A Pragmatic Clinical Trial of the WE BEAT Well-Being Education Program in Adolescent Congenital Heart Disease: WE BEAT CHD Study

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 12 years to 17 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

- Age 12-17 years old
- CHD of moderate or severe complexity (Class II/III, 2018 AHA/ACC ACHD, Table 4)
- English or Spanish language proficiency
- Receives cardiology care at a PHN or PHN auxiliary site
- Parent or guardian and participant willing to comply with protocol and provide written/electronic informed consent and assent

Exclusion Criteria:

- CHD of mild or simple complexity (Class I, 2018 AHA/ACC ACHD, Table 4)
- Prior heart transplant to treat CHD
- Heart disease that is not classified as structural CHD (e.g., connective tissue disease, genetic cardiomyopathy, or acquired heart disease)
- Cognitive or developmental conditions that limit program participation and/or ability to complete self-reported measures as determined by a primary cardiology clinician
- Suicidality, homicidality, or psychosis in the past 12 months as per medical chart review, clinician report, or eligibility screening
- Medically unable to participate (e.g., intubated, unable to respond verbally, active delirium)

Conditions & Interventions

Interventions:
BEHAVIORAL: Telemedicine-based resiliency-building intervention
Conditions:
Patient-Reported Outcome Measures (PROMs), Pragmatic Trial, Adolescent Congenital Heart Disease, Resiliency-building Intervention, Resilience, Psychological, Telemedicine-Based Education
Keywords:
WE BEAT, Well-Being Education Program, Adolescent CHD, Pragmatic Clinical Trial, Telemedicine

More Information

Description:
The goal of this pragmatic clinical trial is to learn if the WE BEAT program, a 5-week group-based online wellbeing and skill-building program, can help teens with congenital heart disease (CHD) improve their ability to handle stress. The main question it aims to answer is if participants who receive the WE BEAT program become more resilient (the ability to bounce back from from tough times or recover from something difficult) and have better quality of life compared to participants who receive usual care. The study also aims to learn if there are connections between participant-reported psychosocial data (such as resilience, feelings about one's life and one's physical, mental, and social wellbeing) and clinical outcomes. Eligible participants who are 12-17-year-old will be in the study for about 6 months and be randomized to receive either the WE BEAT program or usual care. Following completion of the primary WE BEAT intervention at Week 5, intervention arm participants will be randomized to a single-session booster session (occurring at Week 18) vs no booster session. The booster session will be provided in a similar format to the WE BEAT program. A review of all modules/skills introduced in the program will be provided. All participants will complete 4 sets of online surveys and give 3 hair/saliva samples at different timepoints. Some participants may volunteer to give optional blood and urine samples.

Contact(s): Elise Pickering - Elise.Pickering@cchmc.org
Principal Investigator:
Principal Investigator ID:
Phase: NA
IRB Number:
System ID: NCT07525843