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TECHNICAL REPORT

National Evaluation of Safe Start Promising Approaches

Results Appendix N: Toledo, Ohio

In Jaycox, L. H., L. J. Hickman, D. Schultz, D. Barnes-Proby, C. M. Setodji, A. Kofner, R. Harris, J. D. Acosta, and T. Francois, *National Evaluation of Safe Start Promising Approaches: Assessing Program Outcomes*, Santa Monica, Calif.: RAND Corporation, TR-991-1-DOJ, 2011

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TOLEDO, OHIO, SAFE START OUTCOMES REPORT

ABSTRACT

The Toledo Safe Start Program implemented a Child-Parent Psychotherapy (CPP) program for children (ages 0–5) who had been exposed to domestic violence. A full description of the program can be found in *National Evaluation of Safe Start Promising Approaches: Assessing Program Implementation* (Schultz et al., 2010). Toledo attempted to conduct a randomized controlled trial with randomization occurring at the family level. However, inadequate recruitment and retention for follow-up assessments made the evaluation impossible. Toledo enrolled 30 families, retaining only 23 percent of them for the six-month assessment. Due to low enrollment and retention, the evaluation of the Toledo program was discontinued near the end of the project.

At baseline, caregivers reported that children had been exposed to an average of 4.7 types of violence during their lives. Forty-seven percent of enrolled families reported baseline child posttraumatic stress disorder (PTSD) symptoms that fell in the “significant” range, and 73 percent had levels of parental stress that fell in the “clinical” range. Toledo Safe Start families in the intervention group received CPP. Overall, 40 percent of the families in the intervention group received CPP, with an average of 15.8 sessions per family. The sample size limitations mean that no conclusions can be drawn about the impact of the Toledo intervention on child- and family-level outcomes. Overall, the Toledo model requires further testing with a sufficient sample to assess the potential impacts of the intervention on outcomes for children exposed to violence.

INTRODUCTION

The Toledo Safe Start program is located in the city of Toledo, Ohio, in Lucas County. According to Toledo’s original proposal for the Safe Start initiative, Lucas County law enforcement responded to over 8,000 calls related to domestic incidents during 2003. Nearly 1,500 of these resulted in domestic violence charges, and 315 resulted in arrests for domestic violence (Toledo Hospital, 2004).

Prior to Safe Start, there were few resources in Toledo for young children exposed to domestic violence. In particular, developmental assessments and evidence-based treatment for children exposed to violence were not available in the community. In response to this need, Toledo Safe Start was formed as a collaboration of several organizations, including the Cullen Center of Toledo Children’s Hospital and several Help Me Grow program sites. The Cullen Center, the lead organization, provides support and counseling for children and families suffering from different types of trauma. Help Me Grow is Ohio’s statewide early identification program for at-risk families with children ages 0 to three. The Safe Start project sought to develop relationships between these two programs and build capacity within the community for providing evidence-based mental health treatment for children exposed to domestic violence.

The Toledo Safe Start intervention consisted of CPP offered at the Cullen Center. In earlier evaluations of CPP, Lieberman, Van Horn, and Ghosh Ippen (2005) showed medium effects on PTSD symptoms and behavior problems (0.63 and 0.64, respectively).

Because of low enrollment and retention in the Toledo Safe Start program, the evaluation was discontinued near the end of the project, although services continued. The outcomes evaluation detailed here presents descriptive information about baseline observations only.

TOLEDO SAFE START
<ul style="list-style-type: none">• Intervention type: CPP• Intervention length: Up to 12 months• Intervention setting: Clinic• Target population: Children exposed to domestic violence• Age range: 0–5• Primary referral source: Help Me Grow

INTERVENTION

The Toledo Safe Start program involved CPP in a clinic setting. The intervention period lasted up to one year. The program elements are described

briefly in the following paragraphs. For a full description of the Toledo intervention as it was delivered, see Schultz et al. (2010).

Toledo Safe Start provided parent-child dyadic therapy using the Lieberman model for CPP. CPP is a relationship-based intervention designed for use with children up to age 6. It can be used with any child whose relationship to his or her parent or other primary caregiver is impacted by negative circumstances, including family violence. CPP integrates psychodynamic, attachment, trauma, cognitive-behavioral, and social learning theories (NCTSN, 2008). There are two components in CPP: assessment and treatment, with information gained during the assessment used to inform the treatment component. In the intervention component, child-parent interactions are the focus of six intervention modalities aimed at restoring a sense of mastery, security, and growth and promoting congruence between bodily sensations, feelings, and thinking on the part of both child and parent and in their relationship with one another (NCTSN, 2008).

Toledo delivered CPP for domestic violence in weekly one-hour clinic sessions at one of the four treatment sites. The therapy continued until there was mutual agreement between the family and the clinician that treatment goals had been met, and the clinician determined that affect regulation was stable and the relationship was “pleasing” for both the parent and child.

Efforts to monitor the quality of the program included an initial clinician training for the project director of the Cullen Center and the Help Me Grow program therapists that was provided by one of the CPP model developers. The therapists also received “booster” training sessions, had access to materials about the model, and received monthly telephone-based clinical supervision from one of the model developers.

METHOD

Design Overview

The planned study was a randomized controlled trial, with randomization occurring at the family level and eligible children recruited after families were referred to the program. In addition to usual support services provided by the Help Me Grow program (e.g., home visitation and linkage to community-based providers for support services), the intervention group received CPP for up to 12

months. Families assigned to the control group continued to receive the usual support services as well. For both groups, child outcomes and contextual information were assessed at baseline, six, 12, 18, and 24 months. Study enrollment took place between December 2006 and March 2009.

Evaluation Eligibility Criteria

Families were required to be proficient in English to be eligible for the evaluation. Eligible children included those age 5 and younger who had been exposed to violence through direct and/or indirect victimization. Families who were thought to be unlikely to benefit from or stay in treatment were excluded from the program, including those with active substance-abusing parents, parents with low-level functioning or maternal psychosis, and documented long-term history of child abuse by the mother.

If there were multiple eligible children, the target child to serve as the focus of the intervention was selected by the mother based on which child she felt had the greatest need.

Randomization Procedures

On enrollment into the study, the children were randomized into intervention or control groups using a block randomization procedure that allowed for approximately the same number of children in the intervention and control groups (see Chapter Four of the main document [http://www.rand.org/pubs/technical_reports/TR991-1.html]). Because of the possibility that the impact of the intervention could differ by child age, the sample was stratified into two groups. One group included children from 0 to 2 years of age, the second group included children between 3 and 5 years old. There were only two detected missed group assignments. In October 2008, one family was mistakenly moved from intervention to control and another family was moved from control to intervention. These families were retained in the analyses.

Measures

The measures used in this study are described fully in Chapter Two of the main document (see http://www.rand.org/pubs/technical_reports/TR991-1.html). The measures were uniform across the national evaluation but prioritized within each site as to the relevance to the intervention under study.

Given the nature of the Toledo Safe Start intervention, the outcomes were prioritized as shown in Table 1.

Table 1
Prioritized Outcome Measures for Toledo Safe Start

Primary Outcome Measures			
<i>Domain</i>	<i>Source/Measure</i>	<i>Age of Child</i>	<i>Respondent</i>
PTSD Symptoms	Trauma Symptom Checklist for Young Children	3–5 years	Caregiver
Behavior/Conduct Problems	BITSEA and Behavior Problem Index	1–5 years	Caregiver
Social-Emotional Competence	ASQ	0–2 years	Caregiver
Social-Emotional Competence	BITSEA and SSRS (Assertion and Self-Control)	1–5 years	Caregiver
Caregiver-Child Relationship	Parenting Stress Index	All	Caregiver
Secondary Outcome Measures			
<i>Domain</i>	<i>Source/Measure</i>	<i>Age of Child</i>	<i>Respondent</i>
Social-Emotional Competence	SSRS (Cooperation)	3–5 years	Caregiver
Violence Exposure	Juvenile Victimization Questionnaire	All	Caregiver
Violence Exposure	Caregiver Victimization Questionnaire	All	Caregiver
Tertiary Outcome Measures			
<i>Domain</i>	<i>Source/Measure</i>	<i>Age of Child</i>	<i>Respondent</i>
School Readiness/Performance	Woodcock-Johnson III	3–5 years	Child
Background and Contextual Factors	Everyday Stressors Index	All	Caregiver

NOTE: ASQ = Ages and Stages Questionnaire, BITSEA = Brief Infant-Toddler Social and Emotional Assessment, SSRS = Social Skills Rating System.

Enrollment and Retention

From the program’s inception in December 2006 until November 2007, Toledo received all of its referrals from the four local Help Me Grow programs. Help Me Grow service coordinators identified women within their caseloads who had been victimized by domestic violence and referred them to Safe Start. Once a referral was received, the Safe Start project director at the Cullen Center

screened the caregiver via phone to establish eligibility and schedule the baseline assessment at the Cullen Center. After the assessment, the project director implemented the random assignment procedures and informed the family and the Help Me Grow Service Coordinator.

According to data submitted on its Quarterly Activity Reports, Toledo Safe Start enrolled 48 percent of the families referred to the program. The most common reasons that families did not enroll were caregiver-related issues, such as no interest (48 percent), no time (21 percent), or other issues (24 percent).

In Table 2, we present the number and percentage of all enrollees who were eligible for participation at each data collection time point. Toledo program staff enrolled 30 families in the study and completed six-month research assessments for 23 percent of caregivers and 12 percent of children. For subsequent research assessments, Toledo retained from 0 to 20 percent of the families, depending on the assessment point and type.

Toledo's low retention at the six-month follow-up assessment increases the potential for biased results. This degree of attrition may be related to treatment factors that lead to selection bias. For example, if families in more distress are more likely to leave the study and be lost to follow-up, then the results can be misleading.

Table 2
Retention of Toledo Enrollees Eligible to Participate in Assessments at Each Time Point

	Caregiver Assessment				Child Assessment			
	Six Months	12 Months	18 Months	24 Months	Six Months	12 Months	18 Months	24 Months
Intervention								
Received	4	0	0	0	1	0	0	0
Expected*	15	4	2	0	9	4	2	0
Retention Rate	27%	0%	0%	0%	11%	0%	0%	0%
Control								
Received	3	1	1	0	1	1	0	0
Expected*	15	3	3	0	8	3	3	0
Retention Rate	20%	33%	33%	0%	13%	33%	0%	0%
Overall								
Retention Rate	23%	14%	20%	0%	12%	14%	0%	0%

* The number of expected assessments for longer-term assessments differs from the number who entered the study because the field period for collecting data in this study ended in the fall of 2009, before all families entered the window of time for assessments at 12, 18, or 24 months.

Special Issues

Toledo struggled with referrals throughout the project. After slower-than-expected referrals during its first year of implementation, Toledo Safe Start added referral sources. Despite these additional referral sources, the number of referrals did not substantially increase, for reasons that remain unclear. In addition, retention of families for the follow-up assessments was very low. For a more in-depth discussion, see Schultz et al. (2010). Because of low enrollment and retention, the evaluation of the Toledo intervention ended early.

Analysis Plan

First, we conducted descriptive analyses to summarize the sample characteristics: age, gender, race or ethnicity, the family income level, and the child's violence exposure at baseline. Because of the randomized experimental design, we did not expect any major differences between the two groups at baseline. However, to examine this possibility, we tested for differences in child and caregiver characteristics and outcomes at baseline between intervention and control group children using t-tests and chi-square tests.

While 30 children were enrolled in the Safe Start program at baseline (15 in the intervention and 15 in the control group), only seven children were retained at the six-month follow-up in the study. These sample sizes are too small to allow for an estimation of the effect of the intervention. Because of the small sample sizes, we conducted only limited analyses of the Toledo data to compare within-group baseline mean outcomes using t-tests. We were unable to examine differences in outcomes between the intervention and control groups using an intent-to-treat approach or conduct statistical modeling that would allow us to control for child characteristics that could impact the outcome and correlate with the Safe Start intervention.

When conducting large numbers of simultaneous hypothesis tests (as we did in this study), it is important to account for the possibility that some results will achieve statistical significance simply by chance. The use of a traditional 95-percent confidence interval, for example, will result in one out of 20 comparisons achieving statistical significance as a result of random error. We therefore adjusted for false positives using the False Discovery Rate (FDR) method (Benjamini and Hochberg, 1995). Our assessments of statistical significance were based on applying the FDR procedure separately to all of the primary, secondary, and tertiary outcome tests in this report using an FDR of 0.05. However, since none of the results achieved statistical significance using the traditional 95-percent confidence interval, we did not need to make this adjustment for the Toledo analyses.

RESULTS

Baseline Descriptive Statistics

For the descriptive statistics, we provide the characteristics for the full enrolled Toledo sample at baseline. As seen in Table 3, the baseline sample included 53 percent males and 47 percent females, with an average age of 3.5 years. Forty-seven percent of the sample was white, with some black (7 percent) and Hispanic (3 percent) children. A substantial minority (43 percent) of the children were some other race or ethnicity. Nearly three-quarters of families (71 percent) had family incomes of less than \$30,000, with about one-third (32 percent) having family incomes of less than \$5,000. According to the caregiver reports, children in the baseline sample had been exposed to an average of 4.7

types of violence in their lives prior to the baseline assessment. A majority (80 percent) of the caregivers were the parent or guardian of the child. As noted in the table, there were no differences on these characteristics between the intervention and control groups at baseline.

Because only seven families were retained at six months, we did not examine the demographics for the retained group.

We also examined the Toledo sample at baseline on the PTSD and parenting stress outcome measures (Table 4). Overall, 47 percent of the caregivers reported child PTSD symptoms that fell within the significant, range with 25 percent for boys and 67 percent for girls. For the caregiver-child relationship, 73 percent of the sample had total stress levels that fell in the clinical range. For the different subscales, 37 percent of the sample had clinical levels on the parental distress subscale, 63 percent had clinical levels on the parent-child dysfunctional interaction subscale, and 73 percent had clinical levels on the difficult child subscale.

Table 3
Toledo Safe Start Sample Characteristics for Families in the Baseline Assessment Sample

	Combined		Intervention		Control		Test for Comparison P-Value
<i>Child Characteristics</i>	<i>N</i>	<i>Mean</i>	<i>N</i>	<i>Mean</i>	<i>N</i>	<i>Mean</i>	
Age	30	3.5	15	3.6	15	3.3	0.47
CR Violence Exposure	28	4.7	14	4.8	14	4.6	0.89
<i>Gender</i>	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>	
Male	16	53.3	8	53.3	8	53.3	1.0
Female	14	46.7	7	46.7	7	46.7	
<i>Race/Ethnicity</i>	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>	
White	14	46.7	9	60.0	5	33.3	
Black	2	6.7	2	13.3	0	0.0	
Hispanic	1	3.3	0	0.0	1	6.7	
Other	13	43.3	4	26.7	9	60.0	
<i>Caregiver Characteristics</i>	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>	
<i>Family Income Level</i>							
Less than \$5,000	9	32.1	4	30.8	5	33.3	
\$5,000–\$10,000	6	21.4	3	23.1	3	20.0	
\$10,001–\$15,000	2	7.1	1	7.7	1	6.7	
\$15,001–\$20,000	2	7.1	1	7.7	1	6.7	
\$20,001–\$30,000	1	3.6	1	7.7	0	0.0	
More than \$30,000	8	28.6	3	23.1	5	33.3	
<i>Relationship to Child</i>							
Parent-Guardian	24	80.0	13	86.7	11	73.3	0.36
Other Relationship	6	20.0	2	13.3	4	26.7	

NOTES: CR = Caregiver Report. Percentages may not total 100 percent because of rounding.

Table 4
Baseline Assessment Estimates for Toledo Safe Start Families

	Combined		Boys		Girls	
CR PTSD Symptoms for Ages 3–10	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>
Normal	8	47	5	53	3	33
Borderline	1	6	1	13	0	0
Significant	8	47	2	25	6	67
CR Total Parenting Stress for Ages 0–12	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>
Parental Distress—Clinical	11	37	6	38	5	36
Parent-Child Dysfunctional Interaction—Clinical	19	63	11	69	8	57
Difficult Child—Clinical	22	73	10	63	12	86
Total Stress—Clinical	22	73	10	63	12	86

NOTE: CR = Caregiver Report.

Uptake, Dosage, and Process of Care

The process evaluation report documents the services that were made available to Toledo's intervention group families (Schultz et al., 2010). Among the 15 families in the intervention group, the program reported services received for only six of them. These six families received on average 15.8 CPP sessions, ranging between two and 55 sessions each.

Outcomes Analysis

As noted earlier, we were unable to examine the effects of the Toledo intervention over time because of the small sample sizes. In this section we present baseline means for the intervention and control group's primary, secondary, and tertiary outcome measures when the sample size is greater than five. As shown in Table 5, primary outcomes include PTSD symptoms, behavior/conduct problems, some aspects of social-emotional competence, caregiver-child relationship, and violence exposure. Toledo's secondary outcomes include the cooperation aspect of the social-emotional competence domain and the violence exposure domain (Table 6), while the tertiary outcomes included only the background and contextual factor and school readiness/performance domains (Table 7). When the sample size allowed, we examined differences between the intervention and control groups at baseline for Toledo's primary, secondary, and tertiary outcomes. From these analyses, there were no differences observed between the intervention and control groups at baseline for any of the primary, secondary, or tertiary outcomes with a large enough sample size.

Table 5
Baseline Means for Primary Outcome Variables

Primary Outcome	Group	Baseline	
		N	Mean
PTSD Symptoms			
CR Child PTSD Symptoms for Ages 3–10	Intervention	9	49.67
	Control	9	42.00
Behavior/Conduct Problems			
CR Child Behavior Problems for Ages 1–18	Intervention	15	0.61
	Control	15	0.69
Social-Emotional Competence			
CR Child Assertion for Ages 1–12	Intervention	15	-0.14
	Control	15	-0.05
CR Child Self-Control for Ages 1–12	Intervention	15	-0.45
	Control	15	-0.61
Caregiver-Child Relationship			
CR Parent Distress for Ages 0–12	Intervention	15	31.20
	Control	15	29.33
CR Parent-Child Dysfunction for Ages 0–12	Intervention	15	26.93
	Control	15	28.13
CR Difficult Child for Ages 0–12	Intervention	15	37.07
	Control	15	36.40
CR Total Parenting Stress for Ages 0–12	Intervention	15	95.20
	Control	15	93.87

NOTES: CR = Caregiver Report. * indicates statistically significant (p-value < FDR significance criterion); # indicates nonsignificant trend (p < 0.05 and > FDR significance criterion). Data are not shown for outcomes when the cell size is fewer than five for the group. Comparisons were not tested when the group size was fewer than ten for either group.

Table 6
Baseline Means for Secondary Outcome Variables

Secondary Outcome	Group	Baseline	
		N	Mean
Social-Emotional Competence			
CR Child Cooperation for Ages 3–12	Intervention	7	10.43
	Control	7	9.86
Violence Exposure			
CR Total Child Victimization Experiences for Ages 0–12	Intervention	14	4.79
	Control	14	4.64
CR Child Maltreatment for Ages 0–12	Intervention	15	1.20
	Control	12	1.42
CR Child Assault for Ages 0–12	Intervention	15	1.20
	Control	12	0.92
CR Child Sexual Abuse for Ages 0–12	Intervention	12	0.17
	Control	14	0.00
CR Child Witnessing Violence for Ages 0–12	Intervention	14	2.29
	Control	15	2.27
CR Caregiver Total Number of Traumatic Experiences	Intervention	15	0.40
	Control	14	0.43
CR Caregiver Experience of Any Non-DV Trauma	Intervention	15	0.40
	Control	15	0.40
CR Caregiver Experience of Any DV	Intervention	15	0.60
	Control	15	0.67

NOTES: CR = Caregiver Report; DV = domestic violence. * indicates statistically significant (p -value < FDR significance criterion); # indicates nonsignificant trend (p < 0.05 and > FDR significance criterion). Data are not shown for outcomes when the cell size is fewer than five for the group. Comparisons were not tested when the group size was fewer than ten for either group.

Table 7
Baseline Means for Tertiary Outcome Variables

Tertiary Outcome	Group	Baseline	
		N	Mean
Background and Contextual Factors			
CR Caregiver Resource Problems	Intervention	15	14.53
	Control	15	13.60
CR Caregiver Personal Problems	Intervention	15	26.73
	Control	15	24.20
School Readiness/Performance			
Letter Word Identification for Ages 3–18	Intervention	6	2.50
	Control	3	
Passage Comprehension for Ages 3–18	Intervention	5	11.00
	Control	3	
Applied Problems for Ages 3–18	Intervention	6	-4.83
	Control	3	

NOTES: CR = Caregiver Report. * indicates statistically significant (p-value < FDR significance criterion); # indicates nonsignificant trend (p < 0.05 and > FDR significance criterion). Data are not shown for outcomes when the cell size is fewer than five for the group. Comparisons were not tested when the group size was fewer than ten for either group.

CONCLUSIONS

With its implementation of CPP, Toledo’s Safe Start program was able to provide an established therapeutic intervention to very young children with exposure to violence to some families in the community. The planned evaluation involved a randomized controlled trial of the intervention. However, the program enrolled only 30 families in the study and retained only seven of them for the six-month assessment. As a result, the evaluation of Toledo’s program was discontinued near the end of the project, although services continued.

The participants in the study had substantial violence exposure, with caregivers reporting that these young children (average age of 3) had been exposed to an average of 4.7 types of violence in their lives prior to the baseline assessment. At baseline, families enrolled in the study were experiencing PTSD symptoms and parental stress. Nearly one-half of the caregivers (47 percent) reported child PTSD symptoms that fell within the significant range, and almost three-quarters (73 percent) reported levels of parental stress that fell in the clinical range. Difficulties in enrolling and retaining families in the study resulted in too few families in the six-month analysis sample to conduct any outcomes analyses.

Overall, the sample size limitations mean that no conclusions can be drawn about the impact of the Toledo intervention on child- and family-level outcomes. Nonetheless, Toledo Safe Start increased the community's capacity to serve young children exposed to domestic violence by integrating domestic violence awareness and assessment into the Help Me Grow curriculum and by training clinicians to deliver an established therapeutic intervention. In conclusion, the Toledo model requires further testing with a sufficient sample to assess the potential impacts of the intervention on outcomes for children exposed to violence.

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