Prenatally-initiated Psychological Intervention for Mothers of Infants With Congenital Heart Disease (CHD)

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 18 years and over
Healthy Volunteers: This study is NOT accepting healthy volunteers
Both mothers and infants are study participants.

Inclusion Criteria:

1. Pregnant individual carrying a fetus diagnosed with CHD or biological mother of an infant diagnosed with CHD in the neonatal period.
2. Fetus or newborn with CHD anticipated to require cardiac surgery or transcatheter intervention in the first 30 days of life.
3. CHD diagnosis received between 16.0 and 30.0 weeks gestation.
4. Singleton pregnancy.
5. Pregnant mother is planning to continue the pregnancy and pursue surgical or transcatheter intervention for the infant.

5. Pregnant mother is able to participate and complete study assessments in English or Spanish.

Exclusion Criteria:

1. Mother, fetal, or infant medical condition determined by a treating clinician to be contraindicative to study participation.
2. Mother with a severe, untreated psychiatric condition, substance use disorder, or other circumstances that, in the opinion of the investigator, would interfere with engagement with study tasks or safe participation in the trial.
3. Mother with a moderate to severe intellectual disability or is otherwise unable to provide informed consent.
4. Postnatal diagnosis of CHD.
5. Fetus with a comorbid condition with a predictable and major impact on neurodevelopment (e.g., Trisomy 21, DiGeorge syndrome).
6. Pregnant individual is aged <18 years.
7. Pregnant individual is carrying a surrogate pregnancy.
8. Consented mother completes <70% of survey questions at first (baseline) assessment.

Conditions & Interventions

Interventions:
OTHER: HeartGPS
Conditions:
Congenital Heart Disease (CHD)
Keywords:
HeartGPS, CHD, intervention, Parent mental health, Neurodevelopment

More Information

Description:
This is a two-arm, prospective, longitudinal, randomized controlled trial (RCT) that will compare usual care to usual care plus a prenatally initiated, virtually administered psychological intervention, called HeartGPS.

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Phase: NA
IRB Number:
System ID: NCT07582861

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