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Adherence to Care for Children With Congenital Zika Virus Infection in Puerto Rico

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Brief Study Protocol and Methods

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Puerto Rico Department of Health (DOH) guidelines for follow-up of children with possible congenital Zika virus infection recommend developmental monitoring every 6 months from 12 to 60 months of age. We conducted a pilot randomized trial of *Aquí Para Ti*, a 5-session theory-based psychosocial intervention delivered by a community health worker that uses a problem-solving approach and tailored health communication tools to improve adherence to pediatric care.

Intervention design

We recruited caregiver-child dyads to observe outcomes in both. We randomly assigned 50 caregiver-child dyad participants through computer-generated allocation sequence to either the intervention (n=25) or an enhanced control condition (n=25) (ECC). This sample size is consistent with recommendations for randomized pilot studies for preliminary estimation of effect sizes and lower bounds. Randomization occurred at the level of the individual participant, stratified by clinic and the presence or absence of congenital abnormality in the child at the time of enrollment.

Community health worker (CHW) group: The intervention, *Aquí Para Ti*, is by delivered community health workers (CHWs). In this pilot randomized trial, the CHW was a Spanish-speaking clinical research coordinator with experience in public health and a bachelor's degree. Study staff devoted significant time to training the CHW in the intervention protocol. Members of the study staff who developed the intervention were an infectious diseases physician, psychologist, and pediatrician/neonatologists. They trained the CHW in the intervention manual. Due to public health requirements of the COVID-19 public health emergency, CHW training occurred by video conference and involved training in HIPAA-compliance, basic neurodevelopment, congenital Zika virus infection, and the intervention manual. Training occurred through didactic sessions, role-playing, and audio recording of practice sessions with opportunities for feedback. CHWs were supervised in weekly one-hour sessions by videoconference, which allowed for problem-solving issues raised in the sessions.

Participants randomized to the intervention received 5 one-hour sessions with the CHW over six months. Sessions occurred by video conference due to the COVID-19 pandemic public health restrictions. Each session focused on barriers to pediatric Zika services that were raised in our preceding qualitative research. Session 1 is an orientation to the program and focuses on setting goals and balancing priorities. Session 2 focuses on understanding the importance of pediatric care, child development, and the role of the Ages and Stages Questionnaire in monitoring child development. Session 3 focuses on communicating with the pediatrician. Session 4 focuses on training the caregiver in skills for telehealth. Session 5 focuses on reviewing themes from the prior sessions to prepare for future barriers to adherence to pediatrics services.

At each session, the CHW elicits the participant's knowledge (e.g. importance of adherence to pediatric services, caregiver burden, perceived need for pediatric care). The CHW evokes and selectively reinforces the participant's self-motivational statements, focusing on empathy, eliciting change talk, addressing barriers through problem-solving, and promoting self-efficacy. A key feature is the development of activation and self-efficacy to engage in adherence so that participants can sustain adherence behavior. Each visit closes with defining action steps and practice assignments (e.g. finding transportation, meeting with the pediatrician). The sessions incorporate multimedia health communication content developed by the research team with a multimedia company based on formative research with caregivers of children with congenital Zika virus infection in Puerto Rico and their providers. The health communication tools focus on barriers to Zika services and communication with pediatric providers.

Enhanced care condition (ECC): In ECC, participants receive brief five locator outreach calls over 6 months. The CHW also offers printed educational material from the Puerto Rico Department of Health on child development. No navigation services are provided. We chose an ECC design with a general wellness component to reduce the likelihood that intervention effects detected in the intervention arm were not due to nonspecific characteristics such as interaction with study staff.

Data elements: The primary outcome was attendance in ≥1 routine pediatric appointment in months 0–6 post-randomization. The secondary outcomes were attendance in routine pediatric care in both months 0–6 and 7–12 and detection of a new Zika-associated neurodevelopmental abnormalities at months 0–6 and 0–6 and 7–12. An appointment was defined as a routine outpatient pediatric appointment for neurodevelopmental monitoring. A neurodevelopmental abnormality was based on consensus guidelines from the University of Puerto Rico School of Medicine Medical Sciences Department of Pediatrics and Puerto Rico Department of Health criteria, which were based on Centers for Disease Control definitions of anomalies possibly associated with congenital Zika virus infection. Medical records were from the Puerto Rico Department of Health and the University of Puerto Rico Medical Sciences Campus High Risk Clinic in the Department of Pediatrics. Two independent reviewers blinded to participant allocation extracted outcomes from medical records.

Statistical analysis: Participant sociodemographic and clinical characteristics were summarized by intervention allocation with Chi-square tests and t-tests. The primary analysis used the intention-to-treat approach. The primary analysis compared those randomized to the intervention compared with those randomized to the enhanced control condition. We compared the detection rate of a new birth defect or neurodevelopmental abnormality possibly associated with congenital Zika virus infection for each participant from baseline to month 6 and baseline to month 12 using Fisher's exact tests.