

What is this study about?

Learning about your baby's heart condition during pregnancy is unexpected and stressful, and many parents express a need for support.

Working with families and heart care teams, we have developed a program that provides emotional support for parents after prenatal diagnosis of single ventricle heart disease.

We call this program **HeartGPS** because it helps:

- **G**uide parents through emotions
- **P**rovide information and support
- **S**trengthen connections

In this study, we want to learn if **HeartGPS** is useful and effective for parents and their babies when it is offered in addition to their usual care.



Guiding through emotions
Provide information and support
Strengthening connections



Contact us about this study

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Together on this journey

A study exploring the effects of a new psychological support program for parents after prenatal diagnosis of single ventricle heart disease

What is HeartGPS?

We designed **HeartGPS** to support parents during pregnancy as they learn about their baby's heart condition. The program includes 8 virtual sessions with a psychologist, information resources, and a personalized support plan. It focuses on increasing support and wellbeing, as well as helping parents to bond with their baby in ways that feel right for them.

What is usual care?

In usual care, parents receive all the information, support, and resources offered by their heart care team. This may include support from your doctor or nurse, a social worker, psychologist, or support group, as well as information booklets and websites. Your heart care team can provide more information about the supports and resources available to you and your family.

If you choose to take part in this study you will be assigned at random to receive either usual care or usual care plus HeartGPS.

Who can participate?

You can join the study any time before 30 weeks gestation. You are eligible if you:

- Receive a prenatal diagnosis of single ventricle heart disease
- Are having one baby (not twins or triplets)
- Are at least 18 years old
- Speak English
- Are willing to take part in HeartGPS

Our team can provide more information about study eligibility and participation.

How long does the study last?

The study begins in pregnancy and ends when baby is about 12 months old.

What will I do in this study?

In the study, you will be asked to:

- Fill out online surveys at home
- Provide saliva samples
- Provide a blood sample
- Donate some placental tissue after baby's birth
- Participate in a scan of baby during pregnancy, at about 35 weeks gestation
- Participate in a short (5 minute) play activity with baby at your heart center

For babies in the study, we will:

- Collect saliva samples at your heart center
- Collect a blood sample
- Assess baby's development and have a brain scan when they are about 28 days old
- Assess baby's development when they are about 12 months old

Will I be paid to be in this study?

Participants can receive up to \$340 as compensation for their involvement in the study.

Participating heart centers

- Cincinnati Children's Hospital Medical Center
- Children's Hospital Los Angeles
- Vanderbilt University Medical Center
- The Children's Hospital at Westmead
- Sydney Children's Hospital at Randwick

How can I learn more?

cincinnatichildrens.org/heartgps

