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Automated digital counselling with social network support as a novel intervention for patients with heart failure: protocol for randomised controlled trial

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ABSTRACT

Introduction Heart failure (HF) symptoms improve through self-care, for which adherence remains low among patients despite the provision of education for these behaviours by clinical teams. Open Access Digital Community Promoting Self-Care, Peer Support and Health Literacy (ODYSSEE–vCHAT) combines automated digital counselling with social network support to improve mortality and morbidity, engagement with self–care materials, and health-related quality of life.

Methods and analysis Use of ODYSSEE-vCHAT via Internet-connected personal computer by 162 HF patients will be compared with a control condition over 22 months. The primary outcome is a composite index score of all-cause mortality, all-cause emergency department visits, and HF-related hospitalisation at trial completion. Secondary outcomes include individual components of the composite index, engagement with self-care materials, and patient-reported measures of physical and psychosocial well-being, disease management, health literacy, and substance use. Patients are recruited from tertiary care hospitals in Toronto, Canada and randomised on a 1:1 ratio to both arms of the trial. Online assessments occur at baseline (t=0), months 4, 8 and 12, and trial completion. Ordinal logistic regression analyses and generalised linear models will evaluate primary and secondary outcomes.

Ethics and dissemination The trial has been approved by the research ethics boards at the University Health Network (20-5960), Sunnybrook Hospital (5117), and Mount Sinai Hospital (21-022-E). Informed consent of eligible patients occurs in person or online. Findings will be shared with key stakeholders and the public. Results will allow for the preparation of a Canada-wide phase III trial to evaluate the efficacy of ODYSSEE-vCHAT in improving clinical outcomes and raising the standard of outpatient care.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This multisite, single-blind, randomised clinical trial evaluates the efficacy of a novel automated digital counselling programme with integrated social network support (Open Access Digital Community Promoting Self-Care, Peer Support and Health Literacy (ODYSSEE-vCHAT)) for heart failure (HF).
⇒ ODYSSEE-vCHAT is a patient-centred intervention: subjects communicate with healthcare professionals, patient representatives, and each other as they identify, set, and track personal goals for self-care.
⇒ ODYSSEE-vCHAT has the potential to improve outcomes of morORCID
bidity, mortality, and health-related quality of life while relieving the demand for outpatient health services.
⇒ This digital programme is not fully accessible to individuals with poor computer literacy; however, technical assistance and tutorial videos are available.
⇒ ODYSSEE-vCHAT is currently available only in English due to a lack of funding for language translations.

Trial registration number NCT04966104

INTRODUCTION

Heart failure (HF) is a chronic progressive disease characterised by deterioration of the heart's ability to pump blood to meet the metabolic demands of the body.[1] An estimated 46% rise in prevalence is expected by 2030,[2] making HF a major public health concern. Hospitalisation remains high, with over 50% of patients readmitted within 6

months of discharge.[3] A 1-year mortality rate of 20–30% follows diagnosis, and a 45% mortality rate is estimated within 5 years.[4] HF is also a significant cause of physical decline,[5–7] psychological distress,[8] social functioning,[9] and reduced health-related quality of life (HRQL).[10] An improvement in disease management and associated clinical and health status outcomes are a priority.

The cornerstone of HF management is self-care, which includes monitoring symptoms, following medication regimes, engaging in physical activity, and maintaining an adequate diet.[11] Self-care adherence is associated with reduced mortality[12–16] and increased HRQL.[17] Healthcare professionals typically provide education for HF self-care during hospitalisation or clinic appointments, supported by physical handouts and digital resources such as telehealth programmes.[18] Engagement in self-care behaviours remains low among patients despite this standard of care, with only 9–36% demonstrating moderate to high adherence.[19] Two counselling methods for self-care are highlighted in the literature: motivational interviewing (MI), which improves adherence in diverse patient populations,[20] and cognitive-behavioural therapy (CBT), which promotes long-term behavioural change[21] and psychological well-being.[22] Moreover, peer support benefits self-care in patients with chronic conditions through perceived social support.[23 24]

Open Access Digital Community Promoting Self-Care, Peer Support and Health Literacy (ODYSSEE-vCHAT) is a follow-up to our previous CHF-CePPORT (Canadian e-Platform to Promote Behavioral Self-Management in Chronic Heart Failure) trial,[25] which found that engagement with an automated digital counselling programme for HF self-care versus a control condition evoked greater engagement with self-care materials over 12 months. ODYSSEE-vCHAT builds on CHF-CePPORT[25] by supplementing its automated digital counselling method with social networking to promote self-care learning through peer support[26 27] and reinforce positive role modelling through presentations.[28] To our knowledge, this is the first digital self-care intervention for HF patients that combines components of MI and CBT with peer support. ODYSSEE-vCHAT has the potential to improve long-term self-care adherence and clinical outcomes of morbidity and mortality. This programme was developed during the global COVID-19 pandemic, which emphasised the importance of remote interventions given restrictions to face-to-face resources.[29] Compared to a control condition of enhanced usual care (eUC), ODYSSEE-vCHAT is hypothesised to improve outcomes of mortality and morbidity, engagement with self-care materials, and HRQL.

METHODS AND ANALYSIS

Outcomes

The primary objective is to evaluate the effectiveness of ODYSSEE-vCHAT in reducing a composite index of incident all-cause mortality, all-cause emergency department (ED) visits, and HF-related hospitalisation at trial completion (median=14 months, range=6-22 months).

Secondary outcomes include:

- Incidence of each component of the composite index at trial completion.
- Engagement with self-care materials at months 4, 8 and 12 and trial completion, defined by sum logon minutes, sum logons, and number of logon days before a logon lapse greater than or equal to 2 months.[25 30–32]
- Patient-reported outcomes at months 4, 8 and 12 and trial completion in: (1) HRQL (short version of the Kansas City Cardiomyopathy Questionnaire;[33] clinical interpretation based on a group difference of equal to or greater than 5 points),[34] (2) habitual engagement in activities for living well (Evaluation of Goal-Directed Behaviours to Promote Wellbeing and Health (EUROIA)), (3) overall mental health (Mental Component Summary of the 36-item Short Form Survey),[35] (4) self-care behaviours (revised 9-item European Heart Failure Self-Care Behaviour Scale),[36] (5) depression (9-item Patient Health Questionnaire),[37] (6) anxiety (7-item Generalized Anxiety Disorder Scale),[38] (7) loneliness (6-item Revised University of California, Los Angeles Loneliness Scale),[39] (8) psychological well-being (Flourishing Scale),[40] (9) disease management (Self-Efficacy for Managing Chronic Disease 6-item Scale),[41] (10) health literacy, (11) physical activity (Godin-Shephard Leisure-Time Physical Activity Questionnaire),[42] (12) perceived social support (Enhancing Recovery in Coronary Heart Disease Social Support Instrument),[43] and (13) alcohol, nicotine, and cannabis use (Alcohol, Smoking and Substance Involvement Screening Test).[44]

All psychometric instruments are validated excluding the EUROIA and the measure of health literacy, both of which were developed for this trial.

Design

This is a double-arm, parallel-group, randomised superiority trial in which investigators are blinded. Participants have free access to their respective digital intervention on our online platform, hosted by the secure server at our host institution (University Health Network (UHN)). Assessments occur at baseline, months 4, 8 and 12, and trial completion. Duration of participation depends on when subjects are enrolled (figure 1). Data collection began in October 2021 and will end in August 2023, with analysis occurring from September to October 2023.

There are two treatment arms: ODYSSEE-vCHAT and eUC. Our platform proactively sends weekly emails to subjects inviting them to access the resources available to their group. The uniform schedule of contact across arms balances non-specific support. Participants logon to our platform using password-protected personal accounts. Only registered subjects have access to their respective programme, minimising risk of contamination across arms.

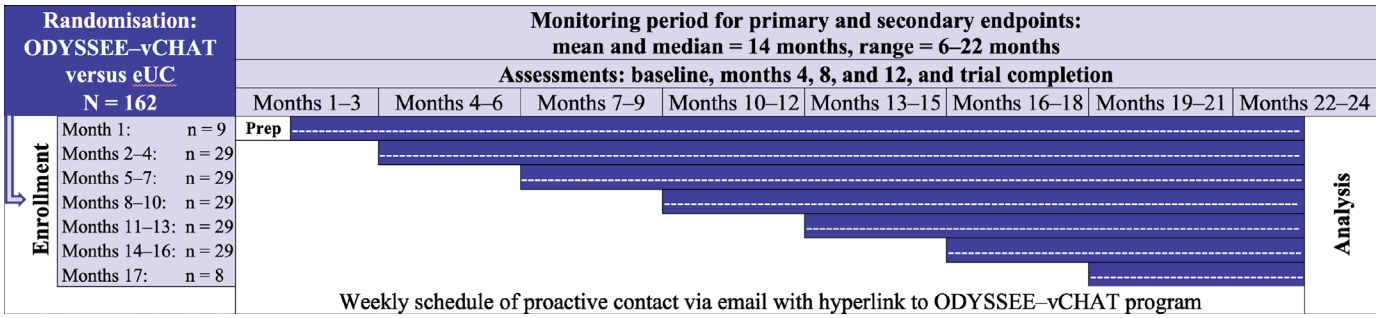

Figure 1 Schema of trial with enrolment targets and contact schedule. eUC, enhanced usual care; ODYSSEE–vCHAT, Open Access Digital Community Promoting Self-Care, Peer Support, and Health Literacy. Illustrated by R G Peiris.[1 2]

Subjects are randomised to each arm based on a ratio of 1:1 immediately following their completion of the baseline assessment. An independent researcher carries out randomisation manually by registering participants in their intervention on our platform according to permuted blocks defined by site and biological sex at birth. Block sizes and fractions are known only by the independent researcher to reduce the predictability of patient allocation. The research team is blinded to ensure impartiality in decisions about procedures and analyses.

Data for the primary outcome are collected from provincial population-based databases in collaboration with the Institute for the Clinical Evaluative Sciences. Data collection for secondary outcomes is obtained via psychometric questionnaires housed on Research Electronic Data Capture (REDCap©) on the secure UHN server. Questionnaires are accessed through a hyperlink that is emailed to participants at each assessment.

Criteria for participation

Patients are eligible to participate if they meet the following inclusion criteria: (1) biologically born males and females who are at least 18 years old and diagnosed with HF with reduced ejection fraction (EF) corresponding to New York Heart Association (NYHA) classes II-IV for 3 or more months prior to enrolment; (2) left ventricular EF less than or equal to 40% with documentation by ventriculography or quantitative echocardiography; (3) no worsening of HF for 1 month prior to recruitment, as determined by a referring physician; (4) medical treatment adhering to Canadian Cardiovascular Society guideline-directed therapy[45] for at least 1 month prior to enrolment; (5) oral and written comprehension of English; (6) personal access to a computer and the Internet; and (7) informed written consent (online supplemental appendix A).

Exclusion criteria include the following: (1) HF with midrange or preserved EF (the high rate of non-cardiac mortality[46] would confound our evaluation of ODYSSEE-vCHAT); (2) advanced surgical therapies (eg, heart transplantation or implantation of a left ventricular assist device) within 3 months of enrolment; (3) diagnosis of severe comorbidity that prohibits full participation (eg, dementia, psychosis, or severe depression); and (4) HF secondary to uncorrected valvular cardiomyopathy, predominant right-sided HF, or non-cardiac disease (eg, complex congenital heart disease).

Interventions

ODYSSEE-vCHAT consists of: (1) chatrooms available 24/7, (2) weekly 30-minute presentations followed by open discussions, and (3) digital counselling resources (online supplemental appendix B, figure 1). Seven themes inform each aspect of ODYSSEE-vCHAT: (1) priorities for 'living well': HRQL, self-care, and COVID-19 prevention; (2) CBT-based guide for promoting HF self-care for diet, exercise, medications, and smoke-free living; (3) CBT-based guide for managing stress, anxiety, and depression with relaxation and meditation; (4) measuring 'living well' progress: digital tools and trackers for HRQL and self-care; (5) social activities: promoting positive mood and HRQL; (6) maintaining self-care and HRQL: staying motivated and managing triggers; and (7) stress management for significant others (figure 2). Themes rotate in an ongoing cycle so that participants have access to the full range of topics.

ODYSSEE-vCHAT chatrooms are moderated by three levels of content filtering to ensure that posts meet conventional standards of ethical conduct. Level 1 is a search algorithm that is automatically updated with banned word lists. Levels 2 and 3 are carried out by patient representatives and research assistants, respectively, who regularly review messages and remove inappropriate content.

ODYSSEE-vCHAT presentations and discussions are hosted weekly on the Zoom Web-conferencing application, which is compliant with the Health Insurance Portability and Accountability Act. Presentations of approximately 30 minutes by healthcare professionals and patient representatives feature an MI-based communication style that is followed by a discussion segment for the remainder of the 60-minute session. The MI-based communication style evokes intrinsic motivation for HF self-care adherence by validating patient experiences, encouraging identification of self-care goals, and resolving ambivalence for behavioural change. Subjects' cameras are turned off to protect their privacy; however, they may turn on their microphone to contribute to the discussion. The meetings are recorded and uploaded to our private YouTube channel. Hyperlinks to the videos are posted on our platform for participants to access at

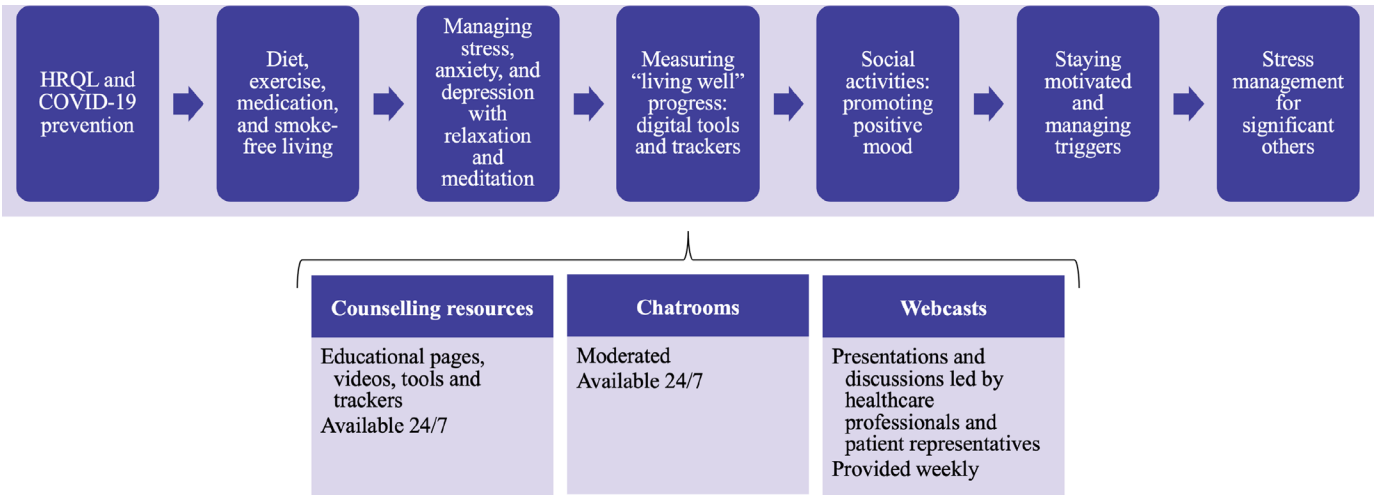

Figure 2 ODYSSEE–vCHAT's chatrooms, presentations and discussions, and counselling resources are informed by a schedule of rotating themes. HRQL, health-related quality of life; ODYSSEE–vCHAT, Open Access Digital Community Promoting Self-Care, Peer Support, and Health Literacy. Illustrated by R G Peiris.[1 2]

any time. Patients who do not wish for their voice to be included in the recordings are encouraged to use the chat function on Zoom. Additionally, subjects are invited to submit comments on the topics discussed in the meetings as audio or video recordings (those who wish to remain anonymous in the ODYSSEE-vCHAT community are encouraged to submit audio recordings rather than videos). These comments, up to 1 minute in length, affirm the active role of patients as they share personal milestones with the virtual community. Submissions are screened for appropriateness of content and posted to our private YouTube channel. Hyperlinks to the videos are shared on our platform.

ODYSSEE-vCHAT's digital counselling resources are delivered using an MI-based communication style and include educational pages (online supplemental appendix B, figure 1), videos (eg, guides for self-care behaviour, dramatic vignettes to reflect and validate patient experiences, and peer discussions), and interactive tools and trackers to monitor self-care behaviours (online supplemental appendix B, figure 2). All materials are available on initial logon and are organised by the seven themes (figure 2). eUC provides educational resources on HF and self-care behaviours that are reflective of content found on websites for professional health organisations such as the Heart Failure Society of Canada, the American Heart Association, and the European Society of Cardiology. The topics covered pertain to symptoms, medical treatments, and recommendations for self-care (active living and exercise, diet, medication adherence, weight monitoring, smoke-free living, immunisations and vaccinations, stress management, and psychosocial support). All materials are available on initial logon. Subjects are expected to view this condition as an enhanced treatment as it consists of resources above and beyond the usual standard of care.[25 30–32]

Sample size estimate

The sample size estimate considers ODYSSEE-vCHAT's usability and efficacy. In terms of usability, the CHF-CePPORT[25] trial achieved moderate programme adherence over 12 months (median sessions accessed=61%), with greater logon time for digital counselling (median=381 minutes, 95% CI 321-441) versus eUC (median=229 minutes, 95% CI 187-270), $p<0.001$. The sample to detect this effect with a two-group design, a type 1 error of 5%, and power of 80% was $N=114$. With 14.7% adjustment for withdrawal or attrition (6.5% patients withdrew and 8.2% were lost to follow-up), our sample estimate is $N=131$. To account for efficacy, we considered a trial by Krum *et. al*,[47] in which structured telehealth support reduced a composite index of all-cause mortality and hospitalisations over 12 months (50.6%) versus usual care (59.3%), $p=0.01$. A sample estimate of 142 was yielded. Using a 14.7% adjustment rate for withdrawal or attrition based on values obtained from CHF-CePPORT,[25] our final total sample size estimate is 162, with a type 1 error of 5% and power of 80%.

Recruitment

We are recruiting HF patients ($N=162$) from cardiology clinics at academic hospitals across Toronto, Canada: UHN, Sunnybrook Hospital, and Mount Sinai Hospital. Clinical staff who are aware of the inclusion and exclusion criteria initiate contact with eligible patients. On receiving verbal consent to be approached, the research team contacts patients in person or by telephone to discuss the trial and obtain written informed consent (online supplemental appendix A). Informed consent occurs either in person at participating clinics or virtually through REDCap and with a research team member on the telephone. The trial is also advertised to HF patients who are not registered at a participating clinic through patient education websites, posters, and mass emails.

Patients who contact the research team are screened for eligibility before undergoing informed consent as noted previously. Participants will be recruited continuously over a period of 18 months until the target sample size is obtained.

Analysis

A time-to-event analysis using a multivariable Cox proportional hazards model will evaluate the primary outcome. Potential confounders (eg, age, gender, ethnicity, NYHA class, and depression) will be selected using forward ($p<0.05$) and backward ($p<0.10$) stepwise selection.

The Cox proportional hazards model will assess individual components of the composite index. A multivariable Poisson model will determine whether ODYSSEE-vCHAT versus eUC is associated with greater engagement with self-care materials. Each model will be adjusted for baseline assessments for each endpoint and potential confounders, noted previously. Generalised linear models will evaluate patient-reported outcomes, and significant interactions will use Bonferroni post hoc tests for relevant subgroups. T- or Chi-squared tests will examine differences in sociodemographic baseline characteristics (eg, gender, ethnicity, and education level). All planned analyses are defined as intention-to-treat as participants will be retained to the group to which they were randomised and data obtained from all subjects will be included, regardless of protocol adherence. Missing data due to withdrawal or death will be excluded from analyses. For missing data not due to withdrawal or death, we will determine if data are missing at random and, if so, resolve using multiple imputation.

Management

All data are stored on a password-protected account on the secure UHN server for 10 years following trial completion. Subject anonymity and confidentiality are preserved. Participants are issued a tracking number when identifying information is transmitted for analysis. In keeping with an agreement that coinvestigators from participating sites have signed with the UHN to share data for their patients, transmission occurs via encryption over the Internet. Only aggregate data will be published. Access to trial data is denied to persons outside the research team. Research team members have signed a contract ensuring that confidential information is not disclosed to outside parties. Access to the laboratory is given to authorised personnel only. A Data Monitoring Committee composed of a single researcher, independent of the sponsor and free of competing interests, oversees the trial's methodological rigour.

A Steering Committee will adjudicate outcomes for primary and secondary endpoints during the final month of each year. Membership includes experts on the research team in statistics and methodology, as well as a patient representative. This group meets quarterly to review ODYSSEE-vCHAT's progress and protocol compliance and to recommend or approve follow-up actions to any adverse incidents. On consenting, participants are informed that responsibility for their care rests solely with their healthcare team and that ODYSSEE-vCHAT is complementary to their medical care (online supplemental appendix A). Notification of any adverse events will be forwarded to the patient's referring physician for treatment at their respective institution.

Any modifications to the protocol that may impact the trial's design, procedures, objectives, sample size, and/or the potential benefit or safety of subjects will require a formal amendment to the protocol. Amendments will be submitted for approval to the research ethics boards (REBs) at participating sites prior to implementation. The trial's registry will be updated accordingly (table 1).

Trial conduct may be audited by the UHN's REB, independent from investigators and the sponsor, to ensure that laws and guidelines are followed. The trial protocol is written according to the Standard Protocol Items: Recommendations for Interventional Trials reporting guidelines.[48]

Compliance, withdrawal, and discontinuation

Compliance issues may arise from a patient's perception that the response burden is disproportionate to the benefit. However, subjects are made aware during informed consent (online supplemental appendix A) that they are provided with resources that are above and beyond the standard of care and that the information learnt from this trial may help us further develop a digital counselling application to help HF patients better manage their condition. We facilitate assessment completion by email reminders and scheduling appointments to assist over the telephone, if needed.

Participants are informed during consent that they may withdraw at any time, for any reason, without repercussion to their medical care (online supplemental appendix A). All information collected up to the point of withdrawal are included in analysis. No new information is collected after that point.

Discontinuation may occur on request by a subject's referring physician if they deem that it is not advisable for the patient to continue participation.

DISCUSSION

ODYSSEE-vCHAT versus eUC is hypothesised to show an improvement in a composite index of incident all-cause mortality, all-cause ED visits, and HF-related hospitalisation at trial completion. This is based on evidence that counselling for HF self-care behaviours[49–51] improves self-care adherence and that self-care adherence is positively linked to clinical outcomes for longevity and HRQL.[12–17] Our CHF-CePPORT trial[25] found that, compared to an enhanced control arm (similar to the eUC condition in the present trial), automated digital counselling for HF self-care evoked greater engagement with self-care materials over 12 months. Furthermore, engagement with self-care materials was associated with better HRQL

Table 1 Trial registration data

Data category	Information
Registry and identifying information	ClinicalTrials.gov: NCT04966104
Date of registration	28 August 2021
Secondary identifying numbers	REB 20–5960, REB 5117, REB 21–022–E, PJT173222
Source of monetary support	CIHR
Contact for public and scientific queries	R P Nolan[1 2]
Public title	ODYSSEE–vCHAT pilot trial for chronic HF
Scientific title	Automated digital counselling with social network support as a novel intervention for patients with HF: protocol for randomised controlled trial
Country of recruitment	Canada
Health condition studied	HF
Interventions	ODYSSEE–vCHAT: chatrooms, presentations and discussions, and digital counselling resources
	eUC: educational resources
Key inclusion and exclusion criteria	Inclusion criteria: 18 years and older, HF with reduced EF (NYHA classes II–IV), left ventricular EF ≤ to 40%, fluent in English, access to a computer and the Internet
	Exclusion criteria: HF with preserved EF, advanced surgical therapies within 3 months of enrolment, severe comorbidities
Study type	Randomised intervention model; parallel assignment masking; single–blind (research personnel); clinical phase II pilot trial
Date of first enrollment	July 2021
Target sample size	162
Recruitment status	Recruiting
Primary outcome	Composite index of incident all-cause mortality, all-cause ED visits, and HF–related hospitalisations (time frame: 22 months)
Key secondary outcomes	Engagement with self-care materials (time frame: 4, 8, 12 and 22 months), patient-reported outcomes of health status (time frame: 4, 8, 12 and 22 months)

All items from the WHO Trial Registration Data Set.[72]
CIHR, Canadian Institutes of Health Research; ED, emergency department; EF, ejection fraction; eUC, enhanced usual care; HF, heart failure; NYHA, New York Heart Association; ODYSSEE–vCHAT, Open Access Digital Community Promoting Self–care, Peer Support, and Health Literacy; REB, research ethics board; UHN, University Health Network.

for the digital counselling arm only. ODYSSEE-vCHAT builds on CHF-CePPORT[25] by supplementing its automated digital counselling method with social networking to promote self-care learning through peer support[26 27] and to reinforce positive role modelling through presentations.[28] Peer support improves self-care adherence,[52] such as taking medications,[53] and is negatively linked with hospital admissions.[54] The social network component may also increase HRQL[55] while reducing perceived social isolation,[56] which is expected to be a shared experienced of participants given the lockdowns and social distancing practices of the COVID-19 pandemic.

In response to a report published by the Institute of Medicine calling for healthcare to be guided by patient needs, preferences, and values,[57] hospitals have incorporated patient-centred care into their service design.[58] Patient-centred care empowers individuals to become more knowledgeable about their diagnosis, better manage their symptoms, and practice self-care behaviours. ODYSSEE-vCHAT aims to improve clinical outcomes and psychosocial functioning using a patient-centred approach to counselling for self-care. Studies on patient-centred self-care education for chronic conditions show that individualised feedback related to circumstance, lifestyle, and medical therapy improves self-care adherence.[59–61] For example, personalised instruction for HF self-care motivates patients to practice regular self-measurements of blood pressure, pulse rate, and weight.[62] ODYSSEE-vCHAT enables patients to connect HF self-care goals with individual needs, preferences, and values through identifying personal goals, setting targets, and tracking progress.

A potential limitation of ODYSSEE-vCHAT is its inaccessibility to individuals with poor computer literacy. The average HF patient is older than those with other chronic illnesses,[63] posing digital usability challenges. Furthermore, older generations tend to rely on handheld devices, and optimal viewing of ODYSSEE-vCHAT is currently available on desktops and tablets due to financial limitations. However, in a study that assessed attitudes about home

monitoring and technology for HF,[64] patients reported having significant others who could help them access digital programmes. The research team also provides technical assistance over the telephone, if needed. Moreover, future development of the intervention will include a user-friendly mobile application. An interesting trend to note is that the Baby Boomer generation will be the largest geriatric cohort to date,[65] making the digital-based nature of this intervention increasingly ideal as the HF prevalence continues to rise.[66]

Another potential limitation of ODYSSEE-vCHAT is its generalisability to patients of ethnic minority groups due to language barriers. Approximately 22% of the Canadian population belongs to an ethnic minority group.[67] HF patients of ethnic minority groups experience worse clinical outcomes than their Caucasian counterparts[68 69] and adhere less to self-care behaviours.[70 71] ODYSSEE-vCHAT does not currently accommodate for non-English speakers due to financial constraints. However, representation of visible ethnic minorities is included in the digital counselling materials, presenting potential role models for ethnic minority participants. Future advances to the programme will include translation into other languages.

Patient and public involvement

The social network component of ODYSSEE-vCHAT fosters a sense of community and encourages engagement through chatrooms, weekly meetings, and audio or video comments. Digital counselling resources are expected to promote intrinsic motivation for self-care as participants identify personal goals, set targets, and track their progress. Patient representatives, who are members of the research team and the steering committee, act as hosts for presentations in the ODYSSEE-vCHAT intervention. They offer insights on the weekly theme from a first-hand experience.

Ethics and dissemination

Trial procedures have been reviewed and approved by the REBs at the UHN (20-5960), Sunnybrook Hospital (5117), and Mount Sinai Hospital (21-022-E). Public access to the full protocol is available at ClinicalTrials.gov (NCT04966104). Subjects who are eligible based on inclusion and exclusion criteria are required to provide informed consent (online supplemental appendix A) either in person or online.

We will collaborate with researchers and stakeholders in cardiovascular and public health to establish a best-evidence pan-Canadian digital counselling service to promote HF self-care and HRQL. We will present findings from this trial to patient representative groups and professional societies in formal and peer-reviewed settings. Topics for presentation or publication will be shared with coinvestigators, who will be requested to provide input. Findings will inform clinical guidelines and digital healthcare policies. We will share the results with the public through social media and press releases.

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Competing interests None declared.

Patient and public involvement Patients representatives are involved in the conduct and oversight of this research. Refer to the Methods and Discussion sections for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Following trial completion, data will be available from the corresponding author pending approval of research ethics boards of participating institutions and on reasonable request received from qualified researchers trained in human subject confidentiality protocols.

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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

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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

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- 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

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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

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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

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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

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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.

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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

Self-Care Tips
TO EAT LESS SALT

AVOID HIDDEN SODIUM IN PROCESSED FOODS

Avoid ready-to-eat foods, fast foods, pickled, cured, processed, smoked or salted foods

READ YOUR FOOD LABELS

Look for 'Sodium' in food labels and find out how much sodium each serving contains

EAT MORE FRESH FOODS

Shop for fresh meats, fish, poultry and fresh or frozen fruits and vegetables

COOK AND EAT AT HOME MORE OFTEN TO CONTROL SODIUM IN YOUR DIET

Use less salt in your cooking or substitute it with other flavourings or spices

MAKE HEART-HEALTHY FOOD CHOICES WHEN EATING OUT

Avoid high sodium dishes and fried foods. Keep these tips in mind when you order.

HEART FAILURE MEDICATIONS

NAME:	EXAMPLES:	FUNCTION:
ALDOSTERONE ANTAGONISTS	SPIRONOLACTONE EPLERENONE	• Reduce aldosterone levels
ANGIOTENSIN CONVERTING ENZYMES (ACE) INHIBITORS	RAMIPRIL BENAZEPRIL PERINDOPRIL	• Expanding blood vessels • Controlling blood pressure • Reduce burden on heart
ANGIOTENSIN RECEPTOR II BLOCKERS (ARB)	CANDESARTAN IRBESARTAN TELMISARTAN VALSARTAN	• Expanding blood vessels • Controlling blood pressure • Reduce strain on heart
ANTICOAGULANTS AND ANTIPLATELETS	WARFARIN ASPIRIN TICLOPIDINE HEPARIN	• Increase heart's ability to expand and contract • Regulate heart rhythm
BETA-BLOCKERS	CARVEDILOL METOPROLOL ATENOLOL BISOPROLOL	• Expanding blood vessels • Controlling blood pressure • Reduce strain on heart
DIGITALIS/ DIGOXIN	LAXOIN NOVODIGOXIN	• Increase heart's ability to expand and contract • Regulate heart rhythm
DIURETICS	FUROSEMIDE METOLAZONE BUMETANIDE CHLOROTHIAZIDE	• Eliminate excess body fluid • Reduce shortness of breath, swelling, and bloating
NITRATES AND VASODILATORS	NITROGLYCERIN HYDRALAZINE ISORDIL	• Prevent blood clots • Reduce blood pressure

My Trackers: Active Living