APPENDIX A

Model Consent Form

Consent Form to Participate in a Research Trial

Trial Title

ODYSSEE-vCHAT (**O**pen Access **D**igital Community Promoting **S**elf-Care, Peer **S**upport and Health Literacy) Pilot Trial for Chronic Heart Failure

University Health Network (UHN) Investigator / Trial Doctor(s)

Dr. Robert Nolan: (416) 340-4800 Ext. 6400 | rob.nolan@uhnresearch.ca
Please do not communicate personal or sensitive information via email as it is not secure.

Contact

Julia Wong, Research Coordinator: (416) 340-4800 Ext. 6400 | odysee@uhnresearch.ca
Please do not communicate personal or sensitive information via email as it is not secure.

Introduction

You are being asked to take part in a research trial. Please read the information about the trial presented in this form. The form includes details on the trial's risks and benefits, which you should know before you decide if you would like to take part in it. Please take as much time as you need to make your decision. You should ask the trial doctor or staff to explain anything that you do not understand. Please free to also speak with anyone you wish, such as your friends, family, and family doctor before signing this consent form. Before you make your decision, feel free to talk about this trial with anyone you wish. Participation in this trial is voluntary.

Background/Purpose

The cardiac clinics and the Division of Cardiology at the UHN are interested in developing and testing the use of a Web-based counselling application to help patients with heart failure. Based on previous work, digital counselling programs can help to improve general health and wellbeing. These interventions have also been shown to assist in reducing mortality and hospitalization, and to improve overall quality of life, which is the focus of this trial. Furthermore, home-based telehealth programs such as our ODYSSEE-vCHAT digital initiative are well-suited to effectively address the recent problem that patients are declining to attend essential outpatient appointments due to fear of COVID-19 exposure.

The digital counselling platform used in this trial is a fully automated, Web-based intervention that uses digital multimedia and interactive tools to increase motivation and self-care skills for chronic disease management. The platform consists of various learning sessions that target self-care behaviours specific for heart failure. Each logon session is designed to provide best evidence information and self-care guidelines to help you manage heart failure. It is also our aim to help you reduce your risk for being exposed to COVID-19 with the information and guidelines in our program as self-care behaviour to promote physical and emotional well-being includes

Page 1 of 8

reducing the risk of exposure to COVID-19. The purpose of this trial is to develop and test the use of an experimental digital program for heart failure patients. It will help establish the effectiveness of digital counselling in improving heart health and quality of life. The research team is interested in understanding how our experimental intervention can help empower patients and encourage them to be more actively involved in managing their heart failure with improved understanding and confidence.

You are being asked to participate because you are being treated for heart failure at one of the cardiac clinics at the UHN. The usual treatment for your heart involves being seen in the cardiac clinic and receiving recommendations to monitor various aspects of your heart failure condition such as symptoms of weight gain, fatigue, and shortness of breath. The digital counselling involved in this trial should be seen as an added complementary feature of your healthcare, and it is not designed to replace or interfere with the treatment prescribed by your cardiologist. The trial will take place over the span of about 22 months and we will recruit around 60 participants from the UHN.

Trial Design

This is a randomized, single-blind trial. This means that if you decide to participate, you will be "randomized" into one of the two trial groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor your doctor can choose what group you will be in. You will have a 50/50 chance of being placed in either group. Your doctor will not know which group you are in. In an emergency, if your group needs to be identified, your doctor can get this information. Participation in this trial will last up to about 22 months.

- If you are in group 1, you will have unlimited access to digital materials that are above and beyond the resources currently available with current medical care. These materials reflect Internet-based educational material that are provided by professional health organizations such as the UHN and the Heart Failure Society of Canada.
- If you are in group 2, you will be provided with digital counselling materials, chatrooms, and online discussions with healthcare professionals and/or other patients.

The main difference between groups 1 and 2 is in the type of materials provided and whether the support available involves the participation of other patients and practitioners. In both groups, you will be contacted via email by the program on a weekly basis to encourage you to take advantage of the resources that are available above and beyond usual care. The research team will let you know which group you are assigned to.

Visits and Procedure

If you agree to participate, you will be asked to complete the following:

- Enroll in the ODYSSEE-vCHAT program, which is a digital counselling platform that uses multimedia and interactive tools to increase motivation and self-care skills for chronic disease management

UHN Toronto General Toronto Western Princess Margaret Toronto Rehab Michener Institute

- Watch tutorial videos on how to navigate ODYSSEE-vCHAT (the research team will be available to provide assistance upon request)
- Participate in your group's activities (please note that participation in any of the following aspects of the trial is voluntary)
    - Group 1:
        - You will receive weekly emails containing links to education modules and guidelines that are available to the public on professional websites (e.g., Heart Failure Society of Canada, American Heart Association European Society of Cardiology, and Health Canada)
    - Group 2:
        - You will receive weekly emails containing links to presentations and group discussions on Zoom and corresponding chatrooms
        - You will have access to 30-minute weekly presentations and discussions over Zoom, followed by 30-minute Q&A periods
        - To protect your privacy, your camera will be turned off
        - During group discussions, you may turn on your microphone to make a comment or ask a question, or you may use the chat feature on Zoom
        - The Zoom sessions will be recorded and uploaded to a private YouTube channel to be accessed by participants freely throughout the duration of the trial
        - You will have access to chatrooms that are available at any time, where you can share comments with other participants about the weekly presentations and discussions
        - You will have the option to submit audio or video comments (up to 1 minute in length) on the weekly presentations and discussions (from suggested self-help tips to reflections about the importance or effectiveness of the self-care techniques, strategies, or behaviours)
            - We will provide instructions (and assistance, if required) on how to email your audio or video comments through FileShare
            - We will review and upload videos to our private YouTube channel to be accessed by other participants in the trial (please note that whatever information you share on the chatrooms will be available to all other participants; therefore, please limit sending any personal or personally identifying information to the chatrooms)
    - Complete a 30-minute online questionnaire package at the start of the trial, 4, 8, and 12 months into the trial, and at the end of the trial on the following:
        - Personal and social background and health history
        - Emotional and mental wellbeing
        - How heart failure has affected your lifestyle
        - Confidence in, and ability to perform, certain tasks or self-care behaviours
        - Social support and your experience of isolation or loneliness
        - Physical wellbeing
        - Use of alcohol, nicotine, and/or cannabis

Toronto General
Toronto Western
Princess Margaret
Toronto Rehab
Michener Institute

Additionally, we would like to use your health card number to link to the Ministry of Health and Long-Term Care (MOHLTC) administrative records. This is done through the Institute for

Clinical Evaluative Sciences (ICES), which is one of the four special entities under the Ontario Privacy law (PHIPA) that is allowed to collect and use health card numbers for research purposes. We are interested in tracking your Emergency Department visits, hospitalizations, and health status. Your health card number is the only way that we can identify this. Your health card number will be kept confidential and secure.

Summary of Procedures

Virtual Visits	Procedure(s)
Recruitment *~15-20 minutes*	Enrollment in the ODYSSEE-vCHAT program
Start of Trial *~30 minutes*	Questionnaire package (verbal assistance over the telephone will be provided upon request) Discussion of any trial-related questions and/or concerns
4 Months *~30 minutes*	Questionnaire package (verbal assistance over the telephone will be provided upon request)
8 Months *~30 minutes*	Questionnaire package (verbal assistance over the telephone will be provided upon request)
12 Months *~30 minutes*	Questionnaire package (verbal assistance over the telephone will be provided upon request)
End of Trial *~30 minutes*	Questionnaire package (verbal assistance over the telephone will be provided upon request) Discussion of any trial-related questions and/or concerns Feedback on experience with ODYSSEE-vCHAT program

Risks

There is a risk that you will feel uncomfortable while using ODYSSEE-vCHAT because you are not familiar with the software, or you may also feel uncomfortable using your computer to access the program. Please keep in mind that the research team is here to support you and to address any questions you may have.

You may feel uncomfortable answering certain questions posed in the questionnaire packages. If you have any concerns about your ability to answer one or more questions, please feel free to contact our office by email or telephone so that we may address your concerns. We will accommodate a refusal to respond to any question(s).

You may feel uncomfortable contributing to the weekly presentations and discussions on Zoom due to privacy concerns. Please remember that your image will not be captured as your

UHN Toronto General Toronto Western Princess Margaret Toronto Rehab Michener Institute

camera will remain disabled throughout the session. Furthermore, verbal participation is entirely voluntary. If you would like to contribute to the discussion without turning your microphone on and speaking, you may opt to use the chat feature on Zoom instead. Comments written in the chat will not be included in the recording of the session. Please do not hesitate to contact our office by email or telephone if you have any questions and/or concerns.

You may feel uncomfortable submitting an audio or video recording of your comments on the weekly presentations and discussions because you would no longer be an anonymous participant in the trial. Furthermore, these audio or video comments may be used for research and educational purposes, as well as for promoting the ODYSSEE-vCHAT program to the wider community of patients with chronic heart failure. Please note that this aspect of the trial is entirely voluntary. If you would prefer to remain anonymous, you are free to refrain from submitting an audio or video comment. We recommend that you consider providing comments in the chatrooms instead. If you have any questions and/or concerns, please do not hesitate to contact our office by email or telephone.

Benefits

You will receive direct support from your digital program in this trial, which provides information and resources for heart health, self-care, quality of life, and protection against COVID-19. Additionally, it provides resources for self-care in managing heart failure. The information learned from this trial may help us understand the different features needed to further develop and improve a digital counselling application for patients with chronic medical conditions. This will allow us to help heart failure patients in partnership with their healthcare team to better manage their disease.

Confidentiality

Your information will be entered into a data file. All personal information in your file, such as your name, date of birth, phone number, and email address, will be removed and replaced with a Participant Code. A list linking the Code with your name will be kept by the Research Coordinator in a secure place, separate from your file.

Please note that if you choose to submit an audio or video recording of yourself commenting on the weekly presentations or discussions, you would no longer be anonymous to the ODYSSEE-vCHAT community (after reviewing the content of each video, we may highlight specific videos on the ODYSSEE-vCHAT platform as examples of participant insights or comments about self-care that are helpful to the ODYSSEE-vCHAT community). We may also use these videos to promote peer support and education on self-care for the wider community of patients with heart failure in the public domain. If your video is selected for presentation to other participants in the trial, or to the public, we will notify you so that you have an opportunity to grant or withhold your permission for this use of your video. If you have any questions and/or concerns, please do not hesitate to contact our office by email or telephone.

Personal Health Information

Toronto General
Toronto Western
Princess Margaret
Toronto Rehab
Michener Institute

If you agree to join this trial, the research team will look at your personal health information and collect only the information they need for this trial. Personal health information is any information that could identify you, and includes your:

- Name
- Email address and phone number
- Date of birth (day, month, and year)
- OHIP number (we are interested in tracking your hospital visits and health status)
- Hospital medical record number (only if you are receiving treatment at a UHN clinic)
- Medical records (including current primary diagnosis and comorbidities and prescribed treatments or planned interventions within the next 6 months, such as waitlists for transplantation)
    - If you are receiving treatment at a UHN clinic, this information will be collected via electronic patient records. If you are being treated by a physician who is NOT affiliated with the UHN, we will collect this information from your doctor using a "Patient Health Information Form". We will send this form to you by email.

Research Information in Shared Clinical Records

Your participation in this trial may be noted in your hospital file and in the UHN computer system. The UHN shares the patient information stored on its computer with other hospitals and healthcare providers in Ontario so they can access the information if it is needed for your clinical care. The research team can tell you what information about you will be stored electronically and may be shared outside of the UHN. If you have any questions and/or concerns, please contact the UHN Privacy Office [(416) 340-4800 ext. 6937 or by email at privacy@uhn.ca].

The following people may come to the hospital to look at the trial records and at your personal health information to check that the information collected for the trial is correct and to make sure the trial is following proper laws and guidelines:

- Representatives of the UHN, including the UHN Research Ethics Board

The trial doctor will keep any personal health information about you in a secure and confidential location for 10 years. You will be assigned a unique identifier which will replace any identifiable information contained in the research data. A list linking your trial number with your name will be kept by the trial doctor in a secure place, separate from your trial file.

Trial Information that Does Not Identify You

All information collected during this trail, including your personal health information, will be kept confidential and will not be shared with anyone outside the trial, unless required by law. You will not be named in any reports, publications, or presentations that may come from this trial.

Voluntary Participation

Toronto General
Toronto Western
Princess Margaret
Toronto Rehab
Michener Institute

Your participation in this trial is entirely voluntary. You may decide not to be in this trial, or to be in this trial now and then change your mind later. You may refuse to participate, or you may withdraw from the trial at any time, without affecting the care you receive from your healthcare provider or the cardiac clinic. We will give you new information that is learned during the trial that might affect your decision to stay in the trial.

Withdrawal

You can also choose to leave the trial at any time. In the event that you withdraw from the trial, all information collected for the purpose of this trial up to the point of your withdrawal may be used in order to answer the research question. No new information will be collected after that point without your permission.

Costs and Reimbursements

You might incur additional charges if you are using cellular data when accessing the ODYSSEE platform on your mobile device. If you go over your coverage limit, this will result in an overcharge as per your phone contract. To avoid this, if you have limited cellular data, please connect your device to a Wi-Fi source when accessing the platform.

Rights as a Participant

If you are harmed as a direct result of taking part in this trial, all necessary medical treatment will be made available to you at no cost. By signing this form, you do not give up any of your legal rights against the investigators or involved institutions for your compensation, nor does this form relieve the investigators or involved institutions of their legal and professional responsibilities.

Questions About the Trial

If you have any questions and/or concerns or would like to speak to the research trial team for any reason, please contact Julia Wong (Research Coordinator) by telephone at (416) 340-4800 ext. 6400 or by email at odyssee@uhnresearch.ca. You may also contact the study doctor, Dr. Robert Nolan, by telephone at (416) 340-4800 ext. 6400 or by email at rob.nolan@uhnresearch.ca.

If you have any questions about your rights as a participant, or concerns about this trial, you may contact the Chair of the UHN Research Ethics Board (REB), or the Research Ethics office, at (416) 581-7849. The REB is a group of people who oversee the ethical conduct of research studies. The UHN-REB is not part of the research trial team. Everything that you discuss with them will be kept confidential.

You will be given a signed copy of this Consent Form.

UHN Toronto General Toronto Western Princess Margaret Toronto Rehab Michener Institute

Consent

This trial has been explained to me and any questions I had have been answered. I know that I may leave the trial at any time.

- I agree to the use of my information as described in this form.
- I agree to respect the autonomy and privacy of other patients in this trial. This means that if I learn about any information about another patient's treatment or self-care behaviour, I will demonstrate respect for their privacy and freedom to choose how they manage their health and life priorities without undue interference.
- I agree to recognize and respect the privacy of other participants in this trial and their right to control information about their personal life or medical history. Therefore, if I learn about any personal or medical information about any individual in this trial, I agree to keep it confidential and private>
- In sum, I agree to take part in this trial in keeping with the issues highlighted in the above paragraph.

Print Participant's Name	Participant's Signature	Date

My signature means that I have explained the trial to the participant named above. I have answered all questions.

Print Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date