PROTOCOL TITLE: *TMW-Newborn Implementation*

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TYPE OF RESEARCH: Randomized implementation trial

INTERVENTION: Experimental Technique to Change Knowledge and Beliefs

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Thirty Million Words Initiative Newborn Implementation Trial
Protocol Narrative

The Thirty Million Words Initiative Newborn Intervention (TMW-Newborn) is a public health effort aimed at increasing awareness about the importance of a child's early language environment in his or her first years of life. This one-time educational intervention will be impacting maternal awareness and knowledge about the importance of children's early language environment, between ages 0 and 3. We envision the intervention to be carried out in the immediate postpartum period because we seek to provide language enriching tools parents can use with their babies from the start. The educational intervention will be delivered in conjunction with the Universal Newborn Hearing Screening (UNHS) in partnering hospitals, an existing public health infrastructure and a routine part of postpartum care.

Background

The Newborn Initiative is both an extension and a focused adaptation of the larger Thirty Million Words initiative. TMW-Newborn is grounded in three main bodies of literature and avenues of research. The first is research on early childhood language acquisition, child development, and child behavior. The foundation of our evidence-based research derives from the differences found in children's language environments, which largely depend on socio-economic status (Hart and Risley 1995). Second is research on maternal health education and health literacy, specifically on prenatal, perinatal and post-natal education. Third is research and data on the Universal Newborn Hearing Screening (UNHS), which occurs during post-partum care. The UNHS is a critical point in time to both deliver the TMW message and to increase follow up for those newborns not passing the initial screening by focusing on the importance of a child's early language environment and the impact of hearing loss on cognitive development.

Our effort therefore lies in bringing these three main bodies of research together to craft a public health intervention, which relies on existing initiatives while adding an important educational component. TMW-Newborn not only aims to impact parents' beliefs about how crucial their role is in creating a stimulating and enriching language environment for their baby, but also seeks to improve rates of re-screening (loss to follow-up) for the universal newborn hearing screening. By emphasizing the importance of talk (and hearing) for cognitive and language development, we seek to encourage families to follow up after the screening if their newborn does not pass.

Importance of Language Acquisition on Cognitive Development:

A child's early language exposure is increasingly acknowledged as pivotal in language development and, more importantly, in ultimate educational and intellectual achievement (Bruner, 1981; Chapman, 2000; Gallaway & Richards, 1994; Hart & Risley, 1995; Huttenlocher, Haight, Bryk, Selzer, & Lyons,1991; Rowe, 2008). Hart and Risley's landmark study demonstrated the tremendous impact of a child's early language milieu on future learning, revealing a significant correlation between the number of words a child is exposed to between ages 0-3 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.

The tragedy for children born into poverty is the overwhelming inequity in their early language experience. Hart and Risley's study revealed a steep socioeconomic gradient in early exposure to words/language. At the end of their third year, children from high socioeconomic status (SES) families heard approximately *forty-five million* words; children from economically impoverished backgrounds heard only approximately *thirteen million*. Hart and Risley found that "with few exceptions, the more parents talked to their children, the faster children's vocabularies were growing and the higher their children's IQ test scores at age three and later." Their follow-up with these children at 9-10 years of age confirmed that preschool/school interventions came too late to alter these trajectories; the reverberations of early linguistic shortfall were likely to follow these children throughout their lives.

But the tragedy for these children is not unalterable. It is neither genetics nor a lack of potential that lies at the heart of this inequity; it is parental knowledge. In 2008, Rowe demonstrated that that the relationship between socioeconomic status and parental communication ability is mediated by parental knowledge (Rowe 2008). Other studies have corroborated this, showing that the effect of socioeconomic status 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 in low-income populations may have a positive effect with parents increasing their use of facilitative language with their children (Oneil-Pirozzi, 2009).

Universal Newborn Hearing Screening and Early Hearing Detection and Intervention:
Since 2000, the number of infants screened for hearing loss at birth has dramatically increased. According to 2011 data (Centers for Disease Control and Prevention, 2013), 97.9 % of all babies in the United States receive the Universal Newborn Hearing Screening. However, 1.8 % of newborns (59,161) do not pass the screening, 35.3% (20,857) of which are not rescreened, failing to receive the next step of treatment. The CDC groups these failed re-screenings into two categories: "Loss to Follow-Up (LFU)" and "Loss to Documentation (LTD)". For infants who did not pass the newborn hearing screening, LFU refers to a failure to receive the next step of treatment, be it rescreening or comprehensive audiologic evaluation. Families are contacted but do not follow up, or cannot be contacted. LTD refers to failure to report the results from hearing screening, rescreening, diagnostic services, and/or treatment services which are needed for comprehensive surveillance and monitoring by Early Hearing Detection and Intervention (EDHI) and the medical home.

In Illinois, all birthing hospitals perform the newborn hearing screening, and 99.4% (156,376 in 2011) of newborns are screened for hearing loss (Centers for Disease Control and Prevention, 2013). According to 2011 data however, of the 2,714 infants not passing the test, 64% (1,736) are LFU or LTD. This is nearly double the national average. The high incidence of newborns not returning for a complete audiologic screening is worrying and constitutes a concern for newborn developmental health. An infant who does not pass his/her newborn hearing

screening has a potential developmental emergency because of the tremendous impact language has on the developing brain.

A Participatory Model of Educational Intervention:
The educational intervention is currently being designed and planned with iterative participation and feedback from the audience we seek to have an impact on. Exploratory and formative qualitative research informs the intervention, drawing insights from pregnant mothers, mothers in immediate post-partum, parents, and healthcare providers. Our intervention is currently being developed with focus groups and individual interviews with mothers and parents, consultation with medical professionals (RNs, OB GYNs, Pediatricians), and visits to community health centers and birthing hospitals in Pensacola, FL to understand the feasibility of implementation of the intervention around the time of the newborn hearing screening.

The TMW-Newborn translates the TMW message into a shorter-format one-time educational intervention that can be delivered to new parents in the hospital as part of routine postpartum care. As a large-scale public health approach, it has the potential for a significant impact on SES-disparities in language development. While the earlier TMW intervention was developed for toddlers, the TMW-Newborn intervention will be tailored for parents of newborns. It will include messages and strategies specifically for children from birth to one year of age with a focus on preverbal communication and mother-child attachment. It will also include video modeling of parents utilizing both spoken and sign language. Given the novelty of this intervention, it will be important to evaluate its acceptability and feasibility with low-SES families and objectively examine evidence of its efficacy. The TMW NI video will be available in both English and Spanish.

The significance of the Newborn Intervention as a Public Health Initiative
The Thirty Million Words Initiative Newborn Intervention is a public health effort to raise awareness about the critical importance of early childhood language development. It will occur at the beginning of a baby's life and during a special time for his or her parents, right after delivery. TMW-Newborn is situated at the intersection of multiple public health initiatives: the Universal Newborn Hearing Screening and Early Hearing Detection and Intervention are crucial public health interventions to timely screen and detect hearing loss. For the intervention, TMW-Newborn will be integrated as part of routine postpartum care in the hospital stay. In the future, we envision having key information about child language development as part of the discharge packet every mother receives after birth. We also seek to have key information of language development milestones in newborns be part of prenatal classes and be included in prenatal educational material.

Previous Research
We conducted two randomized controlled trials to evaluate the feasibility and efficacy of TMW-Newborn in two large Chicago birthing hospitals. Over 600 English- and Spanish-speaking participants were randomly assigned to receive the TMW-Newborn video or a control group educational video about Sudden Infant Death Syndrome (SIDS).

Results showed a significant increase in knowledge survey scores between pre- and post-intervention for participants in the TMW-Newborn treatment group. There was no significant increase in the control group's average scores. The increase for treatment participants remained significant 4 to 6 weeks after the intervention.

In addition to the Knowledge Survey, participants were asked a few questions concerning the UNHS and the video. We found that nearly 92% percent of all participants in the study stated that they understood what the UNHS hearing results meant for them and their infant after watching the video. Furthermore, in response to the questions about the video, 99% of participants found the information in the video helpful. 98% of them reported learning something new from the video and expressed willingness to recommend the video to a friend. 97% of all participants planned to try out strategies from the video at home and 87% of them agreed that it was convenient to view the video during the UNHS.

In summary, mothers of newborns who receive the TMW-Newborn educational intervention show increased knowledge and demonstrate an improved understanding of the critical importance of their newborn's early language environment for cognitive development and school readiness (Suskind et al., 2017).

Purpose

The purpose of the proposed research is to perform testing of the Thirty Million Words Initiative Newborn Intervention (TMW-Newborn) with the primary goal of evaluating various implementation methods.

We hypothesize that the TMW-Newborn intervention will:

1. Significantly impact parent knowledge regarding the importance of UNHS follow-up
2. Significantly impact parent knowledge of child development

Additionally, we hypothesize that:

3. The 7-minute version of the video with questions interspersed will most significantly improve parent knowledge of child development
4. There will be no significant differences in effectiveness of the Spanish and English versions of the TMW-Newborn intervention

The hypotheses rely on the existing research data supporting the idea that parental understanding and beliefs will alter parental behavior, and consequently, that increased parental linguistic input will impact their child's cognitive development.

Protocol

We propose to perform a randomized implementation trial to evaluate the efficacy of various implementation methods of the TMW-Newborn educational intervention. The study will be

conducted in temporal proximity to the administration of the universal newborn hearing screen.

After routine delivery, postpartum mothers are admitted to the mother-baby unit for 48-72 hours. At Sacred Heart Hospital, study participation will be offered to every postpartum mother prior to discharge by a hearing screening technician, registered nurse, or registered hospital volunteer during the patient's hospital stay. Study participation will be offered to every mother whose child is receiving the hearing screening at the University of Chicago Medicine and Baptist Hospital-Pensacola. At the University of Chicago Medicine, study participation will be offered by a research assistant or hearing screening technician. At the Baptist Hospital-Pensacola, study participation will be offered by a nurse. The technician, nurse, or registered volunteer will give each mother an electronic tablet with the HIPAA Compliant TMW-Newborn Tech Platform that houses the TMW-Newborn intervention.

The patient experience through the TMW-Newborn intervention within the TMW Tech Platform is as follows:

- Participant selects language (English or Spanish) for viewing videos and completing surveys;
- Participant views Welcome and Consent Video, in which Dr. Suskind (in English) or another health professional (in Spanish) introduce the study, explain participation, outline risks;
- Participants who agree to participate will then be randomized into one of four conditions:
    - Long TMW-Newborn intervention video without questions interspersed,
    - Long TMW-Newborn intervention video with questions interspersed,
    - Short TMW-Newborn intervention video without questions interspersed, or
    - Short TMW-Newborn intervention video with questions interspersed.

- Participant completes pre-intervention surveys: Baby SPEAK and non-identifying demographics items. These surveys take approximately 10 minutes to complete.
- Participant views TMW-Newborn intervention video, according to her randomized assignment outlined above.
- Participant completes post-intervention surveys: Baby SPEAK, UNHS, and fidelity of implementation.

The hearing screener, nurse, or volunteer will be notified via the TMW Tech Platform to pick up the tablet from the participant upon intervention completion or whenever the participant opts out.

No identifying information is collected within the TMW-Newborn web platform, and the hearing screening technicians will not be able to see or access any of the participants' responses.

This study protocol will only be used at Sacred Heart Hospital, University of Chicago Medical Center, and Baptist Hospital-Pensacola.

Randomization
The hearing screener, nurse, or volunteer will drop off tablets with participants, and only after the participants agree to participate by completing the tablet based consent will they be assigned to one of the four treatment conditions. The TMW-Newborn Web Platform will house the randomization tool that will randomize each participant into one of four treatment groups:

1. Long TMW-Newborn intervention video without questions interspersed,
2. Long TMW-Newborn intervention video with questions interspersed,
3. Short TMW-Newborn intervention video without questions interspersed, or
4. Short TMW-Newborn intervention video with questions interspersed.

There is equal likelihood of each randomization condition occurring.

Participants
Participants will include a goal of 10,000 new mothers at Sacred Heart Hospital, University of Chicago Medical Center, and Baptist Hospital-Pensacola. 2,500 will be randomized into each of the four implementation conditions outlined above.

Exclusion criteria
Individuals that do not have a live birth at Sacred Heart Hospital, University of Chicago Medical Center, or Baptist Hospital-Pensacola or do not receive the UNHS at one of these locations will not be eligible for this study.

Payment
Participants will not be compensated.

Risks and Benefits
Risks are minimal as testing only involves answering a questionnaire and providing demographic information. The data will be stored in password-protected computers and stored in locked file cabinets. Benefits include increased knowledge of the importance of early childhood language and cognitive development, and increased understanding of the Universal Newborn Hearing Screening and the importance of prompt follow-up after failed hearing screens.

Analysis
Paired t-tests will be used to analyze total survey scores before and after intervention. ANOVAs will be used to evaluate differences in outcomes based on SES and other variables in various experimental groups.

Consent

Prior to enrollment, all participants will view a video of the PI, Dr. Dana Suskind (in English), or another healthcare professional (in Spanish), explaining the study, what is involved, and its risks. Written text of this consent message appears below this video. After watching the video and reviewing the consent text, mothers who want to participate may select the "I Agree" button, and will be randomized into the study. Those who do not wish to participate may select the "I Do Not Agree" button and return the tablet to the hearing screening technician. We request that a traditional written informed consent be waived, as collecting patient signatures would require us to collect identifying information in an otherwise de-identified study.

No identifying information is collected in this study. All information collected is de-identified, and will be stored under a coded numerical variable name that is not linked to any identifying information.

Hearing screening techs, research assistants, and nurses who implement the study are trained to address patient questions as outlined in the Quick Guide. Patients with questions not immediately resolved per the Quick Guide guidelines will be referred to the TMW study team.

Confidentiality

The raw data will only be made available to the PI and study personnel listed on the protocol. Survey participants' will be stored under numerical codes and will not contain any identifying information. The data will be carefully monitored to protect patient privacy.

Recruitment

The hearing screening tech, research assistant, or nurse will offer participation to all eligible subjects on the maternity ward. All mothers on the maternity ward or present in the NICU at Sacred Heart Hospital, University of Chicago Medical Center, or Baptist Hospital-Pensacola during the study protocol will be eligble to participate.

There will be no use of advertisements or additional materials for recruitment purposes. The hearing screening tech or research assistant will offer study participation to mothers in their rooms at the start of the newborn's hearing screening. The Welcome and Consent Video in the TMW Tech Platform will describe the study in detail.

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