A community-based music enrichment program to address health and developmental disparities during early childhood

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Study Protocol

The study procedures were approved by the Institutional Review Board at Children's Mercy Hospital. Interested parents were screened via an online questionnaire or in-person interview at a hospital-affiliated primary care clinic. Eligible families were scheduled for two baseline assessment visits: a home visit (~45 min) followed by a lab visit (~45 min). When researchers arrived at the home, parents were given a brief description of study protocols and completed a consent form for their participation and the infant's participation. During the visit, parents filled out study questionnaires. Parents were then provided with instructions to record two days of the infant's natural language environment using the Language Environment Analysis (LENA) devices. Before leaving their home, parents scheduled their second lab assessment visit. This visit was scheduled during a time when the parent felt the infant would be awake, alert, and willing to do the food/non-food reinforcement task. Parents were instructed to avoid feeding their child one hour prior to the visit and to provide the infant's favorite solid food for the food portion of the task. Upon the family's arrival to the lab, researchers interacted with the infants, establishing rapport by using toys and reading books. While infants became familiar with the researchers, parents completed study questionnaires. This orientation period lasted 5–10 min, until the infant had acclimated to their surroundings, as confirmed by the parent. Then, the child was placed in a highchair next to the parent to avoid separation anxiety and stranger anxiety. Parents were informed not to interact with the child during any of the research tasks. After the food/non-food reinforcement task, research staff measured the height and weight of the parent and infant.

After completing both baseline assessment appointments, families were randomly assigned to the music or control group. Families completed follow-up assessments using the same procedure after their first semester (8-week) and second semester (16-week). When possible, the same research staff ran appointments so that families remained familiar with the staff, especially the researcher who delivered the reinforcers to the infants. Lastly, we sent out a parent satisfaction survey via email to all enrolled families to assess the acceptability of the intervention.

Data Analysis Plan

Group baseline characteristics were compared using ANOVA or Pearson's chi-square test for frequency data. We performed an intention-to-treat analysis using all randomly assigned participants, including participants who dropped out of the program. The primary outcomes (RRV_{food} and home environmental enrichment measures) were analyzed with a mixed-model ANOVA, which handles missing data at random using maximum likelihood estimation and retains all randomly assigned subjects in the analysis. In an effort to choose a reasonably fitted model satisfying the model assumptions, the residual plots and the residual-based fit statistics, such as Akaike's Information Criterion, for various covariance structures were examined. The models included group, time (base- line, mid-, and post-intervention), and the group

× time interaction as class variables using the unstructured (UN) covariance structure. As a sensitivity analysis, we also per- formed repeated measures ANOVA for those who had complete data for all timepoints (i.e., the completers). Effect sizes were reported as partial eta squared for mixed model ANOVA, and eta-squares were converted to Cohen's f to ease model comparison. Effect sizes for repeated measures ANOVA similarly were computed from partial eta square and converted to Cohen's f using G*Power 3.1.9.6. Though *p*-values can inform whether an effect exists, Cohen's f can help to assess the strength of that effect and contextualize the results. Given the small sample size, we focus on interpreting group differences when there are medium (0.25) to large (0.4) effect size estimates. Since our study is a pilot study, knowing the expected effect size can inform power analyses for sample size determination of a future larger RCT. All models were performed using PROC MIXED in SAS version 9.4 (©2020, SAS Institute, Cary, NC, USA).