Pilot Adaptive Tool To Encourage Risk reduction in iNfancy (PATTERN)

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Purpose of the Study

The primary objective of this study is to collect information on feasibility and acceptability of an adaptive design for behavior change in obesity risk reduction. The hypothesis is that there will be high parent-reported acceptability at 6 months after undergoing the intervention pathways.

Background & Significance

Obesity is a public health crisis with significant disparities and roots in the first years of life. Obesity prevalence among Hispanic and non-Hispanic black populations is high and begins early, with infants more likely to have high infant weight-for-length from birth to 2 years of age. A recent detailed analysis of the Early Childhood Longitudinal Study Birth Cohort determined that weight gain in the first 9 months of life was the most important contributor to early childhood obesity and infancy weight gain varied significantly by race/ethnicity. Differences in the rate of infant weight gain accounted for 71% of the explained gap in BMI z-score between white and African-American boys. Using a “one-size-fits-all” approach to early obesity risk reduction among racial and ethnic minorities without exploring beliefs is inappropriate and likely to be unsuccessful.

Design & Procedures

This is a behavior change intervention with the primary intervention is targeted support messages relevant to three main domains: feeding, sleep, and physical activity. Participants will be screened for eligibility and if eligible and they consent, complete a questionnaire identifying current potential risks for obesity in infancy. Once one of the three domains is identified, parents will be given targeted educational and supportive messaging relevant to the domain (delivered to participants using a standardized script, which has been uploaded). For example, if the parent identifies mixed bottle and breast feeding and mother desires to breastfeed more, the parent will be given information on breastfeeding sufficiency and connected with lactation support. There will be an interim period of 1-2 months, at which point the risk and parent desires are reassessed and if the goal for intervention is not met, the dyad is randomized to either: 1) receive messages and tools relevant to a second domain or; 2) step up the messaging in the existing domain to include connecting with families between regular visits, essentially doubling the contact with the behavior change messaging. There will be 3 possible in-person contact points corresponding to well child care visits around the time of enrollment (when the child is between 2 weeks and 2 months of age, 6-10 weeks later, and 16-18 weeks later). There will be 4 potential by-phone contact points in the “stepped up” intervention arm. The final end point will be at 9 months and occur in person or by phone.

Participants will complete a questionnaire at each timepoint about their baby's feeding, sleep, and activity. This will be done in person at their baby's clinic appointment, or by phone.

The study team will abstract infant growth data from the EMR for well child visits from enrollment through 12 months of age, including: infant name, date of visit, length, weight, WFL.

We will also be recording information about the follow-up calls including: date of attempt, duration, if contact was made, context and content of call.

Selection of Subjects

Inclusion: non-Hispanic black (as documented in MaestroCare) parents/caregivers with; infants seen in the DCPC Roxboro Road, Brier Creek, or South Durham, under 2 months of age, birthweight between 2500 and 4000g, gestational age is at least 36 weeks.

Exclusion: non-English-speaking; infant with serious disease or disorder affecting growth and nutrition

Subject Recruitment and Compensation

In person recruitment: The study team member (either PI or CRC) will approach parent/caregiver confidentially to discuss study; if they are on restricted research communication, the study team will have a provider or nurse ask the family if it is okay for us to approach them. Phone recruitment: the study team member will call the parent/caregiver after the baby has had their clinic appointment to discuss the study; alternatively, the study team may ask the provider to mention the study to the family and let them know that we will follow up by phone unless the provider tells us otherwise.

The study is focused on racial and ethnic disparities in obesity, and therefore the population of interest is black parents and families. Otherwise, the limited exclusion criteria should provide an equitable opportunity to participate. 40 dyads will be recruited and each parent/caregiver will be given a $20 payment on a Clincard for their time participating in each of 3 possible in-person (or phone, if needed) contact points corresponding to well child care visits to compensate for time with surveys.

Risk/Benefit Assessment

There are no forseeable risks other than potential psychological risk of asking about infant health, feeding, and sleep and supporting changes to these activities. The participants will be allowed to defer or not respond to any questions or engage in any conversation themes that make them uncomfortable and can withdraw at any time. The benefits to participants are related to reflection on their parenting related to an infant. No other forseeable direct benefits to patients other than the improvement of potential interventions that their child or subsequent child may benefit from in a later study.

Data Analysis & Statistical Considerations

Analysis of the primary outcome will be description of feasibility and acceptability components collected throughout the study and at the endpoint corresponding to the infant's 9 month well visit. Analysis will be descriptive. Given small sample size and qualitative focus, there are no sample size calculations or quantitative statistical methods beyond descriptive statistics.

Data & Safety Monitoring

We do not anticipate any increased risks to the infants while carrying out this research. There is a small possibility that infants of parents receiving feeding related guidance may have noticeable growth changes. Parents will be told that they are able to feed the usual volume as required by the infant, and will not be given specific information on the volume to feed. However, some parents may interpret using, for example, smaller bottles and needing to feed a smaller volume than is needed by the infant. Due to regular follow up at 1, 2, 4, 6, and 9 months, these infants' growth will be regularly monitored by both our research team and the primary pediatrics. If for any reason at these visits, an infant's growth is dropping below the 3rd percentile weight-for-age, plateauing, or decreasing, the infant's provider will diagnose and intervene as appropriate, and contact the research team to review, who will also review the records. The clinical research coordinator and I will regularly monitor each enrolled infant's growth throughout the course of the study, and if growth faltering is detected, we will contact the family in addition to the primary provider of the patient.