The SAFE PLACE Program: A Program Review – Interim Project Summary

Project completed by

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April 13, 2017

for

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Introduction

SAFE PLACE is both a theoretical model explicating the relationship between sensory processing, disrupted attachment and complex developmental trauma concerns in children; and a specific 12-week collaborative, interdisciplinary, sensory integration-based trauma-informed intervention program among occupational therapists, psychotherapists, and parents for children with sensory processing disorder (SPD) and complex trauma-attachment concerns. SAFE PLACE provides a therapeutic framework for service providers and parents which emphasizes development of body-based regulatory and adaptive functions with co-regulation and intersubjective experiences, deepening of attachment bonds and security, and processing and healing of traumatic experiences in the context of a sensory integration intervention process.

The purpose of this program review project was a preliminary examination of effectiveness outcomes and a review of the feasibility, acceptability, and safety of the SAFE PLACE intervention model when implemented with a single family.

Study Design

This project utilized a single case mixed methods study with outcome measures at T1 – study enrollment, T2 – pre-intervention, T3 – post-intervention and T4 – follow up. The study was approved by the Spiral Foundation Institutional Review Board.

Methods

Participants

One child and family participated in this SAFE PLACE program review project and were recruited as a sample of convenience. The child, M, was a 4.10 year old male, adopted from Russia, who had received no previous occupational therapy services. He attended a preschool setting. Both parents were professionals and M was often watched by a nanny, who was a family relation. M's mother primarily attended the intervention sessions with M's father attending several and the nanny one session.

Inclusion criteria for the project included the following:

1. Child aged 4-15 years.
2. Child had sensory processing dysfunction and complex trauma and attachment as identified by the OTA SAFE PLACE Intake Coordinator.
3. Family committed to fully participating in the program.
4. Child had no parent/guardian report of Autism Spectrum Disorder.
5. Child had no parent/guardian reported uncontrolled seizure disorder.
6. Child had no parent/guardian reported diagnoses of a neurological motor coordination problem (e.g. cerebral palsy).
7. Child had no parent/guardian reported mental health diagnoses involving psychosis (e.g. manic-depression or schizophrenia).
8. Child and parent/guardian understand sufficient English to fully participate in the study.

Program staff consisted of an assessment occupational therapist (OT) who completed baseline, pre and post-test evaluations of sensory and motor performance as well as the baseline, pre and post-intervention parent goal-setting interviews. This therapists also wrote the child's GAS goals and reviewed progress at the end of the intervention. A second OT provided the SAFE PLACE intervention and did not participate in pre and post-testing. A mental health professional also participated in the provision of the SAFE PLACE intervention.

Outcome Measures

A variety of outcome measures were examined to assist with determination of the most sensitive measures of change for the SAFE PLACE program. Outcomes were selected to assess areas of proximal and distal functioning that may be improved by the SAFE PLACE intervention. Not all data has been finalized at the time

of this report. The specific measures and outcomes used are listed below:

- *Movement Assessment Battery for Children* **– 2** (MABC) (Henderson, Sugden & Barnett, 2007): Motor development.
- *Sensory Integration Clinical Observations* (COs) (May-Benson, 2015): Sensory integration and sensory processing difficulties.
- *The Beery-Buktenica Developmental Test of Visual Motor Integration – 6th Ed.* (Beery, & Beery, 2010): Visual motor problems.
- *The Behavior Rating Inventory of Executive Functioning (BRIEF)* Gioia, Isquith, Guy, & Kenworthy, (2000): Executive functioning skills.
- *Behavior Assessment System for Children – Third Edition (BASC-3)* Reynolds & Kamphaus (2015): Adaptive behaviors and emotions.
- *Sensory Processing Measure Home Form (SPM),* (Parham & Ecker, 2007): Sensory processing.
- *The Social Skills Improvement System Rating Scales (SSIS)* Gresham & Elliot (2008): Social skills.
- *Functional Performance Measure: Pediatric Evaluation of Disability Inventory – Computer Adaptive Test (PEDI-CAT)* Haley et al. (2012): Functional performance.
- *The Roll Evaluation of Activities of Life (REAL) –* Roll & Roll (2013): Activities of daily living.
- *Goal Attainment Scaling (GAS) Goals* (Kiresuk, Smith & Cardillo, 1994: Functional Performance Measure.
- *Parenting Profile for Developing Attachment (PPDA)* (Koomar & Hughes, 2007): Parent preferences for sensory experiences.
- *Parent/Guardian Feasibility & Acceptability Survey***.**
- *SAFE PLACE Fidelity Measure* - May-Benson (2015) in May-Benson & Sawyer, (2015).
- *Staff Feasibility, Acceptability & Safety Survey*

Procedures

1. Occupational therapy and mental health staff were trained in implementation of the SAFE PLACE intervention as specified in the SAFE PLACE Manual.
2. The OTA SAFE PLACE Intake Coordinator completed an intake with the mother seeking occupational therapy services for a child with potential sensory integration and complex trauma difficulties. As a result of the intake and screening confirming complex trauma and probably sensory integration problems, the Intake Coordinator recommended the child for participation in the SAFE PLACE program.
3. At enrollment into the SAFE PLACE program, the family was informed about the program review study and informed consent was obtained for participation in the study.
4. The child was evaluated (T1) with the *Movement ABC* and *Ayres Sensory Integration Clinical Observations* by the assessment OT.
5. The mother completed a *GAS* goal setting meeting with the assessment OT, at which they discussed the child's current performance and goals for therapy. The assessment OT wrote 5 goals and objectives. Mother also completed the parent report measures.
6. A 10-week baseline period was completed during which the child received usual care.
7. At the end of baseline (T2), the child was re-evaluated by the assessment OT and the mother completed all parent report measures.
8. The SAFE PLACE intervention was then provided collaboratively by the treating OT and the mental health professional with the child and the parent present at all treatment sessions. Intervention consisted of the following:
   a) 60 minute treatment sessions 2 times per week for 12 weeks with child, parent, occupational therapist and mental health professional. All sessions were video recorded.
   b) 60 minute parent consultation sessions once per week for 12 weeks with the parent, occupational therapist and mental health.
   c) 60 minute professional collaboration and intervention planning sessions once per week for 12 weeks with the occupational therapist, mental health professional and PI.
9. The PI completed the SAFE PLACE Fidelity Measure on 6 randomly selected treatment sessions.
10. At the end of the intervention phase (T3), the child was again re-evaluated by the assessment OT and the mother completed all parent report measures.
11. The mother met with the PI to discuss the family's experience in participating in the study.
12. The occupational therapist and mental health professional met with the PI to discuss their experiences in participation in the study.

13. All study staff completed safety, feasibility and acceptability questionnaires.
14. After an additional 10-week post intervention baseline (T4), the child will receive a final re-evaluation by the assessment occupational therapist and the mother will complete all final parent report measures.

Results

Recruitment Capability

This study was designed to examine one participant and family. We had little difficulty recruiting a participant. Two individual children were easily identified as possible participants for the project within a 2-3 week time period and one was recruited without difficulty. Our participant easily met the inclusion criteria. The parent commitment to the project was high, something that was needed due to the intensity of the intervention.

Evaluation of Data Collection and Outcome Measures

In this project data collection involved direct assessment of the child, parent interview meetings and parent completed questionnaires. Additional data was collected from the professionals providing assessment and treatment as well as administrative staff involved in scheduling sessions. The parent was motivated to complete the parent measures, but due to the number of measures involved in this preliminary study, the return of the measures was often somewhat longer than anticipated. The parent had no difficulty completing the measures with little missing data. The direct assessment of the child was timely, within a week of the anticipated timeline. The initial assessment resulted in missing data on *Ayres Clinical Observations* due to the child being unable or unwilling to complete the activities and the assessment time running out. At final re-assessment, however, the child was able to complete nearly all items in a timely manner.

Upon completion of the intervention phase, the outcome measures were examined for those that demonstrated little variability in responses and those that did not change markedly over the course of the study. The *REAL*, which examined performance of activities of daily living and independent activities of daily living, demonstrated little variability in performance. It appeared that improvement in distal outcomes requiring skill performance was too much to expect over the relatively short intervention period. Similarly, the *PEDI-CAT*, which also measures functional daily living skills, mobility, social/cognitive skills and responsibility, also was scored within the average range at pre-test and demonstrated little variability in performance. The *Social Skills Improvement System*, which examines skills in areas of communication, empathy, engagement, attention, problem behaviors and skills, etc. also demonstrated little change. On this assessment, the child's performance was rated by the parent in the average or above average range on every item leaving little room for improvement. It was decided to ultimately remove these measures from the outcomes battery. The *BRIEF*, *BASC*, and *SPM* all demonstrated nice changes and will be discussed more under intervention effectiveness.

Feasibility and Acceptability

Retention of the subject in this study was not a problem. The family was very committed to the intervention and expressed a desire for continued services in both the occupational therapy and mental health arenas. The mother expressed that the intervention process, while intensive with 3 hours per week of intervention between child and parent sessions, was invaluable to them and the child. The model of having the parent and child together in the session with both the OT and mental health professional was perceived as a necessary component of the intervention process that the family found very supportive and helpful. The weekly consultation sessions with the parent were also reported to be very necessary in understanding the child better and in learning how to best manage the child outside of therapy.

Several procedural changes and additions were expressed by both the family and the therapeutic staff. Although parents were informed about the nature and expectations of the SAFE PLACE program both the parent and therapists expressed a desire for more parent education on sensory integration and SAFE PLACE prior to the first treatment session. As a result of this feedback, an additional parent session to occur before initiation of the child's treatment has been added to the intervention schedule. In addition, parent materials on these topics will be developed to facilitate this education. This program review also highlighted the need to

designate time (approximately 5-10 minutes) at the end of each session for notewriting for the therapists. An additional concern that arose was the strong desire of the mental health practitioner to provide ancillary advice to the parents on nutrition and diet, areas of expertise for her. Although these topics might be addressed in routine therapy, it was decided that these changes might confound this project. It was difficult for both clinicians to restrict their therapeutic tools to those advocated by the SAFE PLACE program.

Resources and Management of Study Implementation

As expected this study was very resource intense in terms of time, staffing and finances. Several areas emerged as challenges that required consideration before proceeding to a larger study.

Space. OTA the Koomar Center is a large occupational therapy clinic specializing in sensory integration. It has over 11 large treatment rooms available. During the prime treatment hours of 9:00 am to 5:00 pm, there are routinely 11 – 13 clinicians treating in the clinic space. As the SAFE PLACE sessions were videotaped and there were routinely 4 adults and the child present during a treatment session, intervention sessions most desirably occurred (for confidentiality, space management and therapeutic reasons) when there were no other children and therapists around. This requirement challenged scheduling and is a consideration as to the number and timing of children who may be treated in the clinic using this model at any given time.

Clinical Staffing. Recruiting clinical staff for this project was initially challenging. An OT clinician at OTA the Koomar Center was recruited easily but this required some initial movement on her regular full-time treatment schedule to create time for this program. This was possible but required lead time to accomplish prior to the initiation of the program. The mental health practitioner was particularly challenging to recruit. Several clinicians were approached and expressed interest in participating, but the time commitment was difficult for them to accommodate in their already full schedules. A clinician was eventually located who was willing and able to accommodate the scheduling, however, the cost of hiring this consultant was higher than originally budgeted. These experiences highlighted the need to have staff dedicated to the SAFE PLACE program. Time commitments are too challenging for most clinicians to accommodate when they have a full clinical schedule. Hiring new staff on a salaried full or part-time basis with designated hours was determined to be the best way to manage this limitation.

Scheduling. Scheduling presented one of the greatest challenges in the implementation of the study. This is not unusual in clinical practice, but the coordination of multiple individuals increased the complexity. Initial challenges were noted in setting the formal schedule. As noted above this required some initial changes in clinician availability that needed to coincide with clinic space availability. Parent availability was the next challenge. Although the family was available at the designated early morning slot, both parents were professionals with jobs that periodically required appointments, over which they had no control, that were scheduled during treatment sessions. As a result a parent or significant caregiver attended every treatment session however no one single adult attended every session. This actually had a benefit of allowing all adults involved with the child to have an increased understanding of the child's needs.

Other scheduling challenges arose as well. The family was frequently late to treatment sessions for a variety of reasons, sometimes by as much as 30 minutes. The clinicians attempted to accommodate the family as much as possible, often running over time into their planning time, however, it was recognized early on that this type of flexibility would not be sustainable over a larger number of clients. Another issue was that approximately 50% of treatment sessions needed to be rescheduled due to child/parent/clinician illness, holidays, staff vacations, parent work conflicts and inclement weather. Despite this the family completed the intervention in 15 weeks. This experience resulted in the expected schedule of future program implementation to be scheduled for a longer time frame to allow the family to receive the requisite 24 treatment sessions. It was noted that it is not unusual to have tardiness and missed treatment session in routine clinical intervention, but the need to accommodate scheduling in a relatively short amount of time was more extreme than typically seen in clinical practice.

Finances. The financial aspects of the SAFE PLACE program were a consideration. The cost of two therapeutic staff for four hours each per week per child for a 12 week period was examined. Most parents desire insurance reimbursable services, however, as this service involves co-treatment of two therapists, only one service is reimbursable, in this case, the occupational therapy services. The parent consultation session may ultimately be reimbursable as a mental health service for the parent if approval for the center to provide insurance-based mental health services is obtained. This is a need for the future if the program is to be clinically sustainable. The clinician planning session was not reimbursable at all as it was not a direct service. For this project services were provided to the family free of charge but additional financial arrangements will need to be examined for on-going clinical viability.

Study Personnel, Expertise and Management. Study personnel were appropriate for this project. All clinicians had required expertise in their respective areas. The primary investigator and research staff has sufficient expertise to implement the study effectively. For one participant, the PI and research assistant were sufficient for study management. Additional support staff will be needed, primarily for videorecording, for studies with larger numbers of participants.

Fidelity to the Intervention. Fidelity to the SAFE PLACE intervention was examined via use of a preliminary fidelity measure. Six fidelity checks were completed across the study. Intervention was divided by four-session blocks (approximately every two weeks) and a single one hour session was randomly selected from each block. The fidelity checks were completed by the primary investigator who viewed the intervention session and rated each session on the fidelity measure. All sessions met fidelity to the intervention with responses of 85% or greater on the fidelity measure. Thus adherence to the proposed intervention was supported. Feedback on the fidelity measure from the PI and from the study clinicians was collected and will be integrated into revisions.

Preliminary Participant Response to Intervention

Preliminary participant response to intervention was examined via standardized parent-report and direct evaluation assessments, goal attainment scaling and informal participant feedback. Follow-up data from T4 has not yet been completed.

Baseline. Data on standardized measures from T1 (intake) to T2 (pre-intervention) demonstrated general worsening of scores or no change. SSIS and BASC demonstrated improvements in some behaviors. See Table 1.

Table 1. Change in performance over baseline by assessment measure.

Assessment	Change T1 – T2 Performance
Movement ABC	Total Score Got 5 Points Worse
Beery VMI	Not Given T1
Clinical Observations	Total Score Got 4 Points Worse
REAL	Total Score Got 5.3 Points Worse
SSIS*	
BRIEF	6 Subtests Not Scorable 3 Subtests Improved 8 – 12 Points (Shift, Emotional Control, Behavior Regulation Index)
BASC	11/18 Subscores Improved 5/18 Subscores Got Worse 2/18 Subscores No Change
SPM	6/7 Subscores Got Worse 1/7 Subscores No Change Total Score Got 5 Points Worse
PEDI-CAT	4/4 Subscores Got Worse
Parenting Profile for Developing Attachment: Perception of Self	4 Point Improvement
GAS	Not Rated
*All scores in Average or Above Average range	

Pre- to Post-Intervention. Data on T2 (pre-intervention) to T3 (post-intervention) demonstrated general improvement of performance from T2 to T3. In several tests, the child was able to complete testing at T3 that he had not been able to complete at T1 or T2. See Table 2.

Table 2. Change in performance pre- to post-intervention.

Assessment	Change T2 – T3 Performance
Movement ABC	Total Score Improved 4 Points
Beery VMI	Total Score Improved10 Points
Clinical Observations	Total Score Improved 50 Points
REAL	Total Score Got Worse 2.6 Points
SSIS*	
BRIEF	9 Subscores Improved 2 Subscores Decreased 2 Points
BASC	11/18 Subscores Improved 3/18 Subscores Got Worse 4/18 Subscores No Change
SPM	5/7 Subscores Improved 4 – 10 Points 2/7 Subscores Got Worse 3 – 7 Points Total Score Improved 6 Points
PEDI-CAT	1/4 Subscores Improved 1/4 Subscores Got Worse 2/4 Subscores No Change
Parenting Profile for Developing Attachment: Perception of Self	5 Point Improvement
GAS	t-score = 53
*All scores in Average or Above Average range	

Examination of performance to date suggests that the Movement ABC, Beery VMI, and Clinical Observations as direct assessments are sensitive measures which captured change during the intervention. As parent-report measures, the REAL and the PEDI-CAT, which measure primarily functional daily life skills did not demonstrate much change and did not seem to be sensitive enough to measure changes that occurred during the intervention. It is likely that a 12 week intervention is too brief to result in significant functional motor performance-based skill change in life tasks. The SSIS demonstrated mixed performance but results were not very meaningful as all scores were within the average or above range. These three tests were consequently recommended for elimination from future studies. The BRIEF demonstrated nice gains, with the child being able to complete an additional six sections from pre- to post-testing and demonstrated improvement on all but two subsections. The BASC and the SPM both demonstrated gains in the majority of subscores. These measures assessed behaviors and sensory processing skills, both which would be expected to change during intervention as they were the areas most directly addressed during treatment. These three parent report measures demonstrated adequate sensitivity to change and were recommended for inclusion in future studies.

The Goal Attainment Scaling was not scored from the T1 to T2 baseline, although goals were set at intake for the intervention. At post-testing, the GAS t-score was 53. This reflects a greater than expected change for the intervention period. In addition, during consultations and the GAS interview the parent shared anecdotal evidence of a reduction in negative child behaviors including violence towards the parent and parent understanding of those behaviors when they did still occur. Increased parent understanding was reflected in the improvement in perception of the self on the Parenting Profile for Developing Attachment. Both of these measures were recommended for inclusion in future studies.

Conclusion

In conclusion, this preliminary program review demonstrated that the SAFE PLACE program may be implemented with feasibility, safety and at least preliminary fidelity. Parental acceptance and satisfaction with the program was tremendous and very positive. Challenges to conducting larger studies were identified and solutions suggested. Outcome measures were examined, sensitive measures were identified and less useful measures recommended for exclusion from future studies. Preliminary effectiveness is suggested in areas of motor performance, sensory processing and behavioral regulation. Additional examination of these areas as sensitive outcomes is recommended at this time.

The next step in the development of the SAFE PLACE program is to conduct a larger, full scale feasibility and fidelity study with approximately ten participants. This sample size will provide more information on the feasibility of conducting a pilot intervention study and also inform the feasibility of implementing this program in a clinical setting as a routine clinical intervention.

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Acknowledgements

Thank you to the family who participated in this study, Margaret Ingolia, MS, OTR/L, Linda Forsythe, MD, Sarah Sawyer, MS, OTR/L and Melanie Salort OTR/L for their assistance with this project.

Cite as

May-Benson, T. A. & Teasdale, A. (2017). *The SAFE PLACE Program: A Program Review – Interim Project Summary*. Newton, MA: OTA The Koomar Center.