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Study Design

The Women@Heart NS Pilot Project: Rationale and Design of a Community-Based Peer Support Program for Women Living With Heart Disease in Nova Scotia

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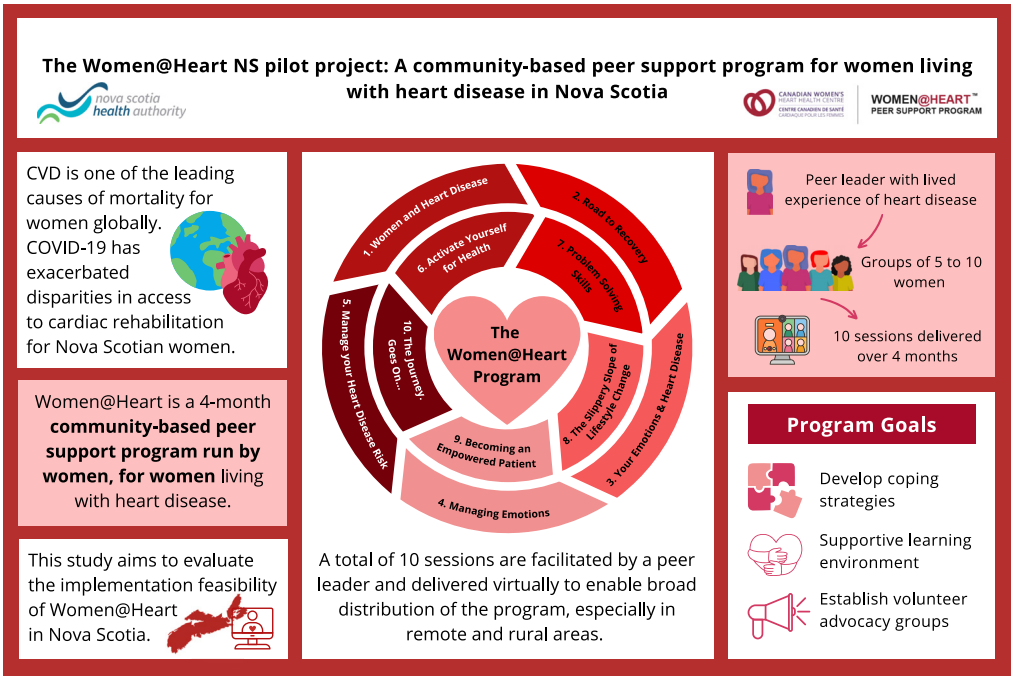

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ABSTRACT

Cardiac rehabilitation is associated with lower mortality and improved psychosocial outcomes. However, disparities exist in referral and access to cardiac rehabilitation for Nova Scotian women, a situation exacerbated by the COVID-19 pandemic. Women@Heart (W@H) is a 4-month community-based peer support program developed and validated by the University of Ottawa Heart Institute, for women living with heart disease. The program aims to empower women with coping strategies, provide a supportive learning environment, and establish volunteer advocacy groups. The primary objective of this study is to evaluate the implementation feasibility of the W@H program for women living in Nova Scotia. The primary outcome is the implementation feasibility of W@H in Nova Scotia, measured through participant attendance and program completion rates. Peer leaders will record participant attendance. The psychosocial impact of W@H will be assessed using psychometric tools that measure the following: social support, adaptive coping, stress, symptoms of anxiety and depression, and health-related and disease-specific quality of life. Data will be collected using a pre- and post-program questionnaire administered to participants. The pilot program is expected to commence in the first quarter of 2024. One peer leader with lived experience of heart disease, who has previously completed the W@H program as a participant, has been trained. Participants have been identified through healthcare provider referral, self-referral, brochures, and peer-networking. Each cohort will consist of 5-10 participants. The W@H pilot project will assess the implementation feasibility and the impact of community-based peer support on the well-being of Nova Scotian women living with heart disease.

RÉSUMÉ

La réadaptation cardiaque est associée à une mortalité plus faible et à des bienfaits psychosociaux. Cependant, il existe des disparités en ce qui a trait à l'orientation et à l'accès à la réadaptation cardiaque pour les femmes de la Nouvelle-Écosse, une situation exacerbée par la pandémie de COVID-19. Femmes@Cœur est un programme de soutien collectif par les pairs, créé et validé par l'Institut de cardiologie de l'Université d'Ottawa, à l'intention des femmes atteintes d'une maladies du cœur. Le programme vise à autonomiser les femmes en leur proposant des stratégies d'adaptation, à leur fournir un environnement propice à l'apprentissage et à former des groupes de bénévoles pour la défense de leurs intérêts. La présente étude a pour principal objectif d'évaluer la faisabilité de la mise en œuvre du programme Femmes@Cœur pour les femmes de la Nouvelle-Écosse. Le critère d'évaluation principal de l'étude est la faisabilité de la mise en œuvre du programme Femmes@Cœur en Nouvelle-Écosse, déterminée par la mesure des taux de participation et d'achèvement du programme. Des responsables parmi les pairs consigneront la présence des participantes. Les répercussions psychosociales du programme Femmes@Cœur seront évaluées à l'aide d'outils psychométriques mesurant une gamme de paramètres : soutien social, stratégies d'adaptation, niveau de stress, symptômes d'anxiété et de dépression, et qualité de vie liée à la santé et à la maladie en question. Les données seront recueillies au moyen de questionnaires administrés aux participantes avant et après le programme, et le projet pilote devrait être lancé le premier trimestre de 2024. Une responsable parmi les pairs, elle-même atteinte d'une maladie du cœur et ayant déjà pris part au programme Femmes@Cœur en tant que participante, a été formée à cet effet. Les participantes ont été trouvées de diverses façons : orientation par un professionnel de la santé, inscription spontanée, brochures et réseautage entre pairs. Chaque cohorte sera par ailleurs composée de 5 à 10 participantes. Enfin, le projet pilote Femmes@Cœur évaluera la faisabilité de la mise en œuvre et les répercussions du soutien collectif entre pairs sur le bien-être des femmes de la Nouvelle-Écosse atteintes de maladies cardiaques.

Lay Summary

Women@Heart is a 4-month community-based peer support program developed and validated by the University of Ottawa Heart Institute (UOHI) by women, for women living with heart disease. The program is facilitated by peer leaders with lived experience and aims to empower participants with coping strategies, provide a supportive learning environment, and establish volunteer advocacy groups. The Women@Heart Nova Scotia pilot project will assess the acceptability and impact of this virtual, community-based peer support program on the health and well-being of Nova Scotian women.

Although cardiovascular disease (CVD) is one of the leading causes of mortality for women globally, cardiovascular care for women remains suboptimal, leading to poorer outcomes in comparison to those of men.[1] After a first cardiac event, women report greater psychological distress and lower self-efficacy and self-esteem, and greater anxiety and depression.[2] The current body of literature suggests that women can benefit equally or more in comparison to men from cardiac treatment, care, and rehabilitation.[3] Despite this ability to benefit, however, disparities exist in referral and access to cardiac rehabilitation (CR) for women, and these have been exacerbated by the COVID-19 pandemic. In Nova Scotia (NS) specifically, since December 2019, no CR program has been available on the South Shore, and the referrals made from the Central Zone have been unmet due to a lack of health professional and public support, compounded by scarce and inflexible services. NS has a largely rural population, at 43%, which can pose a significant barrier to accessing CR and cardiovascular (CV) care.[4]

Another barrier frequently documented by women seeking to enroll in CR is a lack of social support from family and friends.[5] At a provider level, supportive endorsement of CR by a healthcare provider has been shown to improve CR participation rates for women.[5] However, beyond this, peer education and support also have been found to improve patients'

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quality of life after an acute cardiac event.[6] Peers can make a significant contribution to improving the self-care behaviours of other women due to their familiarity with cardiac conditions and having lived experience.[7] In a national survey of 1654 Canadian women, 84% of women with a cardiac diagnosis wanted more opportunities to discuss their illness experiences with other women with heart disease.[8]

The Women@Heart (W@H) program designed and developed by the University of Ottawa Heart Institute (UOHI) is a peer support program led by women, for women living with heart disease. W@H is the first program of its kind, and it has been shown to be efficacious in improving participant psychosocial outcomes and building a community of support for women living with heart disease in Ontario, with over 900 women having enrolled since its inception. To implement the W@H program in NS, our pilot study builds on this established program. The main objective of this study is to evaluate the feasibility of implementation of W@H, a community-based peer support program for women living with heart disease in NS. Initially, this pilot project aims to meet the needs of underserved women in rural NS. If the program is successful, the goal is to then disseminate it broadly throughout the province to improve the well-being of women across in NS.

Methods and Study Design

Study population

The study population will include women living with heart disease (including but not limited to coronary artery disease, angina, coronary artery bypass graft surgery, valvular disease, atrial fibrillation, and spontaneous coronary artery dissection) who have been referred either through self-referral, or through a healthcare provider to the W@H program for CR and support.

Inclusion criteria

The inclusion criteria are as follows: individuals aged $\geq$18 years, identifying as women; able/willing to give informed consent; enrolled in the W@H program in NS; with a cardiac diagnosis (including but not limited to, myocardial infarction, angina, stent, coronary artery bypass surgery, valve disorder, or electrical conduction disorders) who are referred to CR by a physician through the NS Health Authority (NSHA) or through self-referral. Priority will be given to those women who reside in the South Shore region of NS, as they have a paucity of available services. Eligible women must have had no hospitalizations within the last 6 weeks, be able to attend online sessions, understand and speak English, and have no limitations in terms of contributing to or participating in a group setting.

Exclusion criteria

Individuals unable to communicate in English, or those who had a previous enrollment in the program will be excluded.

Screening and informed consent

Prior to registration and enrollment in the program, participants will be required to complete an initial participant consent and screening form. This screening form includes the General Anxiety Disorder (GAD)-7 and Patient Health Questionnaire (PHQ-9) questionnaires, which will be administered using REDCap (Research and Electronic Data Capture). Should participants demonstrate any indication of moderate anxiety (GAD-7 score $\geq$ 10) and/or moderate depression (PHQ-9 score $\geq$ 10), the principal investigator (S.L.M.) will provide additional screening to assess eligibility. If further support is required, we will seek permission from the participant to reach out to their primary care provider for follow-up. Patients will be informed about the objective of the study and the option to withdraw from participating at any time. No identifiable personal data will be used in this study. Patients will be de-identified and anonymized upon completion of the pre- and post-program questionnaires. The NS Health Research Ethics Board has granted this pilot project a review exemption, as our project has been classified as a quality improvement initiative.

Study design

This is a questionnaire-based cohort study of approximately 5-10 participants per cohort, who are enrolled in the W@H program in NS, with data collected at baseline and at the 4-month endline. The primary research question being addressed in this study is "What is the implementation feasibility of community-based peer support CR (ie, the W@H program) for women living with heart disease in NS?". The secondary research question being addressed is "What is the impact of community-based peer support CR (ie, the W@H program) on psychosocial and quality-of-life outcomes for Nova Scotian women living with heart disease?".

What is the W@H program?

W@H is a 4-month community-based peer support program developed and validated by the UOHI, for women living with heart disease. The UOHI administrative resource supporting W@H also supports the Canadian Women's Heart Health Alliance (CWHHA, cwhha.ca), which is a professional and patient advocacy group of volunteers who are active in increasing awareness of heart disease in women throughout Canada.

Program objectives. The W@H program intends to do the following:

- Provide emotional support and promote coping strategies.
- Empower women to implement heart healthy behaviours.
- Create a caring and supportive environment for women living with heart disease.
- Encourage women in volunteerism as advocates for women's heart health in their communities.

The overarching goal of the program is to empower women to take charge of their heart health and to make informed decisions through better understanding of their condition. A visual representation of the key themes and drivers of the W@H program can be found in Figure 1.

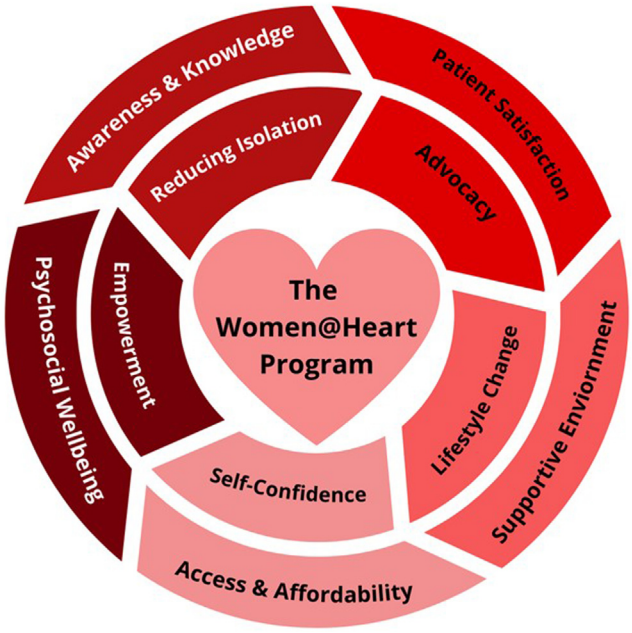

Figure 1. Areas of impact of the Women@Heart program for women living with heart disease.

Peer leaders. Each W@H peer support group is facilitated by a peer leader. Peer leaders are women who have been diagnosed with CVD and are passionate about educating and supporting other women in their recovery. To receive a Peer Leader Certification, interested individuals must have been a member of and have completed the W@H program themselves, prior to applying. Interested individuals then undergo a screening process to determine their eligibility. Once approved, a three-day training program for peer leaders is conducted, during which leaders gain the knowledge and skills to effectively deliver the intervention. Peer leader training consists of disease-specific information, communication skills, support skills, self-care skills, and access to community resources to address role conflict and crisis management. Peer leaders receive a manual with detailed program-implementation instructions for each session, and participants receive a manual with program information and educational materials that reflect each session.

In this study, Nova Scotian women ($n = 2\text{-}3$, $\geq 50\%$ rural) with lived experience of heart disease will be mentored and trained online as peer leaders. One peer leader has already been trained, in preparation for implementation of the program. Ongoing co-leader support is provided by the UOHI. Peer leaders will each lead unique groups of 5-10 Nova Scotian women with the lived experience of heart disease. The program now is designed to be delivered online, but it can be adapted to be in-person in the future.

Structure and content of sessions. The program is taught over 2-hour-long sessions that occur weekly for the first 4 weeks and then biweekly for the remaining 6 weeks, for a total of 10 sessions. All sessions facilitated by peer leaders will occur through the secure, virtual platform Zoom for Healthcare. Participants will gain access to a unique link for the virtual platform upon confirmation of registration in the program, prior to the start date. The peer-to-participant ratio is 1:10 when a full cohort is enrolled. The program follows a closed-group system, which means that once it has started, participants cannot be added. Session topics range from medical and behavioural science to lifestyle education. Each session places an emphasis on supporting women at the point they currently are in their heart health journey. A brief title and description of each session can be found in Table 1.

Outcomes and measures

To assess program feasibility, the following pieces of information will be collected: number of women referred to W@H with CVD over the evaluation period; number of women screened; number of women enrolled in W@H; average number of sessions completed; number of women who completed the program. The primary outcome is to determine the implementation feasibility of W@H in NS, which will be measured through participant attendance and program completion rates. The psychosocial impact of W@H will be assessed using psychometric tools that measure the following: social support [ENRICHD Social Support Instrument (ESSI)], adaptive coping (Brief-COPE), perceived stress [Perceived Stress Scale (PSS)], symptoms of anxiety [Beck Anxiety Inventory (BAI)] or depression [Beck Depression Inventory (BDI-II)], health related quality of life [36-item Short Form Survey mental composite score (SF-36 MCS)], and disease-specific quality of life [Disease-specific Quality of Life Impact Scale (QDIS)].

Sample size

Our target enrollment is 30-50 participants for this pilot study. Our first cohort is estimated to have 10 participants, with 2 peer leaders co-leading all 10 sessions. Based on the UOHI W@H program's reported completion rate to date—approximately 66%—and the additional challenges associated with having participants from rural areas that we have incorporated into our program, we would consider $> 50\%$ program attendance and completion rates to be a success for our pilot study.

Recruitment

Women patients will be prescreened to determine their potential eligibility for the first cohort of the W@H program. All potentially eligible patients will be called to provide them with information about W@H, and if they are interested, the registration process will be initiated.

Data collection and management

A pre- and post-program completion questionnaire will be administered to participants using a unique link generated by REDCap software. Administration of the questionnaire takes approximately 15 minutes. At baseline, participants will receive a demographic and risk factor questionnaire asking for personal information: name, marital status, education, ethnic/cultural background, family history of heart disease, employment status, occupational status, household income, and health behaviours (smoking, eating habits, and physical activity). At the endline, participants will have an opportunity to provide feedback regarding their experience with the program.

Table 1. Brief description of Women@Heart program sessions adapted from the University of Ottawa Heart Institute (Canadian Women's Heart Health Alliance: cwhha.ca)

Session	Concept	Description
1	Women and Heart Disease	Participants learn about common myths and misperceptions surrounding heart disease and gender differences. They also engage in discussion on diagnosis, symptoms, management, and treatment of heart disease.
2	Road to Recovery	Participants share their personal heart disease story with each other and embark on a road to emotional and physical recovery.
3	Your Emotions and Heart Disease	Participants explore the emotions behind surviving a heart event and the most effective ways to cope with change.
4	Managing Emotions	Participants gain specific tools to manage their emotions (explored in session 3) effectively. Tools include relaxation techniques, positive thinking, and effective communication strategies.
5	Manage Your Heart Disease Risk	Participants engage in discussion on key tips to improve their risk factors for heart disease.
6	Activate Yourself for Health	Participants learn how to maintain motivation, addressing issues such as self-confidence, activation, and balance. Participants are introduced to goal-setting and are encouraged to create an action plan to manage their risk factors and lifestyle modifications.
7	Problem-Solving Skills	Participants discuss barriers to making healthy changes, and are encouraged to develop strategies to avoid triggers and maintain a healthy lifestyle.
8	The Slippery Slope of Lifestyle Change	Participants learn to recognize relapses from their health goals and how to effectively prevent or recover from them.
9	Becoming an Empowered Patient	Participants learn how to navigate community resources available to them and work with their healthcare team to create sustainable solutions.
10	The Journey Goes On …	Participants reflect back on key takeaways from the previous 9 sessions, and tie them together to create an action plan for the future.

We have adopted a comprehensive participant satisfaction survey summary report, developed and piloted by the UOHI, which gives participants the opportunity to provide feedback on what they liked best about the program, what changes they would like to see, meeting times, location, and frequency, and how their experience with the W@H program compares to traditional CR, for example. Results from the endline satisfaction questionnaire will be used to inform and make improvements to the program and meet the needs of participants. Participants who choose not to complete the program fully will be contacted so that their reasons for dropout can be elucidated. This information will be recorded through a feedback survey, with the intention to use the data to develop strategies to address any barriers to participation in the program.

The primary outcome of program implementation and feasibility will be assessed using the following collected data: participant enrollment, session attendance, program completion rates, patient activation measures, and Likert-scale satisfaction scores. Peer leaders will keep track of participant enrollment, session attendance, and program completion rates manually, using an encrypted Excel (Microsoft, Redmond, WA) spreadsheet. The secondary outcome of participant psychosocial well-being will be assessed, as aforementioned, using the following tools: social support (ENRICHD-ESSI), adaptive coping (Brief-COPE), perceived stress (PSS-10), symptoms of anxiety (BAI) and depression (BDI-II), health-related quality of life (SF-36 MCS), and disease-specific quality of life (HeartQoL-E). Participant data will be collected and stored securely on REDCap using survey tools.

Statistical analysis

Baseline characteristics of patients and feasibility outcomes will be summarized using descriptive statistics. For the secondary research objective, each of the participants will complete questionnaires prior to starting the program (pre) and then upon completion (post). These questionnaires will be evaluated in aggregate, and the change in assessed parameters from pre to post will be determined. A 1-way repeated measures analysis of variance will be used to assess changes in psychosocial and behavioural outcomes. Analyses will be performed using SPSS, version 25 (SPSS, Chicago, IL). As we recognize the small sample size to be a limitation, we will be using the Bonferroni correction method to account for the type I error this will cause.

Discussion

Women have lower rates of referral and participation in CR programs, owing to multiple barriers, including a lower percentage of automatic referrals from hospital in-patient services, limited access options provincially, and a perceived lack of emotional, social, and physical supports.[5,6] At the social and environmental levels, barriers to engaging in CR include lack of a nearby program, lack of transportation, conflicting family obligations, lack of CR insurance, and/or other financial concerns.[5] The W@H program recognizes these barriers and has been developed to address many of them, including offering a virtual delivery format, providing social support through peer education, and prioritizing topics such as mental, physical, and emotional health in the sessions, all at no cost to participants.

The program was adapted initially to be virtual given that constraints of the COVID-19 pandemic limited women's participation. However, the virtual delivery format of the W@H program now enables broad distribution and overcomes frequent barriers to access, especially in rural and remote communities, which is why it will be used for the NS pilot study. We anticipate that this project will drive the establishment of volunteer advocacy groups across NS, promote

coping skills, and reduce the risk of isolation, depression, and anxiety associated with living with heart disease. This template also has potential to be applied to similar programs supporting women living with other chronic diseases. NS is the first site outside of Ontario to implement the W@H program. We anticipate that other provincial sites similarly will adopt this program with support from the Canadian Women's Heart Health Alliance and that this will lead to potential national comparators in the defined metrics, with the overall goal of improving CV outcomes for women across Canada.

Conclusions

The NS Health W@H pilot project intends to facilitate the successful repatriation and retention of women with a cardiac diagnosis in the community through implementation of an evidence-based, low-cost, peer support program with a high level of patient satisfaction. This program prioritizes Nova Scotian women, living in rural communities within the South Shore, who are underserved in their referral and access to CR. With the COVID-19 pandemic, additional challenges for women's participation in CR arose, and this program was adapted to be provided virtually. This aspect is particularly suitable to those in isolated areas with increased barriers to accessing CR and CV care.

Ethics Statement

The Nova Scotia Health Research Ethics Board in Canada has granted this pilot project a review exemption, as our project has been classified as a quality improvement initiative. The research reported in this article has adhered to the relevant ethical guidelines.

Patient Consent

The authors confirm that patient consent is not applicable to this article. This is a study design article. Patients have yet to be enrolled in the study, and this article does not divulge any patient identification or health information.

Funding Sources

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Disclosures

The authors have no conflicts of interest to disclose.

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