





BMJ Open 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 morbidity, 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 change²¹ 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-CePPORT²⁵ 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; 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.

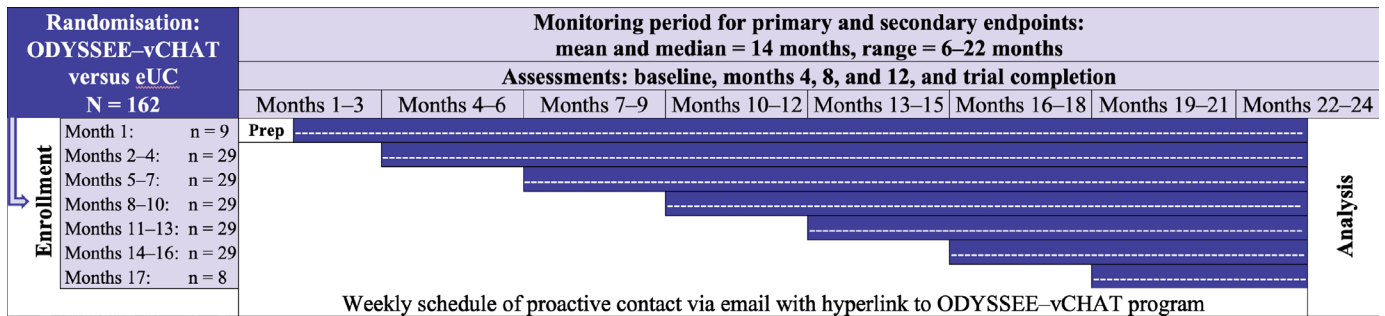


Figure 1 Schema of trial with enrolment targets and contact schedule. eUC, enhanced usual care; ODYSSEE-vCHAT, Open Access Digital Community Promoting Self-Care, Peer Support, and Health Literacy. Illustrated by R G Peiris.^{1,2}

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 therapy⁴⁵ 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 mortality⁴⁶ 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

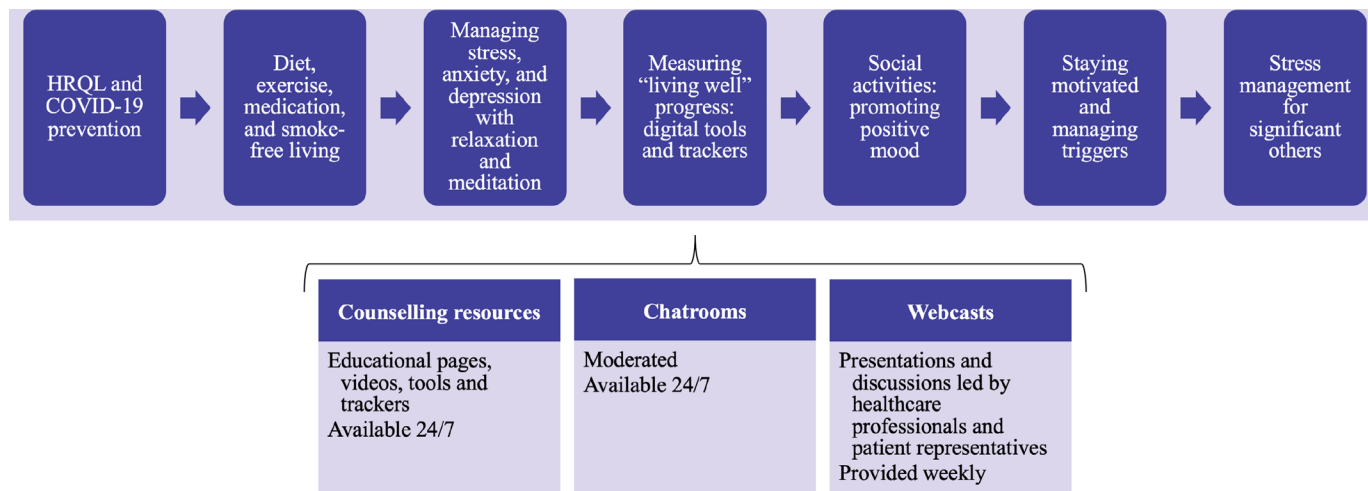


Figure 2 ODYSSEE-vCHAT's chatrooms, presentations and discussions, and counselling resources are informed by a schedule of rotating themes. HRQL, health-related quality of life; ODYSSEE-vCHAT, Open Access Digital Community Promoting Self-Care, Peer Support, and Health Literacy. Illustrated by R G Peiris.^{1,2}

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-CePPORT²⁵ 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 trial²⁵ 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 \leq 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–CePPORT²⁵ 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 HRQL⁵⁵ 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 health-care 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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