

Running head: BABY TALK NEWBORN ENCOUNTER STUDY

The Baby TALK Model Newborn Encounter: A Randomized Controlled Trial on Early  
Intervention Methods with New Mothers in Hospital Obstetric Units

### Abstract

In order to support the proper development and health of very young children, early identification of risk and need is critical followed by resources to ensure children meet their developmental agenda and parents/caregivers remain supported. The research also suggests focus be placed on parental stress as a variable influencing parent engagement in early intervention services. This paper examines the Baby TALK Model's Newborn Encounter Protocol that was used to engage new mothers and their infants in hospital obstetric units and identify risks prior to discharge, thereby identifying needs and risk very early in an infant's life. The authors implemented a randomized controlled trial using a sample of 191 new mothers and their infants identified at delivery and tracked for six months to study the effects of the Newborn Encounter Protocol on parental stress levels, as measured by using the Parenting Stress Index Short Form, Fourth Edition, Short Form (PSI-4-SF). Regression results, defensive rating scores, and implications are discussed in the paper.

*Keywords: Early intervention, Newborn Encounter Protocol, parental stress*

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Experiences in the early years matter (Center for the Developing Child, 2015) and such experiences are inextricably tied to health, mental health, behavioral and social outcomes in adulthood (Anda et al., 2010). While there are well-studied interventions (Oh & Bayer, 2015; Meyer, 2007) and an available workforce to support early development (Fitzerald & Barton, 2000), identification of needs early in a child's life is crucial to supporting development throughout the lifespan. Such efforts to support young at-risk children (i.e., those at risk of developmental delays that would compromise school readiness) began with the early childhood education and other intervention programs of 1965 beginning with Head Start programs. Head Start was developed under President Johnson's "War on Poverty" campaign with the goal of helping disadvantaged children develop the skills needed to be on equal footing with advantaged peers upon entering school (Currie, 2001).

Since then, other early intervention models have been developed alongside randomized evaluation studies to determine whether or not these models – employment diverse support methods such as home visiting, full-day or part-day child care and preschool programs, and center-based programs for parents – are indeed effective and impactful to participants. The Carolina Abecedarian Study (Campbell & Ramey, 1994), the Infant Health and Development Project (McCarton et al., 1997), the High/Scope Perry Preschool Project (Schweinhart, Barnes, & Weikart, 1993) and Early Training Project (Gray, Ramsey, & Klaus, 1983) are all high-profile studies that have been cited in the discussion of the value and impact of early intervention

services in the lives of children at risk of academic failure and other developmental problems (see Barnett, 1995 and Karoly et al., 1998 for further description of studies).

Early intervention models, although distinct in respective methods of intervention, are unified by the same premise of identifying needs of young children birth-to-three years of age, as this is seen as a “critical period” of brain development (Currie, 2001). The identification can happen through pediatricians, early childhood programs, and/or school systems, followed by comprehensive assessments to pinpoint the specific needs (C. Quigg, personal communication, December 2, 2015). After identification, the attention is on providing appropriate services that support development. Intervention services can be delivered in the home or in center-based programs, and the intervention typically focuses on supports to both child and parent (Copple & Bredekamp, 2009; DHHS-ACF, 2005). The process should then lend itself to opportunities for scaffolding development through parent-child engagement, and be designed to address any developmental deficits that could keep a young child from meeting his/her developmental milestones and could undermine school readiness.

According to Hilado, et al. (2012), short- and long-term benefits have been associated with early childhood intervention with the following gains:

- Supports early development and promotes long-term prevention against risk factors that inhibit successful social-emotional, cognitive, and language developmental, and academic outcomes (Kirp, 2007; Olds, Sadler & Kitzman, 2007; Henry, Henderson, Ponder, Gordon, Mashburn, & Rickman, 2003).
- Early intervention is tied to closing the academic gap between children of low-income and high-income families (Copple & Bredekamp, 2009; Kirp, 2007; DHHS-ACF, 2005).

- Long-term socialization benefits that carry through adulthood (Kirp, 2007).
- Reduced risk of educational disability, unemployment, school drop-out, and dependence on welfare assistance (Schweinhart et al., 1993).

A cost-benefit analysis also provides evidence that early interventions are indeed a good investment because they inevitably stave off other costs (e.g., increase in special education classrooms, reduced graduation rates, impacts on the workforce etc.) that could affect the larger community fiscally later in life (DHHS-ACF, 2005; Currie, 2001).

### **The Baby TALK Model: A community-based early intervention method**

The Baby TALK Model is a research-informed early intervention model that is widely used in Illinois and 31 other states as well as Canada. The Baby TALK Model has been an approved evidence-based model for use in Illinois State Board of Education (ISBE) funded Prevention Initiative programs that target at-risk children ages birth to three years and their families. This model was at the center of our study. Research has shown that the Baby TALK Model is able to identify at-risk mothers very early in a child's life and provide appropriate service shortly thereafter (Hilado et al., 2012), allowing for critical identification and intervention when the goal is to lessen the potential harmful effects related to biological and environmental risk (Olds et al., 2007; Henry et al., 2003). Early identification mechanisms are embedded in the infrastructure of the Baby TALK Model, followed by research-informed intervention methods that work to minimize the negative impact of risk factors for the developing child and his family.

The Baby TALK Model revolves around four major components that ensure vulnerable families are identified, served, and supported. Figure 1 illustrates the multi-level approach to supporting families. One critical component of the Model involves universal screening and the

assessment of new mothers with their newborns and this component was the focus of our study. In some Baby TALK communities, professionals encounter families in hospital obstetric units or even prenatal clinics to begin an early relationship with them. Baby TALK prepares professionals with encounter protocols for each opportunity with families and screen for need. The purpose of universal screening is to cast a net over a child-rearing population in order to ascertain that families have appropriate resources to successfully raise their young children. An added benefit is that a universal screening identifies families who may be at-risk in some way, enabling communities to provide more intensive case management or home visiting services to these more vulnerable families. Universal screening can be “strengths-based” rather than seeking families based on deficits. Baby TALK staff approach families looking for the strengths of both the infant and the parents.

At hospital obstetric units, Baby TALK staff use the Baby TALK Newborn Encounter Protocol with each family allowing for one of the earliest opportunities for identification of needs among infants, and their parents, as families are screened prior to discharge. The protocol guides professionals in using their time with families to establish a relationship while also performing a Newborn Behavioral Observation (NBO), designed by Berry Brazelton (Brazelton & Sparrow, 2001), to demonstrate the competencies of both infants and parents. Brazelton’s NBO gives Baby TALK practitioners a way to explore the behaviors of the infant with his parents in order to gain more information about his competence and his particular style of interaction from a strengths-based, validating approach.

At the same time, the Baby TALK Newborn Encounter Protocol promotes reflective listening skills, enabling professionals to identify needs at a critical time in a newborn family’s development while setting a strong foundation for engagement and referrals in the future. The

instrument employs a strength-based approach to affirming parental confidence at a time when the experience of becoming new parents may call into question that competence. In doing so, the Newborn Encounter Protocol enables professionals to connect with new parents, identify needs at a very early stage in the infant's development, and refer for services when new parents are typically most receptive to receiving support (C. Quigg, personal communication, December 2, 2015). This approach is critical for engagement in follow-up services after a need is identified. Professionals using the Newborn Encounter Protocol reported serving higher rates of families with greater needs, and these families eventually demonstrate lower levels of parental stress, heightened sense of parental competence, and more connectedness with community resources. These are the outcomes we are studying with greater rigor.

### **Research Question**

The Baby TALK model was informed by a number of child development theories that emphasize the importance of the early childhood years and the critical attention needed on the parent-child relationship as this relationship sets the foundation for learning and development throughout the lifespan for the child and has implications for parent wellbeing as well. In recognizing the damaging effects of parental stress on parent engagement, parenting competence and help-seeking behaviors, the study sought to test the following research question: *Do new mothers who experience the Baby TALK Newborn Encounter Protocol have lower levels of stress than mothers who do not receive the intervention?* In doing so, we could better examine the Newborn Encounter Protocol's ability to positively engage parents while reducing stress in a way that could support better outcomes for both parent and young child.

## **METHOD**

### **Study Description**

The Baby TALK Newborn Encounter Randomized Controlled Trial was designed to examine rigorously the differences in parental stress based on whether or not new mothers experienced the Baby TALK Newborn Encounter. The aim of this study was to provide preliminary rigorous evidence of the positive parental outcomes associated with Baby TALK's Newborn Encounter Protocol and this was done through randomly assigning new mothers to experience a Baby TALK Newborn Encounter. We also wanted to study the ability of the Newborn Encounter Protocol to identify high-risk infants and parents, as the literature suggests risk factors in the early years can have lifelong effects. Our study screened for risk factors that parallel studies currently conducted by Maternal Infant Early Childhood Home Visiting (MIECHV) and the Mother and Infant Home Visiting Program Evaluation (MIHOPE). The risk factors include the following: low-income, young mother, single parent, low social support, parent with physical or mental health needs, history of domestic violence, history of substance abuse, child with special needs/disability, and adult with disability. Though small in scale and sample, this efficacy study sets the foundation for later on performing larger scale and more refined randomized studies taking into account lessons learned in this small-scale rigorous efficacy study. An overview of the study is provided in Table 1.

The study randomly assigned new mothers who received Baby TALK's Newborn Encounter Protocol in the obstetric units of two hospitals participating in the study. Baselines scores were taken in order to determine if indeed there was any difference in the area of parental characteristics between those who did and those who did not receive the Newborn Encounter Protocol at delivery. Data collection on parental stress using the PSI-4-SF was also taken 1-month, 3-months and 6-months from the date of discharge to assess the changes in the area of parental stress over the time.



**Procedures for Data Collection and Randomization.** Initially, we aimed to recruit 150 parents at two Decatur-based hospital obstetric units at the start of the study that began in March 2015. However, during recruitment, we decided to over-recruit to ensure that even with attrition, we would still have a decent sample for the efficacy study. Thus, at the end of baseline during recruitment, we recruited a total of 191 participants (100 treatment and 91 control).

Participants were randomly assigned based on their delivery date in the selected hospitals. Mothers who were in the Decatur Memorial Hospital Obstetrics unit on Tuesday/Thursday/Saturday and in St. Mary's Hospital Obstetrics unit on Monday/Wednesday/Friday were assigned to the experimental/treatment group. Mothers in the obstetrics units on opposite days were assigned to the control group. The four data collection points were as follows: prior to hospital discharge, 1-month, 3-months, and 6-months following delivery. The data collected prior to discharge served as the baseline. All participant families including family in both treated and comparison groups received diapers with subsequent data collections and occasional check-ins to encourage continued participation.

For the whole duration of the study (i.e. from baseline to 1-month, from 1-month to 3-months, and from 3-months to 6-months), the overall attrition rate was found to range from 29% to 38%. The differential attrition rates between treatment and control ranged from 0.6% to 1.4%. According to both the US Department of Health and Human Services and US Department of Education's standards (see: [http://homvee.acf.hhs.gov/HomVEE\\_brief\\_2014-49.pdf](http://homvee.acf.hhs.gov/HomVEE_brief_2014-49.pdf)), this attrition is considered low and any potential bias is acceptable.

Once participants were recruited and baseline data was recorded, a data collector visited participants at 1-month, 3-months and 6-months from the date of the baseline data collection. Additional measures were taken at each period, then recorded and prepared for analysis.

Participants in both groups received small incentives (i.e., books, diapers, etc.) to support engagement in the study. Attrition rates remained within the acceptable range and data was collected efficiently throughout the study period.

## Measures

Three instruments were used in this study, with details of the information collected for each tool highlighted below and included in Table 1.

- ***Parent Information Form.*** This form collects basic demographic information on the mother, father, child, and family structure; administered at recruitment/baseline
- ***Newborn Encounter Form.*** This records the ‘treatment given’; administered to treatment mothers at baseline and 1-month
- ***Parenting Stress Index, Fourth Edition, Short Form (PSI-4-SF).*** This is a standardized, normed measure that assessed four domains of parental stress: i) Difficult Child (DC), ii) Parental Distress (PD), iii) Parent-Child Dysfunctional Interaction (P-CDI), and iv) Total Stress (Total) which sums up the other three domains; administered at 1-month, 3-months, and 6-months. We also recorded the Defensive Rating Scale score (i.e., a measure within the instrument that examined levels of parent defensiveness to questions based on participant responses), which was included in the measure.

Treatment group participants (100 mothers) experienced a Baby TALK Newborn Encounter prior to discharge and also at 1-month follow-up. This is in addition to the Parent Information Form they completed at the hospital. The PSI-4-SF was also completed by participants at designated data collection points, that is, at 1-month, 3-month, and 6-month.

Control group participants (91 mothers) completed the Parent Information Form and received print materials at the hospitals. Similar to the treatment group, they also completed the Parenting Stress Index (Fourth Edition, Short Form) at the designated data collection points.

### **Data Analytic Method**

Parental stress is the outcome variable in this study and is measured by the PSI-4-SF. Multiple regression was used in the analysis to control for risk factors and demographic characteristics (such as mother's education level, family structure, family income status). A dummy indicator labeled 'treatment' (i.e. being in treatment or control) was included in the regression—a significant value on the treatment indicator would have indicated that there was a significant difference between mothers who experienced a Baby TALK Newborn Encounter and those who did not. Our analysis included regression models that examined parental stress at the 3-month data collection point and at the 6-month data collection point. In addition, our analysis also included regression models that examined them changes in parental stress between the 1-month and 6-month data collection points.

As mentioned, our analyses controlled for important covariates that might influence a family's stress level. Specifically, the covariates controlled for in the model include selected parents' demographic information such as race, educational levels, employment status, marital status, family size, family income, and child birth order and birth weight. Most of this information was obtained from the Parent Information Form administered at baseline. Risk factors (such as receiving Temporary Assistance for Needy families (TANF) status, special needs status, disability status, report of family violence, abuse etc.) were also included in the regression model and these were collected at 6-month, when the researchers and families has become more familiar with each other. Lastly, PSI-4-SF measures if a respondent showed signs

of defensiveness. This defensive rating was also controlled for in the analysis using a dummy variable indicating whether the respondents showed signs of defensiveness.

## **Results**

### **Description of Sample**

In order to determine if the random assignment went well and to ensure confidence in the rigor of evidence obtained, baseline descriptives of both the treatment and control participants were examined. Table 2 presents the demographics of mothers and their families that were recruited when the mothers were about to give birth at the hospitals. As shown, the distribution is closely balanced between the treatment and the control groups, indicating that random assignment went well and we can be confident of the rigor of the results obtained from the study.

From the descriptives, it can be seen that about a third of the participants were low-income, having an annual income of less than \$30,000. About 28 percent of the participants received WIC. Slightly less than half of the mothers had a post-secondary education. Equal proportion of mothers were teenagers in both treatment and control, at about 7 percent.

In addition, we also collected data on the treatment group's Newborn Encounter experience during recruitment and at 1-month follow-up. Table 3 shows the descriptives of the Newborn Encounter experience. From Table 3, in comparison to baseline, at the 1-month follow-up all families had only one or no concerns versus more than one concern. By 1-month, more families were also fully responsive to the Baby TALK staff during the visit. In addition, there were more families with better emotional temperature (somewhat warm + warm) at 1-month when Baby TALK staff entered the room as compared to baseline.

### **Addressing Study Attrition**

As noted earlier, the randomization went well, and both the treatment and control groups were well balanced and there appears to be no systematic difference between the two groups at baseline. However, there was some attrition that occurred during the 6-month period of the study.

The original sample included 100 families in the treatment group and 91 families in the control group. Altogether, 72 families dropped out from the study over the 6-month period, including 38 families from the treatment group and 34 from the control group. The overall attrition rates ranged from 29% to 38% over the 6-month period, and the differential attrition rates between the treatment and control groups over the 6-month period ranged from 0.6% to 1.4%. According to both the US Department of Health and Human Services and US Department of Education's standards, the attrition is low and the potential bias is acceptable<sup>1</sup>. In addition, to assess potential bias due to missing data in the PSI-4-SF scale scores, we also calculated the percent of missing data for the scores at all three data points (1-month, 3-month, 6-month). The overall percent of missing data ranged from 33% to 44%, and the differential missing data percentages ranged from 0.6% to 6.9%. Overall, the missing data rates are within the acceptable range recommended by Department of Education What Works Clearinghouse standards.

### **Results for the Outcomes**

For each PSI-4-SF outcome shown in Tables 4-7 below, multiple regression models were presented for the different data collection time periods and areas of focus. Covariates used in the regression model included those demographic variables that might have a potential influence on a family's stress level. Below are further details of the regression results.

1. Models (1) and (2) examine the relationship between treatment and observed outcomes at 3-months, and

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<sup>1</sup> See: [http://homvee.acf.hhs.gov/HomVEE\\_brief\\_2014-49.pdf](http://homvee.acf.hhs.gov/HomVEE_brief_2014-49.pdf).

2. Models (4) - (7) examine the relationship between treatment and observed outcomes at 6-months.

A summary of the findings is as follows:

### **Difficult Child (DC) Scores**

One component of the PSI-4-SF instrument looked at how parents rated their child in the areas of temperament and general flexibility as an indicator of whether a child was perceived as “difficult.” Those in the treatment group received the Newborn Encounter Protocol and with its positive engagement and observation of the child with the professional, may have shown a difference in score around how the child was perceived. Overall, the regression results suggest that there is no statistical relationship between treatment and **PSI DC T** scores.

### **Parent-Child Dysfunctional Interactions (PCDI) Scores**

The PCDI component of the instrument examines the quality of relationship between parent and child. The 6-month PSI **PCDI T**-score was positively associated with treatment. However, the relationship disappeared after controlling for Defensive Rating, and other covariates. Overall, the regression results did not provide statistical evidence showing that the treatment reduced Parent-Child Dysfunctional Interactions. Additionally, defensive rating scores were linked to responses on the PCDI section of the instrument indicating levels of defensiveness based on the responses provided by the parents. Parents who exhibit the defensive responding subscore on the PSI-4-SF potentially could be underreporting problems and stress, and their scores should be interpreted with caution according to the PSI-4-SF Manual. The potential that scores are not fully valid reports of parental stress may affect the accuracy of analyses using the total and subscale scores on the PSI-4-SF; however, defensive responding scores are not definitive evidence that the other scores are not true responses.

### **Parental Distress (PD) Scores**

The PD subscale examines level of parent stress based on participant responses; an area at the heart of our research hypothesis. The 6-month **PD subscale** T score was positively associated with treatment. However, the relationship disappeared after controlling for the Defensive Rating, and other covariates. Overall, the regression results did not provide statistical evidence showing that the treatment reduced Parental Distress. Among all the outcomes considered and all the models analyzed, Model (6) for the PSI-4-SF PD domain has the most variance explained where  $R\text{-squared} = 0.855$ .

### **PSI Total Scores**

Lastly, the 6-month **PSI-4-SF Total** T score was positively associated with treatment. However, the relationship disappeared after controlling for Defensive Rating, and other covariates. Overall, the regression results did not provide statistical evidence showing that the treatment reduced parental distress across all the domains in PSI-4-SF.

### **PSI Defensive Rating**

The analysis of PSI-4-SF data also controlled for the Defensive Rating scores (where a dummy variable was created to indicate the presence of defensiveness). Statistical tests did not show that there was a significant difference in defensive scores between treated and controlled groups except at the 6-month period, when there are marginally less ( $p=0.06$ ) treatment participants who displayed defensiveness in their ratings (see Table 8).

## **Discussion**

Our study examined of one key Baby TALK Model component – The Newborn Encounter Protocol – and in doing so, the analysis shed light on the five different areas listed below:

- 1) Quality of the study
- 2) Outcomes tied to the Newborn Encounter Protocol
- 3) General outcomes and limitations
- 4) Defensive Rating responses on PSI-4-SF
- 5) The influence of service variance on parental distress

### **Quality of Study**

First, the total number and characteristics of participants in the treatment and control groups were balanced, indicating that randomization went well and we can be confident of the rigor of the evidence obtained from the study. Attrition rates were low and data collection was completed inline with the schedule proposed for the study with very little missing data. From study implementation through analysis, the study was conducted with a high level of professionalism and accuracy. Again, this speaks to the high quality design and execution that supports the rigor of evidence produced by the study.

### **Outcomes Tied to the Newborn Encounter Protocol**

For treatment participants, it appeared that participants “warmed up” to the Baby TALK staff during their Newborn Encounter experience at 1-month as compared to baseline based on the Newborn Encounter Documentation form. Baby TALK believes it is critical to have a strength-based and affirming first encounter with families. Treatment participants met with a Baby TALK professional who administered the Newborn Encounter Protocol (intervention) to assess needs and risk upon delivery of the child. Part of this protocol includes a measure of the “temperature” in the room upon entry and exit. At the same time and as stated by Baby TALK, the approach to administering the tool is *equally* important as the tool itself. The model developers believe the administration of the Newborn Encounter Protocol must affirm parent



competence in their ability to care for their own infant and this is critical to building a relationship that will allow for services to be readily provided and received if a need is present. Baby TALK Model developers also believe there is a need to develop a trusting relationship that supports parents in their ability to identify needs in their child, even at an early stage, and articulate those needs to a professional. The active listening, reflection, and strength-based terminology used throughout the Baby TALK Model lends itself to relationship building.

The findings suggest that the intervention was able, to a certain degree, build a level of “warmth” between the Baby TALK professional and new mother, which was evident at the one-month follow-up for participants in the treatment group. Based on the literature, we understand that early intervention and engagement is important. Although further research is needed, the Newborn Encounter Protocol instrument and its methods of engaging new mothers may prove useful in screening and connecting with families who may be in need of intervention services in the future.

### **General Outcomes and Limitations**

As mentioned earlier, we attempted to address the following research question: *Do new mothers who experience the Baby TALK Newborn Encounter Protocol have lower levels of stress than mothers who do not receive the intervention?* Our analysis showed that there were no significant findings detected between treatment and control participants. The researchers believe this result could be due to the short-term nature of the Newborn Encounter experience. In addition, both the treatment and control participants could receive other Baby TALK services as needed during the study thus fully isolating the outcomes to the Newborn Encounter Protocol was not possible. There were additional factors (such as other Baby TALK services received) that may have influenced the analysis and were included in the sub-analysis that was included in

the previous section. This finding will inform further RCTs examining the same topic wherein all services will be considered in the study design and analysis.

### **Defensive Rating Responses on PSI-4-SF**

One interesting finding is that in responding to the PSI-4-SF, by the end of six months, less treatment participants displayed defensiveness in their responses as compared to control participants.<sup>2</sup> While we do need to use caution in reviewing defensive rating scores – as mentioned, defensive responding scores are not definitive evidence that the other scores are not true responses – this finding can be indicative of the methods of engagement employed by the Newborn Encounter Protocol and the professionals administering the instrument. That is, the Baby TALK approach to engaging and building a relationship with new parents through strength-based and affirming language could support a greater level of trust between professional and parents, resulting in this outcome. Additional research is needed to determine if the characteristics of the participant (i.e., level and types of risk characteristics, culture, etc.) could be relevant variables in understanding PSI-4-SF defensive rating scores and that will be included in future study designs if the PSI-4-SF instrument is used.

### **Conclusion**

Our analysis provided insight into areas for additional research including the effects of other Baby TALK services on parental stress and competence, effects on defensive rating scores given the relational approach used by the model and isolating more model components (e.g., Newborn Encounter, Home visiting, etc.) to study impact. Although there were no findings related to our research hypothesis, the study greatly informs next steps in designing larger-scaled and more nuanced randomized control trials studies that further examine the heart of the Baby

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<sup>2</sup> Note that it is fewer number of treatment participants that had defensive responses, rather than participants who had a lower average defensive rating. This study did not measure the degree of defensiveness by individual or group.

TALK Model critical components. We will look at the duration of study now knowing that degrees of change may be more evident over a longer period of time versus the six-month time frame for this study. We can consider sub-scales and other covariates that can influence the analysis including services received outside of the Baby TALK model during the study period and personal circumstances or risks that were not directly controlled for in the study such as level of risk factors or previous engagement in Baby TALK-sponsored services. We also want to look further at anecdotal data from researchers on the team and Baby TALK professionals for more contextual information that could inform our understanding of the study findings. While we prioritize the importance of randomization and rigorous quantitative analysis, qualitative findings from these sources could provide a clearer picture of experiences in the field that can inform our understanding of the results.

In conclusion, the Baby TALK Model is widely used in Illinois and in other states, touching the lives of thousands of children and families every year. Studies like the Newborn Encounter Randomized Control Trial ensure that there are continued efforts to understand the model and its impact in the lives of families because of the direct connection to early childhood mental health and the mental health of parents/caregivers. The model developers have documented the positive effects of the model's relational and community-based approach to early intervention with families through countless stories and records from families and professionals over the last three decades. Our research provides another lens for understanding impact and with the lessons learned from this study, our work will continue as we seek to further understand the impact of the Baby TALK model on child and parent health and development outcomes.

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Table 1

*Newborn Encounter RCT Study Overview*

	<b>Study Characteristic</b>
<b>Type of study</b>	A six-month randomized control trial examining parental stress levels, parental competence, and community connectedness tied to the Baby TALK Newborn Encounter
<b>Sample size</b>	Targeted recruitment of 150 new mothers; over-recruitment occurred with a total sample of 191
<b>Sample characteristics</b>	<p>The study involved a universal screening of parents of diverse demographics, which included a particular search for families with risk factors, paralleling studies conducted by Maternal Infant Early Childhood Home Visiting (MIECHV)/Mother and Infant Home Visiting Program Evaluation (MIHOPE) and the risk qualities that include:</p> <ul style="list-style-type: none"> <li>• Low-income,</li> <li>• Young mother,</li> <li>• Single parent,</li> <li>• Low social support,</li> <li>• Parent with physical or mental health needs,</li> <li>• History of domestic violence,</li> <li>• History of substance abuse,</li> <li>• Child with special needs/disability, and</li> <li>• Adult with disability</li> </ul>
<b>Sample location</b>	Mothers identified in hospital obstetric units in Decatur, Illinois
<b>Treatment group (100 mothers)</b>	Participants experienced a Baby TALK Newborn Encounter prior to discharge and also at 1-month follow-up. This is in addition to the Parent Information Form they had to complete at the hospital. The Parenting Stress Index (Fourth Edition, Short Form), the Community Resource Tool, and the Infant & Early Parenting Index were also completed by them at designated data collection points.

<b>Control group (91 mothers)</b>	Participants completed the Parent Information Form and received print materials at the hospitals. Similar to the treatment group, they also completed the Parenting Stress Index (Fourth Edition, Short Form), the Community Resource Tool, and the Infant & Early Parenting Index at the designated data collection points.
<b>Incentive</b>	Families in both groups received diapers on each postpartum visit as an incentive for participation
<b>Nature of intervention</b>	Treatment group experienced a Baby TALK Newborn Encounter prior to discharge (baseline) and at 1-month
<b>Timeline for interventions</b>	Mothers identified in the hospital and assessed prior to discharge (baseline) as well as at 1-month, 3-months, and 6-months from discharge
<b>Outcome measures</b>	<ol style="list-style-type: none"> <li>1. Parent Information Form—this form collects basic demographic information on the mother, father, child, and family structure; administered at recruitment/baseline</li> <li>2. Newborn Encounter Form—this records the ‘treatment given’; administered to treatment mothers at baseline and 1-month</li> <li>3. Parenting Stress Index, Fourth Edition, Short Form (PSI-4-SF)—this is a standardized, normed measure that assesses four domains of parental stress: i) Difficult Child (DC), ii) Parental Distress (PD), iii) Parent-Child Dysfunctional Interaction (P-CDI), and iv) Total Stress (Total) which sums up the other three domains; administered at 1-month, 3-months, and 6-months</li> </ol>



Table 2

*Baseline Descriptives at Recruitment and Risk Factors Collected at the End of the Study*

<b>Demographics</b>	<b>Treatment (n=100)</b>	<b>Control (n=91)</b>
<i>Categorical Variables</i>		
<i>Percent</i>		
Teenage mom	7.0%	6.6%
Male baby	49.0%	41.8%
First born	39.0%	25.3%
Income		
Less than \$30,000	37.0%	31.9%
\$30,000-49,000	8.0%	7.7%
\$50,000 and more	33.0%	27.5%
Not reported	22.0%	33.0%
WIC	28.0%	28.6%
English language	91.0%	87.9%
Two parent family	69.0%	70.3%
Mother is married	45.0%	39.6%
Mother has post-secondary education	49.0%	42.9%
Mother full-time employed	45.0%	40.0%
Mother is white	69.0%	67.0%
Father is white	57.0%	48.4%
Risk Factors		
Family receives TANF	10.2%	5.9%
Parent has physical/mental needs	1.7%	4.2%
Parent has disability	0.8%	1.7%
Family has children with special needs	1.7%	0.8%
Reported family violence	1.7%	0.8%
Reported substance abuse	1.7%	4.2%
Reported parent criminality	0.8%	2.5%
<i>Continuous Variables</i>		

	<i>Mean (SD)</i>	
Birthweight (pounds)	7.3 (1.0)	7.3 (1.0)
Mother's age	27.4 (6.8)	27.1 (5.7)
Father's age	30.2 (6.8)	29.6 (6.9)
Family size	4	4

*Note:* The risk factors data were collected at the end of the study, after the researcher became familiar with the participants. At the end of the study, treatment  $n = 61$  and control  $n = 57$ .

Table 3

*Newborn Encounter Experience at Baseline and at 1-Month Follow-Up*

	<b>Baseline (n=99)</b>	<b>1-Month (n=63)</b>
Number of concerns		
0	75.8%	87.3%
1	19.2%	12.7%
2	5.1%	
Referral was made	28.3%	19.1%
Responsiveness of family to Baby TALK staff		
Somewhat not responsive	5.1%	1.7%
Average	8.2%	5.0%
Somewhat responsive	17.4%	8.3%
Fully responsive	69.4%	85.0%
Emotional temperature of room when Baby TALK staff entered		
Very cold	2.0%	1.7%
Neutral	18.4%	1.7%
Somewhat warm	75.5%	63.3%
Warm	4.1%	33.3%
Emotional temperature of room when Baby TALK staff left		
Somewhat cold	1.0%	1.6%
Neutral	2.0%	
Somewhat warm	20.4%	13.1%
Warm	76.5%	85.2%
Change in ratings for room temperature		
-1	1.0%	
0	11.2%	45.9%
1	81.6%	54.1%

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2	6.1%
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Table 4

*Statistical Results from OLS Regression: PSI-4-SF Difficult Child (DC) Domain*

<b>Variable</b>	<b>(1) 3-month</b>	<b>(2) 3-month</b>	<b>(3) 6-month</b>	<b>(4) 6-month</b>	<b>(5) 6-month</b>	<b>(6) 6-month</b>	<b>(7) 1- to 6- month change</b>
Treatment	-0.560 (1.119)	-0.541 (1.264)	0.513 (0.979)	0.825 (1.076)	1.318 (1.191)	1.020 (1.151)	0.778 (1.598)
Defensive rating controlled		Yes		Yes	Yes	Yes	Yes
Covariates controlled		Yes		Yes	Yes	Yes	Yes
Risk factors controlled					Yes	Yes	Yes
1-month PSI-4- SF DC controlled						Yes	
Number of observations	113	83	118	84	84	82	82
<i>R</i> -squared	0.002	0.278	0.002	0.420	0.460	0.554	0.516

\*\*\*  $p < 0.01$ , \*\*  $p < 0.05$ , \*  $p < 0.10$ *Note:* Standard errors in parentheses.

Table 5

*Statistical Results from OLS Regression: PSI-4-SF Parent-Child Dysfunctional Interaction*

*(PCDI) Domain*

<b>Variable</b>	<b>(1) 3-month</b>	<b>(2) 3-month</b>	<b>(3) 6-month</b>	<b>(4) 6-month</b>	<b>(5) 6-month</b>	<b>(6) 6-month</b>	<b>(7) 1- to 6- month change</b>
Treatment	-0.510 (1.011)	-0.615 (1.073)	1.412* (0.814)	1.027 (0.785)	1.386 (0.854)	1.055 (0.886)	0.599 (1.680)
Defensive rating controlled		Yes		Yes	Yes	Yes	Yes
Covariates controlled		Yes		Yes	Yes	Yes	Yes
Risk factors controlled					Yes	Yes	Yes
1-month PSI-4- SF PCDI controlled						Yes	
Number of observations	113	83	118	84	84	82	82
<i>R</i> -squared	0.002	0.374	0.025	0.532	0.579	0.603	0.426

\*\*\*  $p < 0.01$ , \*\*  $p < 0.05$ , \*  $p < 0.10$

*Note:* Standard errors in parentheses.

Table 6

*Statistical Results from OLS Regression: PSI Parental Distress (PD) Domain*

<b>Variable</b>	<b>(1) 3-month</b>	<b>(2) 3-month</b>	<b>(3) 6-month</b>	<b>(4) 6-month</b>	<b>(5) 6-month</b>	<b>(6) 6-month</b>	<b>(7) 1- to 6- month change</b>
Treatment	-0.407 (1.239)	0.812 (0.973)	2.072* (1.149)	0.425 (0.725)	0.454 (0.749)	0.843 (0.792)	-0.838 (1.369)
Defensive rating controlled		Yes		Yes	Yes	Yes	Yes
Covariates controlled		Yes		Yes	Yes	Yes	Yes
Risk factors controlled					Yes	Yes	Yes
1-month PSI-4- SF PD controlled						Yes	
Number of observations	113	83	118	84	84	82	82
<i>R</i> -squared	0.001	0.668	0.027	0.811	0.846	0.855	0.476

\*\*\*  $p < 0.01$ , \*\*  $p < 0.05$ , \*  $p < 0.10$ *Note:* Standard errors in parentheses.

Table 7

*Statistical Results from OLS Regression: PSI-4-SF Total*

<b>Variable</b>	<b>(1) 3-month</b>	<b>(2) 3-month</b>	<b>(3) 6-month</b>	<b>(4) 6-month</b>	<b>(5) 6-month</b>	<b>(6) 6-month</b>	<b>(7) 1- to 6- month change</b>
Treatment	-0.502 (1.024)	0.023 (0.897)	1.700* (0.919)	0.861 (0.776)	1.222 (0.839)	0.998 (0.866)	-0.005 (1.208)
Defensive rating controlled		Yes		Yes	Yes	Yes	Yes
Covariates controlled		Yes		Yes	Yes	Yes	Yes
Risk factors controlled					Yes	Yes	Yes
1-month PSI Total Score controlled						Yes	
Number of observations	113	83	118	84	84	82	82
<i>R</i> -squared	0.002	0.567	0.029	0.682	0.717	0.740	0.466

\*\*\*  $p < 0.01$ , \*\*  $p < 0.05$ , \*  $p < 0.10$ *Note:* Standard errors in parentheses.



Table 8

*Proportion of Families who Displayed Defensiveness (Def) in Their Responses to PSI-4-SF*

	1-month		3-month		6-month		
	Not Def	Def	Not Def	Def	Not Def	Def	
<b>Treatment group</b>	n	37	31	30	27	34	27
	%	54.4	45.6	52.6	47.4	55.7	44.3
<b>Control group</b>	n	36	27	32	24	22	35
	%	57.1	42.9	57.1	42.9	38.6	61.4
<b><math>\chi^2</math> test</b>	$\chi^2(1) = 0.09,$		$\chi^2(1)=0.23,$		$\chi^2(1) =3.47,$		
	$p= 0.75$		$p= 0.63$		$p= 0.06$		

Figure 1 The Baby TALK Model: Critical concepts and framework

