

## **I. Introduction**

### **A. Nature of the research problem**

Studies consistently report high levels of psychological distress, including depressive symptoms, parenting stress, and social isolation, among parents of children with ASDs. Mothers are the most severely affected family member [1-4] and those whose children have more significant impairments have higher levels of distress [2, 5, 6]. Almost 40% report levels of clinically significant parenting stress [2] and between 33% - 59% of mothers report depressive symptoms warranting psychiatric evaluation [3, 5-7]. These data suggest a need for interventions that specifically address parental mental health. However, current intervention approaches for young children with ASDs focus on training parents in behavior management techniques and methods to facilitate joint attention [8-11] and do not routinely address parental functioning in a systematic way. As such, they have not significantly impacted maternal parenting stress and depressive symptoms. The decreased energy, concentration, and lack of motivation associated with depressive symptoms may exert their influence on maternal functioning and affect a mother's capacity to manage the health needs of her child. Among typically developing children, maternal depressive symptoms are associated with decreased adherence to child medication regimens and inappropriate use of routine health services [12-15]. Recommended interventions for young children with ASDs, which have shown the most success, are highly demanding, time-intensive, and actively involve mothers as "adjunct therapists" and advocates in the child's treatment plan [16, 17]. Decreased maternal health management capacities may affect the child's participation in recommended services and have significant consequences for the child's developmental trajectory.

Maternal depressive symptoms represent a modifiable risk factor that may mediate a range of behaviors important to family well-being and to a child's health and development. Preventive interventions targeted to mothers of children with ASDs, who have increased risk of clinically significant depressive symptoms and parenting stress, therefore, represent an opportunity to intervene to support the mother and the child, and overall well-being of the family unit.

### **B. Purpose, scope, and methods of the investigation**

The objective of this project was to determine whether an evidenced-based empowerment strategy, Problem Solving Education (PSE), targeted to mothers of young children with autistic spectrum disorders (ASDs), promotes family well-being by decreasing the burden of maternal depressive symptoms and parenting stress and improving maternal social functioning. We conducted a randomized control trial involving 120 English or Spanish speaking mothers who have children <6 years with confirmed ASDs. Mothers in the intervention group received 6 sessions of PSE. Control group subjects received usual care. Our intervention augmented recommended behavioral and developmental services, focusing specifically on strengthening maternal problem solving abilities as a strategy to prevent and attenuate depressive symptoms and parenting stress.

### **C. Nature of the findings**

Findings described in this report are preliminary. We have ended recruitment and all participants have completed the 3 month assessment. Analyses of intervention effect are ongoing. Findings related to intervention delivery and fidelity demonstrate the feasibility and acceptability of the intervention.

## **II. Review of the Literature**

Comprehensive programs for young children with ASDs involve parents in service delivery. Thus, maternal depressive symptoms, which can impair the functioning of the affected individual [18], have the potential to impact outcomes among children with ASD. For example, research suggests that high levels of parenting stress may counteract the effectiveness of early teaching interventions for young children with ASDs [19]. Studies designed to improve self-efficacy and problem solving skills have demonstrated that individuals with depressive symptoms who receive such interventions are more likely to experience gains in their self-management skills than those who are not depressed and even modest improvements in depressive symptoms are associated with health promoting behaviors [20]. These findings speak to the potential benefit of problem solving interventions, such as the one tested in this study, in improving both maternal psychological functioning and child behavioral outcomes.

A review of existing research supports the need for additional, adequately powered RCTs that examine the effects of interventions designed specifically to address depressive symptoms, parental stress, and social functioning among mothers of children with ASDs. A 2007 systematic review of studies involving young children with ASDs and their families conducted by McConachie and Diggle [8] included 7 randomized-control and 5 control group studies of children ages 1 year – 7 years diagnosed with an ASD, in which the intervention had a significant parent focus. All RCTs in the review included a measure of parenting stress. Parents reported high levels of parenting stress but the interventions evaluated did not significantly decrease parental stress levels. Only one study, which used non-randomized control group design, included a measure of depressive symptoms (Community Epidemiological Depression Scale, CESD); in this study, the intervention group showed a significant decrease in depressive symptoms. This systematic review identifies a significant gap in the literature: none of the interventions focused specifically on parental mental health. In addition, the sample size in all studies was small (range 7-17 per group) and likely did not have adequate power to detect significant group differences. A recent RCT that had larger sample size (N=35 per treatment group) and a clear focus on parental mental health had more encouraging results [9]. This study investigated the effect of a manual-based parent education and behavior management skills curriculum on parental mental health, stress, and family functioning. The curriculum included explicit content on mental health problems, parental stress, and grief. While main effect of treatment group was not significant for any outcomes, subjects with mental health concerns at baseline demonstrated significant benefits from the intervention. Of interest, the magnitude of the improvements increased over time, suggesting the potential of cognitive-behavioral, parent empowerment interventions, such as the one tested in our study, to promote resilience among at-risk families.

## **III. Study Design and Methods**

### **A. Study design**

We conducted a parallel group trial with 1:1 randomization comparing PSE to usual care. Mothers were randomly allocated to intervention (PSE) or control group after completion of baseline measures.

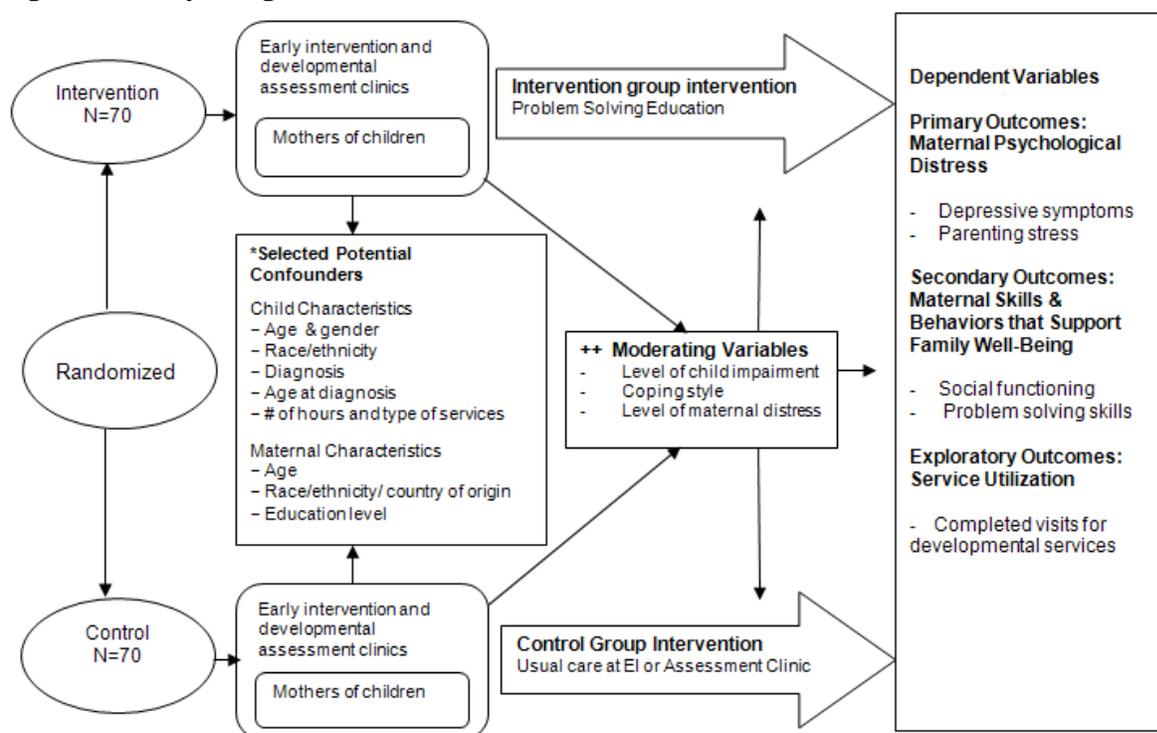
## B. Population studied

Participants were recruited from an autism specialty clinic that serves ethnically diverse, primarily low-income, urban families and 6 Birth to Three early intervention (EI) programs, with which our research team has established a community based research network.

## C. Sample selection

The sample was selected using principles of random assignment. Randomization occurred independently at each study site (6 EI programs and autism specialty clinic). Mothers were stratified based on baseline depressive symptoms. Within strata, randomization was conducted by using random permuted blocks of 4. The allocation sequence was concealed from all study personnel in sequentially numbered, opaque, sealed envelopes, stored in a central location

Figure 1. Study Design



## D. Intervention

The intervention group received PSE. PSE is a manualized cognitive behavioral intervention, adapted from Problem Solving Treatment, itself an evidence-based depression treatment [21]. Our research team adapted Problem Solving Treatment for use as a depression prevention intervention for mothers of young children. The adapted intervention was designed such that it could be taught to, and delivered by, the range of existing multidisciplinary staff who work with families of young children with ASD – e.g. EI providers and early childhood educators. Details of the adaptation process have been described previously [22, 23]. In a PSE session, educators guide subjects in selecting an objective, measurable problem; then proceed through a series of steps that involve goal setting, brainstorming and evaluating solutions, choosing a solution, and action planning. In our study, a full PSE course involves 6 individual sessions (30 to 45

minutes). It is delivered in the home or other location of the mother's choosing as an adjunct to usual care, specifically as part of routine EI home visits or as a supplement to school-based services.

Ten EI staff representing the range of disciplines within EI programs (child development, nursing, speech and language, and social work) served as problem solving educators for mothers recruited from EI programs; 4 graduate students, pursuing degrees in social work and public health, served as educators for mothers who are identified from the autism specialty clinic. Educator training entailed one day of didactics, followed by three to five practice sessions conducted under the supervision of investigators (EF, LE). All training sessions were audiotaped, and each educator received individualized feedback until she met pre-defined criteria for protocol adherence. Educators met in biweekly group sessions at each site for reflective supervision with investigators (EF). Control group mothers receive usual services specified in the child's Individualized Family Service Plan (IFSP) or Individualized Educational Plan (IEP) as treatment for their child.

## **E. Instruments used**

### *Baseline characteristics.*

We assessed maternal and child characteristics at study entry. Maternal characteristics included mothers' age, work and education status, number of children, country of origin, self-described race and ethnicity, and family income. Relative to maternal depression risk and history, mothers were asked about family history of depression, whether they have ever been diagnosed with depression, and whether they are currently receiving psychiatric treatment. Child characteristics included child's age, gender, and age of diagnosis. We collected detailed information about current and past service use: child's age of entry into EI, length of time receiving EI services, and type and intensity of current services (number of hours/week), which are abstracted from the child's IFSP or IEP.

### *Depressive symptom measurement: Quick Inventory of Depressive Symptoms*

We assessed depression symptoms using the Quick Inventory of Depressive Symptoms (QIDS). Because the QIDS has a wide scoring range, it can be used to detect depressive illness in populations with moderate and low-level symptoms, and is sensitive to change over time. It has excellent correlation to the Hamilton Rating Scale (0.94) and the Beck Inventory (0.92) [24, 25], has been validated with community samples and demonstrated reliability in culturally diverse postpartum populations [26] and those with minor depression [27]. We have used the QIDS with over 200 women in our pilot studies and have found it easy to administer and acceptable to our target population.

### *Parental stress: Parenting Stress Index Short Form*

The Parenting Stress Index Short Form (PSI) was selected because of the substantial body of published research linking PSI scores to observed parent and child behaviors, specifically attachment style, social skills, and confidence. The PSI has 3 subscales: Parental Distress, Difficult Child, and Parent-Child Dysfunctional Interaction, and is one of the only valid and reliable instruments that can assess a wide range of parenting behaviors in a single instrument [28]. It has excellent psychometric properties and has been used with diverse populations, including families of children with ASD [29-31].

*Severity of child delay: Adaptive Behavior Assessment System*

Because prior research suggests a positive relationship between severity of a child's impairment and parental psychological distress[2, 5, 6], we used the Parent/Primary Caregiver Form Communication Scale of the ABAS II to assess child functioning. The ABAS II is one of the few self-report measures validated for very young children. The Communication Scale can be completed within 5 minutes and is used successfully among the diverse, low literacy population seen at the autism specialty clinic recruitment site.

*Social Competence/Adjustment: Social Adjustment Scale Self-Report (SAS-SR)*

To examine the impact of the intervention on social functioning, we used the SAS-SR [32], which examines social functioning and instrumental role functioning (performance on expected tasks) or expressive roles (interpersonal relations or satisfactions) in six major areas: work; social and leisure activities; relationships with extended family; role as a spouse or partner; role as a parent; and role as a member of the family unit

*Problem Solving Skills: Social Problem Solving Inventory- Revised (SPSI-R)*

The SPSI-R is a 25 item self-report measure that assesses problem orientation and problem-solving skills. The instrument measures 5 dimensions of problem solving. SPSI-R was validated with a diverse community sample and norms exist for adolescents, young adults, middle-aged adults, and elders. It has been shown to be sensitive to change among mothers of children newly diagnosed with cancer who were taught problem solving skills[33, 34] and is highly correlated with mood among family caregivers of children and adults with disabilities[33, 35, 36].

*Social Support: Medical Outcomes Survey Social Support (MOS-SS)*

This tool comprises 4 functional support scales (emotional/informational, tangible, affectionate, and positive interaction) and an overall social support index. Subscales are reliable (alphas > 0.91) [37].

*Coping Style: Brief Coping Orientation to Problems (Brief COPE)*

The Brief Cope is a 28 item scale that measures 14 different adaptive and problematic coping reactions. Subscale Cronbach alpha scores range from .50-.90[38]. The Brief COPE was included as a measure based on research findings that coping style may moderate PSE's effect on depressive symptoms[39].

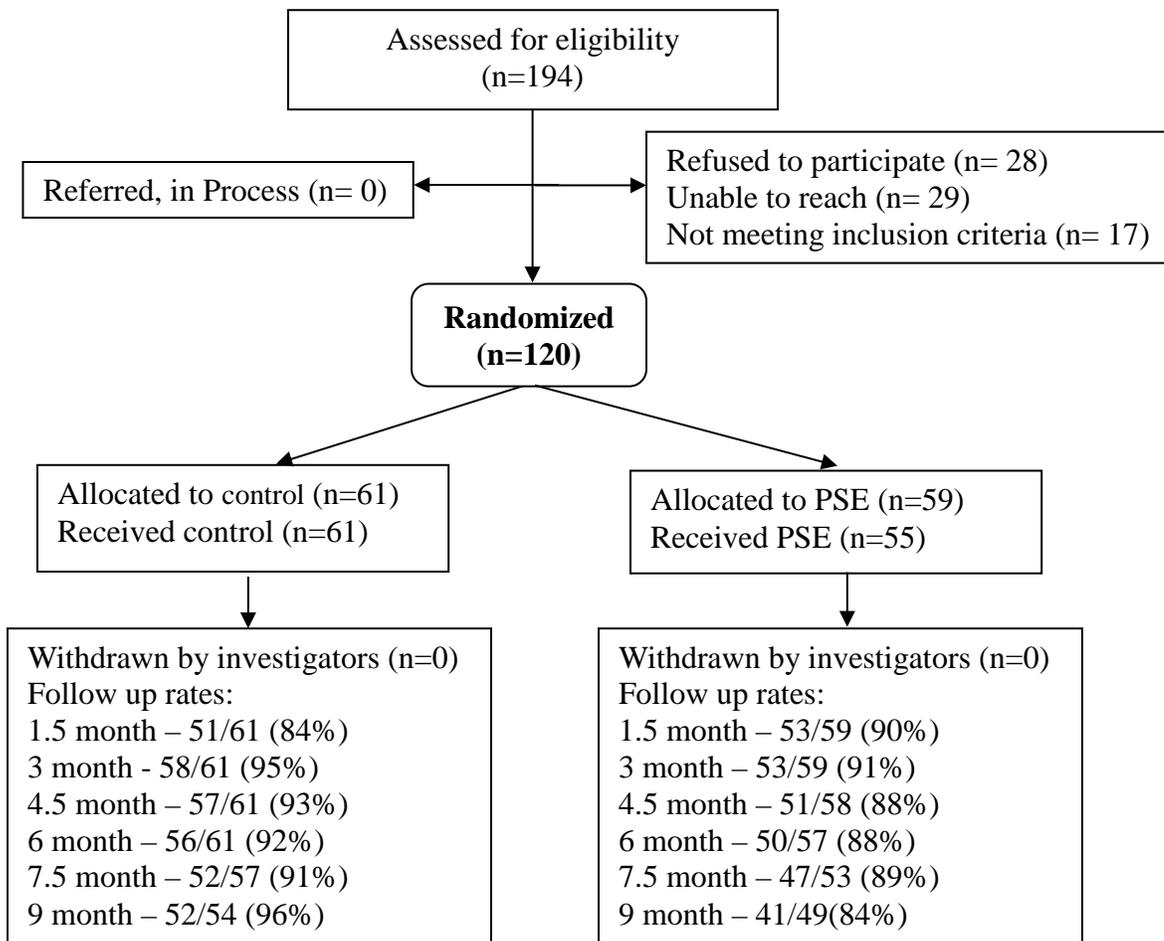
## **F. Statistical techniques employed**

We have assessed outcomes by intention-to-treat analysis. We analyze follow-up QIDS depression scores relative to a pre-specified clinical threshold ( $\geq 11$ ), corresponding to moderately severe symptomatology occurring during a one-week recall period. Previous work among urban postpartum women indicates that this threshold has greater than 88% specificity for predicting a major depressive episode [26]. The 9 month follow-up period was chosen based on evidence that the effect of preventive interventions may not be fully realized during the immediate post intervention period and may accrue additional benefits over time [40]. We compared the proportion of mothers in each group who experienced an episode of moderately severe depression symptoms at the 3 month assessment using chi squared tests and the mean number of such episodes during the 3 month follow-up period by calculating rate ratios using Poisson regression.

Future analyses will examine the main effect of the intervention on parenting and perceived stress, maternal social functioning and problem solving skills. We will examine intervention mediators through structural equation models and trajectories of change over time using latent growth curve models. We also plan to assess effect modification by maternal mental health history, race/ethnicity, and severity of child disability in relevant models.

#### IV. Detailed Findings (to be updated when analyses complete)

**Figure 2. Participant Flow Chart**



Study findings are preliminary and must be viewed cautiously. Future full sample analyses will be submitted as an addendum when the trial and all analyses are completed. However, despite the limited scope of the current analysis, our preliminary findings are encouraging. We have used a rigorous study design and recruited a relatively large sample, which will allow us to assess the efficacy of PSE to improve parental mental health.

The current outcomes show that one hundred and ninety four mothers were referred to the study and screened for eligibility. Twenty-eight refused participation, primarily due to time demands; we were not able to reach 29; and 17 did not meet inclusion criteria; 120 were enrolled. The 120 mothers (n= 59 intervention; n= 61 control) were largely low income (62% < 200% of the federal poverty limit) and minority (60%) with 41% born outside of the United States. Thirty-

four percent reported they had been diagnosed with depression in their lifetime and 58% reported experiencing a significant trauma. The baseline depressive symptom score (QIDS) was 7.0, consistent with mild symptoms [41]; 15% had moderate or severe symptoms (QIDS score  $\geq 11$ ). The mean level of parenting stress (PSI) was 93, a score consistent with the scores of other groups of mothers of young children with ASD [30] and above 90<sup>th</sup> percentile, the cut off used as an indicator that counseling or other supports are required [28, 31].

Children were 82% male, consistent with the skewed gender distribution of ASD [42]. The mean age at time of study enrollment was 35 months and mean age at time of autism diagnosis was 29 months. The average ABAS Communication Scale Score was 3.8 (scaled score mean=10, SD 3), which is consistent with scores of other samples of children with ASDs [43]. On average children were receiving 25 hours of services/month at baseline. All covariates were balanced between treatment groups with the exception of maternal age and number of children, for which differences were not clinically relevant, despite being statistically significant.

Table 1. Maternal demographic characteristics

<b>Mother Characteristics</b>	PSE	Control
	N=59	N=61
Mean age, years*	32	35
Mean number of children*	1.93	2.31
Race/ethnicity (%)		
Black	14	33
Latino	36	28
Asian/Other	8	8
White	42	31
Born outside US (%)	34	48
Did not graduate high school (%)	15	10
Medicaid insurance (%)	66	59
Work outside of the home (%)	31	39

\*p<.05

Table 2. Maternal mental health characteristics

<b>Maternal Mental Health</b>	PSE	Control
	N=59	N=61
Depressive symptoms	%	%
No symptoms (QIDS < 6 at baseline)	41	37
Mild symptoms (QIDS > 6 < 11 at baseline)	44	35
Clinically significant symptoms (QIDS >11 at baseline)	15	28
Diagnosed with depression – lifetime	36	33
Family hx of depression	41	37
Receiving psychiatric treatment	19	16
Experienced a significant trauma	41	43
Parenting stress - mean (SD)	92.5(20.1)	97.56(24.5)

Table 3. Child demographic characteristics

<b>Child Characteristics</b>	<b>PSE</b>	<b>Control</b>
	N=59	N=61
Male gender (%)		82
Age at time of autism diagnosis (months)	29.13	28.07
ABAS Score	3.52	4.14
Mean age at study entry (months)	35	35
Time between dx and study entry (months)	5.79	5.88
Recruitment site (%)		
EI programs	68	59
Diagnostic clinic	30	34
Self-referral	2	7
Ever received EI services (%)	93	98
Mean length of time in EI (months)	14.28	11.09

### **Intervention delivery, satisfaction and follow-up**

Fifty-five of 59 intervention subjects received the study’s intervention, PSE. On average, mothers received PSE within 5 months of their child’s diagnosis. Treatment adherence was high: 78% received the full 6 session course over an average of 2 months, the mean number of sessions was 5, and all but 4 subjects received at least one session. Intervention delivery did not differ by site or by key maternal or child characteristics, including maternal age, race, or baseline depressive symptoms and child age, age at diagnosis or severity of delay. Of the 34/330 randomly selected PSE sessions that were audiotaped and assessed for fidelity, all were judged to be meet fidelity standards, based on a score of >90% on standardized form that assessed whether the all 7 components of the intervention were present and delivered according to protocol.

Intervention satisfaction was rated on a scale of 1(strongly disagree) to 5(strongly agree). Of the 44 mothers who completed satisfaction questionnaires, they rated “Doing PSE with my EI provider was helpful to me,” and “I will use the problem solving skills learned during PSE in the future,” 4.2 out of 5. All mothers said they would agree to learning PSE again. Mothers reported that they were using the skills they learned from PSE to address problems encountered in their daily life on average weekly. Over the 9 month follow-up period, 90% of planned assessments were completed.

### **Intervention effects**

Relative to depressive symptoms, using the accepted QIDS threshold of  $\geq 11$ , PSE mothers had fewer episodes of clinically significant depressive symptoms over 9 months of follow-up (0.09 intervention vs. 0.7 control) compared to mothers whose children received usual care. Adjusting for baseline depressive symptoms, child severity, and accounting for clustering by recruitment site, the rate ratio of clinically significant episodes was 0.47 (95% CI 0.26, 0.83;  $p=.01$ ). Additional analysis of intervention effects is ongoing.

## **V. Discussion and Interpretation of Findings**

### **A. Conclusions to be drawn from findings (with reference to data supporting each).**

To our knowledge, our study is the first to test the efficacy of a parent-focused intervention whose primary goal is to improve the mental health of mothers of young children with autism. Our intervention, which was adapted from an evidence-based depression treatment, differs from existing interventions, which have been evaluated in this population. Such studies have focused on parent education regarding ASD and behavior therapy. They have included measures of parental mental health, most commonly parenting stress, as outcomes and have equivocal results [8, 9, 44]. Current evidence of successful intervention delivery, parental satisfaction, and positive intervention effects support our ongoing efforts to more definitively test the efficacy of this brief, easily replicated intervention.

### **B. Explanation of study limitations**

This study has several limitations.

We do not examine the effects of maternal mental health on child outcomes. Instead, we have focused on assessing the feasibility and efficacy of an intervention whose primary goal is to reduce maternal psychological distress – specifically, depressive symptoms and parental stress, which are highly prevalent among mothers of children with ASD and known to be associated with poor child outcomes. Our theoretical model posits that improvements in maternal mental health will lead to improvements in child outcomes, mediated through greater responsiveness to child developmental needs and greater capacity to fully engage in recommended services. We believe that it is necessary to determine the intervention's main effect relative to maternal outcomes prior to testing its impact on child outcomes. This study is the first step of a longer term research trajectory.

All outcome measures with the exception of service utilization are self-report measures and, as such, subject to social desirability and interviewer bias.

The sample size, although adequate for the purposes of study aims, may not allow us to fully explore effect modification in our analyses. We have identified 4 potential moderating variables based on literature review. We will be able to explore the impact of each individually on treatment effect, but not cumulatively.

The majority of children included in the study were diagnosed with ASD using the Autism Diagnostic Observation Schedule. However, children were not excluded if they were diagnosed using an alternative approach.

The measure used to assess severity of child impairment, the ABAS, is not autism-specific and as a self-report measure, could be influenced by a mother's depressive symptoms. The ADOS severity score, which would have been a reasonable and potentially more objective measure of baseline child severity, was not routinely completed by medical providers who conducted the ADOS for diagnostic purposes. Other self-report parent measures of ASD symptom severity, such as the Social Responsiveness Scale, are not appropriate for very young children who represent the majority of study participants.

**C. Comparison with findings of other studies – To be completed when analyses complete.**

**D. Possible application of findings to actual MCH health care delivery situations**

Our findings have several potential applications to two MCH health care delivery situations – Part C early intervention programs and Developmental and Behavioral Pediatric Clinics that evaluate children for autism. Our experience suggests that offering PSE routinely to families of children recently diagnosed with autism is feasible and well accepted by families served by these settings. In addition, our findings suggest that it is feasible to train existing staff to provide PSE and that training can be done efficiently.

**E. Policy implications**

The 1986 reauthorization of IDEA emphasized the need to provide family support, in addition to developmental services, to children with disabilities, naming parents and other family members as direct beneficiaries of EI services. However, parent responses from the National Early Intervention Study (NEILS), which began in 1996 and followed over 3,000 children until kindergarten entry, suggest a need to improve opportunities for family support. Overall, parents rated the value of EI services highly, but family support services were consistently rated lower than child-focused services [45]. Integrating the proposed intervention in EI could expand the range of family support options for mothers with depression risk and help achieve program goals.

**F. Suggestions for further research**

Our research team has identified several next steps for further research.

*Qualitative study of views of low-income and ethnically diverse parents regarding participation in autism intervention research.* We have 33 interviews of which 27 have been transcribed and coded. We are in the process of completing transcription and coding of the remaining interviews and then will work on manuscript preparation.

*Systematic review investigating the reporting of characteristics of families of young children participating in autism intervention research.* We have completed this review and are in the process of finalizing data analysis and drafting a manuscript.

*Multi-site replication trial.* Assuming the promising results of the intervention's effect on reduction of episodes of clinically significant maternal depressive symptoms are maintained in the full sample, we hope to secure funding for a multi-site replication trial that would include more rigorous measurement of child phenotype at baseline and child service utilization and outcomes at follow-up.

*Comparative effectiveness study.* Our research group is currently conducting several studies to assess the efficacy of patient navigation to improve timely autism diagnosis and intensity, and quality of autism services among underserved families. If results from these studies demonstrate a positive effect, we would like to study the comparative effectiveness of 6 months of patient navigation versus 3 months of an intervention that combines patient navigation and problem solving education.

## **VI. List of products**

### **A. Peer Reviewed Articles**

#### **In progress**

Feinberg E, Augustyn M, Fitzgerald E, Sandler J, Egbert L, Ferreira-Cesar Z, Cabral C, Beardslee W, Silverstein M. *Supporting the mental health of mothers of young children with autism spectrum disorder: Results from a randomized controlled trial.*

Feinberg E, Silva C, Berardi M. *Characteristics of families of young children participating autism intervention research: A comprehensive review.*

Feinberg E, Casner L, Egbert L. *Views of low-income and ethnically diverse mothers regarding participation in autism intervention research.*

#### **Planned**

Feinberg E, Augustyn M, Fitzgerald E, Sandler J, Ferreira-Cesar Z, Cabral C, Beardslee W, Silverstein M. *Mediators of a depression prevention intervention among mothers of children recently diagnosed with autism spectrum disorder.*

### **B. Conference Presentations**

Pediatric Academic Society, Washington DC, May 2013. *Supporting the Mental Health of Mothers of Young Children with Autism Spectrum Disorder: Preliminary Results from a Randomized Controlled Trial.* Submitted.

Boston University School of Public Health Maternal and Child Health Forum, November, 2012. *Characteristics of Families of Young Children Participating Autism Intervention Research: A Comprehensive Review.*

Boston University School of Public Health Research Day, November, 2012. *Supporting the Mental Health of Mothers of Young Children with Autism Spectrum Disorder: Preliminary Results from a Randomized Controlled Trial.* Poster Presentation.

Massachusetts Early Intervention Consortium, Westborough MA, May 2012. *Building Early Intervention Capacity to Support Maternal Mental Health.*

Maternal and Child Health Bureau Expert Workshop on Autism and the Underserved, Washington DC, April 2012. *Engaging Underserved Families in Autism Research: Experience from Supporting the Well-Being of Mothers of Young Children with Autism Spectrum Disorders.*

Boston University School of Public Health Maternal and Child Health Forum, April 2012. *Racial and Ethnic Differences among Mothers of Young Children with Autism Spectrum Disorders.*

Meeting Street Early Intervention Program, Providence RI, April 2012. *Project Solve Update- Addressing Maternal Depressive Symptoms among Mothers of Young Children with Developmental Concerns.*

Massachusetts Postpartum Depression Commission, Boston MA, March 2012. *Implementing Maternal Depression Screening in Pediatric Settings.*

Clinical Research Training Program Seminar, Boston MA, February 2012. *Community Engagement in Research.*

Anne Sullivan Early Intervention Program. Lowell, MA, January, 2012. *Project Solve Update- Addressing Maternal Depressive Symptoms among Mothers of Young Children with Developmental Concerns.*

Bay Cove Early Intervention Program, Boston, MA, November, 2011. *Project Solve Update- Addressing Maternal Depressive Symptoms among Mothers of Young Children with Developmental Concerns.*

Autism Consortium Symposium, Boston, MA, October, 2011. *Supporting the Mental Health of Mothers of Young Children with Autism Spectrum Disorder: Preliminary Results from a Randomized Controlled Trial.* Poster Presentation.

Thom Child and Family Services, Natick MA, April 2011. *Supporting Families Around Diagnosis of ASD: Using Evidence to Develop Best Practice*

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