

**Expanding the Family Check-Up in Early Childhood to Promote Cardiovascular Health  
of Mothers and Young Children (NCT05473767)**

**Study Protocol**

**University Of Pittsburgh IRB STUDY22020096 Approved 4/5/2022**

At Magee, based on medical records, pregnant and postpartum women meeting the study eligibility criteria will be asked to join the study. Following enrollment, mothers will be randomized to one of two groups: FCU-Heart (intervention) or FCU Alone (usual care comparison). The FCU begins with an assessment of parent-child interaction quality, caregiver psychological resources and support, and child risk/promotive factors. FCU assessments are typically one hour in length; using only 30 minutes to complete the FCU alone ecological assessment provides another 30 minutes for evaluating maternal and infant CVH.

**Intervention:** A Family Check-Up family coach will meet with families for a “check-up” about the child’s development and behavior and how to improve their own well-being to support the child’s development. The Family Check-Up typically takes place over the course of 3-5 sessions, each about an hour long. These meetings take place at home or wherever is most convenient including virtually online.

- First, a trained Family Check-Up family coach will conduct an “Initial Interview.” The second step is completing questionnaires about the child and family relationships and social support. An important part of this second step is the family interaction tasks, where mother and child will take part in activities like playing together with toys and puzzles. The Family Check-Up family coach will then highlight parenting strengths during the third meeting, called the Feedback Session.
- Assessments also include measurement of your blood pressure, body mass index, diet quality, exercise, smoking. During the Feedback Session, the Family Check-Up family coach will meet with you for a conversation about strengths and challenges for your child and family as a whole. You’ll be invited to set goals for you and your child to support and maintain strengths, and to address any areas of concern.
- After the Feedback Session families have the option to continue meeting with your family coach to support the child’s development and improve parental well-being.

Participants randomly selected to participate in the Family Check-Up Heart program will also receive information about healthy eating and weight loss, stress management, and smoking and to monitor weight and blood pressure. ENRICH foundational modules will be incorporated as appropriate.

**Maternal CVH:** BP and BMI will be assessed using validated Bluetooth devices and following standardized research protocols. Diet quality will be assessed using the Rapid

Eating Assessment for Participants (REAP-S). Physical activity in mothers will be assessed using (1) the Pregnancy physical activity questionnaire (PPAQ), which measures active and sedentary behavior and (2) bluetooth data from Fitbit devices using standardized research protocols. Smoking will be assessed via questionnaire. These measures allow feedback by the family coaches.

The blood pressure and weight data measured by the iHealth devices is transmitted via Bluetooth to the participant's personal device and loaded into the installed iHealth app. From there, the iHealth app securely transmits the BP data to the participant's iHealth cloud account. Our team will make API requests to download the data from the iHealth cloud to a secure UPMC server and upload it to a REDCap database. The same process will be used to collect Fitbit activity data from the Fitbit app and cloud account. Data transfer over the internet using either the iHealth Cloud API, the Fitbit API, or the REDCap API is secure and encrypted (using the HTTPS protocol). The iHealth and Fitbit cloud data access are authorized at the time of recruitment and are valid for one year. The participant is also able to revoke the access anytime in her iHealth cloud account or the Fitbit cloud account.

Outcomes CVH assessments at 6 months will be conducted remotely when possible for the FCU Alone control group. Control group participants will be sent a body weight scale and BP cuff when they are due for their 6 month measurements. After they receive them, staff will facilitate the measurements virtually and let them keep the devices. We will do in person assessments only as needed, and will provide the scales and BP cuffs to keep at study conclusion.

All participants will be given a handout from NHLBI (uploaded in local supporting documents section) at the study conclusion after they complete the 6-month outcomes assessment. They will also be provided with the American Heart Association's web page that addresses understanding blood pressure readings. If the outcome readings are elevated or high, they will also be advised to consult with their doctor.

Child CVH will be assessed with BP and BMI. BP will be measured following a standardized research protocol using a pediatric-sized cuff.

Implementation measures. We will assess the implementation of the FCU-Heart by collecting data on key implementation measures based on modified FRAME-IT model for early intervention (includes feasibility, reach,

acceptability, maintenance, equity, implementation, and tailorability). At the completion of the FCU and FCU-Heart interventions (6 months), participants will complete a brief acceptability and satisfaction survey, including the Working Alliance Inventory. We will conduct qualitative interviews with FCU-Heart family coaches to assess their perspectives on feasibility, appropriateness of the intervention, and barriers/facilitators of implementation. Program enrollment and completion of sessions will be used to assess feasibility and family engagement. The digital literacy scale will also be administered at 6 months to test whether this construct has an impact on overall engagement in intervention or on engaging in remote/virtual intervention sessions vs in person.

All participants in both groups will receive referral for additional services based on needs identified during the FCU (e.g., developmental services/ Early Intervention, parent/child mental health). In addition, we will communicate findings from assessments performed as part of the FCU and facilitate communication with pediatric providers and/or referrals following the Pitt pediatric teams' routine practice. Participants in the control group who are identified as having elevated blood pressure will be given a handout from NHLBI (uploaded in local supporting documents section) and will be advised to consult with their doctor.

Protected health information (PHI) will be collected for the proposed research project. Participants will be asked to provide access to their electronic medical records (EMRs) and their child's electronic medical record (EMR) during the informed consent process. Upon enrollment in the study, all participants will be assigned a unique study identifier; this study ID is used in place of identifying PHI on all study documents with the exception of the informed consent form.

After a participant gives birth, the study team will mail a greeting card congratulating them on the birth of their baby.

In the event that a participant loses their pregnancy or their infant, the study team will send a greeting card expressing sympathy and offering referrals to grief support, if desired. The participant will be withdrawn from the study.