





BMJ Open Peer-support interventions for women with cardiovascular disease: protocol for synthesising the literature using an evidence map

Monica Parry ¹, Sarah Visintini ^{2,3}, Amy Johnston ^{4,5}, Tracey JF Colella,^{6,7} Deeksha Kapur,⁸ Kiera Liblik,⁹ Zoya Gomes,¹⁰ Sonia Dancey,¹¹ Shuangbo Liu ¹², Catherine Goodenough,¹³ Jacqueline L Hay,^{14,15} Meagan Noble,^{1,16} Najah Adrean,¹⁷ Helen Robert,¹³ Natasha Tang,⁹ Arland O'Hara,¹ Anice Wong,¹⁸ Kerri-Anne Mullen¹⁸

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For numbered affiliations see end of article.

Correspondence to

Dr Monica Parry;
monica.parry@utoronto.ca

ABSTRACT

Introduction The leading cause of death for women is cardiovascular disease (CVD), including ischaemic heart disease, stroke and heart failure. Previous literature suggests peer support interventions improve self-reported recovery, hope and empowerment in other patient populations, but the evidence for peer support interventions in women with CVD is unknown. The aim of this study is to describe peer support interventions for women with CVD using an evidence map. Specific objectives are to: (1) provide an overview of peer support interventions used in women with ischaemic heart disease, stroke and heart failure, (2) identify gaps in primary studies where new or better studies are needed and (3) describe knowledge gaps where complete systematic reviews are required.

Methods and analysis We are building on previous experience and expertise in knowledge synthesis using methods described by the Evidence for Policy and Practice Information (EPPI) and the Coordinating Centre at the Institute of Education. Seven databases will be searched from inception: CINAHL, Embase, MEDLINE, APA PsycINFO, the Cochrane Database of Systematic Reviews and the Cochrane Central Register of Controlled Trials, and Scopus. We will also conduct grey literature searches for registered clinical trials, dissertations and theses, and conference abstracts. Inclusion and exclusion criteria will be kept broad, and studies will be included if they discuss a peer support intervention and include women, independent of the research design. No date or language limits will be applied to the searches. Qualitative findings will be summarised narratively, and quantitative analyses will be performed using R.

Ethics and dissemination The University of Toronto's Research Ethics Board granted approval on 28 April 2022 (Protocol #42608). Bubble plots (ie, weighted scatter plots), geographical heat/choropleth maps and infographics will be used to illustrate peer support intervention elements by category of CVD. Knowledge dissemination will include publication, presentation/public forums and social media.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Publication bias will be mitigated by including sources of evidence written in both English and French, and by performing targeted searches for relevant grey literature.
- ⇒ Inclusion and exclusion criteria will be kept broad and studies will be included if they discuss a peer support intervention and include women (cis and trans) with ischaemic heart disease, stroke or heart failure, independent of the research design.
- ⇒ All team members will receive 1 hour of training on screening titles and abstracts, 1 hour of training on screening full-text reviews and 2 hours of training on data extraction.
- ⇒ Bubble plots (ie, weighted scatter plots), geographical heat/choropleth maps and infographics will be used to graphically illustrate quantitative results.
- ⇒ Although the individual and family self-management theory will consider the broader context of gender and outcomes, a conceptual theory that foregrounds gender within an intersectional lens may have strengthened study methods and results.

INTRODUCTION

The leading cause of premature death for women is cardiovascular disease (CVD), responsible for 35% of total deaths in 2019.¹ Ischaemic heart disease (IHD), stroke and heart failure are the most common causes of mortality,^{1 2} which vary across the lifespan and are influenced by ethnicity, racism and gender.^{3 4} Globally, mortality rates have remained stagnant; however, in 2017, mortality increased in women in two high income countries: Canada and the USA.¹ Young women are now more likely to die within 1 year of a myocardial infarction (MI) compared with men,^{5 6} and women who are transgender have a greater than twofold increase in MI compared with women who are cisgender.⁷

Moreover, most women are unaware of risk factors or symptoms.⁸ Women also have depression,⁹ anxiety^{9 10} and lower health-related quality of life (HRQoL)¹¹ 1 year after an MI and for many women, fear and anxiety about the future and difficulty moving forward in recovery extends beyond 5 years of having an MI.^{12–14} Stroke is the second most common cause of CVD mortality in women worldwide.¹⁵ Getahun *et al*¹⁶ also demonstrated an increased risk of stroke in transgender women. Women have a higher lifetime stroke risk compared with men,¹ with risk being highest during pregnancy, menopause and later in life.¹⁷ Women with heart failure tend to have preserved ejection fraction, peripartum cardiomyopathy and/or Takotsubo syndrome,^{18 19} and there are few to no treatments for specific heart failure phenotypes in women,¹ causing more depression and impaired HRQoL in women compared with men.^{20 21}

International CVD priorities, led by the WHO's Global Action Plan for the Prevention and Control of Non-Communicable Diseases (2013–2020) and the United Nations Sustainable Development Goals (2015–2030), focus on good health, gender equality, innovation and infrastructure, reduced inequalities, and partnerships.²² Good health focuses on ensuring healthy lives and promoting the well-being of all people at all ages, with a focus to reduce premature mortality from non-communicable diseases through prevention and treatment and the promotion of mental health and well-being.²² Individuals 43–70 years with IHD report worse physical HRQoL (38.9 (95% CI 36.9 to 41.0)) compared with the general population.²³ Similar results are reported in women with obstructive (41.9, SD 8.9) and non-obstructive heart disease (43.7, SD 9.4) ($p=0.072$).²⁴ Moreover, a decline in physical vs mental HRQoL is more predictive of hospital readmission²⁵ and mortality in healthy middle-aged and older women ($n=40\,337$)²⁶ and in men and women with heart disease.²⁵ The World Heart Federation has been advocating globally for better CVD outcomes, suggesting advocacy tactics and strategies to reduce CVD by 25% by 2025.²² This includes addressing behavioural risk factors for better prevention and reducing IHD and stroke in women by identifying and aligning with national CVD priorities, strategic communications, media engagement, evidence-based research, partnership development and collaborating with key decision-makers.²² The Lancet Commission advocates for a global imperative to reduce the global burden of CVD in women by 2030.¹

Social support in the form of relationships with family and friends, as well as peer support from other women with CVD, has been identified as an integral component in the recovery process for women following a cardiac event.²⁷ Perceived social support has a direct impact on health outcomes; individuals with low levels of social support have higher CVD-related²⁸ and all-cause mortality rates.²⁹ Results from the Variation in Recovery: Role of Gender on Outcomes of Young AMI Patients study suggested lower social support was associated with worse health outcomes and more depressive symptoms

12 months after an MI, with one in five individuals less than 55 years of age having low social support following an MI.³⁰ Others report that individuals with low social support following an MI had more angina (relative risk, 1.27; 95% CI 1.10 to 1.48), lower HRQoL (mean difference (β) = -3.33 ; 95% CI -5.25 to -1.41), lower mental functioning ($\beta=-1.72$; 95% CI -2.65 to -0.79) and more depressive symptoms ($\beta=0.94$; 95% CI 0.51 to 1.38).³¹ Moreover, the association between social support and HRQoL, depression and physical functioning appears to be stronger in women compared with men.³¹ In the general population, twice as many women have depression^{32 33} and anxiety^{34 35} as men, which are known risk factors for CVD. Depressive symptoms are associated with atherosclerotic IHD (OR 1.07, 95% CI 1.02 to 1.13, per one-point increase in the Patient Health Questionnaire (PHQ-9) score) and death (adjusted HR 1.07, 95% CI 1.02 to 1.14, per one-point increase in the PHQ-9 score) in women younger than 55 years, but not in men or in women over 55 years.³⁶ In postmenopausal women, fatal cardiac events are associated with depression.³⁷ Anxiety has also been linked to developing and the worsening IHD and CVD mortality.³⁸

It has been suggested that social support, specifically from other women who have lived a similar health or recovery experience, may play a key role in women's CVD rehabilitation and recovery.^{8 39 40} Peer support is the provision of assistance and encouragement by an individual that is considered equal⁴¹; it is a form of social support delivered by a layperson who has received some formal training to share experiential knowledge and emotional assistance. Defining attributes of all peer relationships include emotional, informational and appraisal support.⁴¹ Moreover, providing and receiving support benefits both the receiver and the provider of support.⁴² Women ($n=387$) aged 42 ± 6 years who received a peer support intervention reported better cardiovascular risk factor profiles (ie, hypertension, exercise, weight and smoking) compared with women randomised to a control group (difference: 0.75; 95% CI 0.32 to 1.18).⁴³ In patients and caregivers following a stroke, the value of peer support during the recovery process was derived through information and advice, encouragement and empowerment, awareness, being helpful and making connections.⁴⁴ There is some evidence that peer support interventions improve self-reported recovery for individuals with CVD,^{45 46} and hope and empowerment in other patient populations that include those with mental illness, HIV and women who are breast feeding.^{47–49} Women have identified the importance of engagement in several different activities to promote their recovery including behavioural, social and psychological dimensions.²⁷ As individuals focus on their own recovery in the context of multiple social roles, re-evaluation and reprioritisation of self can be a challenging task. Women face unique challenges in managing their health and modifying their lifestyle during recovery.^{50–53} Women often prioritise family, household responsibilities and caregiver tasks, which

subsequently place preventive health behaviours and their own health status as secondary.⁵⁴ There is a need to distinctly enhance the nature and level of care provided to women living with CVD. Although there is some evidence for the beneficial effects of peer support in women with CVD, a more gender-informative and culturally sensitive knowledge synthesis across the lifespan is needed.

Objectives

The overall aim of this study is to describe peer support interventions for women with CVD (IHD, stroke and heart failure) using an evidence map. Specific objectives are to: (1) provide an overview of peer support interventions used in women with IHD, stroke and heart failure, (2) identify gaps in primary studies where new or better studies are needed and (3) describe knowledge gaps where complete systematic reviews are required.

METHODS AND ANALYSIS

The main purpose of performing a broad map of the literature (ie, evidence map) is to identify the range of research and identify gaps and future research needs.⁵⁵ An evidence map is broad in scope, but systematic in its approach to synthesise the evidence.⁵⁵ Evidence mapping is useful in directing future research, including systematic reviews.^{56 57} We are collaborating with women with lived experience (Goodenough, Robert) and the Canadian Women's Heart Health Alliance (CWHHA) and using the Strategy for Patient-Oriented Research (SPOR) Capacity Development Framework,⁵⁸ SPOR Patient Engagement Framework⁵⁹ and the Individual and Family Self-Management Theory^{60 61} to describe peer support interventions used for women with CVD (IHD, stroke,

heart failure). The individual and family self-management theory⁶¹ consists of three dimensions: context, process and outcomes. We have used this in a previous integrated mixed methods systematic review to guide processes related to defining patient-reported outcome variables and variables used for data extraction.⁶² This theory depicts self-management within the broader context of people and other influences (eg, ethnicity, racism, health-care access and institutionalised gender).⁶³ The individual and family self-management Theory⁶¹ has provided a platform for testing clinical interventions that have included the Arthritis Self-Management Programme⁶⁴ and the Diabetes Self-Management Programme.⁶⁵ This model highlights the role of social influence (eg, peer support) and the value of emotional, informational and appraisal support (figure 1).^{61 66}

We used the Preferred Reporting Items for Systematic Reviews and Meta-Analyses for Protocols 2015 checklist when preparing this manuscript (online supplemental table 1).⁶⁷ In addition, the Guidance for Reporting Involvement of Patients and the Public-Long Form (GRIPP 2-LF) was used to document the engagement of women with lived experience (online supplemental table 2).⁶⁸ We will also use a patient partner compensation rate structure described in the Recommendations on Patient Engagement Compensation—Prepared by the SPOR Networks in Chronic Diseases and the PICHI Network⁶⁹: each woman with lived experience will receive a 1-year honorarium of US\$1000 that will include compensation for 4 hours of training and assistance across all other activities of the project (ie, screening, knowledge translation and exchange activities).

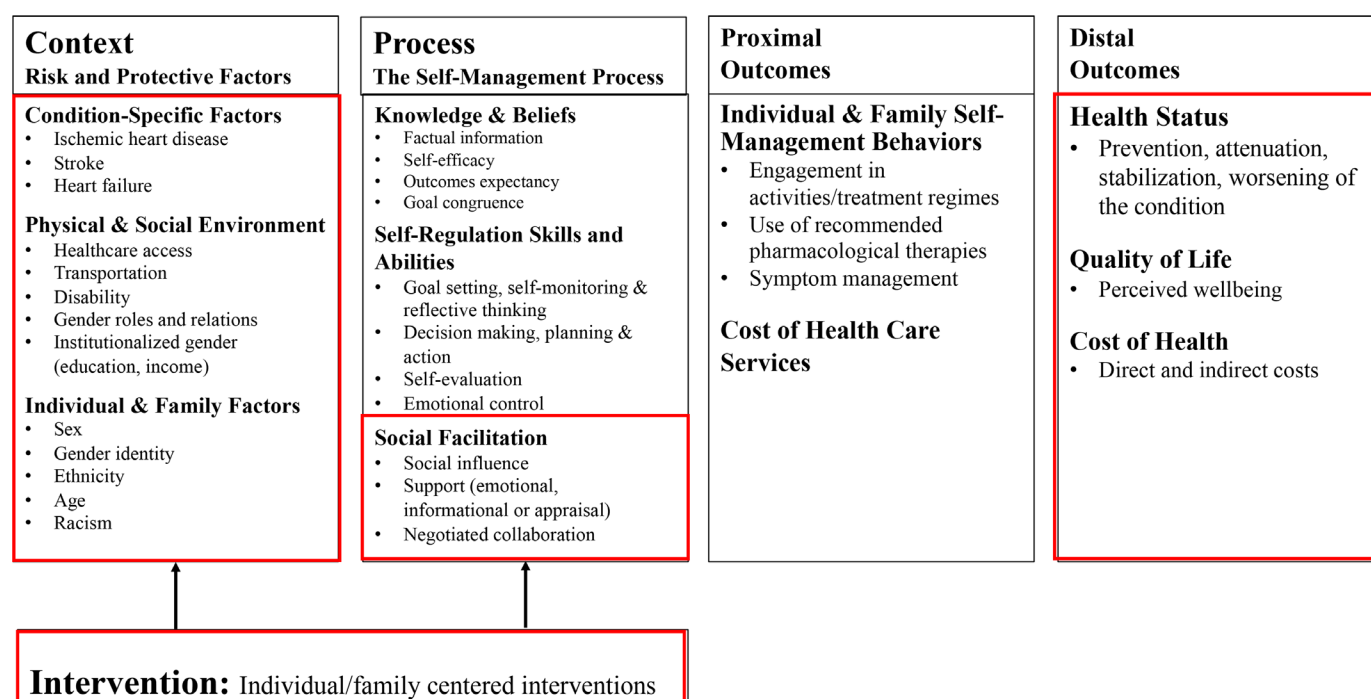


Figure 1 Individual and family self-management theory model.

We will not register our evidence map on PROSPERO, the international prospective register of systematic reviews, as evidence mapping does not meet the inclusion criteria for this registry. However, to manage records and promote transparency, we have registered our project on the Open Science Framework (DOI 10.17605/OSF.IO/E7KQ3).⁷⁰ Assessment of risk of bias, meta-bias(es) or strength of the evidence will not be undertaken. We will follow methods described by the Evidence for Policy and Practice Information (EPPI) and the Coordinating Centre at the Institute of Education,^{57 71–74} using six steps used in performing previous broad maps of the literature⁷⁵: (1) identify the scope of the evidence map, (2) define key variables, (3) establish a comprehensive search strategy, (4) identify clear eligibility criteria, (5) systematically retrieve, screen and classify the evidence and (6) report the findings in an evidence map.

Identify the scope of the evidence map

The initial scope of the work was defined by the research team to focus on the most common causes of CVD mortality in women¹²: IHD, stroke and heart failure. The research question, key variables and eligibility criteria were discussed with women with lived experience (Goodenough, Robert). Our overarching review question was established: What is known about peer support interventions used for women with CVD (IHD, stroke, and heart failure)? This question can be answered by a broad range of evidence that includes randomized controlled trials (RCTs), cohort and cross-sectional studies, case-control studies and case series/reports across reported from urban and rural settings across the globe.

Define key variables

We used the PICO framework to focus our research question and also to inform our broad search of the literature.⁷⁶ The PICO elements included the population, intervention, comparison and outcomes. Keywords and the National Library of Medicine's Medical Subject Headings were combined under two of the PICO categories: (P) women with CVD (IHD, stroke and heart failure) and (I) peer support. We did not search using a comparator or by outcome so that we could maintain breadth and reduce bias in our search strategy. Women with lived experience (Goodenough, Robert) collaborated to identify and confirm search terms as there is evidence that this may increase the number of citations retrieved by 34%.^{55 77} The draft MEDLINE search strategy (table 1) was also informed by searches of existing reviews^{78 79} and executed by a library scientist (Visintini).

Establish a comprehensive search strategy

The literature on peer support interventions used for women with CVD (IHD, stroke and heart failure) will be systematically and comprehensively searched using subject headings and keywords in accordance with the search syntaxes in each bibliographic databases. As noted, the search was drafted in MEDLINE via Ovid (table 1)

Table 1 Draft MEDLINE search, 1946 (database: MEDLINE(R) ALL, Platform: Ovid)

#	Searches
1	*social support/
2	Self-Help Groups/
3	peer group/
4	(peer* adj3 (support* or educat*)).ti,ab,kf.
5	((social adj3 support) and peer*).ti,ab,kf.
6	or/1–5
7	((heart or cardiac) adj2 (disease or surg* or patient?)).ti,ab,kf.
8	exp Myocardial Ischemia/
9	((coronary adj2 (arter* or stenosis* or atherosclerosis* or arteriosclerosis* or syndrome or microvascular)) or (coronary adj5 disease?) or CAD).ti,ab,kf.
10	(small adj2 (arter* or vessel*) adj2 disease*).ti,ab,kf.
11	(angina or stroke? or MINOCA or INOCA or SCAD or Kounis).ti,ab,kf.
12	((heart or myocardial) adj3 infarct*).ti,ab,kf.
13	(isch?emi* adj3 (heart or cardiac or myocardial)).ti,ab,kf.
14	((heart or cardiac or coronary) adj2 (spasm* or vasospasm* or embolism*)).ti,ab,kf.
15	exp Myocardial Revascularization/
16	((aortocoronary or coronary) adj3 bypass*) or CABG).ti,ab,kf.
17	(angioplast* or atherectomy* or endarterectomy* or thrombectomy* or PCI or PTCA or (Percutaneous adj3 (intervent* or revascular*))).ti,ab,kf.
18	exp Stroke/
19	Stroke Rehabilitation/
20	Cardiac Rehabilitation/
21	((brain* or cerebr* or cerebell* or vertebrobasilar or hemispher* or intracran* or intracerebral* or infratentorial* or supratentorial* or anterior circulation or posterior circulation or basal ganglia) adj5 (isch?emi* or infarct* or thrombo* or emboli*)).ti,ab,kf.
22	((brain* or cerebr* or cerebell* or intracerebral or intracran* or parenchymal or intraventricular or infratentorial or supratentorial or basal ganglia) adj5 (h?emorrhage* or h?ematoma* or bleed*)).ti,ab,kf.
23	exp Heart Failure/
24	exp Ventricular Dysfunction, Left/
25	((heart or cardiac) adj2 (failure or resynchroni*)).ti,ab,kf.
26	(cardiomyopath* or Takotsubo or HFrEF or HFpEF).ti,ab,kf.
27	or/7–26
28	6 and 27

by a library scientist. Prior to finalisation and execution, the draft MEDLINE search strategy will be peer reviewed by another librarian.⁸⁰ It will then be translated and run

Table 2 Inclusion and exclusion criteria

Include if study involves	Exclude if study involves
<p>Women</p> <ul style="list-style-type: none"> ▶ Including cis and trans women ▶ Also include if sex/gender is not specified <p>Adults aged 18 and older</p> <p>One or more of the following diagnoses:</p> <ul style="list-style-type: none"> ▶ Heart disease ▶ Ischaemic heart disease ▶ Coronary heart disease ▶ Coronary artery disease ▶ Acute coronary syndrome ▶ Myocardial infarction ▶ Unstable angina ▶ MINOCA (myocardial infarction with non-obstructive coronary arteries) ▶ Spontaneous coronary artery dissection ▶ Microvascular coronary disease ▶ Coronary artery spasm ▶ Coronary embolism ▶ Kounis syndrome ▶ Congestive heart failure <ul style="list-style-type: none"> – Cardiomyopathy – HFrEF (heart failure with reduced ejection fraction) – HFpEF – Takotsubo syndrome ▶ Stroke or Cerebrovascular accident <p>A support intervention led by a peer(s)</p> <ul style="list-style-type: none"> ▶ Could be <ul style="list-style-type: none"> – Individual (1:1) support or group programmes – Virtual/online programmes – The provision of emotional, appraisal and/or informational assistance 	<p>Men only</p> <p>Exclusively the following diagnoses (if none of the inclusion diagnoses on the left are also present):</p> <ul style="list-style-type: none"> ▶ Peripheral arterial disease ▶ Peripheral vascular disease ▶ Heart valve diseases <ul style="list-style-type: none"> – Stenosis – Regurgitation/leaky valve ▶ Arrhythmias <ul style="list-style-type: none"> – Atrial fibrillation – Atrial flutter – Supraventricular tachycardia – Palpitations ▶ Hypertension ▶ Risk factors for cardiovascular disease (eg, physical inactivity or sedentary lifestyle, smoking, depression), but no diagnosis of a cardiovascular disease <p>Support programmes led by healthcare professionals, and not peers with lived experience</p> <p>Informal social support from family, friends, or caregivers, and not peers with lived experience</p> <p>Systematic reviews and meta-analyses, scoping reviews (these types of studies should be flagged and documented in a group Google doc for reference)</p> <p>Descriptive or qualitative papers presenting general principles, frameworks, conceptual models or qualities of peer support, but that do not evaluate a peer support intervention(s), specifically (these types of studies might be useful to flag in our Google doc as reference papers)</p>

from inception in the remaining databases: CINAHL (EBSCO), EMBASE (Ovid), APA PsycINFO (Ovid), the Cochrane Database of Systematic Reviews (Ovid) and the Cochrane Central Register of Controlled Trials (Ovid) and Scopus (www.scopus.com). We will also search Clinicaltrials.gov and the WHO International Clinical Trials Registry Platform. Further grey literature will be identified via Proquest Dissertations and Theses, handsearching abstracts for specific conferences, and a targeted advanced Google search. No date or language limits will be applied to the searches. Citations will be exported from electronic search interfaces to Covidence⁸¹ for duplicate elimination and screening.

Identify clear eligibility criteria

Inclusion and exclusion criteria will be kept broad, and studies will be included if they discuss a peer support intervention and include women, independent of the research design (table 2). Types of participants will include cis and trans women greater than 18 years of age with IHD, stroke or heart failure. To ensure our search is broad, we will not specifically search by 'women'. However, we will ensure women are included in the studies during the screening process. We will not specifically define a minimum sample size of women to minimise selection bias. Moreover, this

will be an important variable to describe in our evidence map. Outcomes will include health status, HRQoL and healthcare costs. We will include disease-specific and generic reports and measures of two patient-reported outcomes: health status (ie, worsening of the condition) and HRQoL (ie, perceived well-being measured using the Minnesota Living with Heart Failure, Kansas City Cardiomyopathy Questionnaire, 12-item short form survey (SF-12), EQ 5D value health instrument).⁸² Estimating direct and indirect costs of peer support using a cost-effectiveness analysis, incremental cost-effectiveness ratio or quality-adjusted life-years will be included.⁸³

Systematically retrieve, screen and classify the evidence

All team members, including women with lived experience, will participate in retrieving, screening and classifying the evidence. All team members will receive: (1) 1 hour of training on screening titles and abstracts, (2) 1 hour of training on screening full-text reviews and (3) 2 hours of training on data extraction (4 hours total). A test batch of studies (n=24) screened as 'include, exclude or unsure' will be compared for inter-rater reliability and discussed between reviewers (including the women with lived experience (Goodenough, Robert)) in a 2-hour meeting to establish title and abstract screening accuracy

and confirm understanding of the inclusion and exclusion criteria.⁸⁴ Title, abstract and full-text articles will be screened by two independent reviewers. Disagreements or conflicts will be resolved by a third reviewer (Parry or Mullen). Data from included studies will be extracted to include article-level data (eg, author/country, publication year) and study-level data (eg, sample size, percent women, study design, population (eg, context), intervention and outcomes). Contextual factors will include participant characteristics as guided by the individual and family self-management theory (eg, sex, gender (roles, relations, identity and institutionalised), ethnicity, racism, age).⁶¹ We will use the Template for Intervention Description and Replication⁸⁵ to extract peer support intervention details that will include intervention procedures, peer background and training, modes of delivery (ie, face to face, group), location of delivery (ie, in-person, virtual), number of times the intervention was delivered over what period of time (ie, duration, intensity, dose) and intervention fidelity. Social facilitation details including type of support (emotional, informational and appraisal support) will also be captured in our data extraction. Outcomes will include health status, HRQoL and healthcare costs. To ensure transparency and rigour, we will describe our methods of locating relevant unpublished and grey literature in a systematic way,^{72 86 87} following processes used in our previous broad map of the literature.⁷⁵

Report findings in an evidence map

The findings of all studies meeting the eligibility criteria will summarised narratively. This will include a description of the participants, settings and peer support interventions. The individual and family self-management theory will guide specific descriptions by context, process and outcomes. Bubble plots (ie, weighted scatter plots), geographical heat/choropleth maps and infographics will be used to graphically illustrate peer support intervention elements by category of CVD (ie, IHD, stroke and heart failure). Analyses will be performed using R, a software environment for statistical computing and graphics.⁸⁸

Patient and public involvement

Two women living with CVD (Goodenough, Robert) are members of our investigative team and members of the CWHHA, a volunteer organisation of over 130 health professionals and women living with CVD. The mission of the CWHHA is to support patients, clinicians, scientists and decision-makers to implement evidence, transform clinical practices and impact public policy related to women's cardiovascular health. CWHHA members, and the 16 patient advocate members, voted in the Fall 2020 strategic planning session to pursue a project focused on peer support for women with CVD. This evidence map review is direct guidance from women who live with CVD. We are using the SPOR Capacity Development Framework⁵⁸ and the SPOR Patient Engagement Framework⁵⁹ to ensure the perspectives of women living with CVD are integrated into all steps of this broad map of the literature,

including developing the research question/objectives, key variables, and eligibility criteria, defining search terms, screening titles/abstracts and full text papers, evaluating results and disseminating findings. The GRIPP 2-LF⁶⁸ has been used to document patient engagement activities and we have used the patient partner compensation rate structure described in the Recommendations on Patient Engagement Compensation-Prepared by the SPOR Networks in Chronic Diseases and the PICHI Network.⁶⁹ The guiding principles of cobuild, inclusiveness, support and mutual respect underpin all patient engagement activities in this study.⁵⁹

Ethics and dissemination

Ethics approval has been granted from the University of Toronto (42608, 28 April 2022). It is not necessary to obtain informed consent for this review. Knowledge will be disseminated through publication, presentation/public forums and social media.

Author affiliations

¹Lawrence S. Bloomberg Faculty of Nursing, University of Toronto, Toronto, Ontario, Canada

²Berkman Library, University of Ottawa Heart Institute, Ottawa, Ontario, Canada

³Health Sciences Library, University of Ottawa, Ottawa, Ontario, Canada

⁴School of Epidemiology and Public Health, University of Ottawa, Ottawa, Ontario, Canada

⁵University of Ottawa Heart Institute, Ottawa, Ontario, Canada

⁶Toronto Rehabilitation Cardiovascular Prevention & Rehabilitation Program, KITE - University Health Network, Toronto, Ontario, Canada

⁷Lawrence S. Bloomberg Faculty of Nursing and the Rehabilitation Sciences Institute, University of Toronto, Toronto, Ontario, Canada

⁸Lawrence S. Bloomberg Faculty of Nursing (Research Assistant), University of Toronto, Toronto, Ontario, Canada

⁹School of Medicine, Faculty of Health Sciences, Queen's University, Kingston, Ontario, Canada

¹⁰Faculty of Medicine, Dalhousie University, Halifax, Nova Scotia, Canada

¹¹Faculty of Medicine, University of Ottawa, Ottawa, Ontario, Canada

¹²Section of Cardiology, Department of Internal Medicine, Rady Faculty of Health Sciences, University of Manitoba, Winnipeg, Manitoba, Canada

¹³Canadian Women's Heart Health Alliance, University of Ottawa Heart Institute, Ottawa, Ontario, Canada

¹⁴Faculty of Kinesiology and Recreation Management, University of Manitoba, Winnipeg, Manitoba, Canada

¹⁵Institute of Cardiovascular Sciences, St Boniface General Hospital Albrechtsen Research Centre, Winnipeg, Manitoba, Canada

¹⁶Indigenous Services Canada, Toronto, Ontario, Canada

¹⁷Department of Surgery, The University of British Columbia, Vancouver, British Columbia, Canada

¹⁸Canadian Women's Heart Health Centre, University of Ottawa Heart Institute, Ottawa, Ontario, Canada

Twitter Monica Parry @parryresearch and Najah Adrean @NajahAdrean

Contributors The PI (MP) and Co-PI (K-AM) conceived the study. DK and MP drafted and revised the manuscript prior to submission. Coauthors (NA, TC, SD, ZG, CG, JH, AJ, DK, KL, SL, K-AM, MN, AO'H, HR, NT and SV) will contribute to all steps of the review. One coauthor (AW) will be responsible for coordinating administrative aspects of the review. Most authors (NA, TC, SD, CG, JH, AJ, DK, KL, SL, K-AM, MN, MP, HR, NT, SV) are grant holders. We thank the two women with lived experience (CG, HR) from the CWHHA who are Co-Is. MP finalised the Research Ethic Board (REB) submission. The Co-PIs (MP, K-AM) will provide day-to-day oversight of the review. Most authors (NA, TC, SD, CG, JH, AJ, DK, KL, SL, K-AM, MN, MP, HR, NT, SV) assisted to build and approve content for the funding application. All authors (NA, TC, TD, ZG, CG, JH, AJ, DK, KL, SL, K-AM, MN, AO'H, MP, HR, NT, SV, AW) approved the final manuscript prior to submission. All authors (NA, TC, SD, CG, JH, AJ, DK,

KL, SL, K-AM, MN, AO'H, MP, HR, NT, SV, AW) are also accountable for all aspects of ensuring the accuracy and integrity of the work across all steps of the review.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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ORCID iDs

Monica Parry <http://orcid.org/0000-0002-6941-1380>

Sarah Visintini <http://orcid.org/0000-0001-6966-1753>

Amy Johnston <http://orcid.org/0000-0003-1934-7867>

Shuangbo Liu <http://orcid.org/0000-0002-8722-0182>

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Supplementary Table 1 PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol and utilized as a general guidance document for this evidence map protocol*.

Section and topic	Item No	Checklist item	Section
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a review protocol	Title Page
Update	1b	If the protocol is for an update of a previous review, identify as such	N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	Abstract, Methods and Analysis
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	Authors and Affiliations
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	Contributors
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	N/A
Support:			
Sources	5a	Indicate sources of financial or other support for the review	Funding
Sponsor	5b	Provide name for the review funder and/or sponsor	Funding
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	N/A
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	Introduction
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	Objectives
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	Identify Clear Eligibility Criteria, Table 2
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	Establish a Comprehensive Search Strategy, Table 1

Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	Table 1
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	Establish a Comprehensive Search Strategy
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility, and inclusion in evidence map)	Systematically Retrieve, Screen and Classify the Evidence
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	Systematically Retrieve, Screen and Classify the Evidence
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	Define Key Variables, Table 1
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	Identify Clear Eligibility Criteria
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	Methods and Analysis
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	Report Findings in an Evidence Map
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2 , Kendall's τ)	Report Findings in an Evidence Map
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	N/A
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	Report Findings in an Evidence Map
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	Methods and Analysis
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	Methods and Analysis

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1): g7647.

Supplemental Table 2 GRIPP2 Long Form.

Section and topic	Checklist item	Included
Section 1: Abstract of paper		
1a: Aim	Report aims of study	
1b: Methods	Describe methods used by which patients/public involved	Yes
1c: Results	Report impacts and outcomes of PPI in study	N/A
1d: Conclusions	Summarize main conclusions of study	N/A
1e: Keywords	Include PPI or alternative terms as keywords	Yes
Section 2: Background to paper		
2a: Definition	Report definition of PPI used and how it links to comparable studies	Yes
2b: Theoretical underpinnings	Report theoretical rationale and influences of PPI	Yes
2c: Concepts and theory development	Report any conceptual models or influences used	Yes
Section 3: Aims of paper		
3: Aim	Report aims of study	Yes
Section 4: Methods of paper		
4a: Design	Describe methods by which patients involved	Yes
4b: People involved	Describe patients involved with PPI activity in study	Yes
4c: Stages of involvement	Report on how PPI used at different stages of study	Yes
4d: Level or nature of involvement	Report level or nature of PPI used at various stages	Yes
Section 5: Capture or measurement of PPI impact		
5a: Qualitative evidence of impact	Report methods to qualitatively explore impact of PPI	N/A
5b: Quantitative evidence of impact	Report methods to quantitatively measure impact of PPI	N/A
5c: Robustness of measure	Report rigour of method used to capture impact of PPI	N/A
Section 6: Economic assessment		
6: Economic assessment	Report method used for economic assessment of PPI	N/A
Section 7: Study results		
7a: Outcomes of PPI	Report results of PPI, including positive and negative outcomes	N/A
7b: Impacts of PPI	Report positive and negative impacts PPI had on research, individuals involved, and wider impacts	N/A
7c: Context of PPI	Report contextual factors the enabled or hindered the process of impact of PPI	N/A
7d: Process of PPI	Report process factors that enabled or hindered PPI	N/A
7ei: Theory development	Report any theory development in PPI that emerged	N/A
7eii: Theory development	Report testing of theoretical models, if any	N/A
7f: Measurement	Report instrument development and testing	N/A
7g: Economic assessment	Report costs or benefits of PPI	N/A
Section 8: Discussion and conclusion		
8a: Outcomes	Comment on how PPI influenced overall study	N/A
8b: Impacts	Comment on impacts of PPI and how they contribute to new knowledge	N/A
8c: Definition	Comment on definition of PPI used and report any suggested changes	N/A
8d: Theoretical underpinnings	Comment on study's contribution to theory development of PPI	N/A
8e: Context	Comment on how context factors influenced PPI	N/A
8f: Process	Comment on how process factors influenced PPI	N/A
8g: Measurement/capture of PPI impact	Comment on how well PPI impact was evaluated	N/A
8h: Economic assessment	Discuss economic costs or benefits of PPI	N/A
8i: Reflections/critical perspective	Reflect on what went well and what did not go well	N/A

PPI=patient and public involvement