The effects of the Safe and Sound Protocol on PTSD symptoms and anxiety in trauma survivors: An observational pilot study

Updated: March 27, 2025

Background & Rationale

Population-based studies from a range of countries show that a majority of adults will experience a traumatic event at some point in their life (Benjet et al., 2016; Burri & Maercker, 2014) and many of these experiences – such as sexual assault, combat experience, or actual or threatened injury – are known triggers for post-traumatic stress disorder (Kessler et al., 2017). PTSD is defined by a cluster of phenomena that include alterations in brain-body patterns of arousal and reactivity which can manifest in irritability and aggression, hypervigilance, which may be caused or maintained by threat-responsive tuning of the autonomic nervous system (Kolacz, Kovacic, & Porges, 2019). The Safe and Sound Protocol (SSP) is a passive acoustic intervention that is designed as a "neural exercise" to promote efficient regulation of autonomic state. Prior research has shown that the SSP can improve autonomic function, auditory hypersensitivities, and emotion regulation in individuals with Autism Spectrum Disorders (Porges et al., 2013; 2014). Though used by some therapists as part of trauma therapy, there are currently no published studies to document its efficacy for PTSD symptoms or comorbidities. This current observational pilot study is being conducted to establish methods for an upcoming randomized controlled trial to test the utility of the SSP for trauma treatment.

Study Procedures

All participants, regardless of study arm, will be recruited from the pool of Spencer Psychology clients who are actively receiving psychotherapy. Participants will continue to receive weekly or bi-weekly psychotherapy during the course of the study. In both arms, participants complete surveys that assess PTSD symptoms (PCL-5), anxiety symptoms (GAD-7), and, autonomic symptoms (BPQ) over the course of 4 timepoints.

<u>Psychotherapy + SSP Arm</u>

After having received an email from the potential subject indicating interest in participation, subjects will be screened online via email to ensure they meet eligibility criteria for the study. If client meets eligibility criteria for study, they will be contacted by a research assistant to schedule their first visit prior to beginning the SSP. Participants will be given an option of either scheduling a session at an Indiana University laboratory building or at Spencer Psychology, where they receive therapy.

When the participant arrives, they will complete a standard COVID-19 screener inside the entrance hallway. Masks will be worn by researcher and participant during the protocol as long as these are part of official state and university guidelines. Masks may be removed if research assistants and participant have proof of complete vaccination. If participant has symptoms or has been in contact with someone likely to have COVID-19, the visit will be rescheduled. If participant passes the screening, they will be led to the laboratory.

Visit 1. The researcher will describe the study, offer to read through the consent form with the participant or have the participant read the consent on their own, and answer any questions. If client consents, data collection will begin.

The participant will complete a set of surveys self-reporting demographics, comorbidities, and psychological well being via Qualtrics on a laptop provided by the researcher (~15 minutes). The RA will then guide the participant through physiological data collection using the iom2 ear clip. Participants will be given instructions on how to put on the earlobe sensor, which attaches via an

ear clip. To stabilize the iom2 cable, an additional clip may be used to attach the iom2 to clothing, waist, or it would be secured on a lab-provided shoulder holster. Once sensor is in place, a researcher will connect the iom2 device to a laptop and begin recording.

The participant will then be cued by a video to move into 3 postures for 3 minutes each: lying down on a cot, sitting up, and standing. After the final posture, the participant will be instructed to remove the measurement device. The device, the cot, and the chair will be sterilized after use with soap and water or other cleaner.

At completion of the first visit, participants will be provided the first $25 Amazon gift card and reminded of the incentive schedule. If the participant knows when their SSP administration will begin, they will be scheduled for their next visit which will take place 1 week after their final listening session. If start date is unknown, the participant will be contacted in 3 weeks about scheduling visit 2.

SSP Sessions and Data Collection

The Safe and Sound Protocol (SSP) will be delivered with 5 hours of increasing frequency modulation over time, as used in prior studies (Porges et al., 2013; 2014), using a phone-based app. Participants will have a choice of 2 music playlists, one that featured popular adult contemporary music and one that primarily featured music from children's movies. Frequency filtering will be applied to playlists using the Safe and Sound Protocol (SSP) using an algorithm to alternate narrowing and expanding the range of acoustic frequencies over time, with the alternations intensifying in frequency range over the course of the music tracks. The filtering is optimized for the frequency response of adult human hearing and intended to mimic the expression of the human voice around a central set of frequencies of 800-1200 Hz. The results of the filtering method are similar to adjusting the treble and bass settings on a stereo system while music is playing; the melody and instruments can still be heard, but the highest and lowest pitches are modulated over time. Music listening will be conducted with high-fidelity, closed-back, over-the-ear headphones while seated. The headphones had a flat frequency response to accurately reproduce music frequencies. The sessions will aim for 30 minutes of listening in each 1-hour session to permit opportunity to discuss client response, and support shifts that happen during listening. The 30 minutes of listening may be discontinuous, with client and therapist each having the possibility to stop the music at any point to discuss and may resume when client is ready. If agreed on by the participant and therapist, some listening time will be completed either at home or in a listening room provided by Spencer Psychology. The room is for those who do not have a distraction-free space and/or over-the-ear headphones at home

Therapists will report on total listening minutes during the session and notes on client response into their standard session reporting form. Spencer Psychology will provide these portions of the session notes to the research team. Researchers will not have access to any additional therapist notes on the client.

Visit 2. The week after the client completes their 5th hour of SSP, a second assessment will be scheduled. As part of this assessment, the client will complete the survey post assessment on the laptop (~10 minutes) and pulse data collection using the iom2 during supine, sitting, and standing postures. Upon completion, the participant will schedule their 4-week post appointment. They will then receive their second $25 Amazon gift card and be reminded of the incentive schedule.

Visit 3. Five weeks after their final SSP session, participants will return for their last assessment. They will then complete the survey post assessment on the laptop (~10 minutes) and pulse data

collection using the iom2 during a supine-sit-stand challenge using the same procedures as previous visits. They will then receive their third $25 Amazon gift card, and another $25 Amazon gift card if they've completed all three assessments.

Data collection from Spencer Psychology medical records.

The study team will receive medical records from Spencer Psychology. Spencer Psychology has a secure, internal database that Spencer Psychology staff will program to output required information. Unique study IDs will be assigned to participants and medical records will be exported and stored with these IDs, not with the names of the participants. We will collect the following information from medical records: Gender, Birth date, Intake and treatment information (date, diagnosis, therapy goals, medication use), session information during SSP administration information (length of use during session), mood and cognitive features during the visit, Changes in treatment objectives, goals, and diagnosis, Clinician comments on visit.

Treatment as Usual (Psychotherapy Only)

If they are interested in participation, they will contact the study team by email provided in the recruitment materials.The study team will send out a link to a screener survey that contains the PCL-5 post-traumatic stress questionnaire. The screener will be used to match this sample to the distribution of the PTSD symptom severity in the SSP study. If eligible for the study based on the screener, the participant will receive an email invitation to participate in the full study, including a link to the survey which contains the Informed Consent Statement and the first full survey.

Subjects will then complete the first survey, which will ask about demographic information; email address for follow up surveys; caffeine, alcohol, nicotine use; medication use; therapy history; PTSD, anxiety, and autonomic symptoms. The survey will close with a statement describing the timing of their next assessments when they will receive the email invitation to complete their next survey, who to contact if they do not receive that email, and that they will receive their digital gift card code via the email address they provided in the survey.

After subjects have consented and completed the first survey, the study team will receive the following information from Spencer Psychology: gender, intake date, diagnosis, client therapy goals. The study team will also receive the following information from session notes for the duration of the study: mood and cognitive features during visits, changes in treatment objectives, goals, and diagnosis, clinician comments on visits.

Questionnaires that assess PTSD symptoms, anxiety symptoms, and, autonomic symptoms will be used for measuring main outcomes. The timeline of surveys was based on average length of SSP listening completion from the SSP+Psychotherapy arm:

1. Survey 1 (10-15 minutes)
2. Survey 2 (5-10 minutes, 45 days after survey 1)
3. Survey 3 (5-10 minutes, 45 days after survey 2)
4. Survey 4 (5-10 minutes, 30 days after survey 3)

Incentives

Participants in the music listening group were compensated up to a total of $125: a $25 gift card for each lab visit and corresponding survey, and an additional $25 gift card for completing all the assessments. Participants in the treatment as usual group were compensated up to $50: a $10 gift card for each of the 4 surveys they completed, with an additional $10 for completing all of the surveys.

Statistical Plan

The goal of the study is to collect exploratory pilot data to inform a large randomized study in the future. Due to the novel nature of the research question there is no prior data to inform power analysis. Results from this small study will be used for power estimates for the upcoming planned randomized study. All efforts will be made to avoid missing data. Research assistants will track potential reasons for missing data in order to strengthen procedures in the follow up study and reduce missing values. Quality assurance steps for data collection will include: Monthly meetings with RAs to visualize and review incoming data, automated range checks, and comparing redundant items that are included in both medical records and self-reports for convergence (e.g., age). Change over time will be modeled using mixed effects modeling with maximum likelihood, which uses all available data on predictors even when some values are missing. Support for non-zero parameters will be indicated by 95% confidence intervals excluding zero. In the SSP+psychotherapy group, earlobe pulse data will be used to quantify inter-beat intervals using automated peak detection with manual checks for accuracy. These will be analyzed for mean heart period and respiratory sinus arrhythmia using previously published methods (Porges, 1985; 1986; Lewis et al., 2012).

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