Protocol Assistant

This form serves as a tool for investigators to verify that the research protocol contains the necessary basic elements required for IRB review. Please note that the IRB may still require additional information.

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Title

Effectiveness of the SoundHeal (Heal) Multi-Sensory Integrative Therapy in Enhancing Emotional Regulation Among Justice-Involved Youth and its Effect on Therapeutic Alliance and Mental Health Outcomes

Sponsor

Soundheal, Inc.

Funding Source

SLO County Juvenile Hall

Version – Date

V8 Date:11/26/2025

List of Abbreviations

In sequential order:

San Luis Obispo (SLO)
Justice-involved youth (JIY)
Cognitive Behavioral Therapy (CBT)
Dialectical Behavior Therapy (DBT)
Eye Movement Desensitization and Reprocessing (EMDR)
Transcranial Magnetic Stimulation (TMS)
Adverse Events (AE)
Serious Adverse Events (SAE)
Substance abuse disorder (SUD)
Legally Authorized Representative (LAR)
Mini-International Personality Item Pool (short form) (Mini-IPIP-A)
Multidimensional Assessment of Interoceptive Awareness, Youth Version (MAIA-Y)
Difficulties in Emotion Regulation Scale – 16 item version (DERS-16)
Therapeutic Alliance Scale for Children - Revised (TASC-R)
Patient Health Questionnaire - 9 (PHQ-9)
General Anxiety Disorder-7 (GAD-7)
Perceived Stress Scale 4 (PSS-4)
Emotional regulation (ER)

Emotional dysregulation (ED)

California State Mental Health Services Act (MHSA)

American Academy of Child & Adolescent Psychiatry (AACAP)

Institutional Review Board (IRB)

Health Insurance Portability and Accountability Act (HIPAA)

SUMMARY

Background

Emotional dysregulation in justice-involved youth (JIY) is a condition that significantly impacts young people, their families, and juvenile justice and public health systems. Affecting an estimated 60-70% of detained adolescents, it is a major driver of aggression, substance use, school failure, and later recidivism. Despite available treatments, managing emotional dysregulation in custody remains challenging, with youth often enduring high arousal, anger, and anxiety that persist into adulthood. Current therapies, including CBT and DBT, other therapy modalities such as EMDR, and brainspotting often fall short in detention because they rely on verbal processing, require multiple scheduled sessions, and need highly trained staff that facilities struggle to retain. Other newer technologies like neurofeedback, biofeedback and TMS are still under some scrutiny for adolescents given their Adverse Events (AEs) occurring at rates between 5-8% for neurofeeback/biofeedback and 10-12% for TMS Recent research has highlighted sensory experiential therapy (like mindfulness, yoga, music, sound, vibroacoustics, light, journaling, etc.) can be a key mechanism in emotional regulation. For example, structured sound and music input, including gentle vibrations, can engage the autonomic nervous system to help reduce arousal. Notably, detention studies and pilots report that such brief non-verbal somatic, sensory, experiential sessions improve immediate regulation and therapy readiness, while a review of the broader literature shows increased heart-rate variability, reduced perceived stress, and better engagement after sound- and music-based sessions, underscoring the need for targeting these pathways.

The primary objective of this study is to evaluate any improvement in emotional regulation with the Heal Intervention for clients in the San Luis Obispo (SLO) County Juvenile Hall for 12- to 18-year-old male and female youth who are moderate- to high-risk and in need of residential treatment. These youth typically struggle from some/multiple mental health illnesses and/or substance abuse disorder (SUD). This study evaluates a novel, non-verbal sound-, music-, and mindfulness-based intervention that delivers calming audio and gentle vibrations along with soothing light followed by brief expressive journaling/writing or drawing to consolidate and

document any changes in the individual's emotional state. By addressing the underlying physiology of emotional dysregulation and then scaffolding top-down skills, we seek to develop a feasible treatment that improves juveniles' outcomes, reduces recidivism risk and relapse, eases the burden on families and facilities, provides mental health and SUD treatment cost savings to tax payers, and eases public systems.

Objectives

Primary Objective

Emotional Regulation: To evaluate the efficacy of the Heal sensory intervention in improving emotional regulation among JIY with mental health disorders and/or SUD. Emotional regulation will be assessed using standardized measures and supported by qualitative analysis of participants' reflective journals, which will be de-identified and coded for changes in emotional expression over the intervention period.

Secondary Objectives

1. Therapeutic Alliance: To assess changes in participants' readiness and openness to therapy, including willingness to talk post-session, depth of journaling, and therapist noting of engagement and receptivity.

2. Mental Health Outcomes: To evaluate changes in mental health outcomes, including depression, anxiety, and stress, using validated measures, thereby providing a broader picture of whether Heal contributes to symptom relief and psychological well-being beyond immediate session effects.

Exploratory Objectives

Coping Skills :To determine whether Heal promotes the acquisition and use of adaptive coping strategies, measured by the kidCOPE scale and reinforced through journal reflections.

Safety/Feasibility Outcomes: number of adverse events (AEs) and serious adverse events (SAEs).

Inclusion/Exclusion

Inclusion Criteria (Summary)

- Age: Youth 12-18 years old. All participants enrolled in this study will be under the age of 18 at time of enrollment.
- Custody: Detained in SLO County, CA Juvenile Hall with at least 8 weeks of expected stay at the time the clinical trial starts

- Diagnosis: Documented history of being at risk or of having a history or current diagnosis of a mental health disorder (depression, anxiety, stress) and/or SUD
- Language/Comprehension: Basic English understanding; accommodations for limited literacy allowed
- Consent/Assent: Eligible juveniles must provide assent, with parent/guardian or Legally Authorized Representative (LAR) consent.
- Ensure that the person providing informed consent understands the information provided, even if that person providing informed consent agrees to be in the research.
- Participation: Willingness to comply with the Heal intervention, journaling, and questionnaires
- Recruitment and selection participation: Eligible participants will be selected in collaboration with facility behavioral-health staff using objective inclusion criteria only. Recruitment procedures are designed to be fair and free from arbitrary influence by facility administrators or peers.

Special Considerations: Because participants are minors and incarcerated, safeguards ensure voluntary participation, protection from coercion, age-appropriate communication, and accommodations for literacy or comprehension limits.

Exclusion Criteria (Summary)

Participants will be excluded if they meet any of the following:

- Age/Status: Not between 12-18 years old, or not currently detained in SLO County Juvenile Hall
- Length of Stay: Expected detention is less than 8 weeks at start of clinical trial
- Clinical Stability: Determined by onsite staff to be medically or psychiatrically unable to participate safely
- Consent/Assent: Unable to provide assent, or if parent/guardian or LAR does not provide consent
- If the person providing informed consent needs more time than is allowed by the research design.
- Language/Comprehension: Cannot understand basic English, even with literacy accommodations
- Participation: Unwilling to comply with the Heal intervention, journaling, or questionnaires
- Research staff will not personally use the device for research purposes. Their role is limited to facilitating device use for participants and monitoring protocol adherence.
- While the Healpod may be available for non-research use in other settings, this protocol strictly limits its use to the described research procedures. Any non-research use will be separated from this study, and no data will be collected from individuals outside of the study.

- Currently pregnant or becomes pregnant during the study period: If pregnant or pregnancy is discovered during participation, the individual will be withdrawn from the study to prevent any potential discomfort or unknown risk exposure related to the device environment (sound, vibration, or lighting).

Special Exclusions

- Juveniles whose participation may be influenced by coercion (e.g., enrollment tied to privileges or probation decisions)
- Juveniles with severe cognitive or behavioral impairment that prevents safe or meaningful participation

Research Activities and Interventions

This study will evaluate the efficacy of the Heal intervention in improving emotional regulation (primary objective), therapeutic alliance, mental health (secondary objectives), coping skills and measuring safety/feasibility outcomes (exploratory objectives) among JIY detained in SLO County,CA Juvenile Hall. Eligible youth (ages 12-18) who are either at risk or have a history or current diagnosis of a mental health and/or SUD, and who have an expected stay of at least 8 weeks will complete baseline assessments (Mini-IPIP-A, MAIA-Y, DERS-16, TASC-R, PHQ-9, GAD-7, PSS-4, and KidCOPE), participate in brief ~5-minute Heal sessions followed by ~5-minute expressive writing/ journaling or drawing. Standardized scales, therapist assessments, and session journals will be used to measure changes in emotional regulation, therapeutic alliance, mental health, coping skills, and safety/feasibility outcomes over 8 weeks. Confidentiality will be maintained with coded study IDs, and participants will complete a final post-intervention evaluation.

Screening and Enrollment

- Eligibility will be confirmed using specific inclusion and exclusion criteria outlined in this document.
- Juvenile participants will provide verbal assent, and parent/guardian or LARs will provide written informed consent prior to any study procedures.

Baseline Assessment

- Collection of demographics, detention status, clinical history, and probation records
- Administration of standardized assessments to establish baseline measures:
    - Mini-IPIP-A (individual personality traits)
    - MAIA-Y (how well young people notice, understand, and respond to their body's internal signals of emotions, breathing, and physical sensations)

- DERS-16 (difficulties in emotion regulation scale)
- TASC-R (therapeutic alliance scale for children)
- PHQ-9, GAD-7, and PSS-4 (measures of symptoms of depression, anxiety, and stress)
- KidCOPE (pediatric coping strategies)

Intervention Activities

- Participating juveniles will use the Healpod, a sensory intervention booth, prior to their 1 to 2 weekly scheduled therapy sessions.
- Each session will involve:
  - 5 minutes of guided sound, music, gentle vibration, and soft light therapy in the Healpod
  - 5 minutes of immediate expressive writing/ journaling or drawing to capture emotional reflections
  - Meeting with their therapist right after each Heal session and after expressive writing/journaling or drawing
  - Post-Heal Therapy Assessment filled out by the therapist.
- The Heal sessions are designed to promote emotional regulation and provide a non-verbal pathway into improving outcomes of traditional therapy.

Therapy Integration

- Expressive writing/journaling or drawing output from each session will serve as a bridge into CBT/DBT talk sessions with therapists.
- Therapists will document observations of engagement, regulation, and openness in the Heal Therapist Assessment form.

Follow-Up Assessments

- Bi-weekly reassessments using forms PHQ-9, GAD-7, PSS-4
- Monthly reassessments using forms of MAIA-Y, DERS-16, TASC-R, kidCOPE

Data Collection and Confidentiality

- Data sources include standardized scales, session journals, and therapist assessments.
- For confidentiality, identifiable information will be separated from research data; participants will be coded with unique study IDs.

End-of Study-Activities

- Upon completion of the 8-week study period, participants will complete a final evaluation.

- Participating juveniles and their parents/guardians or LARs will be informed of study completion, with results summarized in age-appropriate language.
- Data will be securely archived in compliance with IRB and HIPAA requirements.

Duration

8 Weeks

MAIN PROTOCOL

Introduction

Background of the Problem: Epidemiology, Prevalence/Incidence

JIY often have difficulty regulating their emotions and coping with all they are going through. Emotional regulation (ER) in JIY is defined as their ability to manage and respond to emotional ups and downs in a healthy way. Emotional dysregulation (ED) shows up as difficulty in managing anger and/or impulsivity in reacting rather than calmly responding. These emotional tendencies can lead to anxiety, stress, and depression. Studies show that this set of factors worsens over time, and it is seen that many JIY face bigger problems with substance abuse and mental health diseases that never get resolved as they become adults. Research consistently shows that incarcerated populations have far higher rates of ED and mental health disorders than the general youth population. Studies have also shown that ER difficulties in general (i.e., not anger regulation specifically) act as a contributor to aggression and aggressive behaviors. In nationally representative JIY data, emotional dysregulation is the norm rather than the exception: in the "Survey of Youth in Residential Placement," 68% of confined youth reported being "easily upset" and 61% said they "lost their temper easily or felt angry a lot," clear, item-level indicators of dysregulation among detained youth. By contrast, community studies show much lower rates for comparable constructs: the National Comorbidity Survey-Adolescent Supplement estimates 5.3-7.8% lifetime (and 1.7-6.2% 12-month) prevalence for intermittent explosive disorder, while clinical reviews put severe irritability in community youth at roughly 0.1-5%, and epidemiologic summaries place impairing emotional outbursts in about 4-10% of children and adolescents.

Detained teens also show elevated measures of anger on standardized tools, which predict misconduct in custody, underscoring that dysregulation is not only more prevalent in corrections but is also behaviorally consequential.

Going further, an estimated 66.66% of JIY have a diagnosable mental health disorder compared to an estimated 9-22% of the general youth population.

To show how this ED shows up as mental health disorders, a large meta-analysis of detained adolescents found strikingly elevated psychiatric morbidity: major depression (10.1% males, 25.8% females), ADHD (17.3% males, 17.5% females), and conduct disorder (~62% males, 59% females). By contrast, general U.S. youth have far lower trauma-related burden; for example, lifetime PTSD is about 5% overall (2.3% males, 8.0% females).

Another comparison of the general U.S. population versus juveniles as it relates to ED can be seen in a 2016 U.S. community report study that found the overall prevalence of inappropriate, intense, or poorly controlled anger in the U.S. population was 7.8%. Anger was especially common among men and younger adults, and was associated with decreased psychosocial functioning that is directly attributable to lack of adequate coping skills. That number among the JIY in a 7,073-youth sample study had a disproportionate 69.8% who reported being easily upset, 61.2% who admitted to a hot temper, and 62.2% who said they were often angry.

A very similar disproportion also shows up with SUD and alcohol use. According to a 2021 SAMHSA report, 7.5% of adolescents ages 12-17 had an SUD, 7% drank alcohol in the past month, and 14.1% adolescents drank alcohol in the past year. While this SAMHSA report did not have data on JIY, another 2023 report by the Bureau of Justice Statistics on drug and alcohol use, as reported by Youth in Juvenile Facilities, stated that about 60% of youth met the criteria for SUD and 36% for alcohol use disorder, and that more than 63% met the criteria for severe SUD from 2008 to 2018.

Without timely therapeutic interventions, this maladaptive emotional coping can perpetuate cycles of counterproductive behavior. Thus, there is a need for effective innovative rehabilitation approaches that may help these youths strengthen emotional regulation, encourage therapeutic alliance, help improve mental health outcomes, develop healthy coping skills, and thereby potentially reduce recidivism and relapse rates.

However, all of this puts a heavy price-tag and burden on the American tax-payer and the American public health system. The California JJCPA/YOBG annual county reports show the programs and expenses that cover in-custody programming (e.g., pro-social skills, behavioral health groups, trauma work). The cost for all these programs in Juvenile Hall by county ranges from approximately $223,380 per year in Contra Costa County to $531,440 per year in Santa Clara County. These figures of course account for all expenditures by program, including professional services used for in-custody

programming. These reports are where ER contracts are typically coded. To get a sense of the scale of these expenses, these figures are for single counties, and there are 52 counties in California alone. The United States has 3,244 counties and county equivalents, indicating more than approximately a billion dollars for in-custody programming for pro-social skills, behavioral health groups, trauma work, etc.

As far as the therapy that is being provided, CBT /DBT are now the accepted gold standards of talk therapy in addiction and SUD in correctional systems. Additionally, there are other more recent treatment modalities, such as EMDR, brainspotting, TMS, neurofeedback, and biofeedback, all of which can also help with the conditions above. The good news is that JIY show strong evidence of ED being responsive to intervention: a 2023 pilot conducted in a juvenile correctional treatment center (N = 113, ages 13-17) found that after receiving comprehensive DBT, detained adolescents showed statistically significant improvements in emotional regulation (small- to medium-effect sizes) as well as reductions in overall mental health symptoms. Another study of DBT in Washington State's juvenile justice system points out that incarcerated youth often enter facilities with high rates of aggression, trauma exposure, and ED, making engagement and maintaining fidelity of treatment challenging in the detention environment. This same study showed reduction in self-harm, aggression, and negative emotional states among youth in detention with DBT. Other interventions in juvenile detention, such as trauma-processing therapies like EMDR and brainspotting, face practical barriers, such as requiring between 10-30 sessions, each lasting 60-90 minutes with a trained professional. Juveniles often have short, unpredictable lengths of stay that would interrupt these multi-session protocols (e.g., average detention stays are reported at ~7-10 days nationally, with many facilities reporting ~28 days), making it hard to complete phased work that requires the stabilization and repeated sessions that EMDR and brainspotting do. TMS, while FDA-approved for adults, is still under scrutiny for adolescents given its Adverse Events (AEs) occurring at rates between 3.42% and 5.97%.

A study screening juvenile offenders (age ~15-17) showed 66-90% had below-average language skills on verbal subtests, with 46-67% in the "poor" to "very poor" range, with over 60% failing basic literacy thresholds. Given those deficits, verbally mediated interventions may not be effective with many JIY. On the other hand, sound, music and vibroacoustic therapy such as Heal provides may be a more effective option for them. Such non-verbal sensory and experiential therapies are increasingly recognized as valuable treatment modalities if used when complementing CBT/DBT. Rather than replacing CBT/DBT, they provide a different pathway into regulation and engagement, especially for youth who may struggle with talk-based approaches. Current research supports their potential:

- Sensory-based occupational therapy in two Midwestern juvenile correctional facilities significantly improved self-regulation and reduced violent behavior, even when delivered in short, irregular sessions.
- Sound and music therapy programs with JIY (N = 178) demonstrated significant improvements in self-concept, resilience, and stress-coping skills ($p < 0.001$). Youth feedback highlighted the power of listening, songwriting, and music-making to build courage, perspective, and self-recognition.
- Creative arts interventions in at-risk youth programs instead of standard punitive labor have been linked to substantial reductions in recidivism. In one jurisdiction, substituting arts programming for punitive labor reduced one-year recidivism from 54% to 14%.
- A tailored intervention called WRITE ON (Writing and Reflecting on Identity To Empower Ourselves as Narrators) was tested in short-term juvenile detention centers. In a pilot study (N = 53 youth), WRITE ON participants showed significant gains in resilience. Also, sound and music interventions have been piloted with juvenile offenders before.
- Sacramento County's multi-sensory de-escalation room is the first of its kind in a juvenile detention facility in the United States. This innovation creates a safe, trauma-informed environment that allows residents to de-escalate without use of force or an isolation room, which helps prevent violence and increases safety.
- Reviews of whole-body vibration interventions also suggest improvements in cognitive control and attention, which are linked to better emotional regulation.

Together, these findings underscore that structured, creative, and sensory-based interventions can unlock engagement, strengthen coping, and provide meaningful emotional regulation for youth who may otherwise remain resistant or disengaged. By virtue of not depending on verbal processing, requiring minimal specialized staff, and being deliverable flexibly without a fixed number of sessions, sensory-based interventions are uniquely suited to short and unpredictable detention stays, thereby lowering barriers to care while supporting stabilization.

The Heal intervention is one such innovation: a unique, engaging, non-verbal, easy-to-use (no specialized staff needed to operate), sensory-based, experiential therapy treatment modality. It offers a compelling, innovative treatment modality and works seamlessly with CBT/DBT.

The proposed study is intended to be an 8-week clinical trial. Participating juveniles will be selected from the SLO County Juvenile Hall, a custodial commitment camp program in Juvenile Hall for 12- to 18-year-old male and female youth who are at moderate to high

risk and in need of residential treatment. Youth in this facility are ordered to stay 6-12 months and to receive intensive case management, treatment and educational services through collaboration with a local treatment provider, Family Care Network, and the County Office of Education, making it the ideal population to work with within Juvenile Hall. Participating juveniles will be scheduled to use the Healpod between 1-2 times a week before they meet their therapist. They will arrive 10 minutes before their scheduled session with their therapist, sit inside the Healpod to experience the sounds, music and gentle vibrations for about 5 minutes, and then journal/ write or draw about their experience. Therapists will use the journal as a starting point for talk therapy (CBT/DBT) treatment.

The Healpod (the tool for treatment) itself is a physical, rounded 4ft x 6ft telephone booth-like space equipped with speakers, subwoofer, and a touchpad. Once seated inside the Healpod, participants draw the curtains closed and then select a desired guided or unguided meditation track.

This multi-modal approach intends directly to address juveniles' needs by providing calming sensory input and a non-verbal outlet for emotions. As a point of validation for this approach, a recent SLO County Heal Health Agency innovation project, funded by the California State Mental Health Services Act (MHSA) between 2021 to 2025 with justice-involved adults, demonstrated the profound impact and safety of the Healpod and the Heal intervention, laying the groundwork for its translation to youth in Juvenile Hall as envisioned for the present proposed study. In this adult program (N = 105), there were over 1,117 Healpod sessions documented with 0 negative incidents reported, underscoring the method's safety and acceptability. Virtually every participant in that study found value in the Heal experience: over 99% reported gaining at least one new coping skill and over 97% experienced improvements in well-being from their Heal sessions. Therapists observed similarly positive effects. In more than 90% of cases, clinicians noted that after a Heal session their clients entered therapy more emotionally regulated and engaged than otherwise. Quantitative outcomes showed statistically significant emotional improvements across sessions: participants reported dramatically lower stress, anxiety, and depression, coupled with marked increases in feelings of calm (relaxation), positivity, and focus after each 5-minute session. These before-and-after mood shifts were striking (e.g., roughly a 3-fold reduction in stress and a 2-fold increase in relaxation per session). In fact, 97% of individuals showed an increase in positive feelings following Healpod use. Certain therapeutic sound tracks proved especially effective: the "Grounding" meditation produced the largest boost in positive mood on average, and the popular "Meditation of the Day" track also yielded a strong

improvement. Taken together, these results indicate that the Heal approach reliably elicits immediate emotional regulation and well-being benefits in a justice-involved population.

The Heal intervention is non-invasive, non-intrusive, and comparable to the experience of sitting inside a car listening to music. There are no medications, no procedures, and no active effort required from the juveniles beyond listening to sounds and music and experiencing mild vibrations. Youths' familiarity with listening to music only makes them more receptive to this treatment; in fact, some approved detained youth are already permitted to use mp3 players and headphones for music in SLO County Juvenile Hall, where this trial is to be conducted, so listening to calming tracks in the Healpod feels like a natural and non-threatening extension of that. Additionally, by design each session is very brief: about 5 minutes for the meditation portion, which aligns well with youths' short attention spans and the tight scheduling constraints of detention. The American Academy of Child & Adolescent Psychiatry (AACAP) notes in their "Facts for Families" guide that children and adolescents typically spend about 2.5 hours per day listening to music. Also, teens and young adults (especially ages ~16-24) are among the highest music consumption groups.

Prior Adult Study Evidence (SLO County Behavioral Health, 2021-2025):

The Heal Intervention has already been evaluated in a 4-year innovation study conducted by the San Luis Obispo County Behavioral Health Department and the California Polytechnic institute, SLO under the California Mental Health Services Act (MHSA). This county-wide project ("SoundHeal Project Evaluation," pp. 21-28 of the MHSA Innovation Evaluation Report 2021-2025) involved more than 1,100 Heal sessions delivered to 105 adult behavioral-health clients, including justice-involved and forensic populations. Results demonstrated significant reductions in self-reported **stress, anxiety, and depression**, and consistent increases in **calmness, positivity, and focus** after each 5-minute Heal session.

The short duration of the intervention also lowers resistance to its use, as clinicians for the incarcerated in SLO County Heal Health Agency innovation project noted: because sessions are quick, clients are more willing to try them and become consistent in using the Healpod. This makes Heal easy to fit into their scheduled routine of a juvenile facility and adaptable to even a short detention stay. The standard probation staff supervision can ensure every participating juvenile's physical safety throughout the experience inside the Healpod because the Healpod has a 4-inch x 8-inch security window that gives officials a full view of the juvenile; this security window allows officials to make sure the juvenile is safe while also ensuring the juvenile is not disturbed through the experience. No adverse events or safety concerns were reported in the entire 4-year period. Over 97

% of participants described the Heal experience as beneficial, and clinicians reported improved session readiness and therapeutic engagement in > 90 % of encounters. Quantitative analyses from this evaluation confirmed significant pre-/post-session improvements on validated Likert scales and qualitative journals, confirming that Heal safely induces rapid emotional regulation and enhances therapeutic alliance and we anticipate a similar safety profile in juveniles.

This adult evidence base provides a strong ethical and empirical foundation for extending the Heal approach to a juvenile population, with modifications for age, literacy, and custodial safeguards.

Crucially, Heal also facilitates downstream therapeutic alliance through its expressive writing/journaling or drawing component. Immediately after each sound session, youth will be guided either to jot down or do representative drawings of their feelings, sensations, or thoughts. This private journaling exercise helps them process the experience. In the SLO County Heal Health Agency innovation project, this post-meditation journaling proved invaluable: clients' "session journals" captured their emotional state before, during, and after the meditation and were shared with therapists to jump-start deeper conversations in therapy. This approach will be especially beneficial for traumatized youth who struggle to articulate feelings in traditional counseling. The act of writing after a calming meditation can unlock emotions in a non-confrontational way, giving these young people a voice on paper when they might stay silent face-to-face. It fosters greater openness and emotional processing, allowing therapy (even within the limited time available) to focus on issues the youth has identified in their own words. By combining somatic calming with expressive writing/journaling or drawing, Heal may create a bridge from inner emotional regulation to communication to building coping strategies and using them to manage life's challenges; it is our hope that the Heal sessions will help reduce youths' depression, stress, and anxiety, providing a bridge that standard talk therapy alone often fails to build in a detention setting.

In SLO County Juvenile Hall, youths are provided "one-on-one individual counseling sessions in fifteen-minute increments." That stipulation suggests that in that county, at least for some therapists, very short individual counseling sessions are used. During this short window of time, therapists must simultaneously build rapport, regulate clients' heightened emotional states, and then attempt to address deeper clinical issues. Too often, the first half of the session is consumed by achieving emotional regulation, helping a youth calm down enough to even begin discussing their feelings or progress. By contrast, when Heal is introduced immediately before these sessions, the youth enter therapy already calmer, more centered, and emotionally regulated.

The reasoning behind the decision to make the primary objective of this study to measure ER and the secondary objectives to measure therapeutic engagement and mental health outcomes in treatment is that while all show disparities between JIY and the general youth population, as discussed earlier, there is a cause-and-effect relationship between ER and engagement in treatment. The weight of evidence supports a directional, partly causal chain in which improving ER enables more engagement, and adaptive coping, which then improves downstream outcomes, especially in adolescents. This effect is strongest in JIY.

Research shows that when clients improve their ability to regulate emotions, the therapeutic alliance gets stronger and treatment engagement improves. In a large inpatient sample (n=913) ages between 18-25, emotional regulation mediated the relationship between alliance with the care team and symptom improvement, i.e., when regulation improved, alliance-outcome links were stronger. Specifically, In juvenile justice populations, direct tests of the emotional regulation-therapeutic alliance link within secure detention are limited. A systematic review in JIY highlights emotional regulation difficulties as barriers to forming therapeutic alliance, and suggests that stronger ER skills may facilitate such alliance; moreover, in detained samples, gains in emotional regulation predict reduced recidivism. Together with adolescent data showing therapeutic alliance-outcome effects mediated by emotional regulation, this supports testing ER as a mechanism that can strengthen therapeutic alliance and downstream outcomes in juvenile detention.

In adolescents, ER and coping are related but distinct systems. A 212-study meta-analysis (N≈80,850) shows that both predict psychopathology, with ER emerging as a central transdiagnostic mechanism that closely tracks internalizing/externalizing symptoms and overlaps with coping yet remains conceptually separable, supporting ER as the proximal target. Interventional and longitudinal data point from ER results in coping/adjustment. For example, a randomized trial of affect regulation training and related add-ons to ER skills shows that explicitly training ER enhances CBT's effects and reduces symptoms on major depressive disorder (i.e., ER change functions as a mechanism of change rather than as a mere correlate). Youth-focused evidence converges: another meta-analysis of child/adolescent treatments found that improvements in ER are reliably associated with better clinical outcomes, implying ER change is not just epiphenomenal. This study also indicates that specific ER processes prospectively predict symptom trajectories, while emotion-focused strategies mediate links between stress and adjustment, consistent with ER acting upstream of coping patterns and outcomes. Critically for the JIY population at the center of this proposed trial, a large study found that gains in ER while incarcerated predicted lower felony recidivism

one year after release, strengthening the causal story for ER that shifts behavior in justice-involved populations.

Based on this previous research and what we believe is the best way that the Heal intervention has helped the SLO County Behavioral Health adult incarcerated population (results shared below), we plan to target ER first to down-regulate arousal and increase tolerance, awareness, and modulation, and then to target adaptive coping skills such as problem solving, support seeking, and substance-free self-soothing. Our thesis is that these changes will then potentially improve conditions such as anxiety, stress, and depression.

In summary, this proposed study aims to evaluate positive changes in emotional regulation of JIY using the novel Heal intervention, which is designed to engage the brain and body through multiple converging neurophysiological pathways. Auditory stimulation activates the auditory cortex and limbic system, regions deeply involved in emotion, reward, and memory. Music with rhythm, melody, and harmony promotes entrainment, a process in which the brain and body synchronize their neural oscillations and physiological rhythms, such as heart rate and respiration, to external auditory input. This entrainment may help shift JIY from a state of hyper-arousal or sympathetic dominance toward a calmer parasympathetic state, improving ER. Proprioception gives people a *felt sense* of their body's boundaries, movements, and orientation in space. When trauma, addiction, or chronic stress are present, this sense can become muted or distorted. Youth may feel disconnected from their bodies, or even numb. The expectation is that Heal will help rebuild this sensory map. Expressive writing/journaling or drawing further enhance ER by integrating emotional awareness and narrative building once physiological arousal has been reduced. By addressing the underlying biology and the neuropsychology of SUD and mental health diseases, we seek to develop the Heal intervention to measure and improve patient outcomes, potentially reduce recidivism and relapse rates, and help build life skills with a consistent mindfulness practice, thereby potentially enhancing the lives of those affected.

Proposed Hypothesis

This proposed study aims to investigate in JIY the relationship between ER and a brief, multi-sensory intervention incorporating sound, music, gentle vibrations, light, mindfulness, and journaling/writing/drawing, delivered in a 5-minute Healpod session. The primary hypothesis is that the Heal intervention will result in measurable improvements in ER compared to each participant's own baseline ER. This study has a pre-post design.

Justification

Youth in the juvenile justice system demonstrate disproportionately high rates of

emotional dysregulation and co-occurring mental health needs. As many as 65-75% meet criteria for a diagnosable mental health disorder, and more than 60% present with co-occurring SUD. Trauma exposure is nearly universal, with studies showing over 90% of detained youth report at least one traumatic experience, often linked to heightened stress reactivity.

Traditional therapies such as CBT and DBT can be effective; however, in detention settings, they rely on a youth's willingness to verbalize thoughts and feelings and to engage in abstract and significant cognitive work. In practice, the first portion of therapy sessions is often spent simply calming the JIY, leaving little time for actual skills training. Without immediate regulation strategies that take away from valuable therapy time, therapists may find themselves unable to move past crisis management. By contrast, the Heal intervention uses a non-verbal, experiential, somatic approach that requires no specialized operator or provider, can be administered on-demand, and provides immediate ER benefits. When Heal is used just prior to a regular therapy session, the therapist is afforded more opportunity to move beyond crisis management and engage in more substantive therapy. These features make it particularly well-suited for the detention environment, where immediate stabilization and engagement allow the conversation to be impactful right from the start.

Anticipated Benefits, all of which are supported by prior evidence from the SLO County Heal Health Agency innovation project with Heal.

- **Immediate ER:** Post-session reductions in stress, anxiety, and emotional dysregulation following Heal sessions may interrupt negative patterns.
- **Enhanced therapy readiness/alliance:** JIY arrive at counseling sessions calmer and more open, allowing all the clinical time to focus on meaningful therapeutic work rather than spending time on de-escalation efforts.
- **Skill development:** Through expressive writing/journaling or drawing, participants may begin to recognize emotional shifts and build adaptive coping strategies that can be transferred beyond the session and integrated into other areas of their lives.
- **Feasibility and accessibility:** The intervention is non-invasive, requires no special staff to operate, can be delivered consistently despite fluctuating lengths of stay, and does not depend on verbal disclosure or advanced clinical expertise.
- **Potential long-term impact:** By improving emotional regulation and engagement in therapy, Heal may support healthier coping, reduce behavioral incidents, and contribute to better long-term rehabilitation outcomes.

The ethical justification for doing this research with detained youth is reinforced by four years of safe, successful implementation in SLO County adult behavioral-health programs (MHSA Innovation Evaluation Report 2021-2025). In that adult population, which included probation-referred and justice-involved clients, no AEs or SAEs occurred across more than 1,000 sessions, and participants consistently demonstrated immediate reductions in stress, anxiety, and depressive symptoms. This adult evidence demonstrates a well-

characterized safety profile, supporting minimal-risk classification for the proposed juvenile study.

Objectives

Main Objectives in Relation to the Hypothesis

Primary Objective

- **Emotional Regulation:** The primary endpoint for the present study is to evaluate the efficacy of the Heal multi-sensory intervention in improving emotional regulation among JIY in the SLO County Juvenile Hall compared to each youth's own baseline. The study aims to identify the change in DERS-16, MAIA and the score from baseline to post-intervention based on data from the sessions' expressive writing/journaling or drawing and the Heal therapist assessment report, where applicable.

This endpoint has been selected because it directly addresses the primary objective of the study and is considered a critical indicator of treatment efficacy. Emotional dysregulation is a well-documented risk factor for aggression, substance use, and recidivism among JIY and improvements in this construct represent a meaningful clinical outcome.

Secondary Objectives in Relation to the Study

Secondary Objectives

- **Therapeutic Alliance**: To assess changes in participant openness and readiness to engage in therapy, as evidenced by willingness to talk during post-session discussions, depth of journaling reflections, and therapist observations of receptivity. Engagement is a key determinant of success in mandated treatment programs, where building trust and reducing resistance are essential for therapeutic alliance.

- **Mental Hhealth Ooutcomes**: To evaluate changes in psychological symptoms, specifically depression, anxiety, and stress, this study will use validated tools (PHQ-9, GAD-7, and PSS-4). These domains are highly prevalent among JIY and as secondary endpoints represent clinically meaningful outcomes beyond immediate emotional regulation.

Exploratory Objectives

- **Coping Skills**: To evaluate whether the Heal intervention supports the acquisition and use of adaptive coping strategies, such as calming oneself under stress, adopting constructive problem-solving, and letting go of negative thoughts, as measured by the KidCOPE from baseline to post-intervention, the study will use the session journals and Heal Therapist Assessment, where applicable. This endpoint was selected because detained youth often rely on maladaptive coping behaviors such as avoidance, aggression, or substance use, and the ability to adopt healthier coping skills is a critical indicator of treatment impact.

- **Feasibility and Acceptability**: This study will also assess the feasibility and acceptability of delivering the Heal intervention in a juvenile detention facility, and safety profile. These objectives will inform implementation in real-world detention environments, where short and unpredictable lengths of stay often limit access to conventional multi-session treatments.

Study Design

Description of the Study Design

This study is a single-site, pilot, pre-post intervention study designed to evaluate the impact of the Heal multi-sensory intervention on emotional regulation, therapeutic alliance, mental health outcomes, and coping skills in JIY with mental health issues and/or SUD.

All enrolled participants will receive the Heal intervention in addition to standard care, and outcomes will be assessed by comparing within-subject changes from baseline to post-intervention over an 8-week period. This design was selected because it allows measurement of clinical and behavioral outcomes without denying participants access to the intervention, which facility leadership is already interested in integrating into the SLO County Juvenile Hall.

Primary Objective Alignment
The design directly supports the primary objective of evaluating improvements in emotional regulation three ways:

- The study will use validated scales with the DERS-16, MAIA (Baseline + Midpoint + End).
- The sessions' expressive writing/journaling or drawing component will also provide qualitative data for thematic analysis of changes in self-expression and emotional processing, recorded as immediate effects from the intervention.
- Heal Therapist post-session assessment report will note the observational feedback from the therapist where applicable.

Secondary and Exploratory Objectives
To address secondary objectives, the study incorporates standardized tools:

- TASC-R (Baseline + Midpoint + End).

- Structured journaling, therapist observations and validated scales with PHQ-9, GAD-7, and PSS-4 (every 2 weeks) will assess changes in coping strategies and mental health symptoms of depression, anxiety, and stress.
- Exploratory objectives will be addressed through qualitative analysis of journals and the feedback from therapists (by session) where applicable.
- Cognitive and behavioral coping will be evaluated with the standardized KidCOPE assessment tool (Baseline + Midpoint + End).

Key Design Features

- **Single-arm, open-label:** All participants will receive the intervention; no placebo or control group will be used.
- **Pre-post comparisons:** Each participant will serve as their own control, minimizing between-subject variability.
- **Setting:** The trial will be conducted at San Luis Obispo (SLO) County Juvenile Hall. All interventions will occur on-site.
- **Duration:** Each participant will be enrolled for 8 weeks, completing up to 16 Heal sessions plus baseline, bi-weekly, midpoint, and endpoint assessments.
- **Sample Size:** The study will enroll up to 8 participants (male and female youth ages 12-18).
- **Therapist involvement:** Facility therapists and/or probation staff will administer assessments and conduct post-session discussions to support integration of the intervention into therapy and be available for any AE support.

Rationale for Design
A randomized controlled trial (RCT) is not feasible in this setting due to the small population size of up to 18 juveniles in the SLO County Juvenile Hall. The pre-post design provides practical feasibility while still generating meaningful quantitative and qualitative data on changes in emotional regulation, therapeutic alliance, mental health outcomes, and coping. Findings from this pilot will inform the feasibility and effect sizes needed to plan a larger, fully powered RCT in the future.

Also, tracking emotional regulation not only with a dysregulation scale (e.g., DERS-16) but also with a mechanism-focused measure like MAIA will help us see if youths' body awareness/self-regulation improves. This lets us see *how* the Heal intervention might work, not just *if* it works.

Schedule of Assessments

Standardized Test	Start 0	Wk 1	Wk 2	Wk 3	Wk 4	Wk 5	Wk 6	Wk 7	Wk 8
Mini-IPIP-A (Adolescent)	X								
MAIA-Y (Youth)	X				X				X
DERS-16	X				X				X
TASC-R	X				X				X
PHQ9	X		X		X		X		X
GAD7	X		X		X		X		X
PSS4	X		X		X		X		X
KidCope	X				X				X

The youth fill out Heal Session Journals and the clinician/therapist will fill out the Heal Therapist assessments every Healpod session.

Interactions with Participants

Consenting

Prior to any study-related procedures, prospective participants will be provided with age-appropriate, comprehensive information about the study, including its objectives, procedures, potential risks and benefits, and their right to withdraw at any time without penalty. Because participants are minors in custody, a verbal assent process will first be conducted with the youth, followed by parental/ guardian or LAR written consent. If the prospective participant is unable to read the consent form or has limited reading capabilities, then an impartial witness will be present from Juvenile Hall to attest the consent was attained ethically by signing the consent form. If the parent/guardian or the the LAR does not speak English a bi-lingual translator representative from SLO County staff will be provided to translate in Spanish. Under all above circumstances it will be made sure that the prospective participant is not put under any pressure or discomfort to participate in this trial. The prospective participants' clear decsion will be obtained on how they want to proceed as a part of this process. It will be ensured that there is no threat of harm or adverse consequences to the prospective participant for a decision to not take part in the research. It will be ensured that the informed consent process will be stopped once the prospective participant indicates that he or she does not want to take part in the research. It will be ensured that we adapt the presentation of the information to the participant's capacities in terms of intelligence,rationality, maturity and language. Invite the potential participant to ask questions and answer questions from the prospective participant. It will be ensured that no information is provided to the prospective participant or the person providing informed consent that is made to waive or appear to waive any of the prospective participant's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence. It will be communicated to the person providing informed consent all the information in the consent

document or script approved by the IRB. Prospective participant will not be enrolled when the person obtaining informed consent is unwilling to listen to or consider the information, even if the person providing informed consent agrees to be in the research. The informed consent process will continue throughout participation in the study, and consent will be informally verified on a continuing basis and recorded in the probation and clinical staff notes on an on-going basis. As a part of the on-going consent, significant new information will be given to the participant, and continuing consent will be documented as an addendum to probation and clinical staff notes with the PI being timely notified.

Screening and Enrollment
Screening will include review of inclusion and exclusion criteria such as age, custody status, length of stay, assent capacity, parental/guardian or LAR permission, language, and clinical stability and participation in the SLO County Juvenile Hall.

Study Visits
Because participants are housed in SLO County Juvenile Hall facility, all interactions will take place on-site. JIY will participate in baseline assessments at enrollment, followed by structured Heal intervention sessions for 8 weeks. Assessments (questionnaires, scales, journaling) will be repeated at 2-week intervals and at study completion. Session journals will be completed after each session inside the Healpod.

Standardized assessment will be completed as follows: Mini-IPIP-A (At the start), MAIA-Y(Baseline + midpoint + End), DERS-16(Baseline + midpoint + End), TASC-R (Baseline + midpoint + End), PHQ-9 (every 2 weeks), GAD-7 (every 2 weeks) and PSS-4 (every 2 weeks) and KidCOPE (Baseline + midpoint + End). Each “visit” will consist of: (1) HealPod session (~5 minutes), (2) journaling (~5 minutes), and (3) therapy session with a therapist (~15 to 30 minutes).

Interventions
All enrolled JIY’s will receive the Heal intervention, consisting of sitting in the Healpod to have the therapeutic sensory experience (sound, music, vibration and light) followed by brief expressive writing/journaling or drawing. There is no randomization or control group in this pilot; instead, each participant serves as their own control, with outcomes compared pre- and post-intervention. The intervention is designed to support improved emotional regulation, increased therapeutic alliance, improved mental health outcomes and coping skill development; it is delivered as an adjunct to existing therapy services provided by facility staff.

Data Collection
Data will be collected using a combination of validated self-report standardized measures (DERS-16, MAIA-Y, TASC-R, PHQ-9, GAD-7, PSS-4, and kidCOPE), participant session expressive writing/journaling or drawings, and therapist assessments/observations. Assessments will be administered at baseline, every 2 weeks, and at study completion. Journals will be de-identified prior to analysis. No biological samples will be collected. All

data will be securely stored and managed using electronic data capture systems consistent with IRB and HIPAA standards.

Study Completion
At the end of the study period, participants will complete final assessments and be debriefed on the study's purpose and outcomes. A summary of aggregate results (not individual data) may be shared with participants and facility staff, where appropriate. Participants will be thanked for their contributions and reminded that their involvement will not influence probation decisions or facility privileges.

Since the participants in this study are receiving on-going care even after the conclusion of this trial, follow-ups on how they feel with the intervention post-clinical trial will continue with the clinical staff.

Medical Diagnosis/Medical Interventions

Intervention Arm
All enrolled participants will receive the Heal intervention, which consists of a structured, multi-sensory-based experience designed to promote emotional regulation and the development of improved therapeutic alliance, mental health measures, and coping skills. Participants will sit inside the Healpod, a 4 ft × 6 ft enclosed booth equipped with audio speakers, bass shaker, ambient lighting, and a touchscreen interface. Each session lasts approximately 5 minutes, during which time participants select a guided or unguided track that delivers therapeutic sound, music, light, and gentle vibrations. Immediately following the session, participants complete a brief expressive writing/journaling or drawing activity for approximately 5 minutes to process their experience, information that is later used to support therapy discussions.

- **Frequency and duration:** Sessions will occur once or twice weekly for approximately 8 weeks (up to 16 total sessions per participant).
- **Administration:** The intervention will be self-directed by the participant inside the Healpod, with supervision by Juvenile Hall staff for safety. Trained research staff or clinicians will oversee journaling and integration with therapy.
- **Consistency:** All Heal sessions will be delivered according to a standardized protocol to ensure uniformity across participants.

Control Group
This pilot study does not employ a separate control group. Each participant will serve as their own control through within-subject pre-post comparisons, with baseline measures compared to outcomes collected after 8 weeks of intervention. Standard programming and therapy available at the Juvenile Hall will continue unchanged for all participants.

Intervention Delivery and Adherence
The Heal intervention will be delivered under the supervision of SLO County Juvenile Hall

staff and clinicians, who will receive Heal protocol-specific training. Adherence will be monitored through:

- **Automated session logs** generated by the Healpod software, which will record session frequency, duration, and track selection
- **Staff logs** documenting journaling or drawing completion and post-session engagement
- **Therapist notes** reflecting changes in therapeutic readiness and participation following Heal sessions.

Intervention Modification

The Heal intervention is designed to be low-risk and non-invasive. However, if a participant experiences discomfort, distress, or requests to stop a session early, the session will be discontinued immediately. Such events will be documented as protocol deviations, noting the reason for modification, duration of exposure, and any follow-up action taken. Modifications may include reducing session length, adjusting sound volume, or rescheduling a session if needed. No pharmacologic or medical interventions will be altered as part of this study.

Justification

Emotional dysregulation, poor therapist alignment, mental health difficulties and impaired coping skills are highly prevalent among JIY and represent major barriers to rehabilitation. The Heal intervention was selected because it offers a standardized, non-verbal, somatic, experiential, sensory-based tool that can be delivered safely within the constraints of SLO County Juvenile Hall, requires minimal staff training, and complements existing therapeutic services. By employing a structured pre-post design with validated outcome measures, this study will evaluate whether the intervention improves emotional regulation (primary endpoint) and therapeutic alliance and improved mental health outomes (secondary endpoints) in the SLO County Juvenile Hall population.

Study Definition: Evaluation of Heal Intervention Using Healpod Device

This study is evaluating the Healpod, a multi-sensory, non-invasive booth designed to support emotional regulation through music, sound, gentle vibration, ambient light, and journaling/writing or drawing.

The Healpod has been reviewed against FDA criteria for device risk (21 CFR 812.3[m]) and determined to be a Non-Significant Risk (NSR) device, based on the following:

- Not an implant: The Healpod is a free-standing single person booth 4ft x 6ft with a soft curtain to maintain privacy that is constructed from non-invasive materials (wood, CE certified audio components, and integrated dim/ambient lighting).

Participants sit inside the space on a chair provided during the session. No component of the Healepod enters, penetrates, or remains in the body. The device does not interact with bodily tissues, fluids, or organs. It functions externally by delivering sound, music, gentle vibration, and ambient light to create a calming environment. The participant remains seated with plenty of space to sit and stand and in full control of their movements throughout their time inside.

- Not sustaining life: The Healpod is not designed to sustain or support vital functions such as breathing, circulation, or organ performance. It is not a ventilator, defibrillator, infusion pump, or other form of life-supporting equipment.
- Not for diagnosing, curing, mitigating, or treating disease: The Healpod does not diagnose, cure, or directly treat medical conditions. It functions as a supportive, adjunctive intervention to existing CBT/DBT talk therapy..
- No potential for serious risk: The HealPod uses non-invasive, low-intensity sensory input (including low voltage 12V gentle vibrations and RGB light) and does not expose participants to electrical, magnetic, or thermal energy capable of causing harm. The intervention is brief (~5 minutes), non-invasive, and participants remain fully conscious and free to exit at any time. Any time they decide they want to turn it off, they can press the volume button and walk out by moving the curtain. There is no lock or door, just a curtain. No adverse events have been reported in prior use in correctional or behavioral health settings. Oversight by onsite probation and clinical staff further reduces risk. No adverse events have been reported in prior studies over the past 5 years.

- Use of Identifiable Information:Identifiable information (e.g., participant names) is not required for data analysis. Only de-identified and coded data will be used. Any identifiable records (if necessary for care coordination) will remain within the Juvenile Hall Behavioral Health Team and will not be accessible to researchers.

- Protection of Rights and Welfare:The waiver will not adversely affect participants' rights or welfare. All youth and guardians are informed that participation in Heal sessions is voluntary and that declining or discontinuing participation will not affect probation status, privileges, or services received.

- Additional pertinent information after participation: In addition to the constant feedback that the therapist will provide after each Heal session, participants will also be provided with general feedback about the overall results of the program and information about how their participation contributed to understanding youth wellness and emotional regulation outcomes.

- The minimal risks associated with participation are comparable to those that would be considered acceptable for non-detained youth volunteers in community behavioral programs.

- Although the HealPod presents minimal physical risk, the study excludes pregnant participants out of an abundance of caution. While there is no evidence of harm,

the physiological and emotional sensitivity associated with pregnancy warrants exclusion to ensure participant safety.

The HealPod meets all criteria for a Non-Significant Risk device under **21 CFR §812.3(m)**. This study will therefore proceed under the abbreviated IDE requirements for NSR behavioral research and does not require an FDA IDE submission.

- **Drug/Biologics**

NA

- **Food**

NA

- **Cosmetics**

NA

- **Tobacco**

NA

- **Others: Behavioral Research**

Intervention

The Heal study intervention is a carefully designed program aimed at promoting emotional regulation, improved therapeutic alliance, better mental health outcomes and adaptive coping skills among JIY. This program is based on principles from affect regulation theory, mindfulness-based interventions, and sensory modulation approaches, which emphasize the role of both bottom-up physiological regulation and top-down reflective processing. By addressing both bottom-up physiological regulation (through sound, music, and gentle vibrations) and top-down reflective processing (through expressive writing/journaling or drawing), the intervention aims to reduce emotional dysregulation and prepare youth for more effective alignment with therapy.

Components

The Heal intervention program consists of several key components:

- **Sensory intervention:** Participants sit inside the Healpod, a 4- by 6-foot enclosed booth equipped with speakers, bass shaker, ambient light, calming sound, and music for ~5 minutes per session.

- **Expressive writing/ journaling or drawing**: Immediately following the Healpod session, participants spend ~5 minutes journaling or drawing about their experience, emotions, and/or reflections.
- **Therapeutic integration**: Participating juveniles then meet with a clinician for a brief, standard therapy interaction of approximately 15 to 30 minutes, using their Heal session journal as a bridge into deeper therapeutic discussion.

The intervention will be delivered in an individual, in-person format within the the SLO County Juvenile Hall setting. Sessions will occur once or twice weekly over an 8-week period, for up to 16 sessions per participant. Sessions will be supervised by trained facility staff with oversight by licensed clinicians.

Implementation

To ensure consistency and fidelity, a detailed intervention manual will guide all sessions. Staff will undergo protocol-specific training prior to implementation. Adherence will be monitored through session logs, therapist checklists, and participant feedback. All journaling will be de-identified before analysis to protect confidentiality of the JIY.

Accepted Variances

While the intervention is standardized, opportunities for individual tailoring are built in. For example, participating juveniles may select from a set of calming sound tracks, choose whether to sit with the curtain open or closed, or opt to journal through drawing rather than writing. Session length may be shortened if a participant experiences discomfort, and journaling prompts may be adjusted for literacy levels. These adaptations ensure that the intervention remains accessible and effective for diverse participants with varying needs. Some participating juveniles may be read the questions from the standardized questions and may be given details on what the questions are asking if their comprehension skills or reading skills are low.

Naive Condition

This pilot does not include a separate control group. Participants serve as their own controls, with pre-intervention baseline measures compared to post-intervention outcomes. Usual care, such as counseling, behavioral groups, and other programming, will continue in parallel, ensuring no participant is deprived of standard services. The absence of a control group reflects the small population size, ethical considerations, and the feasibility goals of this pilot, while still allowing for meaningful within-subject evaluation of intervention effects.

Confidentiality Protections

All data will be de-identified at the point of collection. Journals will be labeled only with study ID numbers and stored separately from identifying information. Electronic data will be stored in password-protected, HIPAA-compliant systems accessible only to authorized

study personnel. No individual-level data will be shared with probation or facility staff in ways that could affect case decisions.

Consent and Assent Process

Because participants are minors in custody, a two-step process will be followed:

- **Youth assent:** Each participant will be given age-appropriate information and asked for verbal voluntary assent.
- **Parental/guardian or LAR consent:** Parents or legal guardians will be contacted to provide informed consent prior to enrollment. If they are not able to consent in English they will be provided a Spanish translated Consent form.

Consent/assent forms will clearly state that participation is voluntary, that declining will not affect privileges or probation status, and that participants may withdraw at any time.

Participation in this study will have no effect on probation status, case outcomes, or parole decisions. Parole boards and probation staff will not receive information regarding a youth's participation in the study.

Deception

No deception is involved in this study. All participants and guardians will receive full information regarding the study's objectives, procedures, risks, and benefits.

Study Population

Inclusion Criteria

Participants must meet all of the following criteria to be eligible for enrollment:

- **Age:** Youth aged 12-18 years at the time of enrollment
- **Custody:** Currently detained in SLO County Juvenile Hall
- **Diagnosis/clinical characteristics:** Documented history of either being at risk or having a history of or currently diagnosed with a mental health disorder (e.g., stress, depression, anxiety, ADHD, PTSD) and/or SUD, as identified in clinical or probation records
- **Length of stay:** Facility records must project a remaining stay of at least 8 weeks at the time of enrollment.
- **Language/comprehension:** Ability to understand and follow study instructions in English at a basic level. Youth with limited literacy will be allowed to complete journaling through drawings or assisted prompts.

- **Capacity to assent (21 CFR 50.55):** All JIY are between ages 12-18, an age range in which youth are generally capable of providing meaningful assent. The IRB will be provided with (1) a youth-friendly assent script, (2) a description of who will obtain assent (clinical staff), and (3) assurances that assent will be voluntary, with no consequences for refusal or withdrawal. On-site clinical staff will confirm each youth is medically and psychiatrically stable enough to understand and participate in the assent process.
- **Consent/assent:** Youths must provide verbal assent after the study has been explained in age-appropriate language. A parent, legal guardian, or LAR must provide written informed consent.
  Clinical stability: On-site clinical staff must confirm the juvenile is medically and psychiatrically stable enough to participate in the planned activities.
  Willingness to participate: Youths must agree to comply with intervention procedures, including sitting in the Healpod, completing journaling or drawing after sessions, and completing study questionnaires.
- **Concurrent treatment:** Youth receiving standard counseling or prescribed psychotropic medication remain eligible for their normal ongoing treatment.

Vulnerable Populations

- **Inclusion of children:** Because participants are minors, parental/guardian or LAR consent is required in addition to participant assent. All study materials will be presented in age-appropriate language.
- **Inclusion of detained (prisoner) youth:** Individuals who are incarcerated or detained are eligible for this study. Given their custodial status, additional safeguards will be in place to minimize risk of coercion or undue influence:
- **Voluntariness:** Participation is voluntary. Refusal or withdrawal will not affect probation status, privileges, release dates, or case outcomes. “The minor advantages of participation (e.g., opportunity for relaxation, time for journaling, positive interaction with staff) are not of such magnitude that they would impair the youth’s ability to weigh risks and benefits or unduly influence their decision to participate.
- **Independent consent/assent:** Assent will be obtained by trained staff who are not in positions of custodial or disciplinary authority (e.g., not probation officers or detention guards). Youths will be given time to ask questions in private.
- **Age-appropriate materials:** Information sheets and assent scripts will be written in plain, adolescent-friendly language. Translations and verbal explanations will be provided as needed.
- **Parental/Gardian or LAR consent:** Written consent will be obtained from a parent, guardian, or LAR in addition to youth assent.
- **Confidentiality:** All data will be de-identified, stored securely on HIPAA-compliant servers, and not shared with probation or courts.

Regulatory and Ethical Safeguards

The study will adhere to ethical principles and comply with federal regulations governing research with vulnerable populations.

- **Children (Subpart D / 21 CFR 50.55):** Assent will be obtained from all participants capable of understanding the study. Materials will be written at an age-appropriate level, and staff will ensure that youth comprehend their right to decline participation without penalty.
- **Juvenile Prisoners (Subpart C):** The protocol ensures participation will not affect probation status, privileges, or case outcomes, and no coercive incentives will be offered.
- **Confidentiality:** Journals and questionnaires will be de-identified. Data will be stored securely on HIPAA-compliant servers, accessible only to the study team.
- **Risk/benefit balance:** The Heal intervention is non-invasive, brief, and aligned with existing therapeutic activities. Risks are no greater than those ordinarily encountered in detention settings, while potential benefits include improved emotional regulation, therapeutic alliance, mental health outcomes and coping strategies.

- **Continued care:** Since the participants in this study are receiving on-going care even after the conclusion of this trial, follow-ups on progress will continue with the clinical staff.

Exclusion Criteria

- **Age:** Juveniles younger than 12 years or older than 18 years at the time of clinical trial enrollment.
- **Custody/length of stay:** Juveniles with an anticipated remaining detention stay of less than 8 weeks, as determined by facility records
- **Clinical instability**
    - Active suicidal ideation with plan or intent
    - Uncontrolled psychosis, mania, or other acute psychiatric condition requiring immediate intervention
    - Severe cognitive or developmental impairment preventing meaningful participation in the Heal sessions, journaling or drawing, or standardized assessments
- **Medical contraindications**
    - History of seizure disorders triggered by light, music, sound, vibration or sitting in confined spaces
    - Severe sensory impairments such as profound hearing or vision loss that would prevent exposure to the intervention
    - Any other acute medical condition, as determined by facility clinicians, that would compromise the participant's safety
- **Language/comprehension:** Juveniles unable to understand study instructions in basic level English.

- **Safety risks in custody:** Juveniles who present a current, significant risk of violence toward themselves or others who cannot be safely managed within the Healpod environment
- **Concurrent research participation:** Juveniles enrolled in another interventional research study that could confound outcomes of this trial
- **Consent/assent limitations**
    - Inability to provide verbal assent due to comprehension barriers
    - Lack of parental/guardian/LAR consent, where legally required

- **Research staff** will not personally use the device for research purposes. Their role is limited to facilitating device use for participants and monitoring protocol adherence.
- **Non-research use:** While the Healpod may be available for non-research use in other settings, this protocol strictly limits its use to the described research procedures. Any non-research use will be separated from this study, and no data will be collected from individuals outside of the study.

Vulnerable Population (Juvenile Prisoners)

- **Detained individuals not eligible:** Juveniles detained outside of SLO County Juvenile Hall will not be eligible for this trial.
- **Safeguards for detained participants:** For those eligible, participation must be voluntary. Refusal or withdrawal will not affect probation status, privileges, or case outcomes. Recruitment, assent and consent will be conducted by individuals not involved in disciplinary or release decisions.

Study Interventions/Activities

Description of Research Activities and Procedures

Screening and Enrollment: Eligible juveniles will be all those within the SLO County Juvenile Hall. Screening will confirm inclusion and exclusion criteria, including age, detention length, mental health/SUD diagnosis, language ability, and clinical stability. Written informed consent will be obtained from parent/guardian or LAR, and assent will be verbalized and explained to eligible juveniles before participation.

Baseline Assessment: At enrollment, participants will complete standardized measures, including the Mini-IPIP-A (at the start), MAIA-Y(Baseline + Midpoint + End), DERS-16(Baseline + Midpoint + End), TASC-R (Baseline + Midpoint + End), PHQ-9 (every 2

weeks), GAD-7 (every 2 weeks), PSS-4 (every 2 weeks), and KidCOPE (Baseline + Midpoint + End).

Intervention Delivery: Participants will complete up to 16 Heal sessions across 8 weeks (1 or 2 sessions per week). Each 5-minute session includes:

- **Sensory intervention:** 5 minutes of sound, music, and gentle vibrations
- **Journaling:** 5 minutes of expressive writing/journaling or drawing
- **Therapy integration:** ~15 to 30 minutes of discussion with a clinician using the journal as a foundation/bridge

Follow-up Assessments: For the follow-up assessments of the primary endpoint, emotional regulation, we will employ MAIA-Y(Midpoint + End) and DERS-16 (Midpoint + End). For the secondary endpoints we will use TASC-R (Midpoint + End), PHQ-9 (every 2 weeks), GAD-7 (every 2 weeks) and PSS-4 (every 2 weeks). Additionally, the study will incorporate structured session journals with each session, and therapist assessments with each session where applicable. For the exploratory objectives, we will administer kidCOPE at Midpoint and end. Additional assessments will be done through qualitative analyses of journals and the feedback from therapists, session-based where applicable.

Final assessments will be completed at week 8.

Data Collection: Data will include self-report scales, therapist observations, and expressive writing/journaling or drawing content (de-identified before analysis). All data will be stored securely in compliance with HIPAA.

Research Arms or Groups of Interventions

Intervention Arm (Single-Arm Study): All eligible youth who provide assent and whose parent/guardian provides consent will receive the Heal intervention in addition to standard facility care.

Comparator: There is no separate control group. Outcomes will be assessed by comparing participants' post-intervention results to their own baseline measures.

Standard of Care: Routine counseling, group sessions, other treatments and education provided by the facility continue unchanged.

Control Group: There is no separate control group; each participant serves as their own control through pre-post comparisons.

Study Procedures and Timeline

Mini-IPIP-A (at the start), MAIA-Y(Baseline + Midpoint + End), DERS-16(Baseline + Midpoint + End), TASC-R (Baseline + Midpoint + End), PHQ-9 (every 2 weeks), GAD-7 (every 2 weeks) and PSS-4 (every 2 weeks), and KidCOPE (Baseline + Midpoint + End).

- **Baseline (Day 0-7 after consent)**
    - **Mini-IPIP-A**: An adolescent-friendly questionnaire that quickly measures the Big Five personality traits (Extroversion, Agreeableness, Conscientiousness, Neuroticism, and Openness)
    - **MAIA-Y**: measures how well JIY notice, understand, and respond to their body's internal signals such as emotions, breathing, and physical sensations to support emotional awareness and self-regulation.
    - **Emotional regulation**: DERS-16 will be administered in read-aloud format for participants whose literacy is limited
    - **TASC-R:** measures child-therapist therapeutic alliance
    - **Stress, anxiety, depression**: PHQ-9, GAD-7, and PSS-4 will be administered in read-aloud format for participants whose literacy is limited
    - **Coping skills:** KidCOPE will be administered in read-aloud format for participants whose literacy is limited.
- **Intervention phase (Weeks 1-8 in custody)**
    - **Dose/frequency**:For participating juveniles, 1 to 2 Heal sessions per week will be scheduled prior to their regular therapy appointments.
    - **Client session journal:** Participating juveniles will complete journal entries or drawing after each Heal session.
    - **Heal Therapist Assessment form:** Therapists will fill out the Therapist Assessment form after each therapy session with a participating juvenile.
    - **Modality**
        - **Sensory-guided intervention (Healpod):** Each 5-minute Heal session provides the following non-verbal somatic/ experiential/ sensory experiences inside the Healpod:
            - Curated calming music/soundscapes, such as slow tempo 60-80 BPM nature sounds
            - Optional vibroacoustic delivery of gentle vibrations, operated per the Healpod safety parameters and approved by the facility
        - **Expressive writing/journaling or drawing**: Following the session in the HealPpd, participants will complete very brief journaling or drawing to capture their feelings post-session,
- **Bi-weekly (Week 2±1, 4±1, 6±1)**
    - Repeat PHQ-9, GAD-7, PSS-4 (read-aloud if needed)
    - Check for willingness to continue
- **Mid-point (Week 4 ±1):**

- Repeat MAIA-Y, DERS-16, TASC-R, PHQ-9, GAD-7, PSS-4, and KidCOPE
- Check for willingness to continue

- **End-of-custody participation (Week 8 or pre-release/transfer):**
  - Repeat MAIA-Y, DERS-16, TASC-R, PHQ-9, GAD-7, PSS-4, and KidCOPE
  - Extract facility incident data during study window where needed
  - Conduct exit interview with probation or clinical staff (≤10 minutes)

- **Early release/transfer:**
  - Collect available end-of-participation measures prior to departure
  - If withdrawal occurs due to pregnancy, available end-of-participation measures will be collected when feasible.

Administration of Drug/Devices/Food/Cosmetics

This study does not involve administration of drugs, biologics, food, cosmetics, or regulated devices. The Healpod is a non-invasive, non-medical, sensory-guided intervention tool that uses commercially available speakers and bass shakers to deliver sound and gentle vibration.

End of Study Activities

Study Completion Criteria: The study will be considered complete once all participants complete the 8-week intervention, final assessments are collected, and any protocol deviations/adverse events are resolved.

End-of-Study Visit: At week 8, participants will:

- Complete final assessments (MAIA-Y, DERS-16, TASC-R, PHQ-9, GAD-7, PSS-4, and KidCOPE).
- Submit final journals.
- Participate in a debriefing to review study purpose and confirm voluntary participation.

Data Management: All collected data will be de-identified, scanned, coded, and analyzed according to the statistical analysis plan and per HIPAA regulations.

Participant Communication: Participants will be thanked for their contributions. Summaries of results may be shared with participants, parents/guardians or LARs, and facility staff as appropriate.

Archiving and Retention: All records, including consent forms, journals, and therapist assessments, will be securely archived for a minimum of 7 years, per regulatory requirements.

Study Closure: After data analysis, reporting, and archiving, the study will be formally closed with submission of a final report to the IRB and any relevant authorities.

Safety Management

Safety Plan

Definitions

- **Adverse Event (AE):** Any unfavorable or unintended psychological or physical effect that occurs during the study, whether or not it is related to the Heal intervention
- **Serious Adverse Event (SAE):** Any event that results in death, is life-threatening, requires hospitalization, or causes significant disability
- **Severity of Events:** Categorized as mild, moderate, or severe, based on the extent of disruption to normal activities
- **Unanticipated Problems (UPs):** Any incident or outcome that is unexpected, related or possibly related to the intervention, and suggests greater risk to participants or others than previously known
- **Events of Special Interest:** Heightened agitation, severe emotional distress, or behavioral escalation during or after the Heal session
- **Relatedness:** Events will be classified as unrelated, possibly related, or definitely related to the Heal intervention
- **Expectedness:** Events will be judged as expected (e.g., mild drowsiness, transient emotional responses) or unexpected (e.g., extreme agitation, panic)

Safety Monitoring and Reporting

Participants will be monitored throughout the study for physical, psychological, and behavioral safety as needed. Since the participating juveniles will be in custody, such monitoring will be easy to do on an as-needed basis. Juvenile Hall staff and study clinicians will remain present and observe participants during their Heal sessions through the Healpod observation window, ensuring immediate response to any visible distress.

- **AE monitoring:** All AEs will be documented using a standardized AE reporting form. Examples of possible AEs include emotional upset, refusal to continue, or reports of increased anxiety.
- **SAE reporting:** Any SAE will be reported immediately or within 24 hours to the Principal Investigator (PI) and forwarded to the WCG IRB.
- **Unanticipated problems:** Other unanticipated problems will be reported promptly, but no later than 7 days, to the IRB, together with a proposed corrective action plan.

Risk Mitigation

To reduce potential risks to the juveniles enrolled in this study, the following steps will be undertaken:

- **Informed consent/assent:** Participants and parent/guardian/LAR will be informed of possible emotional changes and reassured of their right to stop participation at any time.
- **Screening procedures:** Clinical staff will confirm psychiatric stability before enrollment to minimize risk of harm and will continue to monitor participants at every session for any associated changes.
  During the initial screening, participants will be asked whether they are currently pregnant. If so, they will not be enrolled in the study. Staff will also remind participants to inform the research team if they become pregnant at any point during the study so they can be safely withdrawn.
- **Emergency protocols:** Facility mental health staff and probation officers at the SLO County Juvenile Hall will be immediately available in the event of participant distress.
- **Session design:** Heal sessions are brief (~5 minutes), non-invasive, and similar to simply listening to music, which is already permitted in Juvenile Hall; these elements of the intervention reduce risk exposure.
- **Ongoing monitoring:** Clinicians will review participants' journals and post-session reflections for signs of distress that might require follow up.

- **Post-trial monitoring:** participants in this study will contine receiving on-going care even after the conclusion of this trial. Follow-ups on how they feel with the intervention post-clinical trial will continue with the clinical staff.

This risk mitigation and safety expectation is supported by empirical data from the SLO County Behavioral Health 4-Year Innovation Evaluation (2021-2025), which documented **zero adverse or serious adverse events** in > 1,100 adult Heal sessions, even among participants with significant mental-health comorbidities. These findings justify treating the present juvenile study as **minimal risk**, with expected AEs limited to mild, transient emotional responses (e.g., tearfulness, relaxation fatigue).

Data Safety Oversight

Given the minimal-risk nature of this behavioral intervention:

- The PI will review all safety reports monthly.
- Facility clinical staff will conduct immediate debriefing for any participant exhibiting distress.

Pregnancy Reporting and Follow-Up

This study does not include pregnant participants, if a pregnancy is discovered during the study, it will be documented and reported. The participant will no longer stay eligible or continue in the research study. No inducements, monetary or otherwise, will be offered to terminate a pregnancy. Individuals engaged in the research will have NO part in any decisions as to the timing, method, or procedures used to terminate a pregnancy. Individuals engaged in the research will have no role in determining the viability of a neonate.

Subpart C: Prisoner Protections

Because participants are detained youth, they qualify as “prisoners” under 45 CFR 46 Subpart C. To ensure compliance with these provisions, this study is structured as follows:

- Participation is voluntary, and refusal or Discontinuation will not affect probation status, privileges, or access to services.
- Risks are minimal, limited to mild emotional change comparable to ordinary daily life in custody. Any risks arising from the Heal intervention are further mitigated since youths will meet with their therapist directly after every Heal session for ~15 to 30 minutes of therapy.
- The research presents a reasonable probability of direct benefit to participants by improving their emotional regulation, therapeutic alliance, mental health and coping skills.
- Selection of subjects is fair, with recruitment facilitated by clinicians and probation officers based on clinical stability, not by staff preference.
- Any possible advantages of participation (~5 minute sessions, journaling or drawing, increased readiness for therapy) are modest and comparable to ordinary recreational or therapeutic activities within the facility. They are not of such a magnitude that they could impair participants’ ability to weigh risks against benefits.
- Pregnant individuals are excluded from participation, which provides additional protections for pregnant women. Given the absence of pregnancy-related data on vibro-acoustic and light-based interventions, the study adopts an exclusion.
- The risks involved in participation are commensurate with those that would be acceptable to non-detained adolescents participating in behavioral health research. The Heal intervention is non-invasive, brief, and similar in nature to standard wellness activities such as listening to music, mindfulness, or journaling and drawing. Sessions are overseen by clinical staff, and participants remain fully conscious and free to withdraw at any time. No risks unique to detention are introduced, and no greater risks are presented than would be expected in a comparable non-prisoner study population.
- The potential advantages of participating in the HealPod program are modest and comparable to those available through standard therapeutic services. They are not of such magnitude that they could impair a youth’s ability to weigh risks or make a voluntary decision to participate within the custodial environment.

- **Follow-up care:** Adequate provisions have been made for follow-up examination or care after participation ends, recognizing the varying lengths of individual sentences. Participation in the HealPod program does not require any medical follow-up. Youths will continue to receive standard clinical and therapeutic services provided regardless of whether they show any signs of emotional distress or not after participation, and their therapists will remain available for ongoing support. Participants will be informed during the consent/assent process that these follow-up provisions are in place and that their access to routine care is unaffected by study completion.
- **Parole board protections:** Adequate assurance has been established that participation in this research will not be considered by parole boards, probation officers, or other decision-making authorities when determining parole status, probation terms, or release dates. Participation or non-participation in the study will have no influence on legal outcomes, and this assurance will be communicated to both participants and their guardians during the consent/assent process.

Subpart D: Children and Minors in Research

Because participants are minors under 18, Subpart D applies. To ensure compliance with these regulations, this study is structured as follows:

- Parental/guardian/LAR consent will be obtained along with youth assent in age-appropriate language.
- The study involves minimal risk and offers a direct prospect of benefit through improved emotional regulation, improved therapeutic alliance, better mental health and improved coping skills.
- Youths with limited literacy will be supported by means of such assistance as non-guided/sounds-only sessions, journaling by drawing, and assisted prompts.
- Consent/assent documents will explicitly affirm the right to withdraw at any time without penalty.

Statistical Analysis

Study Purpose and Analytic Frame

This proposed research is a pilot, single-arm, pre-post interventional study with an expected enrollment of no more than 18 JIY detained in SLO County Juvenile Hall. The primary aim is to assess feasibility, safety, and preliminary signals of efficacy for the Heal intervention. Given the small sample size, analyses will emphasize within-person change estimates, effect sizes with confidence intervals, and graphical trajectories, rather than

confirmatory hypothesis testing. The data will provide estimates to inform a subsequent larger and adequately powered trial.

Variables and Endpoints

- **Primary outcome:** Emotional regulation, measured by the MAIA-Y, DERS-16 at baseline, mid-study, and study completion along with self-reported session journals.
- **Secondary outcomes:** Therapeutic alliance (TASC-R) measured at baseline, mid-point and end, and therapist assessment session journals. Mental health outcomes of depression (PHQ-9), anxiety (GAD-7), stress (PSS-4) measured every 2 weeks.
- **Exploratory outcomes:** Coping skills (kidCOPE) measured at baseline, mid-point and end, and study feasibility. Safety profile outcomes of AEs and SAEs.
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Sample Size Rationale

A target enrollment of no more than 18 participants reflects practical feasibility, given the facility population, expected length of stay, and consent requirement, and aligns with early-phase pilot norms. This sample is not designed to provide definitive efficacy testing; instead, it will yield effect-size estimates and variance parameters that will guide formal power calculations for a subsequent trial.

Primary Analyses

- **Primary endpoint (Emotional Regulation):**
  Change in DERS-16 from Baseline to Week 8 will be the primary analysis.

- **Mechanism (Interoceptive Awareness):**
  Change in **MAIA-Y** (Baseline, Week 4, Week 8) will be analyzed in parallel to test whether interoceptive awareness improves alongside DERS-16.

- **Therapeutic Alliance (Proximal clinical relevance):**
  Change in **TASC-R** (Baseline to Week 4 to Week 8)

Secondary Analyses

- **Therapeutic alliance (detail):** Beyond the primary association analysis, report TASC-R domain-level changes (if scored) with paired tests and effect sizes.

- **Mental health symptoms: PHQ-9, GAD-7, PSS-4** (Baseline, Weeks 2/4/6/8).

Exploratory Analyses

- **Coping skills:** shifts in adaptive vs. maladaptive domains where applicable. **KidCOPE** scores (Baseline, Week 4, Week 8).

- Adverse events (AEs), and serious adverse events (SAEs): All AE's/SAE's will be documented and compiled into the analytic dataset. We will measure "counts and percentages" by event type (emotional, sensory, physical), severity (mild, moderate, severe), relatedness to the Heal intervention (unrelated / unlikely / possible / probable / definite) and expectedness (expected / unexpected)

Missing Data

Because some youth may be released, transferred, or choose to withdraw before completing the study, missing data are expected. To address this, this study will:

- **Use of all available data:** Analyses will include every data point that participants provide, even if they do not complete all sessions or the full 8-week period.
- **Handle incomplete cases:** If a participant is missing end-of-study data, their last available score will be carried forward as a sensitivity check to confirm whether results are consistent.
- **No complex imputation**: Given the small sample size, advanced statistical methods such as multiple imputation will not be used.
- **Transparency**: Results will be presented with clear notes about how many participants provided data at each timepoint, so that findings can be interpreted in light of attrition.

Safety Monitoring Analysis

All AEs, SAEs, and Unanticipated Problems will be collected and documented. Because of the expected low event frequency, no inferential testing will be conducted for safety data. Any serious adverse events (SAEs) or unanticipated problems that arise will be reported.

Consent Process

Traditional Consent Process (Paper & Wet Ink)

- The person providing consent (parent/legal guardian/LAR) will be given as much time as they need to review study information and to make an informed decision.
- If more time is needed than the research timeline allows, the juvenile will not be enrolled.
- Probation/clinical staff at the SLO County Juvenile Hall will assess whether the parent/guardian/LAR or juvenile is under any pressure to decide quickly, and enrollment will not proceed if undue influence is suspected.
- No threat or adverse consequences will result if the parent/guardian/LAR declines participation.
- If the parent/guardian/LAR or juvenile indicates they do not wish to participate, the consent process will stop immediately.

- Probation/clinical staff will assess for coercion or undue influence by others and will not proceed if it is present.
- The consent process with the Junveniles will be conducted in age-appropriate basic level English.
- Presentation of the information will be adapted to the capacities of the parent/guardian/LAR and the juvenile in terms of intelligence, rationality, maturity, and language. The process will be culturally sensitive and be conducted in either basic level English or Spanish.
- All questions will be invited and answered.
- Probation/clinical staff will evaluate whether the parent/guardian/LAR and juvenile understand the study; if not, enrollment will not occur.
- No language will suggest waiving legal rights or releasing the sponsor/institution from liability.
- All the information in the consent document or script approved by the IRB will be communicated to the parent/guardian/LAR and the juvenile.
- The juvenile will not be enrolled if informed consent is not obtained.

Alternate Consent Process

Alternative approaches may be used if in-person paper consent is not feasible. Options include:

- **Asynchronous consent:** Parent/guardian/LAR may review consent forms online, discuss the study with research staff by phone or video, and then return signed forms via secure mail, email, or in person.
- **Language and literacy accommodation**: For families with limited literacy, study staff will read forms aloud or provide simplified explanations in either basic level English or Spanish. Eligible juveniles will assent through both verbal affirmation and written signature.

Electronic Consent Process (compliant with part 11 for FDA-regulated studies)

Where in-person consent is not possible, electronic consent could be used that will meet 21 CFR Part 11.

- The probation/clinical staff will introduce the study through a secure electronic consent platform.
- Parent/guardian/LAR will review the materials independently and will have time to ask questions.
- Questions can be addressed through phone, video call, or secure platform messaging.
- After review and discussion, eligible juveniles and their parent/guardian/LAR will provide electronic signatures within the platform.

- The platform will meet 21 CFR Part 11 standards for identity verification, audit trails, secure storage, and authenticity of electronic records.

Waivers (Documentation Waivers, Consent Waivers, HIPAA Waivers)

Consent Waivers

A waiver of parental/guardian/LAR consent is not requested for this study, as participants are minors and juveniles. Written parental/legal guardian/LAR consent will be provided.

HIPAA Waivers

Recruitment will be conducted solely by San Luis Obispo County Juvenile Hall behavioral health staff. The research team will not access identifiable health information prior to consent. Therefore, a HIPAA waiver and HIPAA authorization are not required.

Privacy and Confidentiality

Protecting juvenile privacy and ensuring data confidentiality are paramount to the ethical conduct of this research. A robust data protection plan will be implemented to safeguard participant information throughout the study.

Data Minimization and Pseudonymization

Only information directly relevant to the study objectives will be collected. Identifiable data, such as names, booking numbers, probation ID, court case number, and medical record numbers will not be included in the research dataset. Each participant will be assigned a unique study ID. A secure linking log will be maintained locally at SLO County Juvenile Hall to connect study IDs with source records, available only to authorized site staff for audit, safety monitoring, or regulatory purposes. Research analyses will be conducted on pseudonymized datasets.

Data Security

A multi-layered data protection plan will be implemented:

- **Access control:** Only clinicians and study staff will have access to identifiable information. Access will be restricted on a role-based, need-to-know basis.
- **Encryption:** All electronic data will be encrypted in transit via secure file transfer and at rest through password-protected, encrypted drives.

- **Secure storage:** Data will be stored on secure servers with institutional firewalls, intrusion detection, and password protections. Paper-based consent forms and journals will be locked in secure cabinets accessible only to study staff.
- **Backups and recovery:** Routine encrypted backups will be performed, with recovery procedures in place to prevent data loss.

Participant Information

Participating juveniles and their parents/guardians/LARs will be informed about how their data will be collected, stored, and used during the consent/assent process. They will be told that no information disclosed in journals or data from study measures will affect probation status, legal standing, or treatment access. Juveniles will be reassured that their privacy will be respected, and that de-identified data will be used for reporting.

Data Sharing

Any data sharing will comply with HIPAA, Subpart C prisoner protections, and local juvenile justice confidentiality laws. Only de-identified or aggregated results will be shared outside the research team.

Breach Response

A breach response plan will be in place, including:

- Immediate containment of the breach
- Notification of the Principal Investigator and IRB within required timelines
- Investigation to determine scope and impact
- Notification of affected participants and their parents//guardians/LARs and regulatory authorities, as required by law
- Corrective measures to prevent recurrence.

Compliance

This protocol complies with HIPAA Privacy Rule requirements, 45 CFR 46 Subpart C (prisoner research protections), and WCG IRB guidance for behavioral research. Privacy safeguards will be regularly reviewed by the PI to ensure ongoing compliance.

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