

We invite eligible pregnant women to enroll in an important study.

# Heart2HEART Study

## Developing Brain Institute

### What is the study about?

We are studying whether a prenatal maternal Cognitive Behavior Therapy (CBT) intervention could improve maternal and infant outcomes in pregnant women carrying fetuses with a diagnosis of congenital heart disease (CHD).

### Do I qualify for this study?

If your baby's cardiologist determines that your baby has CHD, you and your baby could be eligible for this study. If you are unsure whether you qualify, you should ask your cardiologist or you can call us and we will check with your doctor.

### What happens if I join this study?

By joining this study:

- You will complete questionnaires remotely to describe your mood, overall health and to measure psychological stress.
- We will ask you to provide a small sample of your saliva to measure stress hormones.
- You will be randomly assigned to participate in a CBT intervention or continue to receive usual care. If randomized to CBT, you will complete virtual sessions with a licensed psychologist before and after your baby is born.
- Before your baby is born, you will have the option to meet us to take special pictures (or scans) of your baby using safe, non-invasive MRI.

After your baby is born, we will follow up with you and your baby.

- You will complete a number of questionnaires remotely at 6 weeks, 3 months, 12 months and 18 months after giving birth.

### Joining the study will NOT:

- Harm your baby in any way.
- Change the way your doctors manage your pregnancy or your baby.
- Divulge your or your baby's identity to anyone else outside the study, except to ensure your safety.

### How do I benefit from participation?

We anticipate that the CBT intervention will reduce anxiety and stress experienced during and after your pregnancy, providing potential benefits to both of you and your baby. If we see anything unusual on the MRI, we will tell you and your doctor, with your written consent.

### You will receive:

- Free parking during your visits to Children's National.
- \$75 compensation after each in-person visit in gratitude for your participation in the study.
- Another \$50 for completing both the online prenatal (\$25) and postnatal (\$25) questionnaires.
- MRI pictures of your baby.

### I want to enroll. What do I do next?

If you would like to hear more about Heart2HEART, contact our research team at:

Email: [FetalBrain@ChildrensNational.org](mailto:FetalBrain@ChildrensNational.org)

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