

TMW Center for Early Learning & Public Health Community-Wide Demonstration Project

Protocol Title: TMW Center for Early Learning & Public Health Community Wide Demonstration Project

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Funding: Internally funded, department funds

Sponsor: University of Chicago PI

Type of Research: Behavioral intervention

Intervention: Experimental curricula to change parental knowledge and beliefs

Protocol Version Date: 3/23/2020

TMW Center for Early Learning + Public Health
Community-Wide Demonstration Project
Protocol Narrative

1. Introduction

The TMW Center for Early Learning + Public Health has developed and individually tested a series of digital interventions aimed at impacting parent and caregiver knowledge, beliefs, and behavior to foster a child's foundational language, cognitive, and social-emotional development. The interventions include 3Ts-Newborn, 3Ts-Well Baby, 3Ts-Home Visiting, and 3Ts-Let's Talk!, all of which comprise the TMW interventions. The 3Ts interventions were named for the three easy to use strategies that are shared with parents/caregivers to support their child's development: Tune In, Talk More, and Take Turns. To date, the TMW Center has tested each of these interventions in randomized controlled trials, with an ultimate aim of implementing each as part of a comprehensive, multiple touchpoint intervention approach from birth through age three years (see Figure 1 below). To this end, the TMW Center is launching a community-wide demonstration project in partnership with the Children's Services Council of Palm Beach County, Florida, in which the TMW interventions will be delivered at scale through partners who work with families across health, education, and social service systems. The goal of this partnership is to reach 60% of all families with children age birth through three with at least one TMW intervention over the five-year partnership, with a significant percentage of families receiving more than one intervention. The TMW Center will evaluate the efficacy of the multiple intervention approach in impacting parent knowledge, beliefs, and behavior and child developmental outcomes, and develop an implementation model that can be used in other communities.

Importance of Language Acquisition on Cognitive Development

A child's early language exposure is a primary component of language development and in ultimate educational and intellectual achievement (Bruner, 1981; Chapman, 2000; Gallaway & Richards, 1994; Hart & Risley, 1995; Huttenlocher, Haight, Bryk, Selzer, & Lyons, 1991; Rowe, 2008). Betty Hart and Todd Risley (1992) conducted a landmark study that demonstrated the tremendous impact of a child's early language milieu on future learning, revealing a significant correlation between the number of words to which a child is exposed between the ages of 0-4 years and his/her ultimate IQ and academic success (Hart & Risley, 1992; 1995). Their findings were both significant and alarming, demonstrating the critical and time-sensitive role that early language exposure plays in a child's life. Their follow-up with the same children at 9-10 years of age confirmed that preschool and elementary school interventions came too late to alter these trajectories; the reverberations of early linguistic deprivation were likely to follow these children throughout their lives.

Children born into poverty experience an overwhelming inequality in their early language experience. Hart and Risley's study revealed a steep socioeconomic gradient in early exposure to language. At the end of their third year of life, children from families of high-socioeconomic status (SES) heard approximately forty-five million words while children from low-SES backgrounds

heard only approximately thirteen million. The tragedy for these children is not unalterable. It is neither genetics nor a lack of potential that lies at the heart of this inequality. Rather, it is inadequate parental knowledge of child language development. Rowe (2008) demonstrated that the relationship between SES and parental communication ability is mediated by parental knowledge. Other studies have corroborated this, showing that the effect of SES on a child's vocabulary was primarily dictated by maternal speech (Hoff, 2003). Encouragingly, studies have also demonstrated that a well-planned parent-directed language intervention may increase low-SES parents' use of facilitative language with their children (Oneil-Pirozzi, 2009; Suskind et al., 2013). The TMW Center for Early Learning + Public Health – formerly the Thirty Million Words Initiative – was founded, in part, to develop and implement such interventions, via the suite of TMW Curricula.

Advancing the science of scaling

Several of the TMW interventions have already been implemented and evaluated individually at small scale through randomized controlled trials and have demonstrated efficacy in raising parents' knowledge of child development and improving the quality of parent-child interactions (Leung et al. 2018, Suskind et al. 2018, Suskind et al. 2016). Yet little is known about the way findings from small-scale, controlled experiments are affected when the interventions are scaled up, calling into question the applicability of experimental findings to broad-scale interventions, with crucial implications for policymakers and researchers. As discussed in a series of papers from Al-Ubaydli et al. (2017), neither the population nor the situation of experimental studies are usually representative of the larger population and situation they would be generalized to (for example, the intervention is delivered in a different way, or adherence is usually lower at scale). Therefore, the effects found in experimental studies can substantially differ from the effects that one would observe at large scale. This community-wide implementation will allow the TMW Center to document the challenges involved in the scaling process and give us a unique opportunity to evaluate the effects of the interventions in a non-experimental and more realistic setting.

In 2018, the TMW Center conducted a request for partnership process and identified the Children's Services Council of Palm Beach County, Florida (CSC) as its partner in developing and implementing this community-wide implementation approach. The TMW Center and CSC are committed to a five-year partnership through 2023, during which the TMW interventions will be offered to families receiving care or participating in programming in Palm Beach County hospitals, pediatric clinics, and community agencies. The CSC is a governmental agency in Palm Beach County charged with allocating a local property tax revenue stream that is dedicated to supporting services for children from birth to age 18 outside of K-12 education, with a focus on prevention and early intervention services. In this vein, the CSC funds social service agencies across Palm Beach County that deliver services to pregnant women, children, and families. The TMW Center will train CSC partner agencies that already work in hospitals and CSC-affiliated pediatric clinics to distribute TMW interventions with local Palm Beach families. See below for detailed descriptions of the relationships between TMW Center, CSC, CSC-funded agencies, and participating hospitals and clinics.

Program implementation

Beginning in early 2020, the interventions will be delivered in one hospital (St. Mary’s Medical Center) and three to five pediatric clinics (Soma Medical Center, P.A. #3, Soma Medical Center, P.A. #4, Military, and others still to be named). Once the implementation model is developed further, TMW Center and CSC partners will then extend programming to other CSC partner hospitals, clinics, and community agencies in the county. Three interventions will be offered to parents/caregivers across the birth through age three range:

1. *3Ts-Newborn*, a video shared with parents/caregivers during a universal screening in hospital mother-baby units;
2. *3Ts-Well Baby*, four videos shared during well child immunization visits at 1-, 2-, 4-, and 6-months in pediatrician offices; and
3. *3Ts-Let’s Talk!*, a series of eight group classes involving education, feedback, and goal setting for parents/caregivers of children age one through three, delivered in a community-based organization.

The TMW Center and its partners will offer the interventions to parents/caregivers of children within the eligible age range in the partner birthing hospitals, pediatric clinics, and community agencies of Palm Beach County. The interventions will be offered to all parents/caregivers who:

- can engage in English or Spanish content,
- have a child in the specified age range for each intervention, and
- are receiving services or engaging in programming in partnering institutions.

Further selection criteria for each intervention are described in the “TMW Interventions Description” section below. The institutions CSC will engage to participate in this study are all within a target set of zip codes that has been determined by CSC.

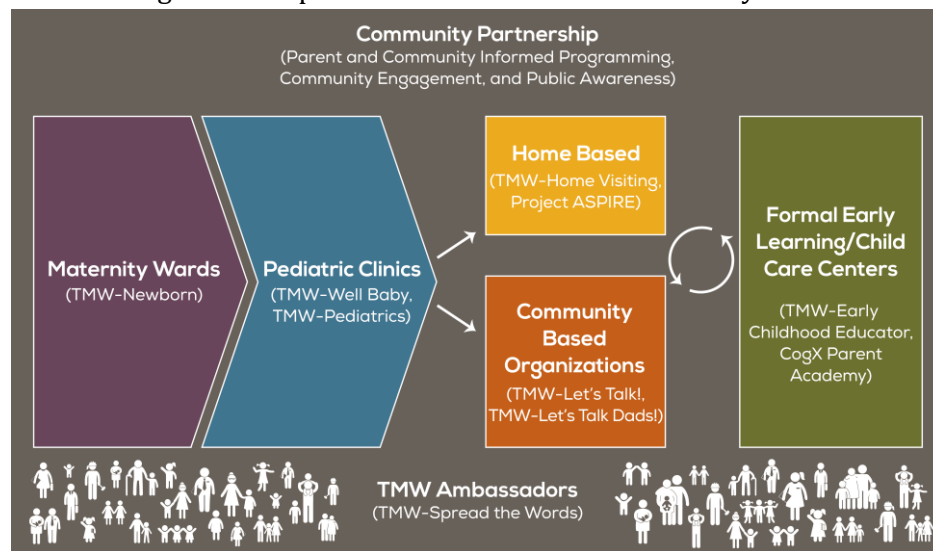


Figure 1 : TMW Interventions

TMW Tech Platform

To facilitate the delivery of the digital interventions to parents/caregivers, support providers in offering the interventions to families, and collect data for the program evaluation, TMW Center has built the TMW Tech Platform. This Tech Platform will collect informed consent, play the video interventions, facilitate the collection of survey data, and provide a dashboard for The TMW Center to monitor parents/caregivers’ progress through the intervention. Participants will

complete surveys during the interventions in partner sites and will be texted or emailed links to complete surveys in the later time points not connected to specific interventions, as specified in the Study Timeline on page 7 below. There is a parent-facing component that participants can access using a phone, tablet, or computer. The TMW Tech Platform will also send text messages or nudges to encourage further participation throughout the interventions and to reinforce content so as to help parents/caregivers build habits (York et al. (2018) and Doss et al. (2018)). These text messages will be content nudges to remind participants of ways they can use the strategies learned throughout the interventions in their day to day life. For example, “remember to use the 3Ts to build your baby’s brain while you drive to school!”

Through the parent-facing component, participants will be given access to additional videos and educational resources that they can continue to view after completing the educational interventions. These online educational components are optional and parents/caregivers can view as many or as few as they wish throughout the course of the study. Samples of screens that the parent/caregivers will see while logged into the app are included in Appendix D

2. Protocol

General idea

To evaluate the impact of the interventions, we need to compare the outcomes of families who receive them (*treated families*) to the outcomes of families who do not (*comparison families*), making sure those two types of families are on average comparable initially. The sample of treated families will consist of all the families who enroll in the TMW interventions in the hospitals and clinics of the treated community (the target zip codes for intervention delivery). To define the sample of comparison families, the TMW Center and CSC will work to find a comparison hospital with similar socioeconomic characteristics and child developmental outcomes as the treated community. Then within this comparison group, we will define a sample of comparison families who have similar individual characteristics as the treated families (based on data shared by CSC and baseline data we will collect). Once the samples of treated and comparison families are defined, we will follow them over time to compare the evolution of their outcomes. Comparison group data collection will begin in 2021. The enrollment and data collection plan will be established in conjunction with the CSC and elaborated in this protocol prior to enrolling any participants.

We will collect survey data from all participants who enroll in a TMW program. In doing so, we will collect data at a population level that will allow for deeper machine learning analysis and for eventual optimization of the metrics that need to be collected at a population level to monitor program effects.

The ideal progression through the TMW interventions is the following: parents/caregivers enroll in the program on the mother-baby unit, on a continuous basis, in all the hospitals where the *3Ts-Newborn* intervention will be in place. Before watching the *3Ts-Newborn* video, we will gain informed consent and then collect demographic information and a survey eliciting participants’ beliefs and expectations of child development. We will then engage with families in partnering pediatric clinics, starting at their first well-child checkup, where they will receive the *3Ts-Well Baby* intervention. In later years of the partnership (beginning in 2021), parents/caregivers can

participate in the *3Ts-Let's Talk!* intervention through a local participating social service agency. Throughout this participation, parents/caregivers' beliefs and behaviors as well as children's development will be regularly assessed through surveys administered by the TMW Tech Platform before and after each program.

The TMW Tech Platform is designed modularly, so that parents/caregivers are not required to have participated in a previous intervention to participate in a subsequent intervention. For instance, a parent could participate in *3Ts-Newborn*, but not *3Ts-Well Baby*, and then could participate in *3Ts-Let's Talk!* at a later time, or they could participate solely in *3Ts-Well Baby*. Prior to engaging with TMW interventions for the first time – regardless of which intervention is selected – participants will complete the informed consent module on the TMW Tech Platform.

In the comparison group, we will ask participants to fill out the same series of surveys, at the same age points (birth, 6, 9, 12, 24 and 36 months). This large-scale continuous data collection in both the treated and comparison groups is crucial to evaluate the impact of the interventions, and will also be a valuable source of real time information for clinics on the population's needs. Comparison group families will also complete an informed consent module before filling out any surveys. Further detail regarding recruitment and enrollment of this comparison group of families will be amended to this protocol prior to beginning that phase of the study.

TMW Intervention Descriptions

Please see below for further information about each of the TMW interventions.

3Ts-Newborn

This intervention is completed with parents/caregivers of newborns while they are still on the maternity ward. Participants will complete the *3Ts-Newborn* educational intervention after finishing Florida's Universal Infant Risk Screen, conducted by the HomeSafe agency. After completing the eConsent module and providing basic demographic data (parent name, child date of birth, and parent date of birth), participants will complete the 20-item version of the SPEAK survey using the tablet. After this, they will watch the 10-minute education intervention video, also on the tablet. Finally, parents/caregivers will complete a post-intervention 10-item version of the SPEAK survey using the tablet.

3Ts-Well Baby

The *3Ts-Well Baby* Intervention will take place in pediatricians' offices during regularly schedule immunization appointments. All participants at participating locations will be offered the opportunity to complete a video module at their child's appointment from the ages of 1 to 6 months. This intervention will take place in the clinic entirely on a tablet. If a participant did not complete the *3Ts-Newborn* intervention, they will complete the eConsent module, provide basic demographic information (parent name, child name, child date of birth, parent date of birth), and the 10-item SPEAK survey prior to viewing the first educational module. Participants who return for multiple well-child appointments while the child is younger than 7 months may complete up to a total of 4 educational video modules, one per visit. All participants who complete Module 4 will also complete a post-intervention 10-item SPEAK survey, using the tablet.

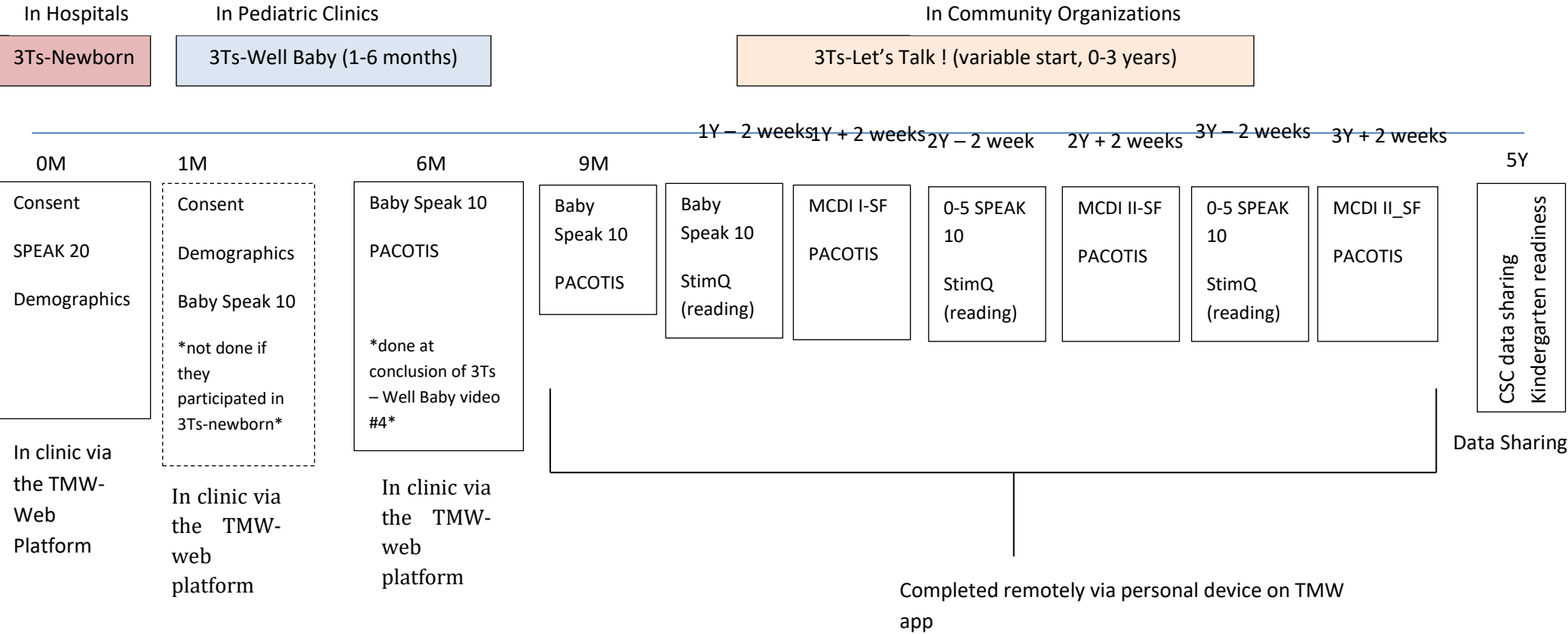
3Ts Let's Talk!

Beginning in 2021, the *3Ts-Let's Talk!* intervention will be offered to parents/caregivers who engage in community programming in Palm Beach County. Participants need not have completed previous interventions to be part of this intervention, and if this is their first interaction with TMW, will complete the eConsent module, provide basic demographic information (parent name, child name, child date of birth, parent date of birth), and complete the 10-item SPEAK. *3Ts Let's Talk!* will take place at partnering community organizations and participants will review educational modules with other parents/caregivers in a group setting.

Measures

The study timeline below presents the measures we plan to collect, at which ages, for the three dimensions of interest: parent behaviors, parent beliefs, and child development (see the Appendix A.1. for the list of acronyms). We have prioritized scales that have been validated, have evolutive versions allowing them to be used longitudinally, have a Spanish version, are relatively short, and predict longer run outcomes. We outline below the full set of measures that we will collect from families who participate in every TMW intervention starting at birth. For families who participate in fewer than the full set of interventions, we will collect data starting from their first intervention (e.g. the first *3Ts-Well Baby* session) through the remainder of their participation. In addition, basic demographic information (parent name, child name, child date of birth, parent date of birth) will be collected by all participants only once at the start of their first intervention, regardless of child's age. Participants can choose to opt out from the interventions at any time, or to not participate in a particular assessment time point. All measures will be completed by the participant through the TMW Tech Platform.

Study Timeline



Baseline

These measures will be collected at the parent's first interaction with the TMW study, regardless of time point. Following the eConsent, participants will be asked to provide contact information and basic demographic information, including their name, their date of birth, and their child's date of birth. Then participants will be asked to fill out one survey, the Survey of Parental Expectations and Knowledge about Language Learning (SPEAK) that assess their knowledge and beliefs. The version of the SPEAK to be used will depend on the child's age and at which intervention they are completing the baseline measures. If done at the *3Ts-Newborn* intervention, participants will complete SPEAK-20. If done at the start of the *3Ts-Well Baby* intervention, participants will complete the Baby SPEAK-10. Consent and surveys will be collected digitally through the secure online platform.

6 months

At age 6 months participants will be asked to fill out the Baby SPEAK-10 and PACOTIS surveys, either onsite at their pediatric visit via the tablet provided by CSC partners or at home by logging into the TMW Tech Platform. Participants in the treatment community will have access the surveys upon completion of the fourth *3Ts-Well Baby* intervention Video, while participants in the comparison group will receive a notification from the TMW Tech Platform that it is time to complete the surveys. These surveys will take approximately 10 minutes to complete.

9 months

At age nine months, all participants will be asked to fill out two surveys, the Baby SPEAK-10 and the PACOTIS. The PACOTIS is a self-report measure of the respondent's perceived impact on their child's development. All participants will receive a notification from the TMW Tech Platform that it is time to complete the surveys. These surveys, which are completed through the TMW Tech Platform, will take approximately 10 minutes to complete.

12 months

Two weeks before the child turns 12 months, participants will receive a notification from the TMW Tech Platform that it is time to complete their next surveys. They will be asked to complete the Baby SPEAK-10 and the StimQ-Reading Subscale. The StimQ is a parent report measuring parental verbal responsivity and involvement in their child's development.

Two weeks after the child turns 12 months, participants will receive another notification from the TMW Tech Platform asking them to complete a second set of surveys, consisting of the MacArthur-Bates Communicative Development Inventories: Short Form Level 1 (MCDI I-SF) and the PACOTIS. The MCDI I-SF is a parent report assessing children's vocabulary comprehension and production, appropriate for children 8-18 months. These surveys, which are completed through the TMW Tech Platform, will take approximately 10 minutes to complete.

24 months

Two weeks before the child turns 24 months, participants will receive a notification from the TMW Tech Platform that it is time to complete their next surveys. They will be asked to complete the SPEAK-10 and the StimQ-Reading Subscale. These surveys, which are completed through the TMW Tech Platform, will take approximately 10 minutes to complete.

Two weeks after the child turns 24 months, participants will receive another notification from the TMW Tech Platform asking them to complete a second set of surveys, consisting of the MacArthur-Bates Communicative Development Inventories: Short Form Level 2 (MCDI II-SF) and the PACOTIS. The MCDI II-SF is an extension of the MCDI-I-SF and is appropriate for ages 16-30 months. These surveys, which are completed through the TMW Tech Platform, will take approximately 10 minutes to complete.

36 months

Two weeks before the child turns 36 months, participants will receive a notification from the TMW Tech Platform that it is time to complete their next surveys. They will be asked to complete the SPEAK-10 and the StimQ-Reading Subscale. These surveys, which are completed through the TMW Tech Platform, will take approximately 10 minutes to complete.

Two weeks after the child turns 36 months, participants will receive another notification from the TMW Tech Platform asking them to complete a final set of surveys, consisting of the MacArthur-Bates Communicative Development Inventories: Short Form Level 2 (MCDI II-SF) and the PACOTIS. Spanish speaking participants will not complete the MCDI II-SF at 36 months, because the Spanish version does not go beyond 30 months, while an extension to 37 months has recently been developed in English. These surveys, which are completed through the TMW Tech Platform, will take approximately 10 minutes to complete.

Project stakeholders and exact location of research

This partnership consists of many stakeholders who are involved in varying capacities with the delivery of the TMW interventions. The following chart lays out the stakeholders and their roles with the project.

Stakeholder	Role
TMW Center	Research center at the University of Chicago. Intervention creation, training, technical assistance, evaluation. Project owner for the research evaluation.
Children's Services Council of Palm Beach County (CSC)	<p>Governmental, countywide agency in Palm Beach County, FL. Convener of implementing parties in Palm Beach County, partner in development of a replicable intervention implementation model. The CSC funds various services for children and families across Palm Beach County, including services provided by HomeSafe (detailed below). No CSC staff will have direct interaction with participants.</p> <p>TMW Center and CSC have a signed MOU in place that provides for the five-year partnership. The two parties will exchange identifiable and anonymous-level data per the terms of a data sharing agreement amended to their MOU.</p>

HomeSafe	<p>Social service agency that serves as the entry agency for CSC's System of Care. HomeSafe delivers a universal Infant Risk Screening in all birthing hospitals across Palm Beach County. HomeSafe's Hospital Liaisons will offer the 3Ts-Newborn intervention to parents/caregivers in conjunction with their delivery of the Infant Risk Screening at St. Mary's Medical Center.</p> <p>The CSC funds HomeSafe and has a contractual agreement in place to provide for HomeSafe's participation in the 3Ts-Newborn intervention. TMW Center is establishing a reliance agreement with HomeSafe to recognize University of Chicago's IRB as the single site of record for the study.</p>
St. Mary's Medical Center	Largest birthing hospital in Palm Beach County. HomeSafe Hospital Liaisons will offer 3Ts-Newborn postpartum to parents/caregivers in the St. Mary's mother-baby unit. No St. Mary's medical staff will be involved in the delivery of the 3Ts-Newborn intervention. TMW Center has secured permission from St. Mary's Medical Center to deliver 3Ts-Newborn in their hospital to their patients.
Soma Medical Center	Group of adult and pediatric primary care medical clinics in Palm Beach County. Soma Medical staff will offer 3Ts-Well Baby to parents/caregivers of children receiving care in Soma clinics. As detailed below in Section 4, Soma's front desk staff will offer the 3Ts-Well Baby intervention to parents/caregivers at the start of their clinic visit. Soma medical assistants (MAs) will assist parents/caregivers in accessing the videos and surveys and close out intervention sessions on the tablets.

Figure 2 : Project stakeholders

Please see Appendix B for the partnership structure and contractual agreements that support this work.

Over the course of the five-year partnership, more hospitals and clinics will begin to offer TMW interventions in the context of their care. The TMW Center and CSC will work to identify appropriate partner agencies to offer *3Ts-Let's Talk*, anticipated to begin in 2021. The TMW Center will work with each stakeholder to establish a reliance on the University of Chicago's IRB prior to that stakeholder offering the intervention to any parents/caregivers. The TMW Center and CSC have a signed MOU in place for the partnership that will be updated annually.

All survey collection for the 9, 12, 24, and 36 month time points will be completed via the TMW Tech Platform that a participant can access via their personal smartphone, tablet, or computer.

3. Statistical methodology

Assessing the impact of a program at large scale raises several statistical challenges. To identify the causal effect of a program, one needs to compare the outcomes of families who receive the interventions to the outcomes of families who did not receive them, making sure the two types of families are on average initially comparable. At small scale, such comparability is obtained through randomization of families into treatment or control group pre-intervention and comparison of average outcomes post-intervention. When the treated unit is an entire community,

applying such an experimental method would require obtaining a sample of communities, and implementing the program in a randomly selected subset of them. This poses a substantial logistical and financial challenge. In practice, interventions will be implemented in only one community, so we will need to rely on non-experimental techniques such as difference-in-differences, matching, and synthetic control. Those methods, although they rely on different types of data and assumptions, all aim at recovering the (counterfactual) situation of the community receiving the interventions, had it not received any intervention.

The synthetic control approach consists of using all available comparison groups and weighting their outcome (e.g. school readiness score) such that the weighted sum of control outcomes is as close as possible to the outcome of the treated community before intervention. The impact of the intervention is measured as the difference between the outcome of the treated group after intervention and the weighted sum of control outcomes after intervention (i.e. the "synthetic" control), computed with the weights that have been determined before intervention (Abadie & Gardeazabal (2003), Abadie et al. (2010)). Given that this approach requires outcome data for several untreated groups, during several years before intervention, we will only be able to use it for measures that hospitals, pediatric clinics or schools of PBC already collect (e.g. pediatricians' screeners or school readiness measures).

The difference-in-differences approach consists of choosing one comparison group and comparing the evolution of the outcome of the treated group before and after intervention to the evolution of the outcome of the comparison group between the same dates. The impact of the intervention is measured as the difference between these two trends (being themselves differences over time, hence the name), assuming outcomes evolve the same way in the comparison group as in the treated group, had it not received any intervention (Card (1990)). For this assumption to be plausible, the choice of the comparison group, as well as the choice of the sample of families to be surveyed inside this group to measure average outcome, is crucial. To help determining the comparison group and control families, we will combine difference-in-differences with matching methods.

Matching consists of using pre-intervention characteristics of the treated and control units (communities, families) and finding for each treated unit the control unit that has the same characteristics. If we observe a large number of characteristics, it becomes impossible to match treated and control units on all these characteristics, so we instead compute for each unit a score that summarizes these characteristics in one dimension, and match treated and control units based on this score (propensity-score matching). Those methods guarantee that treated and control units have similar observed characteristics and are thus more likely to evolve the same way.

Difference-in-differences method requires data from only one comparison group (as opposed to synthetic control), so it will be suitable for the measures we need to collect on our own (Table 1). Statistical tests will be used to assess the level of significance of the impacts. We will also use machine learning techniques to investigate the heterogeneous impacts of the interventions.

4. Recruitment and exclusion criteria

Staff of the partner agencies and clinics (outlined in Figure 2, above) will be trained to offer the TMW interventions to parents/caregivers in the course of their regular work in hospitals and clinics. These staff will be trained by the TMW Center to initiate a parent's interaction with the TMW Tech Platform, and will offer potential participants a tablet (iPad or other) on which they can view an informational video and complete the eConsent module if they choose. The informational video will be created by the TMW Center to introduce potential participants to the TMW interventions, present the opportunity to participate in the study, and outline potential risks and benefits of participation.

Parents/caregivers on the postpartum mother-baby unit will be systematically and continuously approached in their rooms at the end of the newborn's hearing screening or infant risk screening (both of which are conducted universally in all Florida hospitals) and offered to enroll in the TMW interventions and engage with *3Ts-Newborn*. All parents/caregivers with a live birth who speak English or Spanish will be offered participation at this time point, with the exception of parents/caregivers whose newborn is very ill and in the NICU and parents/caregivers with open cases with the Department of Children and Families in which the child may be removed from custody. These participants may participate in the TMW interventions at later time points and will not be excluded from later participation. Underage parents/caregivers age 16 and older are considered emancipated by Florida law upon the birth of their child and will be offered the intervention.

Parents/caregivers will be offered the opportunity to receive the *3Ts-Well Baby* interventions during the first six months of Well Child pediatric visits. Front desk staff at partner pediatric clinics will be trained by the TMW Center to briefly describe the study and ask any parent with a child within the target age range (0-6 months) if they would like to learn more about participating. If the parent expresses interest, the front desk staff will look them up in the TMW Tech Platform, using their name and birthdate as an identifier, to determine if they have already participated in any 3Ts programming (*3Ts-Newborn* or earlier *3Ts-Well Baby* modules). If the participant has already consented as part of a previous intervention, they will be given the iPad to watch the next *3Ts-Well Baby* educational video. If they are new to the system, the front desk staff will set them up with a new account and have the participant view the informed consent module before beginning the intervention. No identifying information about the parent or child will be saved in the TMW Tech Platform until the parent has given informed consent.

Per discussions with our partner pediatric clinics, front desk staff are the ideal staff to introduce the study to eligible families and set them up to use the tablet because they have more time to give parents/caregivers one-on-one attention than other medical staff. Because of this, our partner pediatric clinics have advocated strongly for the front desk staff to address parents/caregivers about participation. These front desk staff are trained on how to support parents/caregivers and share resources with them, and will be thoroughly trained by TMW staff on how to present the intervention. Parents/caregivers will take the tablet with them throughout the clinic visit to engage in the survey and video components during downtime. Medical Assistants (MAs) will support participants' use of the tablet as needed during the visit, and will close out sessions on the tablet once a participant has finished.

Beginning in 2021, parents/caregivers will also be offered the opportunity to receive *3Ts-Let's Talk!* upon engaging with a partner agency that is offering the *3Ts-Let's Talk!* parent classes. All

engagement for this participation will be conducted via the TMW Tech Platform. At all times, if the parent has not previously enrolled in the TMW interventions, he/she will first receive the informed consent module and provide basic demographics information (parent name, child name, and parent and child DOBs) before receiving any other content.

Exclusion criteria are as follows: 1) parents/caregivers under the age of 18 who are not emancipated minors (In Florida, all minors 16 and older who give birth are automatically considered to be emancipated minors, and therefore will be eligible for this study), 2) parents/caregivers who do not have legal custody of their child, 3) parents/caregivers who do not speak enough English or Spanish to receive their educational information in that language. As mentioned earlier, parents/caregivers whose infant is very ill will not be approached at the *3Ts-Newborn* time point, but will have opportunity to participate in subsequent TMW programs.

5. Consent

Because we will be offering the intervention universally through programming in hospitals, clinics, and community agencies across Palm Beach County, it is critical that the consent process be consistent in order to ensure that participants are fully informed of the nature of the study and their rights. We will therefore deliver the consent through the TMW Tech Platform, which allows us to standardize this process and ensure each potential participant receives the same information, and to ensure that all signed consents are documented and stored in a secure manner.

Prior to enrollment, all participants will engage in the TMW Tech Platform's informed consent module. This module will be shown at the first time point the participant engages with. For example, if a participant does not engage with the *3Ts-Newborn* intervention, they will view the informed consent module prior to beginning the *3Ts-Well Baby* intervention. This consent module will grant consent to participate in any number of subsequent TMW interventions so that participants do not have to be re-consented at each time point. In this module, participants will watch a short informational video that introduces the TMW interventions, explains the study, outlines risks and benefits, and clarifies the optionality of participation. Embedded throughout this video are quiz questions that check for understanding of the content of the video and reinforce the important points of participating. The participant will then be offered the opportunity to enroll and will read and digitally sign the consent form. Only once this consent is complete will the participant be able to engage with the TMW interventions. Upon signing, a digital copy of the consent will be made available to the participant by a link sent to their email or phone number (via SMS text).

After answering each comprehension check question, the correct information about the study will be reinforced to the participant. Please see Appendix C for the workflow of this eConsent process.

The TMW Center team will work with the IRB to finalize the script of this consent video, the comprehension check questions, and the workflow of the eConsent process prior to creating the eConsent video and building out the module on the Tech Platform. Spanish speaking participants will receive the informed consent module in Spanish. After receiving IRB feedback and approval on the English consent script and document, the materials will be translated into Spanish.

Participants have the contact information of the TMW Center's Technical Assistance coordinator who is local to Palm Beach County. The Coordinator can answer any questions that they have about the study both before enrolling and during their participation in the study.

As part of the eConsent module, participants will complete a separate HIPAA authorization form, through a digital signature on the TMW Tech Platform, to allow their data to be shared between the TMW Center, CSC, and the Florida Department of Health.

6. Confidentiality and Data Sharing

The TMW Tech Platform will collect and store all assessment and participation data from enrolled participants. The TMW Tech Platform is currently being designed and built, in alignment with the security and authentication specifications of the University of Chicago Information Security Office (ISO). The TMW Tech Platform is hosted on the servers of the University of Chicago Center for Research Informatics' (CRI) Kenwood Data Center. CRI will provide the Tech Platform's ongoing support and maintenance. We will secure a full Authorization to Operate for the Tech Platform from the ISO prior to beginning this evaluation.

Data will be collected exclusively in electronic form via the TMW Tech Platform. Only trained and authorized research personnel will have access to the data. Data will be carefully monitored on an ongoing basis to ensure the privacy and confidentiality of participant data. Participant records will be assigned anonymous alphanumeric unique identifiers in order to minimize the risk of data being associated with a participant's identity. Access to the database and the ability to modify the system will be restricted to trained research personnel with specific reason to access it.

Per the terms of a data sharing agreement executed by University of Chicago's University Research Administration (URA), identifiable data for enrolled participants that includes program participation, assessment scores, and kindergarten readiness data will be shared with and received from the Children's Services Council of Palm Beach County. The TMW Center and CSC will link participants' unique identifiers from the TMW Tech Platform and CSC's data collection system in order to verify the records to share. All data will be transmitted through a secure file transfer protocol (or similar) and will be maintained according to the data sharing agreement. Participants will grant permission for this during the informed consent process. The TMW Center will share the following information with CSC: Data about which 3Ts interventions a participant completed, enrollment and opt-out rates, results from surveys administered throughout the study (as listed in the Measures section of this document). In order to match records, the TMW Center will disclose the parent name, parent date of birth, child name, and child date of birth. The CSC will share the following information with the TMW Center: Data about what CSC and community programming a participant completes and any parent or child assessments collected as part of those programs, and kindergarten readiness scores which the CSC collects in the course of their work with families. Neither the TMW Center nor CSC will share this information with anyone else.

The TMW Center will also receive identifiable demographic information for enrolled participants from Florida's Department of Health's vital statistics through a data sharing agreement. These data will include the participant's zip code, household income, education level, birth metrics,

insurance status, and other household and demographic information. Participants will grant permission for this during the informed consent process and through a stand-alone HIPAA authorization form. The TMW Center will not share this information with anyone else.

7. Financial considerations

Participants will not be compensated for their participation. There is no financial cost to participants.

8. Risks and benefits

Given the educational nature of this research, minimal risks are anticipated. Participation involves receiving educational materials and answering survey questions. Sharing this information poses a risk of a potential loss of confidentiality. As described above, these risks will be mitigated by a comprehensive data privacy and security strategy with the TMW Tech Platform and thorough training for research personnel to ensure data are handled appropriately.

For parents/caregivers, potential benefits include increased knowledge of the importance of early childhood language and cognitive development and skills to support that development. For the hospitals and clinics, benefits include evidence-based educational materials for their patients and valuable information on their patients' and community's needs.

9. Conflict of interest

There is no COI with regard to the conduct of this project.

10. Publication plan

Dr. Suskind, Prof. List, and their research teams will publish the primary findings of the project in academic journals and field-specific publications. Results will be analyzed for a first manuscript during or after the second year of the study and additional manuscripts will follow.

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Appendix A. List of acronyms

A.1. Measures:

MCDI-SF	MacArthur-Bates Communicative Development Inventories–Short Form <i>[parent report assessing children's developing abilities in early language, including vocabulary comprehension, production, gestures, and grammar]</i>
PACOTIS	Parental Cognition and Conduct Toward the Infant Scale <i>[parent report assessing perceived self-efficacy and parental impact]</i>
SPEAK	Survey of Parents’/Providers’ Expectations And Knowledge <i>[parent report developed by TMW Center to assess knowledge and expectations of early development and parenting practices]</i>
StimQ	<i>[parent report measuring parental verbal responsivity and involvement in developmental advance]</i>

A.2. Interventions:

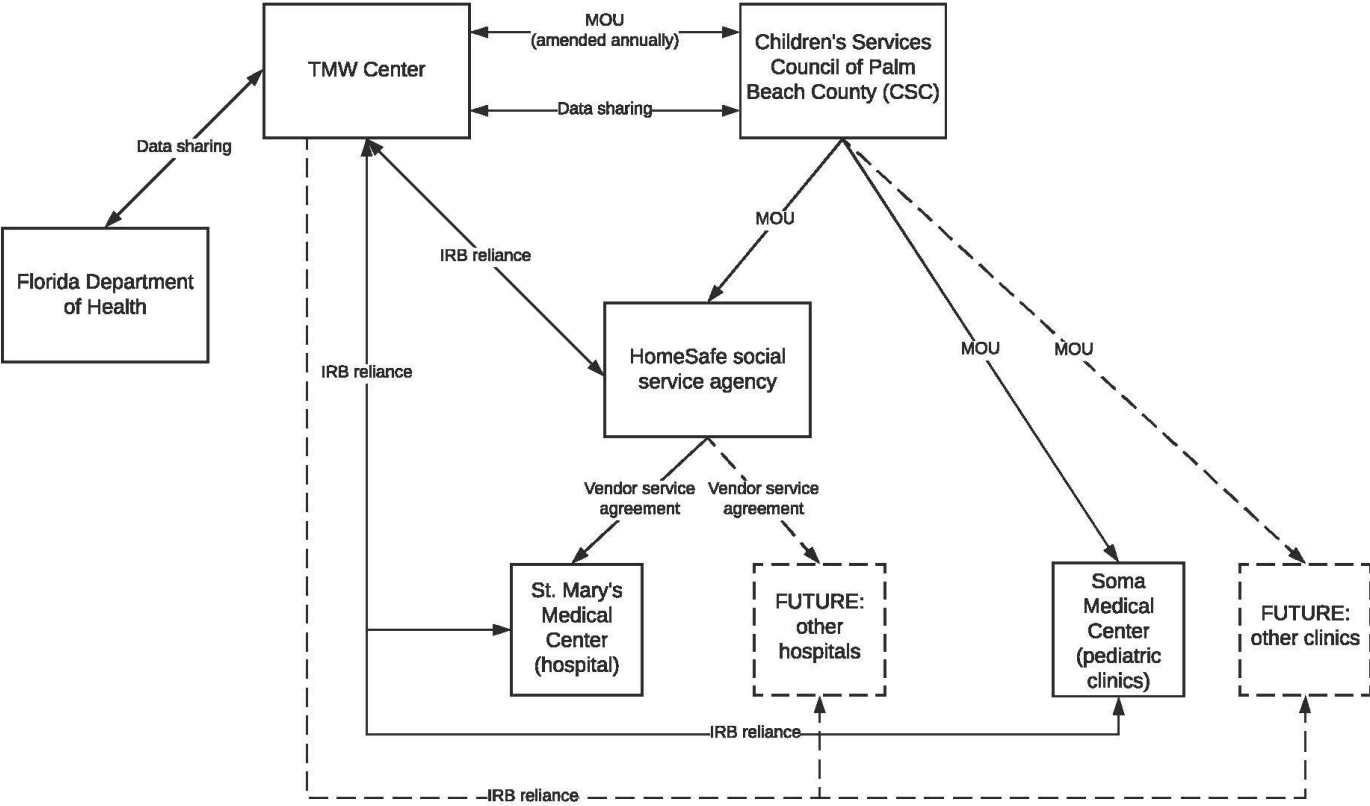
NB	3Ts-Newborn <i>[a video shared with parents during the Universal Newborn Screening in maternity wards]</i>
WB	3Ts-Well Baby <i>[four videos shared during immunization visits at 1 week, 2, 4 and 6 months in pediatrician offices]</i>
LT!	3Ts-Let’s Talk! <i>[a series of group classes for parents/caregivers of 1 to 3 years old children delivered in a community-based organization]</i>

A.3.Stakeholders

CSC	Children’s Services Council <i>[Governmental countywide agency in Palm Beach County, FL. A primary implementation partner]</i>
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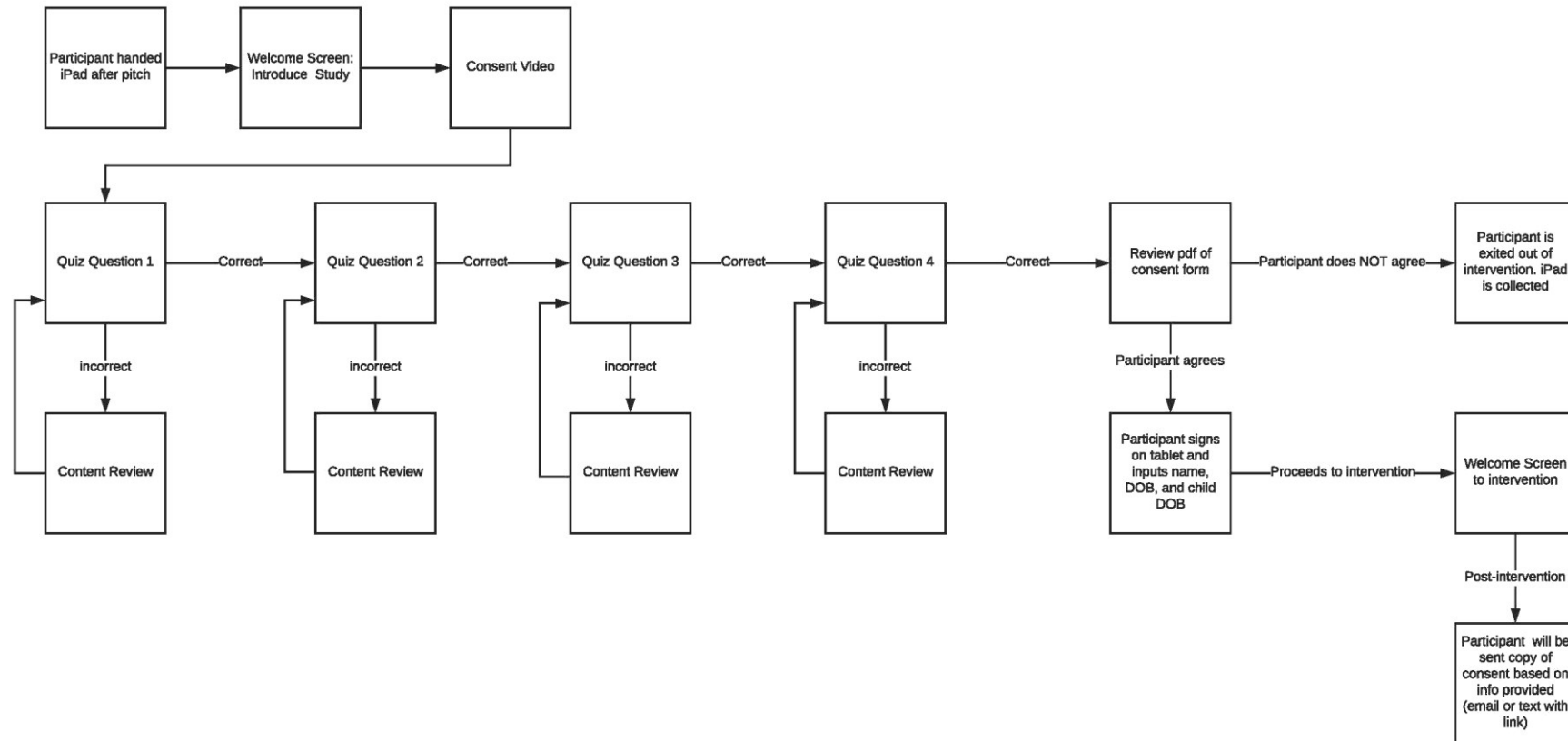
Appendix B: TMW Center Partners and Agreements

TMW Center Community-Wide Demonstration Project
Partners and Agreements
Updated 09/30/19



Appendix C. e-Consent Workflow and script

eConsent Flow Chart



e-Consent Script

Video with parent-child B-roll and voiceover: What is the purpose of the 3Ts Program study?

In the first years of life, your child's brain is like a sponge that soaks in all that is going on around her. Each word you say, each hug you share, each tear you dry. Your interaction when your child is young affects the rest of his life. How he will learn to talk, read, get along with others, and manage his feelings. As a parent, your role is crucial – every moment you interact with your child builds his brain.

The TMW Center at the University of Chicago and the Children's Services Council of Palm Beach County want to partner with you in your child's first years. We've made the 3Ts program to support you and teach you ways to help your child learn and grow.

You can find the 3Ts program in your hospital, doctor's office, community centers, and online.

This is an educational research study to learn how well the 3Ts program supports young children's development.

In the 3Ts program, you will fill out surveys. We will ask about your child, your household, and your ideas about child development. This will help us learn how well 3Ts program works. We will use the results to make the program better for you, your child, and other families.

Let's make sure we're being clear.

Question: What is the purpose of this study?

- a. To give medical advice and care
- b. To test an educational program

Let's Review: The 3Ts program is educational. It was designed to teach parents and caregivers about their young children's cognitive development. There is no medical care involved.

What is involved in the study?

This study takes place in the hospital, clinics, and community agencies. You will watch educational videos on a tablet.

You will fill out surveys about your child, your household, and your ideas about your child's development. If you complete all parts of the study, you will take surveys nine times over four years.

Question: What will I be asked to do in the study?

- a. Have blood tests and extra medical visits
- b. Watch videos and fill out surveys

Let's Review: You will watch videos and take surveys. No medical tests are part of this study.

What if I don't want to participate in this study?

This study is optional. You do not have to join. You may quit at any time. If you choose not to participate, it will not affect your or your child's care with your doctors, clinics, or any local agencies.

Question: Is this study voluntary?

- a. Yes. You have the right to choose if you want to participate. You may quit at any time.
- b. No. You are required to participate in this study.

Let's Review: This study is optional. You do not have to join. You can quit at any time.

What is required for this study? Are there risks?

This is an educational program. There is no cost to you or your insurance.

There could be a loss of privacy when you share your data with us. Our team takes great care to keep your information safe.

There may be a benefit of learning how to enhance your child's development. We hope the results from this study will help other families.

What about my information?

We will ask your name, your date of birth, and your child's date of birth. We will also ask for your phone number or email. This information is called personally identifiable since it can identify you or your child.

We will keep all information private and safe. Only trained staff will see your records. We will never disclose your or your child's identity.

We will share data with the Children's Services Council of Palm Beach County. We will receive your Healthy Start Prenatal and Infant Risk screening data. This was collected by the Children's Services Council along with your child's birth certificate.

We will receive data from the Florida Department of Health. This information is gathered with your child's birth certificate. All information we collect through this study will be kept private.

Question: Will my information be kept confidential?

- a. Yes, my information will kept private and safe. Only the trained staff will see my records.
- b. No, my information will be shared with anyone who asks for it.

Let's Review: All of your data will be kept private and safe. Only members of the research team can view it.

If you have questions, call the research team at 773-834-8629 or email the3Ts@bsd.uchicago.edu.

Want to participate? Please review the consent form below and sign. You will be sent a copy of this consent form via email or text.

[Consent form displayed on screen to scroll through/review]

The research project has been explained to me. I have not been given a guarantee of benefits from participating. I will be sent a signed copy of this consent form.

I agree to participate in this study. My participation is voluntary and I do not have to sign this form if I do not want to participate.

I certify that I have legal custody of my child. I agree to let my child to participate in this study.

Signature: _____ *[will sign via finger on iPad]*

[iPad will capture date and time of signature]

Name: _____ *[enter on iPad]*

Date of birth: _____ *[enter on iPad]*

Child's date of birth: _____ *[enter on iPad]*

Where should we send you a copy of this form?

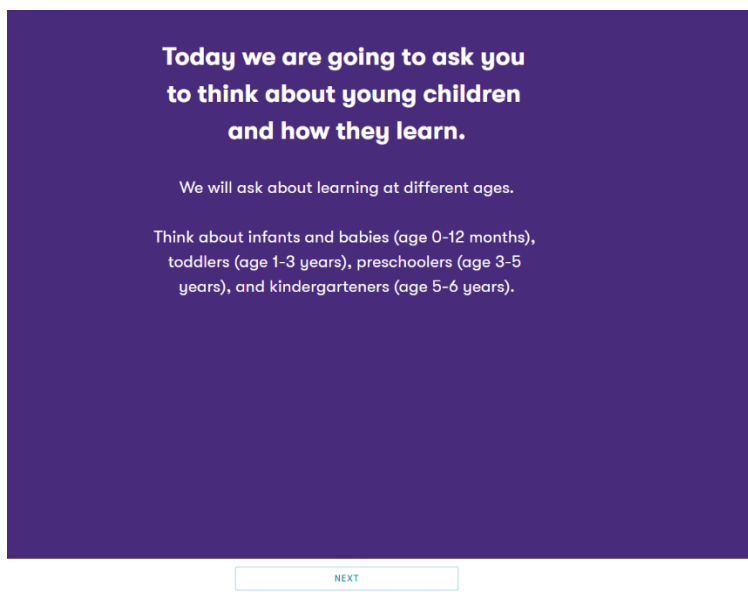
Text: *[Enter phone number]*

Email: *[Enter email]*

Your phone number and/or email will be used to send you a copy of this consent form. We will also use it to offer you additional 3Ts video resources and let you know when it is time to complete your surveys. We will not share this information with anyone.

Appendix D. Visual examples of online parent content.

Introduction to a survey – participants will be directed to the parent-facing component of the secure TMW Tech Platform to complete surveys in the later time points not connected to specific interventions.



Example of Video Content – participants can watch videos to learn more about the topics shown in the 3Ts Interventions.



See the 3Ts In action!

Tune In: Dad notices what catches his son's attention.

Talk More: Dad puts words to what his child does.

Take Turns: Dad responds to his toddler's movements as if they are words.

[WATCH VIDEO](#)

Example of educational resources: In addition to videos, parents can view text and image based reminders of how to use the 3Ts

**Small moments,
big impact!**



From playtime to meal preparation, these activities weren't unusual.



But, by using the 3Ts, these parents created brain-building experiences for their children.



You make a lasting impact on your child when you talk and interact with her.

[NEXT](#)