

MyHEARTSMAP COVID-19 Study Consent Form

Please review the consent form below.

Thank you!

PARTICIPANT INFORMATION AND CONSENT FORM

Study Title: Using MyHEARTSMAP During the COVID-19 Pandemic to Determine the Impact on the Psychosocial Status of Canadian Children and Youth and Inform Mental Health Resource Planning

Principal Site Investigator:

Quynh Doan, MDCM, MHSc, PhD, FRCPC
Assistant Professor, Department of Pediatrics
University of British Columbia
Division of Pediatric Emergency Medicine
BC Children's Hospital
604-875-2345, ext. 3691

Co-Investigators:

Garth Meckler, MD, MSHS, University of British Columbia, BC Children's Hospital (BCCH)

Tyler Black, MD, University of British Columbia, Child and Adolescent Psychiatric Emergency [CAPE] Unit

Jana Davidson, MD, MSc, University of British Columbia, BC Children's Hospital (BCCH)

Skye Barbic, PhD, MSc, University of British Columbia, Centre for Health Evaluation & Outcome Sciences

Evelyn Stewart, MD, University of British Columbia, BC Children's Hospital (BCCH)

Sponsors: Canadian Institutes of Health Research

If you are a parent or legal guardian of a child who may take part in this study, permission from you and the assent (agreement) of your child may be required. When we say "you" or "your" in this consent form, we mean you and/or your child; "we" means the doctors and other staff.

1. Invitation

You are invited to take part in this study because you are under the age of 18 and a resident of British Columbia.

2. Your participation is voluntary

Your participation is voluntary. You have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences to the medical care, education, or other services to which you are entitled or are presently receiving.

Please take time to read the following information carefully and to discuss it with your family and friends before you decide.

3. Who is conducting this study?

This study is being conducted by a research team that consists of clinicians that work in the pediatric emergency department and researchers at the University of British Columbia and BC Children's Hospital.

4. Background

Since the time COVID-19 was declared a pandemic, provinces across Canada have implemented public health responses that include social distancing, school closures, and limiting non-essential travel. During this challenging time, the stress and uncertainty of the pandemic, along with these necessary public health measures may have an impact on the mental health of children and teens, and we need to adjust the type and amount of resources available to our children. Since self-isolation measures limit in-person support for mental health needs, we believe that an online mental health self-assessment, MyHEARTSMAP, will help us reach families so they can learn which aspects of their mental health may be of concern, where they might benefit from support resources, and how to find these resources in BC.

This will inform us on what specific types of mental health support resources are needed to help address the needs of our children and youth in the face of the COVID-19 pandemic and guide our mental health system planning to ensure we can provide appropriate resources.

MyHEARTSMAP is a validated online self-assessment tool that screens for mental health concerns and connects children, youth and families to the right resources. In recent studies, we have used this tool to identify mental health concerns among youth in the Emergency Department (ED). MyHEARTSMAP consists of a series of 10 sections related to youth mental health, and stands for Home, Education and activities, Alcohol and drugs, Relationships and bullying, Thoughts and anxiety, Safety, Sexual health, Mood, Abuse and Professional Resources. With help from guiding questions, youth and families score the youth's mental health in each section to help identify if the youth is struggling with any mental health concerns. Based on their scores, and specifically the presence and severity of concerns identified, the tool will provide a description of appropriate mental health resources that families may access.

5. What is the purpose of the study?

The purpose of this study is to identify the frequency of mental health concerns in children and youth, as well the severity and access to resources for these concerns, to guide families to relevant mental health services in BC, and to inform further mental health resource planning during the COVID-19 pandemic.

6. Who can participate in this study?

Parents of children and youth aged 6-17 years who live in British Columbia can participate in this study. Due to the nature of the psychosocial assessment instrument, children and youth can only participate (conduct the self-assessment themselves) in this study if they are aged 10-17 years and live in British Columbia. Parents (guardians), children or youth (any number), can participate as a pair or as a single participant in the family.

7. Who should not participate in this study?

Parents and/or youth who meet any of the following criteria will not be eligible for enrolment in this study:

- Participants who have previously enrolled in this phase of the study
- Patients and/or families unable to communicate in English

8. What does this study involve?

If you decide to participate, you will be sent a link to complete our study survey. The survey will ask you for the following information:

- Your child's sex, gender, race, and sexual orientation (all optional)
- The first three characters of your postal code
- Your child's pre-pandemic health and mental health status
- Your pre-pandemic employment status
- Your child's pre-pandemic schooling status
- Your current employment status
- Your child's current schooling status
- Your household size and composition
- The number of household members that identify as an essential worker
- If any household/family members were confirmed with or hospitalized for COVID-19 and how they are doing

You and/or your child will then receive separate web links to access the MyHEARTSMAP tool and score each section based on your child's mental health. Once you are sent the link, we ask that you complete MyHEARTSMAP within one week. We will send you reminders via email if MyHEARTSMAP is not completed by day 3 and day 7.

Once you have finished the MyHEARTSMAP self-screening, you have the option to save and/or print the MyHEARTSMAP generated self-screening report and recommendations. You may use this report to share with your mental health providers when accessing them. You may choose not to follow-up with recommended supports. Recommendations and information on how to access services will be available to through the MyHEARTSMAP tool, if and when you choose to access them.

Your child will also have the option to save and/or print their MyHEARTSMAP generated self-screening report. It is up to your child if they want to share their report with you.

If your report or your child's report from the self-assessment tool triggers any severe or urgent concerns, specifically relating to safety of your child or others, a research nurse will first contact your child (if they provided their phone number) and then will contact you to check in and ensure that your family is able to access the appropriate level of care. If an imminent threat to safety is perceived and not adequately addressed, the research nurse may contact emergency support services as necessary to ensure your child's safety and the safety of those around them. Imminent threats to safety would include concerns that recommend you access crisis support lines, protective services, or the emergency department.

If the research nurse needs to contact emergency support services, your confidentiality will be broken, but this will only be done for the purpose of ensuring your child's safety and the safety of those around them.

At three months, you will be asked to complete a follow up survey and a MyHEARTSMAP self-assessment. The same procedures as above also apply for the follow up survey and MyHEARTSMAP self-assessment.

You can choose if you would like to receive a reminder about the 3-month survey and MyHEARTSMAP self-assessment over the phone or by email. If you request email reminders, we will email you with the survey and MyHEARTSMAP assessment links. Reminder emails will be sent up to five times and will stop once the survey and MyHEARTSMAP are complete. If the MyHEARTSMAP assessment and questions are not complete after five emails are sent, we will call you to remind you. We will attempt up to five phone calls.

If you request phone reminders, we will call you, and if we reach you, we will email the survey and MyHEARTSMAP assessment links. We will attempt up to five phone calls. If we do not reach you after five attempts, we will email with the links to the survey and MyHEARTSMAP self-assessment. Reminder emails will be sent up to five times and will stop once the survey and MyHEARTSMAP are complete.

We expect a total time commitment of 50 minutes for this study (30-minutes today and 20-minutes for the 3-month follow-up). We will have 510 youth participants and their families in this study across British Columbia.

9. What are my responsibilities?

If you agree to participate in this study, you will be asked to answer some questions about your child, pandemic-related information, and complete the MyHEARTSMAP self-screening assessment tool. You will also be asked to answer the same questions and the MyHEARTSMAP self-screening tool again in three months.

10. What are the possible harms and discomforts?

We do not anticipate any physical risks associated with this study. If a question makes you or your child uncomfortable, you do not have to answer it. There is a potential risk of inducing emotional stress if previously unknown mental health challenges are identified. If you or your child experience emotional stress, or if you want further information, our study team can provide you with resources. If the report presents an urgent concern, a research nurse will contact you to explore the situation and guide you to access appropriate level of care. If the research nurse perceives an imminent threat to safety that is not adequately addressed, the appropriate emergency services will be contacted.

11. What are the potential benefits of participating?

There may or may not be a direct benefit to you or your child from taking part in this study. You and your child may benefit from identification of mental health concerns, and receiving information about appropriate resources, and how to access them.

12. What if new information becomes available that may affect my decision to participate?

During the course of the study, should we learn of any information that is relevant to your participation in this study we will share this information with you.

13. What happens if I decide to withdraw my consent to participate?

You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, you have the right to request the withdrawal of your information collected during the study. This request will be respected to the extent possible. Please note however, that there may be exceptions where the data will not be able to be withdrawn. For example, where the data is no longer identifiable (meaning it cannot be linked in any way back to your identity) or where the data has been merged with other data. If you would like to request the withdrawal of your data, please let the study team know.

14. How will my taking part in this study be kept confidential?

Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the Investigator or his or her designate, and by the UBC Children's and Women's Health Centre of British Columbia Research Ethics Board for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law. You and your child's name will not be disclosed outside the study. Any report published as a result of this study will not identify you or your child by name.

You and your child's information will be kept in a highly secure, web-based application designed exclusively to support data collection for clinical research studies. The database is licensed by the BC Children's Hospital Research Institute (BCCHR) Clinical Research Support Unit (CRSU) who also keeps the application and data on servers located on site ensuring that all data and backups are housed in Canada. The database can only be accessed using a unique login and password and only specifically designated users can access the project.

You will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify you (e.g., it will not include your Personal Health Number, SIN, or your initials, etc.). Only this study number will be used on any research-related information collected about you during the course of this study. Your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate until all data is collected. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected. Further details about these laws are available on request to your study doctor.

Your electronic consent form will be stored in the BC Children's Hospital Research Institute's secured network in Vancouver, BC. Only authorized personnel will be able to access it.

We are asking to collect your email address in order to send you a copy of your electronic consent form. You need to know that emails sent to some webmail services (e.g. Gmail, Hotmail, etc.), may be stored/routed outside of Canada (for example, in the United States) and governed by foreign laws. Due to the fact that the email with your consent form will contain personal information about you, including your name, the Freedom of Information and Protection of Privacy Act requires that we obtain your consent before we continue. All of the information which you provide to us will be kept completely confidential. Providing your email address means that you voluntarily agree and give your consent for the study team to use email to communicate with you.

You do not waive any of your or your child's legal rights by signing this consent form.

By completing this study, you give permission for the collection of information on your child. At the University of British Columbia, study information is required to be kept for five years after study completion. Even if you withdraw your child from the study, the information, which is obtained for study purposes, may not be destroyed.

15. What will the study cost me?

Reimbursement: You will not be reimbursed for any study-related expenses. You will not incur any cost by participating in this study.

Renumeration: You will not be paid for participating in this study.

16. Who do I contact for information about the study during my participation?

If you have any questions or desire further information with respect to this study, you may contact Dr. Quynh Doan and the study team at myheartsmmap@bcchr.ca.

17. Who do I contact if I have any questions or concerns about my rights as a participant?

If you have any concerns about your treatment or rights as a research subject, you may contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598). Please reference the study number (H20-01658) when contacting the Complaint Line so the staff can better assist you.

18. After the study is finished:

Upon completion of the study (approximately July 2021), you may ask to receive a copy of the results by contacting the study team at myheartsmmap@bcchr.ca.

19. Future Studies:

We may want to contact you in the future for follow up studies related to this study.

If you wish or do not wish to be contacted in the future, please check the appropriate box the box below.

- Yes, I agree that a member of the research team may contact me or my child in the future for follow-up or further research related to this study.
- No, I do not want me or my child to be contacted in the future for follow-up or further research related to the study.

20. Signatures

Using MyHEARTSMAP during the COVID-19 Pandemic to Determine the Impact on the Psychosocial Status of Children and Youth and Inform Mental Health Resources Planning

Parent/Guardian Consent:

My signature on this consent form means:

- I have read and understood the information in this consent form.
- I have been able to ask questions and have had satisfactory responses to my questions.
- I understand that my participation in this study is voluntary.
- I agree to using MyHEARTSMAP to screen my child's mental health.
- I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time, and that this will not change the quality of care that my child receives.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I consent to participate in this study.
- I consent for my child to participate in this study (if applicable).

This consent form was read by the parent(s)/guardian(s)/substitute decision-maker (legally authorized representative), and both the person reading this consent form and the investigator are satisfied that the information contained in this consent form was explain was accurately explained to, and apparently understood by, the child/participant, that the child/participant was given an opportunity to ask questions, and all questions have been answered, and that the child/participant assents to participating in the research.

I will receive a signed and dated copy of this consent form for my own records.

Parent/Guardian Name:

Relationship to Child/Youth:

Parent/Guardian's email address:

I agree to participate in this study:

- Yes
 No