College of Education Faculty Research and Publications

Education, College of

Home-Based Parent Child Therapy for Young Traumatized Children Living In Poverty: A Randomized Controlled Trial

Joanna R. Love
Marquette University

Robert Fox
Marquette University, robert.fox@marquette.edu

Home-Based Parent Child Therapy for Young Traumatized Children Living In Poverty:

A Randomized Controlled Trial

Joanna R. Love and Robert A. Fox

Marquette University

REVISED MANUSCRIPT

Author Note

Correspondence concerning this article should be addressed to Robert A. Fox, Professor, Marquette University, Department of Counselor Education and Counseling Psychology, College of Education, Schroeder Complex, P. O. Box 1881, Milwaukee WI 53201-1881. E-mail: robert.fox@marquette.edu; Phone: 414-288-1469. Joanna R. Love, M.A., doctoral student, Marquette University, Department of Counselor Education and Counseling Psychology, College of Education, Schroeder Complex, P. O. Box 1881, Milwaukee WI 53201-1881. E-mail: Joanna.love@marquette.edu.

Abstract

A randomized control trial was used to evaluate the effectiveness of a home-based, parent-and-child therapy program specifically developed for toddlers and preschoolers living in poverty with trauma symptoms. Sixty-four children 5-years of age and younger were referred to a community-based clinic for behavior problems and emotional difficulties. All children had experienced one or more potentially traumatic events and met the *DSM-5's* criteria for *Post-Traumatic Stress Disorder in Children Six Years of Age and Younger*. All families received government assistance indicating that their income met the federal definition for poverty. Participants were randomly assigned to either immediate treatment or wait list control groups. Significant between-group differences on all post-treatment measures were found. After the waitlist group completed treatment, significant improvements for both groups were found on all measures at six-weeks follow-up. Outcomes included reductions in challenging behaviors and emotional symptoms of trauma, improved caregiver-child relationships, and increased caregiver adherence to treatment strategies. This study offers support for early intervention of children with trauma symptoms and identifies the clinical challenges and advantages of providing therapy services in a home setting for very young children in poverty.

Keywords: home-based trauma treatment, young children, poverty

Home-Based Parent-Child Therapy for Young Traumatized Children Living in Poverty:

A Randomized Controlled Trial

Many children are adversely affected by traumatic experiences. In 2014, 700,358 children experienced substantiated abuse or neglect in the United States (U.S. Department of Health & Human Services, 2016). It has been estimated that about 60% of children are victims of physical abuse, 5% of children are victims of sexual abuse; and 40% of children have witnessed domestic or community violence (Finkelhor, Ormond, & Turner, 2009). Unfortunately, even very young children are not protected from experiencing traumatic events. Rather, children under the age of five-years-old are one of the highest risk groups for experiencing traumatic incidents, including physical and sexual abuse, neglect, and witnessing violence (Lieberman, Chu, Van Horn, & Harris, 2011). One report estimated that 26% of children in a healthy birth cohort would witness or experience a potentially traumatic event before the age of four-years-old (Briggs-Gowan, Ford, Fraleigh, McCarthy, & Carter, 2010). Complicating the picture further, young children from families exposed to urban poverty face a disproportionate risk of exposure to trauma due to factors associated with poverty such a living in unsafe neighborhoods, racial discrimination, and the challenges associated with daily living (Collins et al., 2010). These early stressful experiences can alter the brain's architecture and physiologic stress response systems of a developing child. Moreover, the resulting toxic stress from trauma in early childhood can have significant, harmful long-term psychological and physical health consequences (Shonkoff et al., 2012). Therefore, early intervention that addresses the impact of toxic stress is essential for the long-term well-being of our children.

The field of early childhood mental health is evolving, but there still is a relative lack of empirical research regarding treatment for very young children (birth to five years of age) who

have experienced trauma (Chu & Lieberman, 2010). The need for effective trauma-informed

therapy is even more salient for children living in poverty, who are disproportionately more

likely to experience potentially traumatizing events (Lieberman, Chu, Van Horn, & Harris,

2011). Some evidence-based trauma therapy programs have been developed for use with

children such as Trauma-Focused Cognitive Behavioral Therapy (TF-CBT; Cohen, Mannarino,

& Deblinger, 2006) and the Attachment, Self-Regulation, and Competency program (ARC;

Arvidson et al., 2011; Blaustein & Kinniburgh, 2010). An even smaller number of trauma-

informed therapy programs are designed specifically for children under five years old, such as

Child-Parent Psychotherapy (CPP; Lieberman & Van Horn, 2008) and Attachment and

Biobehavioral Catch-up (ABC; Bernard, Dozier, Bick, Lewis-Morrarty, Lindhiem, & Carlson,

2012). While some of these trauma therapy programs have conducted efficacy research with

diverse, low-income populations, these treatment programs rarely provide additional details

regarding how to use a culturally-informed approach with families living in poverty. For

example, research has found that effective therapy with families living in poverty often involves

using a collaborative approach in setting goals for treatment and allows for flexibility within the

therapy process. While some of the evidence-based treatment programs are intended to be

tailored depending on the needs of the family, goals are typically determined by the nature of the

program. Moreover, the completion of some long-term programs (such as CPP and ARC, both

which recommend about 50 treatment sessions) may not be feasible for families with multiple

life stressors. Furthermore, the design of some treatment programs requires a stricter adherence

to a treatment manual, which may not allow for the kind of flexibility necessary when working in

the context of families living in poverty. For example, the use of TF-CBT is reportedly

contraindicated in situations where a caregiver also has untreated trauma, mental health

concerns, or high levels of distress, or in families where there is household instability, serious

ongoing conflict in the home, or basic needs are not being met (Chadwick Center for Children

and Families, 2008; Cohen, Mannarino, & Deblinger, 2003; Lang, Ford & Fitzgerald, 2010).

Exclusion criteria such as these may unintentionally preclude children and families experiencing

ongoing stress who are most at need of therapeutic interventions.

Additionally, children living in poverty are less likely to have access to appropriate

mental health services due to barriers including the lack of transportation or childcare, difficulty

keeping regular appointments, variable schedules for work or school commitments, caregiver

physical or mental health problems, child illness, mistrust of mental health services, high costs of

mental health care, and/or inadequate insurance coverage for appropriate mental health services

(Rowan, McAlpine, & Blewett, 2013;). The practical challenges associated with accessing

therapy services can be partially addressed by using an in-home treatment model. However, most

evidence-based trauma therapy programs are conducted in an outpatient setting, rather than in the

client's home environment.

The *Early Pathways (EP) Program* was developed and tested through randomized

controlled studies to address significant behavior problems in very young children (5 and

younger) living in poverty using a home-based delivery system (Fung & Fox, 2014; Harris, Fox,

& Love, 2015). It also received high ratings as an evidence-based program by the Substance

Abuse and Mental Health Services Administration's National Registry for Evidence-Based

Programs and Practices. Moreover, the California Clearing House for Evidence Based Programs

rated *EP* as highly relevant for use by child welfare agencies. For the present project, starting

with *EP* as the core treatment program, the trauma literature and available trauma-informed

programs were reviewed (e.g., Briere & Scott, 2012; Cohen, Mannarino, & Deblinger, 2006;

Ford, Courtois, Steele, Van der Hart, & Nijenhuis, 2005; National Child Traumatic Stress

Network, 2012; Herman-Smith, 2013; Thompson, 2014). Practical treatment strategies based on

attachment theories to address parent-child relationships and cognitive-behavioral therapy to

focus on symptom reduction and emphasize positive parenting strategies for caregivers were

integrated with *EP*. Recent research in the treatment of toxic stress in early childhood, following

an ecobiodevelopmental framework (Shonkoff et al., 2012) also was included. For example, this

research suggested treatment of early toxic stress should include a safe and stimulating home

environment. While few existing evidence-based programs include a specific focus on the home

environment, we added multiple strategies for assisting caregivers to accomplish this goal.

Method

Participants

This study was approved by the Internal Review Board of a Midwestern University.

Participants were 64 children ages one-to-five years old referred to a clinic that specializes in

serving very young children in poverty with emotional and behavioral problems (Fox, Keller,

Grede, & Bartosz, 2007). Eligibility criteria for participation in the research study were the

following:

(a) The child was five years old or younger at the start of treatment.

(b) The child experienced some type of potentially traumatizing event, as indicated on the

Traumatic Events Screening Inventory - Parent Report Revised (TESI-PRR). To qualify for

participation the study, at least one response on the TESI-PRR was endorsed positively.

(c) The child exhibited at least four symptoms of posttraumatic stress disorder (PTSD) as

defined by the *DSM-5*; at least one symptom was an *intrusion* symptom and one was an

avoidance and negative alterations in cognition symptom. This approach is consistent with

previous research using clinical trials which required four DSM-IV-TR defined posttraumatic

stress symptoms for study eligibility with at least one symptom of *re-experiencing/intrusions* and

one of *avoidance* (Meiser-Stedman, Smith, Yule, & Dagleish, 2008; Sheeringa, 2011).

   (d) The family received public assistance, indicating that the household income was

below the federal poverty level.

   (e) Signed consent was obtained by the child's legal guardian.

   (f) The child and primary caregiver completed the comprehensive intake evaluation and

at least five treatment sessions. Previous studies conducted with a similar population with

behavior problems without trauma used a minimum number of 3 treatment sessions as part of

treatment completion criteria (Fung, Fox, & Harris, 2014). Given the complex nature of trauma,

it was hypothesized that more minimum treatment sessions would be needed to produce change,

and therefore participants were included in the final sample only if they completed at least five or

more treatment sessions. Participants in the wait list control group were included in primary data

analyses if they completed the initial intake and a second intake 4-6 weeks later. Participants in

the wait list (WL) control group who subsequently completed at least 5 treatment sessions were

also included in follow-up analyses. Children with autistic spectrum disorders, severe to

profound intellectual disabilities, or serious physical illnesses were not included in this study and

were referred to more appropriate services. Children who were eligible for in-home counseling

services but did not meet all inclusion criteria for this research study and/or refused to be part of

a research study received the full complement of mental health services offered.

Procedure

   A comprehensive intake evaluation was completed for each participant in their home

settings. A semi-structured parent interview was conducted to gain information regarding the

child's background, strengths, family composition and mental health history, child's health

history, daily routines and living skills, specific problem behaviors, and trauma history. The

pretest assessment using the measures described below was also completed. All items were read

to caregivers unless they preferred to answer them on their own. Any child meeting the PTSD

diagnostic criteria from the *DSM-5* (APA, 2013) was given a psychiatric diagnosis that was

reviewed by a qualified professional (e.g., licensed psychologist, licensed professional counselor,

or a licensed clinical social worker). Treatment sessions were scheduled to occur once per week

for one hour or longer if needed. The caregiver and therapist collaborated to identify treatment

goals at the first session. Each week a treatment plan was reviewed with treatment goals and

strategies to be practiced during the following week with a copy provided to the caregiver.

Treatment sessions began by reviewing and documenting progress toward treatment goals and

completing the weekly assessments. *EP* with the added trauma component was originally

designed to take an average of 16 weeks to complete, depending on the individual needs of the

child and family. However, the number of sessions varied depending on the needs of the child

and the availability and motivation of the child's primary caregiver. Additional booster sessions

were sometimes provided after the 4-6-week follow-up session, depending on the needs of the

family and clinical judgment of the therapist.

Treatment program. The treatment program involved an integration of the evidence-

based *EP* along with the new trauma-informed components. A copy of the integrated treatment

program manual can be downloaded freely at www.marquette.edu/education/early-pathways.

The program was piloted with three separate therapists and families prior to implementation.

The five core elements of the *EP* were retained and included: (a) strengthening the parent-child

relationship through child-led play, attunement practices and other nurturing activities; (b)

helping parents maintain developmentally appropriate expectations for their child (c) helping

parents learn cognitive strategies to respond calmly and thoughtfully to their child's challenging

behaviors; (d) using positive reinforcement to strengthen the child's pro-social behaviors and

listening sessions to improve the child's compliance to parent requests; and (e) using limit-

setting strategies to reduce the child's challenging behaviors, such as redirection, ignoring, or

time-out (Fox, 2017). Limit-setting strategies were modified to reflect best practices in trauma-

informed care. For example, a *Time-In* strategy was used in place of time-out or ignoring in cases

where a child's emotional outburst was triggered by a trauma reminder rather than a functional

temper tantrum, or in cases where the child had not developed the ability to self-regulate

emotions.

In addition to these core elements, the trauma-informed treatment components included:

Basic Safety, Caregiver-Child Relationship, Predictable and Nurturing Environment, Trauma-

Informed Limit Setting Strategies, Calming Strategies, Naming and Practicing Feelings, Healthy

Thoughts and Feelings, Identifying Sources of Support, Building Prosocial Skills, Trauma

Narrative Development and Implementation and Seeking Closure. Many of these treatment

components were adapted from existing evidence-based programs such as *Trauma-Focused*

*Cognitive Behavioral Therapy (*Cohen, Mannarino, & Deblinger, 2006) or were developed to

meet the unique needs of very young traumatized children in poverty. Parent handouts were

developed to match the educational levels of the families.

Finally, in addition to the treatment program, we also routinely provide advocacy services

for the family by referring them to available community resources (e.g., rent assistance, food

pantries, pediatricians who accept Medicaid insurance, counseling for parents who were

traumatized themselves, etc.). Often, we also provided direct advocacy services such as

providing safety locks for cabinets, doors and windows, toys for the children, among other needed items in the home.

Clinician Training. Clinicians included licensed mental health professionals and graduate students enrolled in mental health programs. Spanish-speaking clients received the treatment program from either a bilingual therapist or an English-speaking therapist with a translator; all parent handouts were translated into Spanish for these families. All therapists trained in the new trauma-informed components of the treatment program had already received extensive training and experience with *EP*. The didactic training component for trauma-informed components included formal workshops, weekly staff meetings and additional training sessions as well as an ongoing review of the integrated treatment manual. All staff and graduate students received weekly group supervision sessions with a licensed psychologist; students also received weekly individual supervision. A treatment fidelity checklist was used with each case to ensure that the program was implemented with fidelity. Therapists were asked to indicate which treatment components were discussed with the family or implemented in each treatment session; these checklists were reviewed during supervision to ensure adherence to *EP*. Not every individual treatment activity was necessary for each family. For example, providing psychoeducation to parents who were victims of intimate partner violence was a necessary treatment component for children who had witnessed this violence, but may not be a relevant component for families who had not experienced this form of violence. For each of the categories of topics (e.g., Family Safety) therapists were trained to use clinical judgment to determine the extent to which each specific topic needed to be addressed with each family.

Measures

Traumatic Events Screening Inventory - Parent Report Revised (TESI-PRR). The

TESI-PRR (Ghosh-Ippen, et al., 2002) includes 24 items such as "Has your child experienced the

death of someone close to him/her" and is answered by a caregiver with either *Yes*, *No*, or

Unsure. Inter-rater reliability for the original TESI (Ford & Rogers, 1997) was reported to range

from .73 to 1.0 for the different types of traumatic events (Gray & Slagle, 2006).

The Early Childhood Behavior Screen. The ECBS (Holtz & Fox, 2012) is a 20-item

caregiver-report measure which assesses the frequency of a young child's prosocial behaviors

(e.g., "Shares toys") and challenging behaviors (e.g., "Hits others"). Items are rated by the

primary caregiver on a three-point Likert scale (3 = often, 2 = sometimes, 1 = almost never).

Only the Challenging Behavior Scale (CBS) was used in the present study. Total scores on the

challenging behavior scale (CBS) range from 10 to 30 with higher scores indicating a greater

frequency of challenging behaviors. This tool was developed for use with children from low-

income families and is written at a 3.9 grade level. Field-testing was conducted with a

representative, diverse sample of 439 parents from low socioeconomic status in an urban

community. The internal consistency using coefficient alpha was .87. The CBS demonstrated

adequate levels of concurrent validity ($r = .75$) with the Eyberg Child Behavior Inventory (ECBI;

Eyberg & Pincus, 1999), as well as adequate levels of sensitivity (82%) and specificity (80%)

based on the relationship with the ECBI. Harris, Fox, and Holtz (2016) conducted a confirmatory

factor analysis that provided support for the ECBS' factor structure. Receiver operating

characteristics (ROC) curve analyses were used to test the CBS's ability to distinguish between

428 clinic-referred children and 245 non-clinic referred children. Results showed an acceptable

fit model for the ECBS, providing further evidence of its construct validity. Optimal cut-scores

by child age derived from the ROC curve analyses were provided. Sensitivity rates for cut scores

ranged from 0.76 to 0.83 and specificity rates ranged from 0.88 to 0.95. Acceptable test–retest

reliability and good internal consistency also was observed.

The Pediatric Emotional Distress Scale (PEDS). Two subscales from the PEDS

(Saylor, Swenson, Reynolds, & Taylor, 1999) were used to assess for possible trauma symptoms:

Anxious/Withdrawn (PEDS-AW) and Fearful (PEDS-F). The PEDS was designed for use with

children ages two to ten years old and the items were written at a 4.0 grade level. The PEDS-AW

includes six items (e.g., "Seems worried"), with subscale scores ranging from 6-24, and the

PEDS-F includes five items (e.g., "Has bad dreams") with subscale scores ranging from 5-20.

Items are rated on a four-point Likert scale (1 = Almost Never, 2 = Sometimes, 3 = Often, 4 =

Very Often). Four geographically and developmentally diverse samples were used to determine

preliminary psychometrics. The authors reported adequate alpha coefficients for the PEDS-AW

($r = .74$) and the PEDS-F ($r = .72$). Concurrent validity was demonstrated with significant

correlations between parents' reports of PTSD symptoms on the Child Posttraumatic Stress

Reaction Index (CPTS-RI; Frederick, 1985) with both PEDS-AW ($r = .62$) and PEDS-F ($r = .59$).

Parent-Child Relationship Scale (PCRS). This scale was used to measure the

clinician's subjective assessment of quality of the caregiver-child relationship as well as the

caregiver's adherence to the treatment program (Fox & Nicholson, 2003). The PCRS uses a scale

of 0-100 with five anchors at 20-point intervals: poor (ranging from 0-20), below average

(ranging from 20-40), average (ranging from 40-60), good (ranging from 60-80), and exceptional

(ranging from 80-100). Multiple descriptive markers are provided for each interval to improve

inter-rater reliability (e.g., "Parent is often thoughtful when interacting with child" or "Parent can

be responsive to child's needs and set appropriate limits on child's behavior, but not

consistently"). Inter-rater reliability was determined based on 101 cases, and a kappa coefficient

of .57 was reported (Fung & Fox, 2014), indicating moderate agreement between observers

(Viera & Garrett, 2005).

Therapist Treatment Report (TTR). The TTR was completed during or immediately

following each weekly treatment session. This report includes clinical notes, observations, and

progress toward parent and child goals. The treatment report also included a four-item scale

based on the primary objectives of *EP*, designed to assess caregiver adherence to program

strategies. These items are: (a) "Does the parent maintain appropriate expectations?" (b) "Does

the parent stop and think before responding?" (c) "Does the parent utilize rewards

appropriately?" and (d) "Does the parent utilize appropriate discipline?" Items are rated by the

clinician using a three-point Likert scale (1 = rarely/not at all, 2 = sometimes, 3 = most times).

The four scores were combined for a composite score that ranged from 4 to 12, with higher

scores representing greater caregiver adherence to treatment. For the present study, therapists

were trained to rate these items in the context of the child's trauma. For example, parent use of

appropriate discipline refers to appropriate trauma-informed discipline strategies. Reliability for

this scale was determined from 102 observations (Fung & Fox, 2014). Two clinicians

independently scored the items, and kappa coefficients were computed for each scale item:

appropriate expectations = .89, stop and think = .92, utilized rewards = .95, utilized discipline =

.89. The coefficient alpha of the entire scale for the sample was .88, indicating good agreement

between observers (Viera & Garrett, 2005).

Family Satisfaction Survey (FSS). A 7-item survey was used to assess caregiver

satisfaction with the treatment services. This scale is used anonymously to facilitate caregivers

providing honest feedback. On a 7-point Likert rating scale, caregivers were asked to rate: the

quality of services received (1 = *poor* to 7 = *excellent*), how the services contributed to their

child's improvement (1 = *not at all* to 7 = *a lot*), how the clinic helped them to improve

management of their child (1 = *not at* to 7 = *a lot*), if caregivers would use the clinic again if

needed (1 = *no, definitely not* to 7 = *yes, definitely*), current status of the child's referral concern

(1 = *considerably worse* to 7 = *greatly improved*), if caregivers would recommend the clinic to

others (1 = *no, definitely not* to 7 = *yes, definitely*), and the caregiver's confidence in managing

their child's behavior in the future (1 = *not at all confident* to 7 = *very confident*). Total scores

range from 7 to 49, with higher scores indicating greater satisfaction with services. In a similar

study, internal consistency for this measure was reported to be r=.82 (Fung & Fox, 2014).

Research Design

A convenience sample of children referred to the clinic for participation in the trauma

therapy program was used. Eligibility for the trauma study was determined after the completion

of the intake evaluation. Therefore, consecutively referred participants meeting full criteria for

inclusion were randomly assigned to immediate treatment (IT) or wait list (WL) groups using a

computer-derived random numbers table upon completion of the intake evaluation. Participants

in the IT group were scheduled to start treatment within one week of their initial intake.

Participants randomly assigned to the WL group waited four to six weeks for treatment services

after their initial intake. Using a six week wait list was based on previous studies with

populations living in poverty (Harris, Fox, & Love, 2015; Fung & Fox, 2014). This shortened

length of time on the wait-list was to avoid the risk of increased attrition due to a longer wait

times to receive services.

All measures were administered for both IT and WL at intake (Time 1), except the

satisfaction survey, which was only administered at the completion of the program. The TESI-

PRR was only administered at Time 1 to screen for the presence of potentially traumatizing

events. The primary assessments (ECBS-CBS, PEDS-AW, PEDS-F, and therapist Treatment

Report (TR) were completed at each treatment session and at treatment completion. The WL

group completed the measures again when beginning the treatment program (Time 2), and again

at the completion of the program (Time 3). For IT and WL groups, a follow-up occurred six

weeks after the final posttest to assess for maintenance of treatment gains using the study's

primary measures (ECBS-CBS, PEDS-AW, PEDS-F, TR, and PCRS).

Results

Participants

The final sample included 64 participants with 32 in the immediate treatment (IT) group

and 32 in the wait list (WL) control group (see Table 1 for demographic information). There

were 44 males (68.8%) and 20 females (31.3%). Children were African American (42.2%),

multiracial (28.1%), Latina/o or Hispanic (18.8%), and European American (10.9%). Children

were an average of 39.11 months old ($SD = 13.32$), and 20.3% of children had been previously

diagnosed with a developmental delay. Families were asked to identify their primary referral

concern at intake and again at post-treatment. At intake, the most common primary referral

concerns were temper tantrums (40.6%) and aggression toward others (37.5%). Twenty-three

percent of children had been exposed to two different potentially traumatic events in their

lifetime, and 73% of children had been exposed to three or more different traumatic events.

Caregivers were biological mothers (57.8%), both biological parents (18.8%), foster/kinship

caregiver (15.6%), or other relatives (7.8%). Caregivers were more likely to be single (57.8%

never married, 14.1% were separated, and 12.5% were divorced), and about one-half of

caregivers were unemployed (51.6%). Of the children's biological parents, 15.7% of mothers and

32.4% of fathers had completed less than a 12th grade education, 70.6% of mothers and 61.8% of

fathers had completed 12th grade, and 10.9% of mothers and 5.9% of fathers had completed at

least some post-high school education. Average caregiver age was 31.52 years (SD = 10.55).

The immediate treatment (IT) and wait list (WL) groups were compared on demographic

variables using independent-group t-tests for continuous variables and chi-square tests for

categorical variables (see Table 1). No significant differences were found on demographic

variables. However, participants in the IT group endorsed more potentially traumatic events in

the child's lifetime based on the TESI-PRR [t (62) = 2.20, p = .031].

Attrition

A Consort Diagram (see Figure 1) was used to show the flow of participants in each

group throughout the entire study from intake through follow-through. As shown in Figure 1, a

total of 12 (27.2%) participants in the IT group dropped out prior to completing five treatment

sessions and 5 (13.5%) participants in the WL group dropped out prior to completing a second

intake. Treatment completers and non-completers were compared on demographic variables and

pretest measures using independent-group t-tests for continuous variables and chi-square tests for

categorical variables. There were no significant differences in demographic or pretest variables

between treatment completers and non-completers.

The average program duration and number of treatment sessions also were compared

between the IT and WL treatment groups. The average program duration was 21.84 weeks (SD =

10.01) for the IT group and 20.31 weeks (SD = 9.54) for the WL group. Within the WL group,

there was an average wait time of 7.25 weeks (SD = 5.52) from first intake (Time 1) to second

intake (Time 2). The IT group completed an average of 10.22 sessions (SD = 5.10). For the

combined sample, there was an average length of 7.5 weeks (SD = 8.85) between posttest session

and short-term follow-up session.

Data Analyses

The IBM SPSS Statistics for Windows, Version 21.0 program was used to conduct the

quantitative statistical analyses for this study. For all participants who met inclusion criteria,

intention-to-treat (ITT) analyses were used with the last observation carried forward (Gupta,

2011). This means that families in the immediate treatment (IT) group who dropped out of

treatment after the fifth treatment session were still included in statistical analyses and their final

measures were used for data analyses. Participants in the IT group who did not complete an

intake and at least five treatment sessions were eliminated from the database and designated as

non-completers. Similarly, participants in the wait list (WL) control group who did not complete

a second intake (at Time 2) were eliminated from the database and designated as non-completers.

Cohen's effect size was used for all significant results (Cohen, 1998).

Results for the study's primary dependent measures by group are shown in Table 2. A

significant group difference was found between the IT and WL groups on the ECBS-CBS with a

large effect size [F (1, 61) = 25.55, $p < .001$, Cohen's d = .97). Results of a MANCOVA

demonstrated significant differences on the two PEDS measures [F (2, 59) = 13.08, $p < .001$].

Univariate results showed significant between-group differences on the PEDS-AW with a large

effect size [F (1, 60) = 22.97, $p < .001$, Cohen's d = 1.05), and a medium effect size on the

PEDS-F [F (1, 60) = 8.04, $p < .01$, Cohen's d = .59). Results of an ANCOVA revealed a

significant between-group difference in the PCRS with a medium effect size [F (1, 56) = 7.70, p

$< .01$, Cohen's d = .52]. Results of an ANOVA also revealed a significant between group

difference in TR scores at Time 2 with a large effect size [F (1, 62) = 53.11, $p < .001$, Cohen's d

= 1.82]. Finally, a repeated measures analyses of variance (ANOVAs) was conducted to determine if significant changes were made across the three measurement points (pretest, posttest, and follow-up) for the combined sample of both groups among participants who completed at least five treatment sessions (see Table 3). For the WL group, pretest scores from the second intake were used in analyses. Results showed a significant change on the ECBS-CBS from pretest to follow up with a medium effect size [F (2, 40) = 10.78, $p < .001$, Cohen's d = .75]. Analyses also revealed significant changes with large effect sizes in both the PEDS-AW [F (2, 40) = 11.99, $p < .001$, Cohen's d = 1.04) and PEDS-F [F (2, 40) = 8.57, $p < .01$, Cohen's d = .80]. Results demonstrated significant changes across time with large effect sizes on the PCRS [F (2, 30) = 10.53, $p < .01$, Cohen's d = .97), and the TR [F (2, 32) = 47.66 $p < .001$, Cohen's d = 1.94). There were no significant between-group differences on any of the outcome measures at follow-up. We also compared the informal symptom checklist between the immediate and delayed groups. For the WL group, all children continued to display their primary referral concern at intake and the second pretest (e.g., aggression, tantrums, excessive crying, self-injury). For the immediate treatment group, only 28% of the children continued to have symptoms following treatment (e.g., nightmares, oppositional behaviors, tantrums, and aggression). Scores from each of the seven items on the Family Satisfaction Survey were summed to create a total score that ranged from 7 (low satisfaction) to 49 (high satisfaction). The mean score at posttest was 46.40 (SD = 2.38) for the IT group, indicating a high level of satisfaction.

Discussion

This study involved the development, implementation, and evaluation of the expanded *EP Program*, a home-based parent-and-child therapy program for very young children living in

poverty who have significant behavioral and emotional problems and experienced traumatic

events. Results of this study revealed that children who participated in *EP* decreased challenging

behaviors as well as anxious/withdrawn and fearful symptoms of trauma (such as sleep

disturbance, clinging behavior, or being easily startled). In addition, based on clinician

observation, the quality of the caregiver-child relationship improved and caregivers improved in

their abilities to use therapy strategies (such as remaining calm, maintaining fair expectations,

implementing positive parenting strategies, etc.). Caregivers also reported a high level of

satisfaction with the program after their participation. Moreover, these improvements were

maintained at least 4-6 weeks after ending services.

       These results are similar to previous studies using *EP* (Fox & Holtz, 2009; Fung, Fox, &

Harris, 2014). The results of this present study also are comparable with the results of TF-CBT

research, which also used an RCT methodology (Sheeringa, Weems, Cohen, Amaya-Jackson, &

Guthrie, 2011). Both *TF-CBT* and *EP* incorporated some similar aspects to treatment such as:

enhancing safety, providing psychoeducation, and developing coping skills (such as cognitive

coping and relaxation techniques). Given the positive impact of both treatment approaches, the

results of the present study may indicate that a more strictly manualized treatment approach with

rigid exclusion criteria may not be necessary to produce positive effects.

       The results of the present study indicated that trauma-informed therapy can be effective

with families living in poverty. Previous research has identified poverty as a risk factor for poor

treatment adherence (Armbruster & Fallon, 1994; Kazdin & Mazurick, 1994), yet children living

in poverty are significantly more likely to be exposed to violence, abuse, or other sources of

chronic stress (Lieberman, Chu, Van Horn, & Harris, 2011), and therefore are in greater need for

trauma-informed therapy. Despite the challenges associated with service delivery and program

completion (e.g., attrition), children in this study experienced overall improvements with

impressive effect sizes. Importantly, the mean scores on symptom measures (ECBS and PEDS)

fell generally within normal ranges based on cutoff scores for clinical significance at both

posttest and follow-up. This indicates that after receiving services, the frequency of these

challenging behaviors or symptoms of anxiety and fear are comparable to a general population of

same-aged children.

Limitations and Directions for Future Research

The study used a convenience sample of clients referred to the clinic for mental health

services. However, a strength of using the normal referral procedure to recruit participants is that

they are more likely to reflect typical cases (Jensen et al., 2014). Another methodological

weakness is that the therapists both provided the therapy services and administered the measures.

Thus, there is a risk of researcher allegiance bias as therapists were not blind to the treatment

condition. As this was a preliminary study with a new treatment program, there were multiple

factors that are yet unknown, including the actual minimum number of treatment sessions needed

to produce change. There were two cases out of the original sample who were reported by

therapists to have completed the treatment "successfully," but were omitted from the research

study because they had only completed four treatment sessions. While these two cases were

certainly outliers (as families in the study completed treatment with an average of 10 sessions), it

does lead to the question of treatment dosage. Barkham et al. (2006) proposed a good enough

level model of dose-effect relations, suggesting that "in routine practice, level of improvement

and treatment duration are mutually regulated so that treatments tend to end when clients, on

average, have improved to a degree or level that is *good enough*" (p. 161). This model of

treatment dosage also encompasses the idea of "therapist responsiveness" in which the length of

treatment is determined by the psychosocial context of the therapeutic environment (Barkham et al., 2006; Stiles, Honos-Webb, & Surko, 1998). Future research studies may identify the minimum necessary number of treatment sessions needed to produce reliable change in a population of very young children who have experienced trauma. In addition to determining the most efficient and efficacious dose, future research may also identify which specific components of the therapy program are most beneficial to children and caregivers and best predict successful treatment outcomes.

Family attrition remains a consistent challenge for professionals who choose to work with young children in poverty with significant mental health problems. These families frequently experience barriers that often limit their regular participation in treatment over a prolonged period. Recently, Gresl, Fox, & Besasie (2016) developed a *Treatment Barriers Scale* for families with young children in poverty. This study found that the number of barriers endorsed by a family predicted treatment success.

Clinical Implications

There are multiple clinical implications resulting from this study. From an ethical perspective, poverty cannot remain a reason that families in greatest need of support do not receive adequate mental health services. There are several strategies that mental health providers may employ to help counteract the "logistical, attitudinal, and systemic barriers" to receiving services (Santiago, Kaltman, & Miranda, 2013, p. 117). These strategies may include: establishing frequent phone contact prior to beginning services, providing services in the home or community, offering flexible scheduling, providing culturally congruent services, offering bilingual services, and when relevant, acknowledging clients' experiences of oppression or racism (Santiago, Kaltman, & Miranda, 2013). The American Association of Pediatrics (AAP)

has suggested that the community may be the most effective means of reaching vulnerable

children, and recommended that empirically validated, community- and home-based

interventions be replicated on a larger scale (Garner et al., 2012). Therefore, it would be valuable

to continue training mental health service providers in *EP*. Finally, as premature termination of

treatment remains an ongoing challenge for this population. While there is no simple solution to

this problem, our research has found that we can identify families by the third treatment session

who are likely to succeed. For those who are not showing expected progress for their children,

we have a frank discussion about the caregivers' level of engagement in the treatment process

including motivational interviewing strategies. For some families, this helps them become

motivated and more engaged. Other families acknowledge that current barriers they are facing

need to be addressed before they can fully commit to the treatment program for their children.

Clearly, more research on young children with mental health problems who live in poverty are

needed. Unfortunately, this line of research is only in its infancy.

Conflict of Interest

On behalf of all authors, the corresponding author states that there is no conflict of interest.

References

American Psychiatric Association. (2013). *Diagnostic and statistical manual of mental disorders*

    (5th Ed.). Arlington, VA: American Psychiatric Publishing.

Armbruster, P., & Fallon, T. (1994). Clinical, sociodemographic, and systems risk factors

    for attrition in a children's mental health clinic. *American Journal of*

    Orthopsychiatry, 64, 577-585. doi.org/10.1037/h0079571

Arvidson, J., Kinniburgh, K., Howard, K., Spinazzola, J., Strothers, H., Evans, M., …

    Blaustein, M. (2011). Treatment of complex trauma in young children:

    Developmental and cultural considerations in application of the ARC intervention

    model. *Journal of Child & Adolescent Trauma, 4,* 34-51.

    doi.org/10.1080.19361521.2011.545046

Barkham M., Connell, J., Stiles, W. B., Miles, J.N., Margison, F., Evans, C., & Mellor-Clark, J.

    (2006). Does-effect relations and responsive regulation of treatment duration: The good

    enough level. *Journal of Consulting and Clinical Psychology, 74,* 160-167.

    doi.org/10.1037/0022-006x.74.1.160

Bernard, K., Dozier, M., Bick, J., Lewis-Morrarty, E., Lindhiem, O., & Carlson, E.

    (2012). Enhancing attachment organization among maltreated infants: Results of a

    randomized clinical trial. *Child Development, 83, 6*23-636. doi.org/

    10.1111/j.14678624.2011.01712.x.

Blaustein, M. E., & Kinniburgh, K. M. (2010). Treating traumatic stress in children and

    adolescents: How to foster resilience through attachment, self-regulation, and

    competency. New York: Guilford Press.

Briere, J., & Scott, C. (2012). *Principles of trauma therapy: A guide to symptoms, evaluation,*

    and treatment, 2nd edition. Thousand Oaks, CA: Sage.

Briggs-Gowan, M. J., Ford, J. D., Fraleigh, L., McCarthy, K., & Carter, A. S. (2010). Prevalence

    of exposure to potentially traumatic events in a healthy birth cohort of very young

    children in the northeastern United States. *Journal of Traumatic Stress, 23,* 725–733.

    doi.org/10.1002/jts.20593

Chadwick Center for Children and Families. (2008). Assessment-based treatment for traumatized

    children: A trauma assessment pathway (TAP). Retrieved from

    http://www.taptraining.net

Chu, A., & Lieberman, A. (2010). Clinical implications of traumatic stress from birth to age five.

    Annual Review of Clinical Psychology, 6, 469-494.

    doi.org/10.1146/annualrev.clinpsy.121208.131204

Cohen, J. (1998). *Statistical power analysis for the behavioral sciences* (2<u>nd</u> <u>Ed.).</u> Hillsdale, NJ:

    Lawrence Erlbaum Associates.

Cohen, J. A., Mannarino, A. P., & Deblinger, E. (2006). *Treating trauma and traumatic grief in*

    children and adolescents. New York, NY: Guilford.

Collins, K., Connors, Il, Davis, S., Donohue, A., Gardner, s., Goldblatt, E., Hayward, … and

    Thompson, E. (2010). Understanding the impact of trauma and urban poverty on family

    systems: Risks, resilience, and interventions. Baltimore, MD: Family Informed Trauma

    Treatment Center. Retrieved from <u>http://nctsn.org/nccts/nav.do?pid=ctr_rsch_prod_ar</u>

    or <u>http://fittcenter.umaryland.edu/WhitePaper.aspx</u>

Eyberg, S., & Pincus, D. (1999). *Eyberg Child Behavior Inventory & Sutter-Eyberg Student*

    Behavior Inventory-Revised: Professional Manual. Odessa, FL: Psychological

Assessment Resources.

Finkelhor, D., Ormond, R.K., & Turner, H.A. (2009). Lifetime assessment of poly-victimization

in a national sample of children and youth. *Child Abuse & Neglect, 33,* 403-411.

doi.org/10.1016/j.chigbu.2008.09.102

Ford, J. D., Courtois, C. A., Steele, K., Hart, O. V. D., & Nijenhuis, E. R. (2005). Treatment of

complex posttraumatic self-dysregulation. *Journal of Traumatic Stress, 18,* 437-447.

doi.org/10.1002/jts.20051

Ford, J., & Rogers, K. (1997, November). *Empirically based assessment of trauma and*

PTSD with children and adolescents. Paper presented at the Annual Convention

of the International Society for Traumatic Stress Studies. Montreal, Canada.

Fox, R. A. (2017). *Early Pathways: Home-Based Mental Health Services for Very Young*

Children in Poverty. Unpublished manuscript, Marquette University (Available for free

download at www.marquette.edu/education/early-pathways.

Fox, R.A., & Holtz, C.A. (2009). Treatment outcomes for toddlers with behavior problems from

families in poverty. *Child and Adolescent Mental Health, 14,* 183-189.

doi.org/10.1111/j.1475-3588.2009.00527.x

Fox, R.A., Keller, K.M., Grede, P. L., & Bartosz, A. M. (2007). A mental health clinic for

toddlers with developmental delays and behavior problems. *Research in Developmental*

Disabilities, 28, 119-129. doi:10.1016/j.ridd.2006.02.001

Fox, R. A., & Nicholson, B. C. (2003). *Parenting young children: A facilitator's guide.*

Longmont, CO: Sopris West.

Frederick, C. (1985). Children traumatized by catastrophic situations. In S. Eth & R. S. Pynoos

(Eds.), *Posttraumatic stress disorder in children* (pp. 73-99). Washington, DC: American

Psychiatric Press.

Fung, M.P., & Fox, R.A. (2014). The culturally-adapted early pathways program for young

Latino children in poverty: A randomized controlled trial. *Journal of Latina/o

Psychology, 2*, 131-145. doi-10.1037/lat0000019

Fung, M., P., Fox, R. A., & Harris, S. E. (2014). Treatment outcomes for at-risk young children

with behavior problems: Toward a new definition of success. *Journal of Social Service

Research*, *40,* 623-641. http://dx.doi.org/10.1080/01488376.2014.915283

Garner, A.S., Shonkoff, J. P., Siegel, B.S., Dobbins, M. I., Earls, M. F., Garner, A. S.,… &

Wood, D. L. (2012). Early childhood adversity, toxic stress, and the role of the

pediatrician: Translating developmental science into lifelong health. *Pediatrics, 129,*

e224-e231. doi.org/ 10.1542/peds.2011-2662

Ghosh-Ippen, C., Ford, J., Racusin, R., Acker, M., Bousquet, K., Rogers, C., … & Edwards, J

(2002). *Traumatic Events Screening Inventory: Parent report revised.* San Francisco: The

Child Trauma Research Project of the Early Trauma Network and The National Center

for PTSD Dartmouth Child Trauma Research Group.

Gupta, S. K. (2011). Intention-to-treat concept: A review. *Perspectives in Clinical Research*, *2,*

109-112. doi:10.4103/2229-3485.83221

Gray, M. & Slagle, D. (2006). Selecting a potentially traumatic event screening measure:

Practical and psychometric considerations. *Journal of Trauma Practice, 5,* 1-19.

doi.org/10.1300/J189v05n02-01

Gresl, B., L., Fox, R. A., & Besasie, L. A. (2016) Development of a barriers scale to predict early

treatment success for young children in poverty with behavior problems. *Clinical*

Practice in Pediatric Psychology, 4, 249-262. doi.org/10.1037/cpp0000124

Harris, S. E., Fox, R. A., & Holtz, C. A. (2016). Screening for significant behavior problems in

young children living in poverty. *Journal of Child and Family Studies, 25,* 1076-1085.

doi:10.1007/s10826-015-0300-x

Harris, S. E., Fox, R.A., & Love, J.R. (2015). Early Pathways therapy for young children in

poverty: A randomized controlled trial. *Counseling Outcome Research and Evaluation,*

6, 3-17. doi: 10.1177/2150137815573628

Herman-Smith, R. (2013). Intimate partner violence exposure in early childhood: An

ecobiodevelopmental perspective. *Health and Social Work, 38,* 232-

239. doi.org/10.1093/hsw/hlt018

Holtz, C. A., & Fox, R. A. (2012). Behavior problems in young children from low-income

families: The development of a new screening tool. *Infant Mental Health Journal, 33*,

82-94. doi:10.1002/imhj.20341

Jensen, T. K., Holt, T., Ormhaug, S. M., Egeland, K., Granly, L., Hoaas, L.C., … & Wentzel-

Larsen, R. (2014). A randomized effectiveness study comparing trauma-focused

cognitive behavioral therapy with therapy as usual for youth. *Journal of Clinical Child &*

Adolescent Psychology, 43, 1–14. doi.org/10.1080/153744162013.822307

Kazdin, A. E., & Mazurick, J. L. (1994). Dropping out of child psychotherapy: Distinguishing

early and late dropouts over the course of treatment. *Journal of Consulting and Clinical*

Psychology, 62, 1069-1074. doi.org/10.1037/0022-006X.62.5.1069

Lang, J. M., Ford, J. D., & Fitzgerald, M. M. (2010). An algorithm for determining use of

    trauma-focused cognitive behavioral therapy. *Psychotherapy: Theory, Research,*

    Practice, and Training, 47, 554– 569. doi.org/10.1037/a0021184

Lieberman, A. F., Chu, A., Van Horn, P., & Harris, W. W. (2011). Trauma in early childhood:

    Empirical evidence and clinical implications. *Development and Psychopathology, 23,*

    397-410. doi.org/1017.s0954579411000137

Lieberman, A.F., & Van Horn, P. (2008). *Psychotherapy with infants and young children:*

    Repairing the effects of stress and trauma on early attachment. New York: The Guilford

    Press.

Meiser-Stedman, R., Smith, P. Glucksman, E., Yule, W., & Dagleish, T. (2008). The

    posttraumatic stress disorder in preschool- and elementary school-age children exposed to

    motor vehicle accidents. *American Journal of Psychiatry, 165,* 1326-1337.

    doi.org/10.1176/appi.ajp.2008.07081282

National Child Traumatic Stress Network (2012a, April). ABC: Attachment and Biobehavioral

    Catch-up. Trauma-informed interventions. Retrieved from www.NCTSN.org

Rowan, K., McAlpine, D. D, & Blewett, L. A. (2013). Access and cost barriers to mental health

    care by insurance status, 1999–2010. *Health Affairs, 32,* 1723-1730.

    doi.org/10.1377/hlthaff.2013.0133

Santiago, C., Kaltman, S., & Miranda, J. (2013). Poverty and mental health: How do low-income

    adults and children fare in psychotherapy? *Journal of Clinical Psychology, 69,* 115-126.

    doi.org/10. 1002/jclp.21951

Saylor, C.F, Swenson, C. C., Reynolds, S.S., & Taylor, M. (1999). The Pediatric Emotional

     Distress Scale: A brief screening measure for young children exposed to traumatic

     events. *Journal of Clinical Child Psychology, 28*, 70-81.

     doi.org/10.1027/S15374424jccp2901-6

Sheeringa, M. S. (2011). PTSD in children younger than the age of 13: Toward developmentally

     sensitive assessment and management. *Journal of Child & Adolescent Trauma, 3,* 181-

     197. doi.org/10.1080./19351521.2011.597079

Sheeringa, M. S., Weems, C. F., Cohen, J. A., Amaya-Jackson, L., & Guthrie, D. (2011).

     Trauma-focused cognitive-behavioral therapy for posttraumatic stress disorder in three-

     through six-year-old children: A randomized clinical trial. *Journal of Child Psychology*

     and Psychiatry 52, 853–860. doi.org/10.1111.ji1469-7610.2010.02354.x

Shonkoff, J. P., Garner, A. S., & The Committee on Psychosocial Aspects of Child and Family

     Health, Committee on Early Childhood, Adoption, and Dependent Care, and Section on

     Developmental and Behavioral Pediatrics. (2012). The lifelong effects of early childhood

     adversity and toxic stress. *Pediatrics, 129,* 232–246. Retrieved from http://aappolicy.aap-

     publications.org/cgi/content/full/pediatrics;129/1/ e232

Stiles, W. B., Honos-Webb, L., & Surko, M. (1998). Responsiveness in psychotherapy. *Clinical*

     Psychology: Science and Practice, 5, 439-458. doi.org/10.1111/j.1468-

     2850.1998.tb00166.x

Thompson, R. A. (2014). Stress and child development. *The Future of Children, 24,* 41-59.

U.S. Department of Health & Human Services, Administration for Children and Families,

     Administration on Children, Youth and Families, Children's Bureau. (2016). *Childhood*

maltreatment 2014. Retrieved from http://www.acf.hhs.gov/programs/cb/research-data

technology/statistics-research/child-maltreatment.

Viera, A.J., & Garret, J. M. (2005). Understanding inter-observer agreement: The Kappa

statistic. *Research Series, 37,* 360-363.

Figure 1 Participant flowchart from random group assignment through short-term follow-up evaluations.
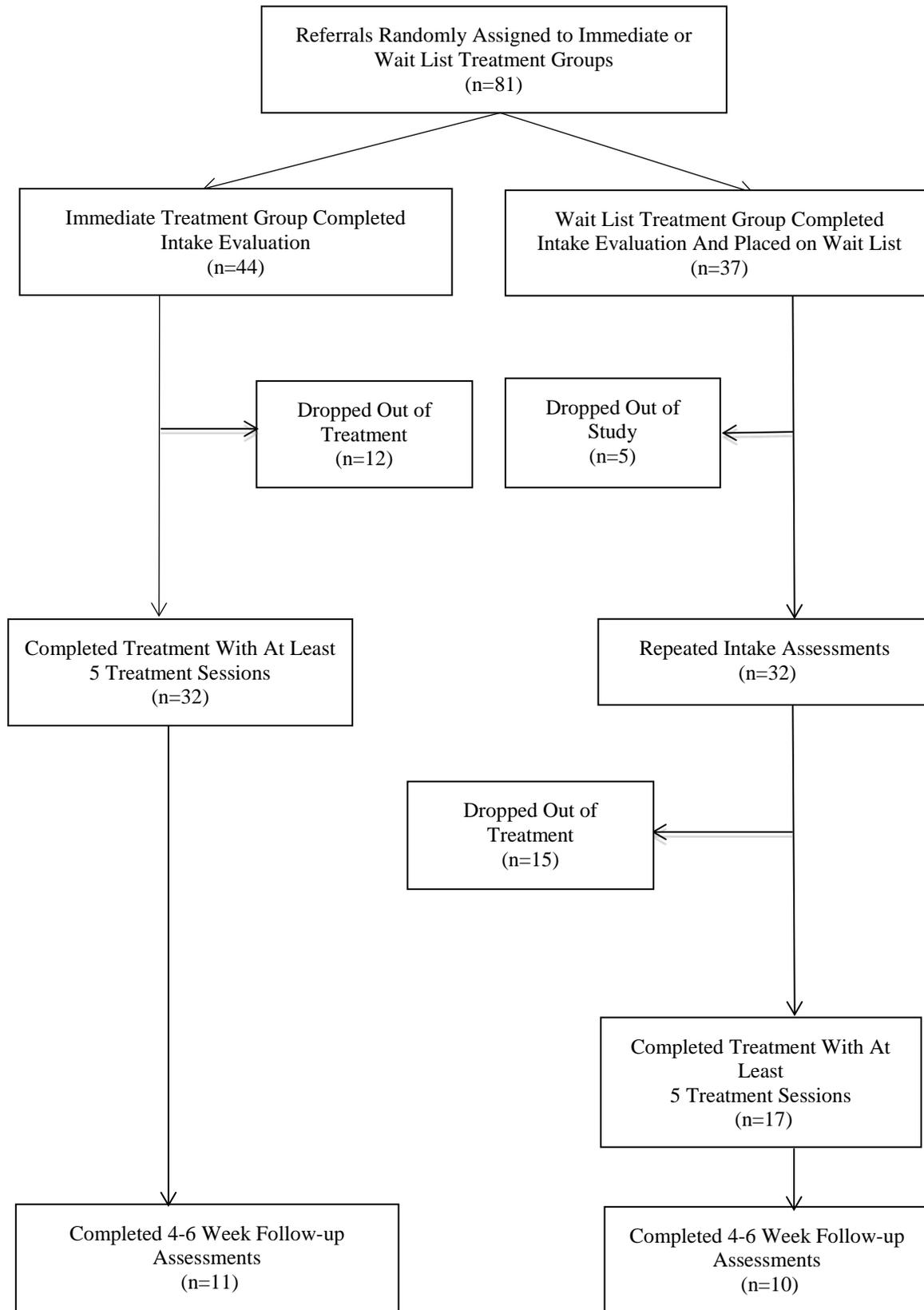
Table 1

Between Group Comparisons of Demographic Variables for Immediate Treatment and Wait List Groups

Variable	Immediate (n = 32)			Wait List (n = 32)		
	%	X	SD	%	X	SD
Child Age (months)		40.91	14.31		37.31	12.20
Child Gender						
Males	78.1			59.4		
Females	21.9			40.6		
Has developmental delay	18.8			21.9		
Child Race						
African American	31.3			53.1		
Multiracial	34.4			21.9		
Latina/o	21.9			15.6		
European American	12.5			9.4		
Caregiver						
Biological mother	53.1			62.5		
Both parents	25.0			12.5		
Foster/kinship	15.6			15.7		
Other relative	6.3			9.4		
Caregiver age		32.16	10.25		30.91	10.95
Caregiver married	15.6			15.6		
Caregiver employed	50.0			46.9		
Mother finished 12th grade	84.0			84.6		
Father finished 12th grade	76.5			58.8		
Children in home		2.63	1.41		2.56	1.08
Number of traumatic events		5.06*	2.72		3.78	1.84

*Note: *p<.05*

Table 2

Analyses of Covariance for Dependent Measures for Immediate Treatment (IT) and Wait List (WL) Groups at Pretest and Posttest/Pretest 2

	Time 1				Time 2				
	IT Pretest		WL Pretest		IT Posttest		WL Pretest 2		
Measures	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	*d*
ECBS-CBS	23.03	4.25	22.81	4.24	17.70***	4.49	22.17	4.73	.97
PEDS-AW	11.44	3.47	11.81	4.06	8.52***	2.06	11.10	2.80	1.05
PEDS-F	12.13	3.29	11.97	3.43	8.69**	3.33	10.65	3.32	.59
PCRS	60.47*	14.67	52.03	13.13	64.77**	18.38	56.44	3.96	.52
TR	n/a		n/a		9.81***	1.99	6.47	1.66	1.82

*Note. *p<.05, ** p<.01, ***p<.001.* Adjusted Time 2 scores based on analyses of covariance (ANCOVA). The notation *d* refers to Cohen's *d* effect size of ANCOVA comparisons at Time 2 with pretest scores as covariates, based on adjusted mean scores. For TR, the notation *d* refers to Cohen's *d* effect size of ANOVA comparison at Time 2.

Table 3

Repeated Measures ANOVAs with Pairwise Comparisons for Both Groups Combined at Pretest, Posttest, and Follow-up

Measures	Pretest		Posttest		Follow-up		
	M	*SD*	*M*	*SD*	*M*	*SD*	*d*
ECBS-CBS	21.62	4.96	16.48**	5.02	17.24**	6.63	.75
PEDS-AW	10.86	2.65	8.19**	2.46	8.38***	2.38	.99
PEDS-F	9.71	3.00	7.24**	2.34	7.48*	2.54	.80
PCRS	60.00	16.53	72.81***	13.54	74.38***	14.13	.97
TR	6.53	1.66	10.53***	1.81	10.35***	2.23	1.94

*Note: *p<.05, ** p<.01, ***p<.001*. The notation *d* refers to overall effect size from pretest to follow-up.