

HeartGPS: A Study Exploring the Effects of a Psychological Intervention for Parents and Their Babies After Prenatal Cardiac Diagnosis

Status: RECRUITING

Eligibility Criteria

Sex: ALL

Age: 18 years and over

Healthy Volunteers: This study is NOT accepting healthy volunteers

Inclusion Criteria

1. Pregnant person carrying a fetus diagnosed with single ventricle congenital heart disease (CHD).
2. Single ventricle CHD diagnosis between 16 and 30 weeks gestation.
3. Singleton pregnancy.
4. Pregnant person is planning to continue with the pregnancy.
5. Pregnant person is able to participate and complete study assessments in English.

Exclusion Criteria

1. Fetus with comorbid condition with a predictable adverse impact on neurodevelopment (e.g., DiGeorge Syndrome).
2. Fetal or maternal medical condition determined by treating physician to be contraindicated to study participation.
3. Parent with an untreated major psychiatric condition, substance use disorder, or other circumstances that would interfere with study engagement or safe participation in the trial.
4. Parent with a moderate to severe intellectual disability.
5. Parent age <18 years.
6. Surrogate for pregnancy.

Prenatal administration of oral or intravenous corticosteroids for fetal lung maturation will be recorded but are not a reason for exclusion.

Conditions & Interventions

Interventions:

BEHAVIORAL: HeartGPS

Conditions:

Heart Defects, Congenital, Anxiety in Pregnancy, Depression, Postpartum, Trauma, Psychological, Neurodevelopmental Disorders

Keywords:

Congenital Heart Disease, Prenatal, Mental Health, Neurodevelopment, Neurobehavior, Fetal Cardiology, Psychological Intervention, Mother-Infant Attachment, Mother-Infant Bonding, Medical Traumatic Stress, Neuroimaging, Brain Development, Fetal Neuroimaging, Perinatal Mental Health, Medical Psychology

More Information

Description:

Babies with single ventricle congenital heart disease (SVCHD) are often diagnosed during pregnancy. While prenatal diagnosis has important clinical benefits, it is often stressful and overwhelming for parents, and many express a need for psychological support. HeartGPS is a psychological intervention for parents who receive their baby's diagnosis of SVCHD during pregnancy. It includes 8 sessions with a psychologist, coupled with tailored educational resources, and a personalized care plan. The intervention focuses on fostering parent psychological adjustment and wellbeing, and supporting parents to bond with their baby in ways that feel right for them. Through this study, the investigators will learn if HeartGPS is useful and effective for parents and their babies when it is offered in addition to usual fetal cardiac care. The investigators will examine the effects of the HeartGPS intervention on parental anxiety, depression, and traumatic stress; fetal and infant brain development; parent-infant bonding; and infant neurobehavioral and neurodevelopmental outcomes. The investigators will also explore mechanisms associated with stress biology during pregnancy, infant brain development and neurodevelopmental outcomes, and parent and infant intervention effects.

Contact(s): - heartgps@cchmc.org

Principal Investigator:

Principal Investigator ID:

Phase: NA

IRB Number:

System ID: NCT06175104

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