“A Study to Improve Physician-Youth Communication and Medical Decision Making (CHATT)”

NCT05835063

Date: 2/9/2024

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

CAREGIVER

NAME OF STUDY AND RESEARCHERS

Title of Project: WE CHATT: A Pilot Study to Improve Physician-Youth Communication and Medical Decision Making

Principal Investigator: Melissa Cousino, PhD, Associate Professor of Pediatrics, Medical School, MM Pediatrics-Psychology

GENERAL INFORMATION

We're doing a study to learn more about a physician-directed, communication-focused intervention, WE CHATT. The development of WE CHATT, a decision-making tool to guide physician communication with patients, was informed by patients and their caregivers, with the goal of improving patient-centered communication for young people ages 12-24 years old with advanced heart disease. The primary outcome of this pilot study is determining feasibility and acceptability. To get information, we'd like 40 people to answer some surveys. We expect it to take about 30 minutes to complete the surveys.

Answering the surveys is voluntary. You don't have to answer if you'd rather not. You can skip any questions that you don't want to answer, whatever the reason, and you don't have to tell us why. Choosing not to answer our surveys won't affect the medical care you might receive at the University of Michigan Health System.

It's possible that some of the questions may make you feel uncomfortable. If a question makes you uncomfortable, you can just skip it and go to the next question. Dr. Cousino, study Principal Investigator and a licensed clinical psychologist, will be available to provide assessment and mental health referrals when needed for participants experiencing distress or discomfort in response to completing this study.

To keep your information confidential, we will label your survey with a code, rather than your name or any other details that someone could use to identify you. Although we'll keep a list of all the people who answered our survey, no one outside our study team will be able to figure out who answered the survey or which people gave which answers. We plan to publish what we learn from this study, but we won't include any personal information that could reveal who answered the survey.

Answering our surveys won't benefit you directly. We hope what we learn will help other people in the future. If there is information that you would like us to share with your cardiac healthcare provider team about how you would like to participate in healthcare communication, please let us know.

With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

To thank you for taking part in our study, we'll send you $25.00 gift card after you take the survey. The University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.

A description of this clinical trial may be available on www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

As a rule, the researchers will continue to use information about you until the study is over and will keep it secure until it is destroyed. Limited information about you may continue to be used after the study is over, for other research, education, or other activities. But use of this information would not reveal your identity.

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information see http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

CONTACT INFORMATION

To find out more about the study, to ask a question or express a concern about the study, or to talk about any problems you may have as a study subject, you may contact one of the following:

Principal Investigator: Melissa Cousino, PhD Mailing Address: 1500 E. Medical Center Dr., SPC Telephone: (734) 615-2577 Email: Melcousi@med.umich.edu	Study Coordinator: Cynthia Smith, RN Mailing Address: L2110 Women's, SPC 5204 Ann Arbor, MI 48109-5204 Telephone: 734-615-0590 Email: csmithw@med.umich.edu

You may also express a concern about a study by contacting the Institutional Review Board:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
734-763-4768
E-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study, you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

SIGNATURES

Research Subject:

I understand the information printed on this form. My questions so far have been answered.

Signature of Subject: _____ Date: _____

Name (Print legal name): _____

Patient ID:_____ Date of Birth: _____

Legal Representative (if applicable):

Signature of Person Legally
Authorized to Give Consent_____ Date: _____

Name (Print legal name): _____ Phone: _____

Address: _____

Check Relationship to Subject:

☐Parent ☐Spouse ☐Child ☐Sibling ☐Legal Guardian ☐Other: _____

[If this consent is for a child who is a ward of the state (for example a foster child), please tell the study team immediately. The researchers may need to contact the IRBMED.]

Reason subject is unable to sign for self:

_____

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____