience

Brooklyn Gratzer, OTD-S
Katherine Jones, EdD, OTR/L, CLT-LANA & Briana Bonner, OTD, OTR/L (Faculty Advisors)
Occupational Therapy Department, A.T. Still University, Mesa, AZ

Doreen Hunt, OTR/L (Community Mentor)
Children's Therapy of Woodinville, Bothell, WA

Developing Research

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
Adults with breast cancer	Randomized Controlled Trial (RCT)	Impact of SSP on reducing anxiety and depression, improving quality of life, and physiological measures (HRV)	Data collection
Child-serving professionals	Two-group, randomized pre-post test	Impact of the SSP on vagal tone (HRV) and co-regulation	Data collection
Pediatric Patients and their Families	Feasibility Pilot Study	Impact of SSP delivered in a guided home-based model on improving neurobiological regulation of both the individual and the family as a whole	Data Collection

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 RRP 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
	Iranian school children (7-10)	Randomized Controlled Trial (RCT)	Impact of the SSP on improving anxiety, and physiological measure (cortisol and HRV)	Data analysis

GRANT AWARD

A Frequency-Modulated Music Intervention to Enhance Cognitive Processing Therapy (CPT) for PTSD

AWARD DETAILS

Award Granting Institution: US Department of Defense

Principal Investigator: Dr. Jacek Kolacz

Institution Receiving Reward: Ohio State University

Award Amount: $3,821,118

THE OHIO STATE UNIVERSITY
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BACKGROUND

PTSD is common among military personnel. While cognitive processing therapy (CPT) is effective in reducing PTSD symptoms, many continue to experience residual hyperarousal symptoms. Frequency-filtered music has shown positive effects on emotional arousal and could be a scalable adjunctive therapy to enhance CPT outcomes.

METHOD

Design
Two-arm, randomized double-blind clinical trial with a longitudinal follow-up.

Participants (N=100)
Civilian and military personnel with PTSD or subthreshold PTSD with hyperarousal.

INTERVENTION

Delivery Model
Participants will receive massed CPT and be randomly assigned to listen to 15 minutes of either frequency-filtered classical music (SSP Core) or a sham playlist with no filtering (SSP Connect) before each therapy session

Assessment
Participants' stress responses during listening and therapy sessions will be evaluated for physiological arousal. PTSD symptoms and hyperarousal will be repeatedly assessed for up to 6 months post-listening. Participants will wear a Fitbit device and complete surveys to track sleep quality, mood and movement.

Learn more

Clinical Research Partnerships

Children's Wisconsin
Kids deserve the best.

JG|U
Brain Imaging and Neurostimulation
University of Mainz - GroppaLAB

peace4kids
community as family.

wielkopolskie centrum onkologii

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SPENCER
PSYCHOLOGY

DOMINICAN
UNIVERSITY
NEW YORK

RESIDENTS
IN
RECOVERY

75 years
Kinsey Institute
INDIANA UNIVERSITY

Preliminary Pilot Data

Rest and Restore Protocol Pilot Data

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.

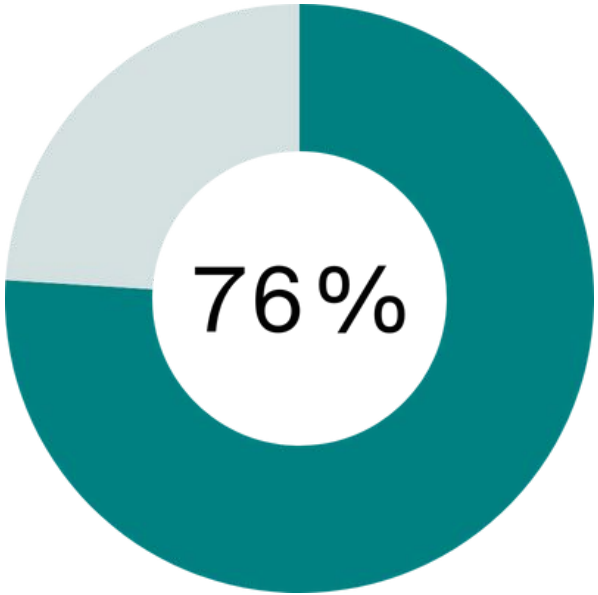
In addition, gastrointestinal improvements with RRP were reported consistently by participants, with these findings supported by improvements in the digestive problems subscale on the Brain-Body Center Sensory Scales (BBCSS).

RRP Pilot Data: Sleep (AIS)

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 for RRP:

- 76% reported 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.

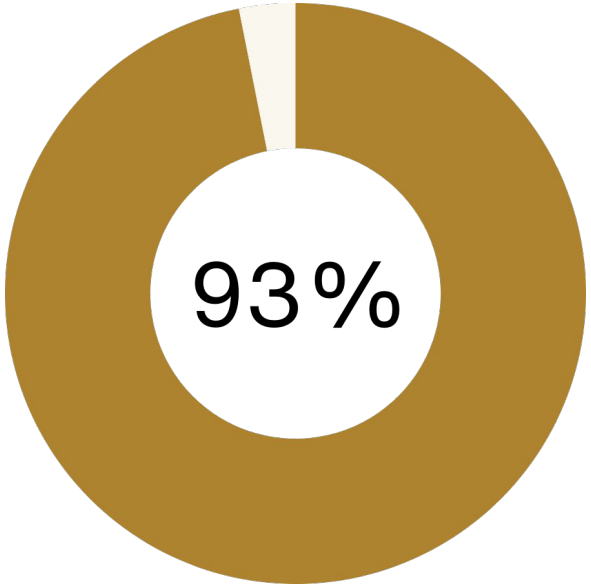


RRP Pilot Data: Anxiety (GAD-7)

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 for RRP:

- 93% reported 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.

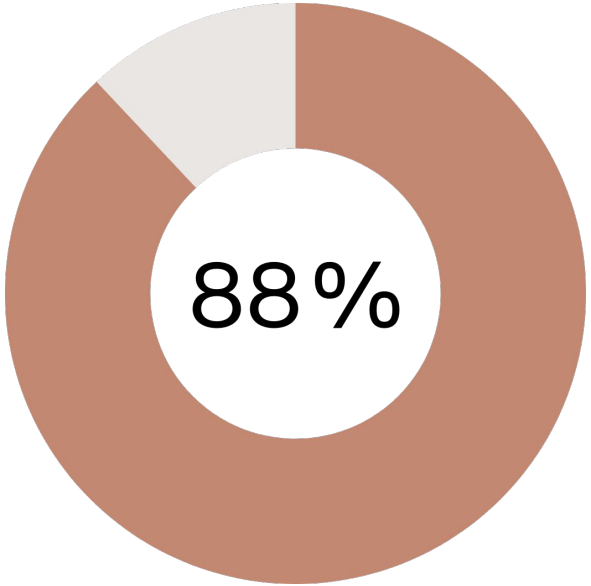


RRP Pilot Data: Trauma (PCL-5)

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 for RRP:

- 88% reported 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.

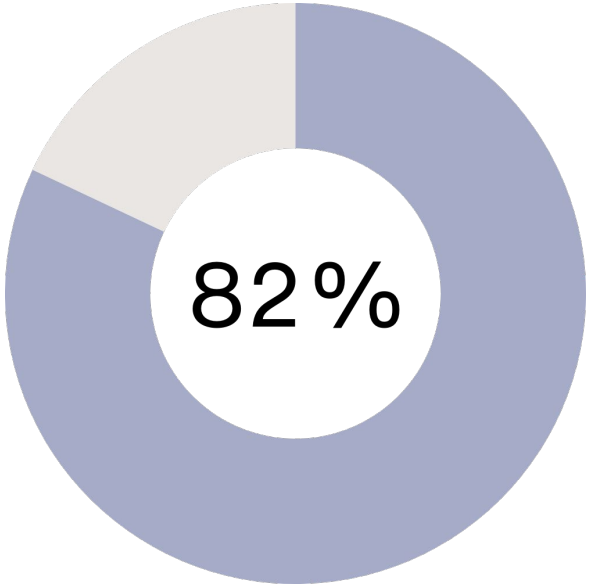


RRP Pilot Data: Depression (PHQ-9)

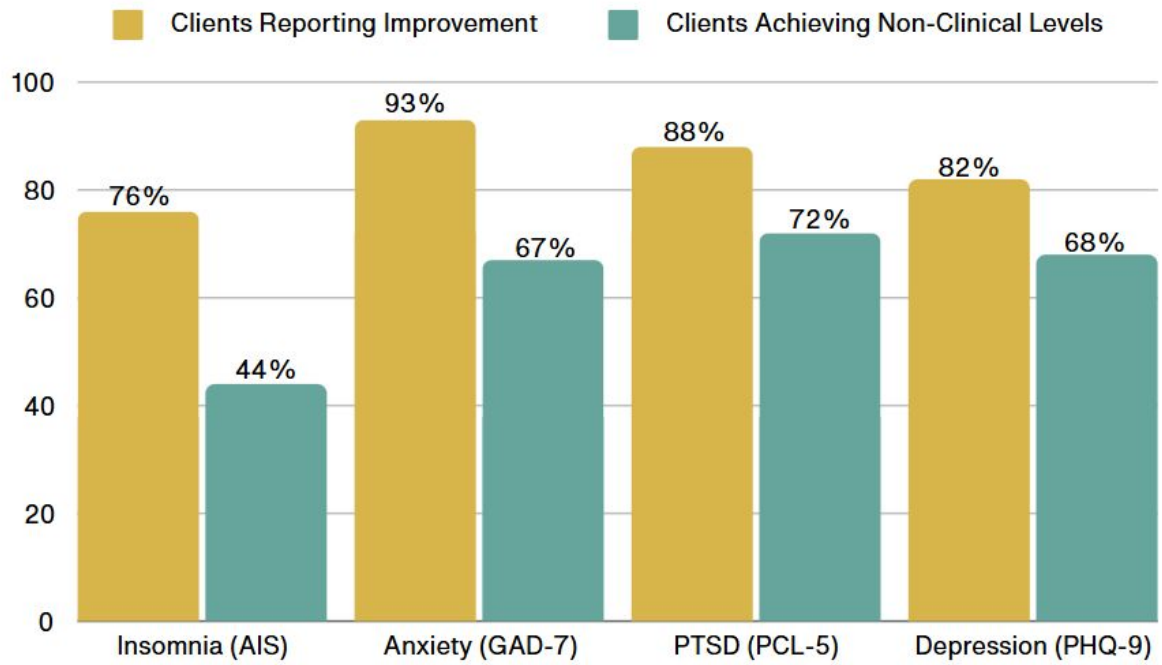
In the pilot group, 22 clients reported significant symptoms of depression on the PHQ-9 before starting the RRP program.

Following completion of at least 1 hour for RRP:

- 82% reported 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.

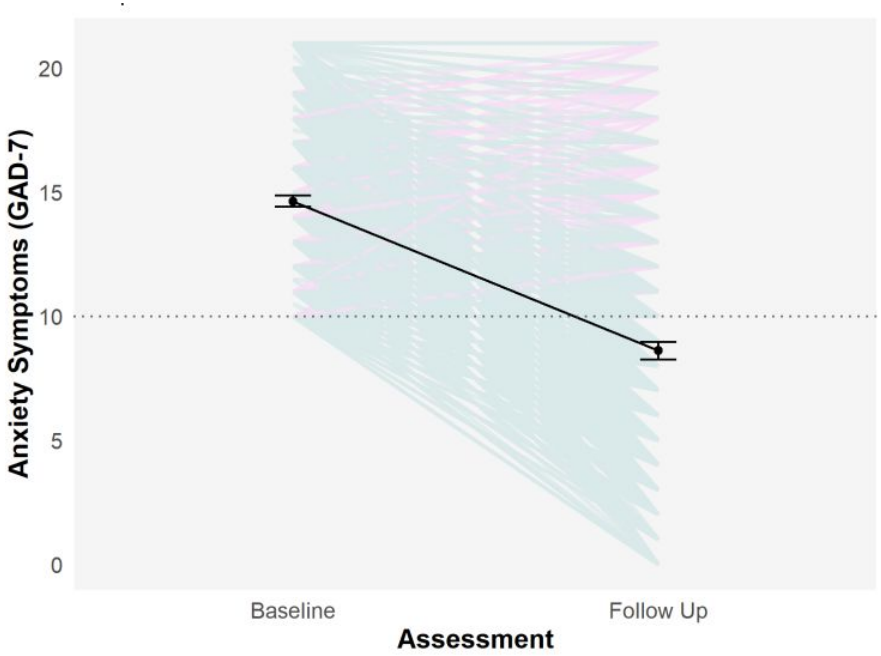


RRP Pilot Data Summary



Real World Evidence

Real World Evidence: Anxiety (GAD-7)



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 SSP Core:

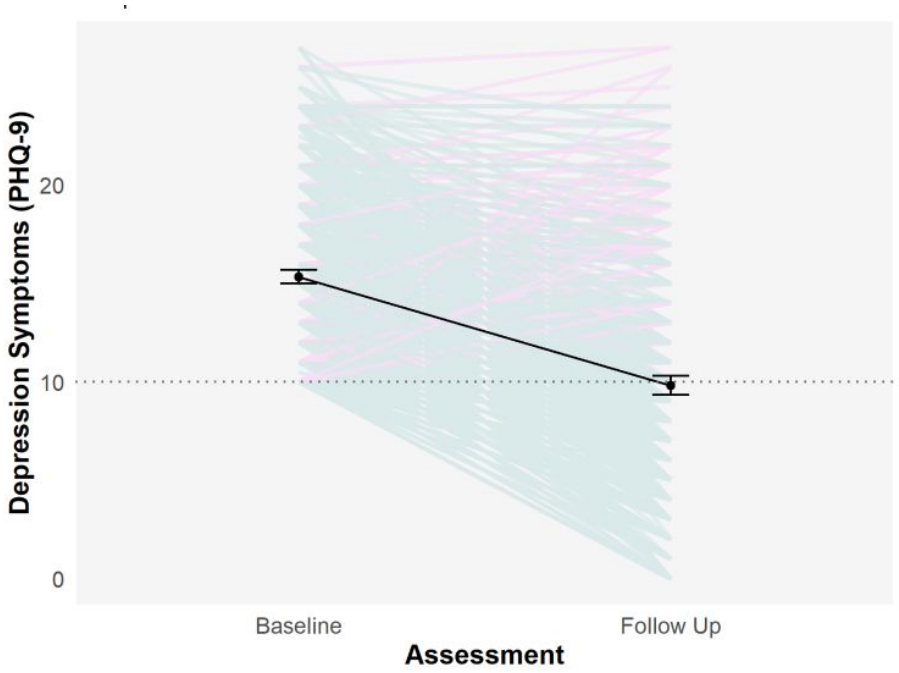
85% of clients reported an improvement in symptoms.

The average score on the GAD-7 decreased from **14.6 (high severity) to 8.6 (mild severity).**

63% of clients moved from clinical to non-clinical level (score less than 10).

Publication date: 6 Dec 2024

Real World Evidence: Depression (PHQ-9)



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 SSP Core:

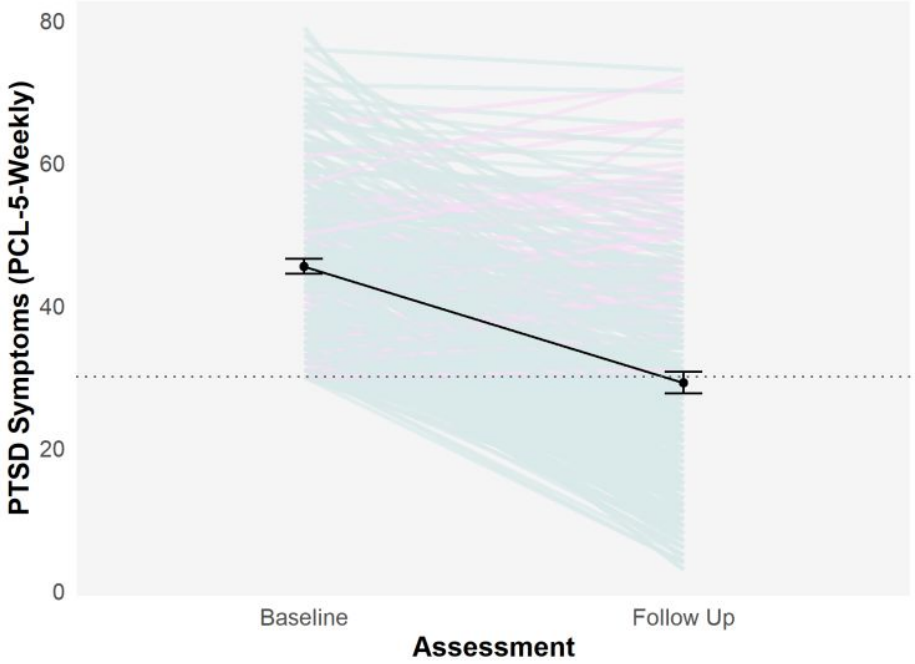
81% of clients reported an improvement in symptoms.

The average score on the PHQ-9 decreased from **15.3 (high severity) to 9.8 (mild severity).**

53% of clients moved from clinical to non-clinical level (score less than 10).

Publication date: 6 Dec 2024

Real World Evidence: Trauma (PCL-5)



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 SSP Core:

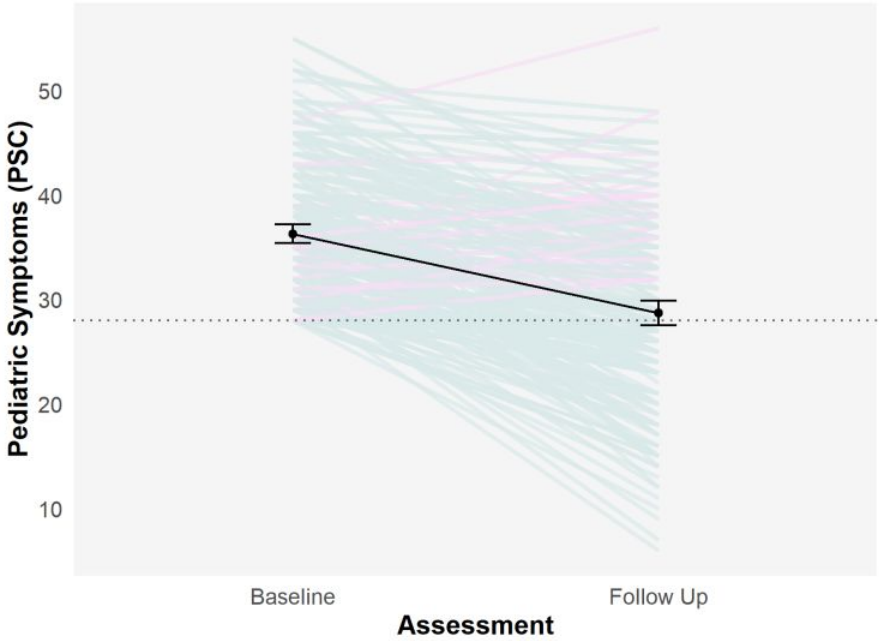
87% of clients reported an improvement in symptoms.

The average score on the PCL-5 decreased from **45.4 (severe) to 29.2 (moderate)**.

57% of clients moved from clinical to non-clinical level (score less than 32).

Publication date: 6 Dec 2024

Real World Evidence: Psychosocial (PSC)



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

In a real-world data sample, caregivers of 206 children reported at least some challenges with psychosocial functioning before starting the SSP Core program.

Following completion of SSP Core:

84% of clients reported an improvement in symptoms.

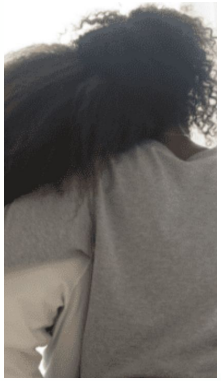
The average score on the PSC decreased from 36.3 to 28.7.

48% of clients moved from ‘impaired’ to ‘not-impaired’ category (score less than 28).

Publication date: 30 Oct 2024

SSP Case Studies

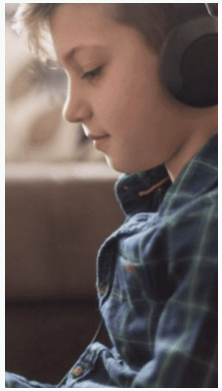
A full list of Case Studies can be found here.



Discovering the Bonds of Connection

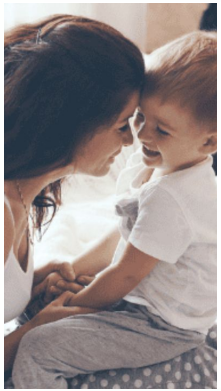
"AB has been demonstrating **less reactivity, fewer angry outbursts, more bids for connection with Mom, and better acceptance of co-regulation from parents.**

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."**



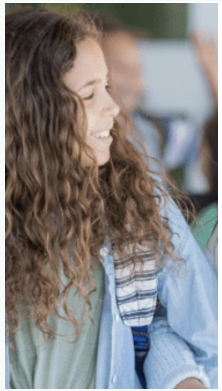
SSP and co-regulation from family helps 1st grader increase awareness and emotional regulation

"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.**

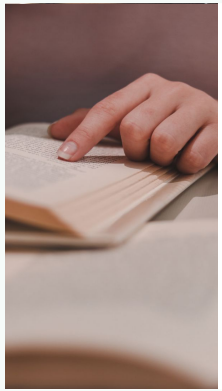
ILS Case Studies

A full list of Case Studies can be found here.

Brain Stem Injury

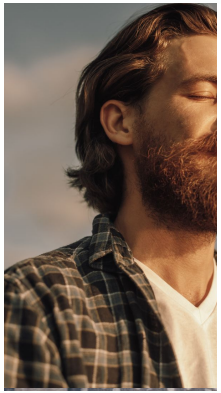
In addition to the **objective changes on the SCAN-A**, client is now able to attend church, go to restaurants and attend meetings. **Balance has improved enormously** and client has been taking a Zumba class and notes that her coordination has also improved. At her most recent optometry exam she needed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

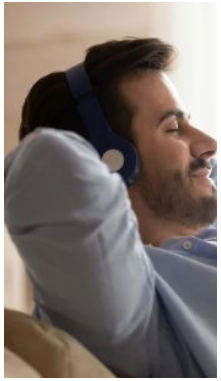
Improvement on standardized test scores, able to get a job and received promotion, improvement in relationships, no depression or anxiety reported.

"GD seems less defensive."

"A new feeling of self, constant happiness, almost energized."

RRP Case Studies

A full list of Case Studies can be found here.



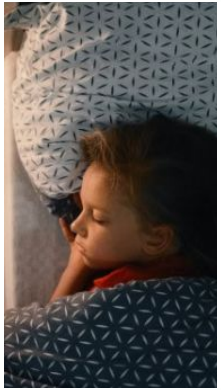
Sleep Challenges

SF's score on the Athens Insomnia Scale (AIS), a measure of **sleep difficulty, dropped from a clinically significant (a score greater than 6) to a clinically insignificant.**

He noted feeling "**relaxed, more receptive and open**" after sessions. He felt **less reactive during conversations**. Between RRP sessions, SF felt **more grounded and centered**, leading to feeling more at ease in his daily life.

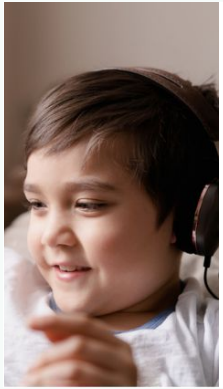
Relief of Tension

This client felt "**an immediate reduction in tension**" following her first RRP session. In the successive sessions, she began to notice where she was holding tension, allowing her to be **more present and aware in her body**. After she progressed to the second level, she felt an **immense improvement in her relaxation** levels, even falling asleep while listening.



Sleep and Improved Energy

This 11-year-old could fall asleep faster and for longer after beginning RRP. This better quality and increased sleep translated into **improved emotional and behavioral regulation** on a daily basis. He became more receptive to changes in his routine and has improved energy, allowing his playfulness and competitive spirit to emerge.



Emotional Regulation

"The transformation in Garth has been profound. **He is no longer trapped in fight-or-flight mode** in response to every stressor. Instead of reacting impulsively, Garth now takes the time to pause and think before responding. Before starting RRP, he would retreat into himself, trying to go unnoticed. Now, **he confidently approaches peers to say hello or wave—behaviors that were unheard of before RRP.**"

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.”
- Dalyce 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.

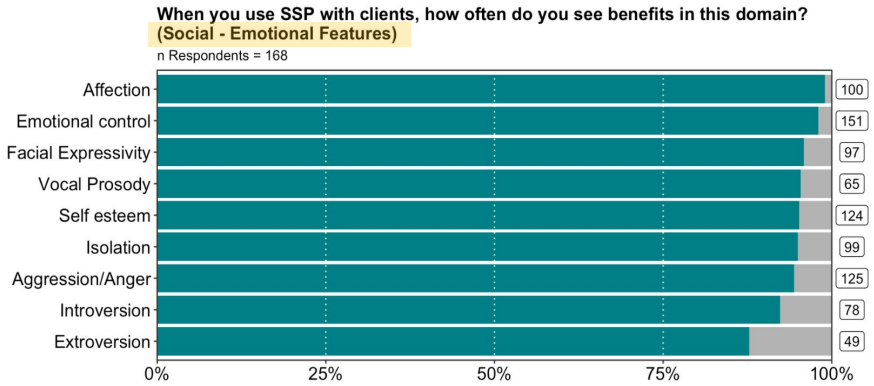
- In addition to the observed impact on social-emotional, sensory, speech-language and behavioral features, the results indicate strong impact in certain psychiatric (namely anxiety, phobias and depression) and bodily features (namely sleep/fatigue, pain and GI).

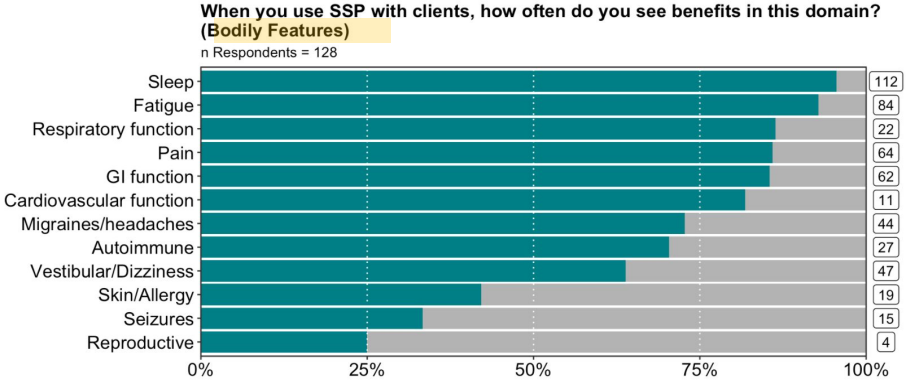
The data validates the notion that the SSP is supportive to a wide range of modalities, and drives meaningful benefits when paired.

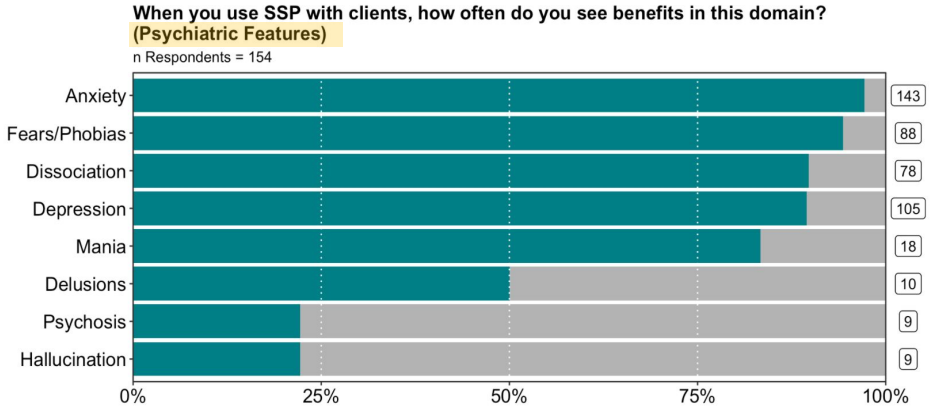
- This is true for both adult/trauma-focused modalities (e.g. SE, EMDR, etc.) and pediatric modalities (SI, DIR Floortime, Play, etc.)

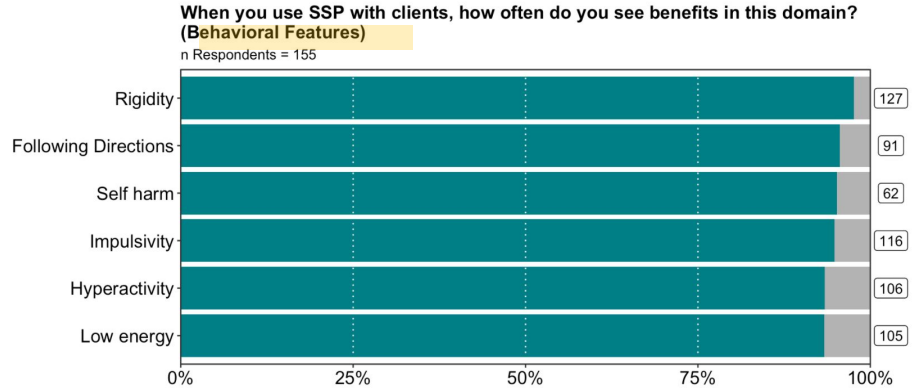
The research supports the hypothesis that a client's trauma history, autonomic patterns, access to support and psychoeducation are the most important factors affecting approach to, and pace of, delivery.

Provider Survey: Key Takeaways









Resources

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.

States of Defense

VENTRAL VAGUS, PARASYMPATHETIC **SOCIAL ENGAGEMENT SYSTEM**	Neuroception of Safety
SYMPATHETIC **MOBILIZATION**	Neuroception of Danger
DORSAL VAGUS, PARASYMPATHETIC **IMMOBILIZATION**	Neuroception of Life Threat

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 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	Results & Application
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.	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.
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.	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.*
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.	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.

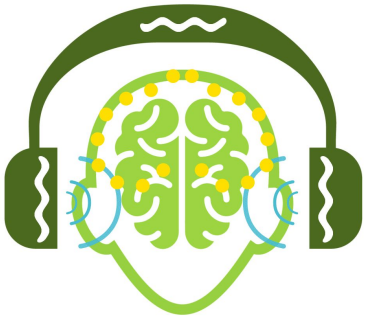
Specially-filtered, therapeutic music, delivered through air and bone conduction

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.

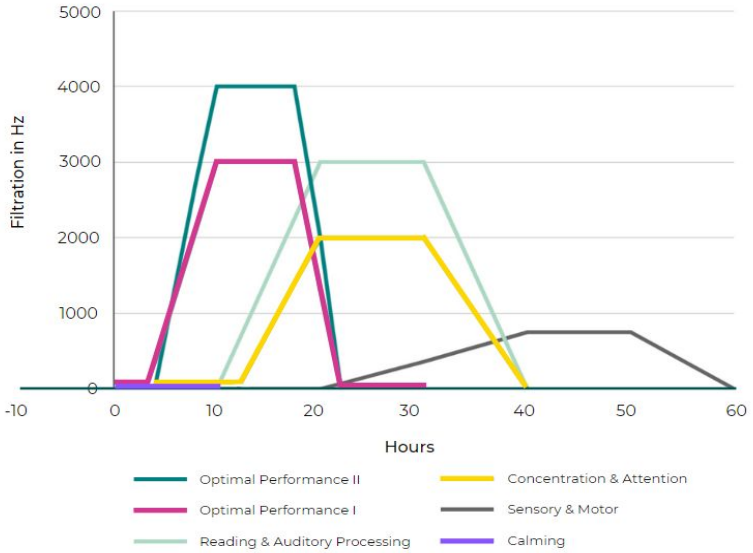
The simultaneous, synchronous firing of neurons in different areas of the brain as a result of multisensory activity promotes increased neural connectivity between these areas (Hebb's Law).

Evidence for the ILS 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!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