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## Peer Support Interventions for Women with Cardiovascular Disease: Protocol for Synthesizing the Literature Using an Evidence Map

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**Title:** Peer Support Interventions for Women with Cardiovascular Disease: Protocol for Synthesizing the Literature Using an Evidence Map

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## ABSTRACT

**Introduction** The leading cause of death for women is cardiovascular disease (CVD), including ischemic heart disease, stroke, and heart failure. Previous literature has demonstrated that 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 ischemic 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** Women living with CVD are members of our investigative team and will collaborate in all steps of the review. We are also collaborating with the Canadian Women's Heart Health Alliance and using the Strategy for Patient-Oriented Research (SPOR) Capacity Development Framework, SPOR Patient Engagement Framework, and the Individual and Family Self-Management Theory. We are also 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. Six steps will be followed: 1) identify the scope, 2) define key variables, 3) establish a broad and systematic search strategy, 4) identify study eligibility criteria, 5) comprehensively retrieve, screen, and classify the evidence, and 6) report findings in an evidence map.

**Ethics and Dissemination** The University of Toronto's Research Ethics Board granted approval on April 28<sup>th</sup>, 2022 (Protocol #42608). Bubble plots (i.e., weighted scatter plots), geographic 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.

**Keywords** Evidence Map, Peer Support, Cardiovascular Disease, Women, Patient-Oriented Research

**Registration:** Open Science Framework (DOI 10.17605/OSF.IO/E7KQ3)

## STRENGTHS AND LIMITATIONS OF THE REVIEW

- This is the first evidence map to critically examine and synthesize the literature on peer support programs utilized for women with ischemic heart disease, stroke, and heart failure.
- Women with lived experience (i.e., patient partners) will collaborate in identifying search terms as there is evidence that this increases the number of citations by 34%.
- 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. Women with lived experience will also verify terms used in the literature search strategy.

## INTRODUCTION

The leading cause of premature death for women is cardiovascular disease (CVD), responsible for 35% of total deaths in 2019.<sup>1</sup> Ischemic heart disease (IHD), stroke and heart failure are the most common causes of mortality;<sup>1,2</sup> which vary across the lifespan and are influenced by ethnicity, racism, and gender.<sup>3,4</sup> Globally, mortality rates have remained stagnant, however in 2017, mortality increased in women in two high income countries: Canada and the United States.<sup>1</sup> Young women are now more likely to die within one year of a myocardial infarction (MI) compared to men,<sup>5,6</sup> and women who are transgender have a greater than two-fold increase in MI compared to women who are cisgender.<sup>7</sup> Moreover, most women are unaware of risk factors or symptoms.<sup>8</sup> Women also have depression,<sup>9</sup> anxiety,<sup>9,10</sup> and lower health-related quality of life (HRQoL)<sup>11</sup> one year after an MI, and for many women, fear and anxiety about the future and difficulty moving forward in recovery extends beyond five years of having an MI.<sup>12-14</sup> Stroke is the second most common cause of CVD-mortality in women worldwide.<sup>15</sup> Getahun et al.<sup>16</sup> also demonstrated an increased risk of stroke in transgender women. Women have a higher lifetime stroke risk compared to men,<sup>1</sup> with risk being highest during pregnancy, menopause, and later in life.<sup>9</sup> Women with heart failure tend to have preserved ejection fraction, peripartum cardiomyopathy, and/or Takotsubo syndrome,<sup>17,18</sup> and there are few to no treatments for specific heart failure phenotypes in women,<sup>1</sup> causing more depression and impaired HRQoL in women compared to men.<sup>19,20</sup>

International CVD priorities, led by the World Health Organization'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.<sup>21</sup> 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.<sup>21</sup> Individuals 43 to 70 years with IHD report worse physical HRQoL (38.9 [95% CI, 36.9-

1  
2 41.0]) compared to the general population.<sup>22</sup> Similar results are reported in women with obstructive  
3  
4 (41.9, SD 8.9) and non-obstructive heart disease (43.7, SD 9.4) ( $p=0.072$ ).<sup>23</sup> Moreover, a decline in  
5  
6 physical versus mental HRQoL is more predictive of hospital readmission<sup>24</sup> and mortality in healthy  
7  
8 middle-aged and older women ( $n=40,337$ )<sup>25</sup> and in men and women with heart disease.<sup>24</sup> The World  
9  
10 Heart Federation has been advocating globally for better CVD outcomes, suggesting advocacy tactics  
11  
12 and strategies to reduce CVD by 25% by 2025.<sup>21</sup> This includes addressing behavioral risk factors for  
13  
14 better prevention and reducing IHD and stroke in women by identifying and aligning with national  
15  
16 CVD priorities, strategic communications, media engagement, evidence-based research, partnership  
17  
18 development, and collaborating with key decision-makers.<sup>21</sup> The Lancet Commission advocates for a  
19  
20 global imperative to reduce the global burden of CVD in women by 2030.<sup>1</sup>  
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24

25 Social support in the form of relationships with family and friends, as well as peer support from  
26  
27 other women with CVD, has been identified as an integral component in the recovery process for  
28  
29 women following a cardiac event.<sup>26</sup> Perceived social support has a direct impact on health outcomes;  
30  
31 individuals with low levels of social support have higher CVD-related<sup>27</sup> and all-cause mortality rates.<sup>28</sup>  
32  
33 Results from the Variation in Recovery: Role of Gender on Outcomes of Young AMI Patients  
34  
35 (VIRGO) study suggested lower social support was associated with worse health outcomes and more  
36  
37 depressive symptoms 12 months after an MI, with one in five individuals less than 55 years of age  
38  
39 having low social support following an MI.<sup>29</sup> Others report that individuals with low social support  
40  
41 following an MI had more angina (relative risk [RR], 1.27; 95% confidence interval [CI], 1.10, 1.48),  
42  
43 lower HRQoL (mean difference [ $\beta$ ] = -3.33; 95% CI, -5.25, -1.41), lower mental functioning ( $\beta$  = -  
44  
45 1.72; 95% CI, -2.65, -0.79), and more depressive symptoms ( $\beta$  = 0.94; 95% CI, 0.51, 1.38).<sup>30</sup>  
46  
47 Moreover, the association between social support and HRQoL, depression, and physical functioning  
48  
49 appears to be stronger in women compared to men.<sup>30</sup> In the general population, twice as many women  
50  
51 have depression<sup>31,32</sup> and anxiety<sup>33,34</sup> as men, which are known risk factors for CVD. Depressive  
52  
53 symptoms are associated with atherosclerotic IHD (odds ratio [OR]=1.07, 95% CI, 1.02, 1.13, per one-  
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1  
2 point increase in the Patient Health Questionnaire [PHQ-9] score) and death (adjusted hazard ratio  
3  
4 [HR]=1.07, 95% CI, 1.02, 1.14, per one-point increase in the PHQ-9 score) in women younger than 55  
5  
6 years, but not in men or in women over 55 years.<sup>35</sup> In postmenopausal women, fatal cardiac events are  
7  
8 associated with depression.<sup>36</sup> Anxiety has also been linked to developing and the worsening IHD and  
9  
10 CVD mortality.<sup>37</sup>

11  
12  
13 It has been suggested that social support, specifically from other women who have lived a  
14  
15 similar health or recovery experience, may play a key role in women's CVD rehabilitation and  
16  
17 recovery.<sup>8,38,39</sup> Peer support is the provision of assistance and encouragement by an individual that is  
18  
19 considered equal<sup>40</sup>; it is a form of social support delivered by a layperson who has received some  
20  
21 formal training to share experiential knowledge and emotional assistance. Defining attributes of all peer  
22  
23 relationships include emotional, informational, and appraisal support.<sup>40</sup> Moreover, providing and  
24  
25 receiving support benefits both the receiver and the provider of support.<sup>41</sup> Women (n = 387) aged 42 ±  
26  
27 6 years who received a peer support intervention reported better cardiovascular risk factor profiles (i.e.,  
28  
29 hypertension, exercise, weight, smoking) compared to women randomized to a control group  
30  
31 (difference: 0.75; 95% CI, 0.32, 1.18).<sup>42</sup> In patients and caregivers following a stroke, the value of peer  
32  
33 support during the recovery process was derived through information and advice, encouragement and  
34  
35 empowerment, awareness, being helpful, and making connections.<sup>43</sup> There is some evidence that peer  
36  
37 support interventions improve self-reported recovery for individuals with CVD,<sup>44,45</sup> and hope and  
38  
39 empowerment in other patient populations that include those with mental illness, HIV, and women who  
40  
41 are breastfeeding.<sup>46-48</sup> Women have identified the importance of engagement in several different  
42  
43 activities to promote their recovery including behavioural, social, and psychological dimensions.<sup>26</sup> As  
44  
45 individuals focus on their own recovery in the context of multiple social roles, re-evaluation and re-  
46  
47 prioritization of self can be a challenging task. Women face unique challenges in managing their health  
48  
49 and modifying their lifestyle during recovery.<sup>49-52</sup> Women often prioritize family, household  
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51 responsibilities, and caregiver tasks, which subsequently place preventive health behaviours and their  
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1  
2 own health status as secondary.<sup>53</sup> There is a need to distinctly enhance the nature and level of care  
3  
4 provided to women living with CVD. Although there is some evidence for the beneficial effects of peer  
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6 support in women with CVD, a more gender-informative and culturally sensitive knowledge synthesis  
7  
8 across the lifespan is needed.  
9

## 10 11 **OBJECTIVES**

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13  
14 The overall aim of this study is to describe peer support interventions for women with CVD  
15  
16 (IHD, stroke, heart failure) using an evidence map. Specific objectives are to: 1) provide an overview  
17  
18 of peer support interventions used in women with ischemic heart disease, stroke, and heart failure, 2)  
19  
20 identify gaps in primary studies where new or better studies are needed, and 3) describe knowledge  
21  
22 gaps where complete systematic reviews are required.  
23  
24

## 25 26 **METHODS AND ANALYSIS**

27  
28 The main purpose of performing a broad map of the literature (i.e., evidence map) is to identify  
29  
30 the range of research and identify gaps and future research needs.<sup>54</sup> An evidence map is broad in scope,  
31  
32 but systematic in its approach to synthesize the evidence.<sup>54</sup> Evidence mapping is useful in directing  
33  
34 future research, including systematic reviews.<sup>55,56</sup> We are collaborating with women with lived  
35  
36 experience (Goodenough, Robert) and the Canadian Women's Heart Health Alliance (CWHHA) and  
37  
38 using the Strategy for Patient-Oriented Research (SPOR) Capacity Development Framework,<sup>23</sup> SPOR  
39  
40 Patient Engagement Framework,<sup>24</sup> and the Individual and Family Self-Management Theory<sup>25,26</sup> to  
41  
42 describe peer support interventions used for women with CVD (IHD, stroke, heart failure). The  
43  
44 Individual and Family Self-Management Theory consists of three dimensions: context, process and  
45  
46 outcomes.<sup>100</sup> We have used this in a previous integrated mixed methods systematic review to guide  
47  
48 processes related to defining patient-reported outcome variables and variables used for data  
49  
50 extraction.<sup>57</sup> This theory depicts self-management within the broader context of people and other  
51  
52 influences (e.g., ethnicity, racism, healthcare access, institutionalized gender).<sup>108</sup> The Individual and  
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1  
2 Family Self-Management Theory<sup>100</sup> has provided a platform for testing clinical interventions that have  
3  
4 included the Arthritis Self-Management Program (ASMP)<sup>109</sup> and the Diabetes Self-Management  
5  
6 Program.<sup>110</sup> This model highlights the role of social influence (e.g., peer support) and the value of  
7  
8 emotional, informational, and appraisal support (*Figure 1*).<sup>100,111</sup>  
9

10  
11 -Insert Figure 1-  
12

13 We used the Preferred Reporting Items for Systematic reviews and Meta-Analyses for Protocols  
14  
15 2015 (PRISMA-P 2015) checklist when preparing this manuscript (Supplementary Table 1).<sup>58</sup>  
16  
17 Additionally, the Guidance for Reporting Involvement of Patients and the Public – Long Form (GRIPP  
18  
19 2 - LF) was used to document the engagement of women with lived experience (Goodenough, Robert)  
20  
21 (Supplementary Table 2).<sup>59</sup> We will also use a patient partner compensation rate structure described in  
22  
23 the Recommendations on Patient Engagement Compensation – Prepared by the SPOR Networks in  
24  
25 Chronic Diseases and the PICHI Network<sup>60</sup>: each (Goodenough, Robert) will receive a one-year  
26  
27 honorarium of \$1000 that will include compensation for 4-hours of training and assistance across all  
28  
29 other activities of the project (i.e., screening, knowledge translation and exchange [KTE] activities).  
30  
31  
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33

34 We will not register our evidence map on PROSPERO, the international prospective register of  
35  
36 systematic reviews, as evidence mapping does not meet the inclusion criteria for this registry.  
37  
38 However, to manage records and promote transparency, we have registered our project on the Open  
39  
40 Science Framework (DOI 10.17605/OSF.IO/E7KQ3).<sup>61</sup> Assessment of risk of bias, meta-bias(es), or  
41  
42 strength of the evidence will not be undertaken. We will follow methods described by the Evidence for  
43  
44 Policy and Practice Information (EPPI) and the Coordinating Centre at the Institute of Education,<sup>56,62-65</sup>  
45  
46 using six steps utilized in performing previous broad maps of the literature<sup>66</sup>: 1) identify the scope of  
47  
48 the evidence map, 2) define key variables, 3) establish a comprehensive search strategy, 4) identify  
49  
50 clear eligibility criteria, 5) systematically retrieve, screen and classify the evidence, and 6) report the  
51  
52 findings in an evidence map.  
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55

### 56 57 **Identify the Scope of the Evidence Map** 58

1  
2 The initial scope of the work was defined by the research team to focus on the most common  
3  
4 causes of CVD mortality in women<sup>1,3</sup>: IHD, stroke and heart failure. The research question, key  
5  
6 variables, and eligibility criteria were discussed with women with lived experience (Goodenough,  
7  
8 Robert). Our overarching review question was established: *What is known about peer support*  
9  
10 *interventions used for women with CVD (IHD, stroke, and heart failure)?* This question can be  
11  
12 answered by a broad range of evidence that includes RCTs, cohort and cross-sectional studies, case  
13  
14 control studies and case series/reports across reported from urban and rural settings across the globe.  
15  
16

### 17 **Define Key Variables**

18  
19  
20 We used the PICO framework to focus our research question and also to inform our broad  
21  
22 search of the literature.<sup>115</sup> The PICO elements included the population, intervention, comparison and  
23  
24 outcomes. Keywords and the National Library of Medicine's Medical Subject Headings (MeSH) were  
25  
26 combined under two of the PICO categories: (P) women with CVD (IHD, stroke and heart failure) and  
27  
28 (I) peer support. We did not search using a comparator or by outcome so that we could maintain  
29  
30 breadth and reduce bias in our search strategy. The draft MEDLINE search strategy was informed by  
31  
32 searches of existing reviews (*Table 1*) and executed by a library scientist.<sup>116,117</sup> Women with lived  
33  
34 experience (Goodenough, Robert) collaborated to identify and confirm search terms as there is  
35  
36 evidence that this may increase the number of citations retrieved by 34%.<sup>112,118</sup>  
37  
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40

### 41 **Establish a Comprehensive Search Strategy**

42  
43 The literature on peer support interventions used for women with CVD (IHD, stroke, and heart  
44  
45 failure) will be systematically and comprehensively searched using MeSH headings and keywords in  
46  
47 accordance with the search criteria in the bibliographic databases. Publications will need to be available  
48  
49 in English or French. The following five databases will be searched: CINAHL, EMBASE, MEDLINE,  
50  
51 APA PsychInfo, the Cochrane Database of Systematic Reviews and the Cochrane Central Register of  
52  
53 Controlled Trials, and Scopus. We will also search Clinicaltrials.gov and the WHO International  
54  
55 Clinical Trials Registry Platform (ICTRP). Further grey literature will be identified via Proquest  
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Dissertations and Theses, handsearching abstracts for specific conferences, and a targeted advanced Google search. Citations will be exported from electronic search interfaces to Covidence<sup>119</sup> for duplicate elimination and screening.

**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 gangli*) 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

## 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 minimize 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 (i.e., worsening of the condition, etc.) and HRQoL (i.e., perceived wellbeing measured using the Minnesota Living with Heart Failure, Kansas City Cardiomyopathy Questionnaire, SF-12, EuroQoL 5D-3L, etc.).<sup>67</sup> Estimating direct and indirect costs of peer support using a cost-effectiveness analysis (CEA), incremental cost-effectiveness ratio (ICER), or quality-adjusted life years (QALYs) will be included.<sup>68</sup>

**Table 2** Inclusion and Exclusion Criteria.

<b>Include if study involves:</b>	<b>Exclude if study involves:</b>
<ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Women               <ul style="list-style-type: none"> <li><input type="checkbox"/> Including cis and trans women</li> <li><input type="checkbox"/> Also include if sex/gender is not specified</li> </ul> </li> <li><input checked="" type="checkbox"/> Adults aged 18 and older</li> <li><input checked="" type="checkbox"/> One or more of the following diagnoses:               <ul style="list-style-type: none"> <li><input type="checkbox"/> Heart disease</li> <li><input type="checkbox"/> Ischemic heart disease</li> <li><input type="checkbox"/> Coronary heart disease</li> <li><input type="checkbox"/> Coronary artery disease</li> <li><input type="checkbox"/> Acute coronary syndrome</li> <li><input type="checkbox"/> Myocardial infarction</li> <li><input type="checkbox"/> Unstable angina</li> <li><input type="checkbox"/> MINOCA (myocardial infarction with non-obstructive coronary arteries)</li> <li><input type="checkbox"/> Spontaneous Coronary Artery Dissection (SCAD)</li> <li><input type="checkbox"/> Microvascular coronary disease</li> <li><input type="checkbox"/> Coronary artery spasm</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Men only</li> <li><input checked="" type="checkbox"/> Exclusively the following diagnoses (if none of the inclusion diagnoses on the left are also present):               <ul style="list-style-type: none"> <li><input type="checkbox"/> Peripheral arterial disease</li> <li><input type="checkbox"/> Peripheral vascular disease</li> <li><input type="checkbox"/> Heart valve diseases                   <ul style="list-style-type: none"> <li><input type="checkbox"/> Stenosis</li> <li><input type="checkbox"/> Regurgitation/leaky valve</li> </ul> </li> <li><input type="checkbox"/> Arrhythmias                   <ul style="list-style-type: none"> <li><input type="checkbox"/> Atrial Fibrillation</li> <li><input type="checkbox"/> Atrial Flutter</li> <li><input type="checkbox"/> Supraventricular tachycardia</li> <li><input type="checkbox"/> Palpitations</li> </ul> </li> <li><input type="checkbox"/> Hypertension</li> <li><input type="checkbox"/> Risk factors for cardiovascular disease (e.g., physical inactivity or sedentary lifestyle, smoking, depression), but no diagnosis of a cardiovascular disease</li> </ul> </li> </ul>

<ul style="list-style-type: none"> <li>○ Coronary embolism</li> <li>○ Kounis syndrome</li> <li>○ Congestive Heart failure <ul style="list-style-type: none"> <li>▪ Cardiomyopathy</li> <li>▪ HFrEF (heart failure with reduced ejection fraction)</li> <li>▪ HFpEF (heart failure with preserved ejection fraction)</li> <li>▪ Takotsubo syndrome</li> </ul> </li> <li>○ Stroke or Cerebrovascular accident</li> <li><input checked="" type="checkbox"/> A support intervention led by a peer(s)</li> <li>○ Could be <ul style="list-style-type: none"> <li>▪ Individual (1:1) support or group programs</li> <li>▪ Virtual/online programs</li> <li>▪ The provision of emotional, appraisal, and/or informational assistance</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Support programs led by health care professionals, and not peers with lived experience</li> <li><input checked="" type="checkbox"/> Informal social support from family, friends, or caregivers, and not peers with lived experience</li> <li><input checked="" type="checkbox"/> Systematic reviews and meta-analyses, scoping reviews (these types of studies should be flagged and documented in a group Google doc for reference)</li> <li><input checked="" type="checkbox"/> 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)</li> </ul>
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### Systematically Retrieve, Screen and Classify the Evidence

All team members, including women with lived experience (Goodenough, Robert), will participate in retrieving, screening and classifying the evidence. All team members will receive: 1) one-hour of training on screening titles and abstracts, 2) one-hour of training on screening full-text reviews, and 3) two-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 two-hour meeting to establish title and abstract screening accuracy and confirm understanding of the inclusion and exclusion criteria.<sup>69</sup> 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 (e.g., author/country, publication year) and study-level data (e.g., sample size, percent women, study design, population (e.g., context), intervention and outcomes. Contextual factors will include participant characteristics as guided by the Individual and Family Self-Management Theory (e.g., sex, gender [roles, relations, identity and institutionalized], ethnicity, racism, age).<sup>100</sup> We will use the Template for Intervention Description and Replication –

TIDieR)<sup>120</sup> to extract peer support intervention details that will include intervention procedures, peer background and training, modes of delivery (i.e., face-to-face, group), location of delivery (i.e., in-person, virtual), number of times the intervention was delivered over what period of time (i.e., 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 rigor, we will describe our methods of locating relevant unpublished and grey literature in a systematic way,<sup>20,121,122</sup> following processes used in our previous broad map of the literature.<sup>66</sup>

### **Report Findings in an Evidence Map**

The findings of all studies meeting the eligibility criteria will be summarized 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 (i.e., weighted scatter plots), geographic heat/choropleth maps, and infographics will be used to graphically illustrate peer support intervention elements by category of CVD (i.e., IHD, stroke, and heart failure). Analyses will be performed using R, a software environment for statistical computing and graphics.<sup>70</sup>

### **ETHICS AND DISSEMINATION**

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

### **AUTHOR CONTRIBUTIONS**

The PI (Parry) and Co-PI (Mullen) conceived the study. Kapur and Parry drafted and revised the manuscript prior to submission. Co-authors (Adreak, Colella, Dancey, Gomes, Goodenough, Hay, Johnston, Kapur, Liblik, Liu, Mullen, Noble, O'Hara, Robert, Tang, Visintini) will contribute to all steps of the review. One co-author (Wong) will be responsible for coordinating administrative aspects of the

1  
2 review. Most authors (Adreak, Colella, Dancey, Goodenough, Hay, Johnston, Kapur, Liblik, Liu, Mullen,  
3  
4 Noble, Parry, Robert, Tang, Visintini) are grant holders. Two women with lived experience  
5  
6 (Goodenough, Robert) from the CWHHA are Co-Is. The CWHHA is a volunteer organization of over  
7  
8 130 health professionals and women living with CVD. Their mission is to support patients, clinicians,  
9  
10 scientists, and decision-makers to implement evidence, transform clinical practices, and impact public  
11  
12 policy related to women's cardiovascular health. CWHHA members, and the 16 patient advocate  
13  
14 members, voted in the Fall 2020 strategic planning session to pursue a project focused on peer support  
15  
16 for women with CVD. This evidence map review is direct guidance from women who live with CVD.  
17  
18 Parry finalized the Research Ethic Board (REB) submission. The Co-PIs (Parry, Mullen) will provide  
19  
20 day-to-day oversight of the review. Most authors (Adreak, Colella, Dancey, Goodenough, Hay,  
21  
22 Johnston, Kapur, Liblik, Liu, Mullen, Noble, Parry, Robert, Tang, Visintini) assisted to build and  
23  
24 approve content for the funding application. All authors (Adreak, Colella, Dancey, Gomes,  
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26 Goodenough, Hay, Johnston, Kapur, Liblik, Liu, Mullen, Noble, O'Hara, Parry, Robert, Tang, Visintini,  
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28 Wong) approved the final manuscript prior to submission. All authors (Adreak, Colella, Dancey,  
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30 Goodenough, Hay, Johnston, Kapur, Liblik, Liu, Mullen, Noble, O'Hara, Parry, Robert, Tang, Visintini,  
31  
32 Wong) are also accountable for all aspects of ensuring the accuracy and integrity of the work across all  
33  
34 steps of the review.  
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51  
52 Funding Decision, CIHR Reviews.

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4 **Figure 1** Individual and Family Self-Management Theory.  
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For peer review only



**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	Page
<b>ADMINISTRATIVE INFORMATION</b>			
Title:			
Identification	1a	Identify the report as a review protocol	1
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	2, 8
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1, 15-16
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	13-14
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	1
Support:			
Sources	5a	Indicate sources of financial or other support for the review	14
Sponsor	5b	Provide name for the review funder and/or sponsor	14
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	13-14
<b>INTRODUCTION</b>			
Rationale	6	Describe the rationale for the review in the context of what is already known	4-7
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	7, 9
<b>METHODS</b>			
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	11-12, 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	9-10
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits,	Table 1

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		such that it could be repeated	
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	8, 10
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)	11-13
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	12
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	9, 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	11
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	8
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	13
	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 <sup>2</sup> , Kendall’s τ)	13
	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	13
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	8
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	8

**\* 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.

<b>Section and topic</b>	<b>Checklist item</b>	<b>Page</b>
<b>Section 1: Abstract of paper</b>		
1a: Aim	Report aims of study	2
1b: Methods	Describe methods used by which patients/public involved	2
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	2
<b>Section 2: Background to paper</b>		
2a: Definition	Report definition of PPI used and how it links to comparable studies	6
2b: Theoretical underpinnings	Report theoretical rationale and influences of PPI	7
2c: Concepts and theory development	Report any conceptual models or influences used	7
<b>Section 3: Aims of paper</b>		
3: Aim	Report aims of study	7
<b>Section 4: Methods of paper</b>		
4a: Design	Describe methods by which patients involved	9, 12, 13-14
4b: People involved	Describe patients involved with PPI activity in study	14
4c: Stages of involvement	Report on how PPI used at different stages of study	9, 12, 13-14
4d: Level or nature of involvement	Report level or nature of PPI used at various stages	9, 12, 13-14
<b>Section 5: Capture or measurement of PPI impact</b>		
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
<b>Section 6: Economic assessment</b>		
6: Economic assessment	Report method used for economic assessment of PPI	N/A
<b>Section 7: Study results</b>		
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
7e: 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
<b>Section 8: Discussion and conclusion</b>		
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

# BMJ Open

## Peer support interventions for women with cardiovascular disease: protocol for synthesizing the literature using an evidence map

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2022-067812.R1
Article Type:	Protocol
Date Submitted by the Author:	20-Sep-2022
Complete List of Authors:	<p>Parry, Monica; University of Toronto, Lawrence S. Bloomberg Faculty of Nursing</p> <p>Visintini, Sarah; University of Ottawa Heart Institute Berkman Library; University of Ottawa, Health Sciences Library</p> <p>Johnston, Amy; University of Ottawa, School of Epidemiology and Public Health; University of Ottawa Heart Institute</p> <p>Colella, Tracey; University Health Network, KITE - Toronto Rehabilitation Cardiovascular Prevention &amp; Rehabilitation Program; University of Toronto, Lawrence S. Bloomberg Faculty of Nursing and the Rehabilitation Sciences Institute</p> <p>Kapur, Deeksha; University of Toronto, Lawrence S. Bloomberg Faculty of Nursing (Research Assistant)</p> <p>Liblik, Kiera; Queen's University Faculty of Health Sciences</p> <p>Gomes, Zoya; Dalhousie Medical School</p> <p>Dancey, Sonia; University of Ottawa Faculty of Medicine</p> <p>Liu, Shuangbo; University of Manitoba, Section of Cardiology, Department of Internal Medicine, Rady Faculty of Health Sciences</p> <p>Goodenough, Catherine; University of Ottawa Heart Institute, Canadian Women's Heart Health Alliance</p> <p>Hay, Jacqueline; University of Manitoba, Faculty of Kinesiology and Recreation Management; St Boniface General Hospital, Institute of Cardiovascular Sciences, Albrechtsen Research Centre</p> <p>Noble, Meagan; University of Toronto, Lawrence S. Bloomberg Faculty of Nursing; Indigenous Services Canada</p> <p>Adreak, Najah; The University of British Columbia, Department of Surgery</p> <p>Robert, Helen; University of Ottawa Heart Institute, Canadian Women's Heart Health Alliance</p> <p>Tang, Natasha; Queen's University Faculty of Health Sciences</p> <p>O'Hara, Arland; University of Toronto, Lawrence S. Bloomberg Faculty of Nursing</p> <p>Wong, Anice; University of Ottawa Heart Institute, Canadian Women's Heart Health Centre</p> <p>Mullen, Kerri-Anne ; University of Ottawa Heart Institute, Canadian Women's Heart Health Centre</p>
<b>Primary Subject Heading</b>:	Cardiovascular medicine

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Secondary Subject Heading:	Patient-centred medicine
Keywords:	Heart failure < CARDIOLOGY, Ischaemic heart disease < CARDIOLOGY, Stroke < NEUROLOGY





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2 **Peer support interventions for women with cardiovascular disease: protocol for synthesizing the**  
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4 **literature using an evidence map**  
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7 Monica Parry,<sup>1</sup> Sarah Visintini,<sup>2,3</sup> Amy Johnston,<sup>4,5</sup> Tracey JF Colella,<sup>1,6,7</sup> Deeksha Kapur,<sup>1</sup> Kiera  
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## ABSTRACT

**Introduction** The leading cause of death for women is cardiovascular disease (CVD), including ischemic 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 ischemic 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 PsychInfo, 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 summarized narratively, and quantitative analyses will be performed using R.

**Ethics and dissemination** The University of Toronto's Research Ethics Board granted approval on April 28<sup>th</sup>, 2022 (Protocol #42608). Bubble plots (i.e., weighted scatter plots), geographic 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.

**Study registration** Open Science Framework, DOI:10.17605/OSF.IO/E7KQ3.

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**Keywords** Evidence Map, Peer Support, Cardiovascular Disease, Women, Patient-Oriented Research

For peer review only

## 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 ischemic heart disease, stroke or heart failure, independent of the research design.
- All team members will receive one-hour of training on screening titles and abstracts, one-hour of training on screening full-text reviews, and two-hours of training on data extraction.
- Bubble plots (i.e., weighted scatter plots), geographic 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) Ischemic 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 United States.(1) Young women are now more likely to die within one year of a myocardial infarction (MI) compared to men,(5, 6) and women who are transgender have a greater than two-fold increase in MI compared to 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) one year after an MI, and for many women, fear and anxiety about the future and difficulty moving forward in recovery extends beyond five 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 to 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 to men.(20, 21)

International CVD priorities, led by the World Health Organization'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 to 70 years with IHD report worse physical HRQoL (38.9 [95% CI,

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2 36.9-41.0]) compared to the general population.(23) Similar results are reported in women with  
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4 obstructive (41.9, SD 8.9) and non-obstructive heart disease (43.7, SD 9.4) ( $p=0.072$ ).(24) Moreover, a  
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6 decline in physical versus mental HRQoL is more predictive of hospital readmission(25) and mortality  
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8 in healthy middle-aged and older women ( $n=40,337$ )(26) and in men and women with heart  
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10 disease.(25) The World Heart Federation has been advocating globally for better CVD outcomes,  
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12 suggesting advocacy tactics and strategies to reduce CVD by 25% by 2025.(22) This includes  
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14 addressing behavioral risk factors for better prevention and reducing IHD and stroke in women by  
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16 identifying and aligning with national CVD priorities, strategic communications, media engagement,  
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18 evidence-based research, partnership development, and collaborating with key decision-makers.(22)  
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20 The Lancet Commission advocates for a global imperative to reduce the global burden of CVD in  
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22 women by 2030.(1)

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27 Social support in the form of relationships with family and friends, as well as peer support from  
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29 other women with CVD, has been identified as an integral component in the recovery process for  
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31 women following a cardiac event.(27) Perceived social support has a direct impact on health outcomes;  
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33 individuals with low levels of social support have higher CVD-related(28) and all-cause mortality  
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35 rates.(29) Results from the Variation in Recovery: Role of Gender on Outcomes of Young AMI  
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37 Patients (VIRGO) study suggested lower social support was associated with worse health outcomes and  
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39 more depressive symptoms 12 months after an MI, with one in five individuals less than 55 years of  
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41 age having low social support following an MI.(30) Others report that individuals with low social  
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43 support following an MI had more angina (relative risk [RR], 1.27; 95% confidence interval [CI], 1.10,  
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45 1.48), lower HRQoL (mean difference [ $\beta$ ] = -3.33; 95% CI, -5.25, -1.41), lower mental functioning ( $\beta$   
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47 = -1.72; 95% CI, -2.65, -0.79), and more depressive symptoms ( $\beta$  = 0.94; 95% CI, 0.51, 1.38).(31)  
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49 Moreover, the association between social support and HRQoL, depression, and physical functioning  
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51 appears to be stronger in women compared to men.(31) In the general population, twice as many  
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53 women have depression(32, 33) and anxiety(34, 35) as men, which are known risk factors for CVD.  
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2 Depressive symptoms are associated with atherosclerotic IHD (odds ratio [OR]=1.07, 95% CI, 1.02,  
3 1.13, per one-point increase in the Patient Health Questionnaire [PHQ-9] score) and death (adjusted  
4 hazard ratio [HR]=1.07, 95% CI, 1.02, 1.14, per one-point increase in the PHQ-9 score) in women  
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6 younger than 55 years, but not in men or in women over 55 years.(36) In postmenopausal women, fatal  
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8 cardiac events are associated with depression.(37) Anxiety has also been linked to developing and the  
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10 worsening IHD and CVD mortality.(38)

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16 It has been suggested that social support, specifically from other women who have lived a  
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18 similar health or recovery experience, may play a key role in women's CVD rehabilitation and  
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20 recovery.(8, 39, 40) Peer support is the provision of assistance and encouragement by an individual that  
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22 is considered equal(41); it is a form of social support delivered by a layperson who has received some  
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24 formal training to share experiential knowledge and emotional assistance. Defining attributes of all peer  
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26 relationships include emotional, informational, and appraisal support.(41) Moreover, providing and  
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28 receiving support benefits both the receiver and the provider of support.(42) Women (n = 387) aged 42  
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30  $\pm$  6 years who received a peer support intervention reported better cardiovascular risk factor profiles  
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32 (i.e., hypertension, exercise, weight, smoking) compared to women randomized to a control group  
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34 (difference: 0.75; 95% CI, 0.32, 1.18).(43) In patients and caregivers following a stroke, the value of  
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36 peer support during the recovery process was derived through information and advice, encouragement  
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38 and empowerment, awareness, being helpful, and making connections.(44) There is some evidence that  
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40 peer support interventions improve self-reported recovery for individuals with CVD,(45, 46) and hope  
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42 and empowerment in other patient populations that include those with mental illness, HIV, and women  
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44 who are breastfeeding.(47-49) Women have identified the importance of engagement in several  
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46 different activities to promote their recovery including behavioural, social, and psychological  
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48 dimensions.(27) As individuals focus on their own recovery in the context of multiple social roles, re-  
49  
50 evaluation and re-prioritization of self can be a challenging task. Women face unique challenges in  
51  
52 managing their health and modifying their lifestyle during recovery.(50-53) Women often prioritize  
53  
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1 family, household responsibilities, and caregiver tasks, which subsequently place preventive health  
2 behaviours and their own health status as secondary.(54) There is a need to distinctly enhance the  
3  
4 nature and level of care provided to women living with CVD. Although there is some evidence for the  
5  
6 beneficial effects of peer support in women with CVD, a more gender-informative and culturally  
7  
8 sensitive knowledge synthesis across the lifespan is needed.  
9  
10  
11  
12

### 13 **Objectives**

14  
15  
16 The overall aim of this study is to describe peer support interventions for women with CVD (IHD,  
17  
18 stroke, heart failure) using an evidence map. Specific objectives are to: 1) provide an overview of peer  
19  
20 support interventions used in women with ischemic heart disease, stroke, and heart failure, 2) identify  
21  
22 gaps in primary studies where new or better studies are needed, and 3) describe knowledge gaps where  
23  
24 complete systematic reviews are required.  
25  
26  
27  
28  
29

### 30 **METHODS AND ANALYSIS**

31  
32 The main purpose of performing a broad map of the literature (i.e., evidence map) is to identify the  
33  
34 range of research and identify gaps and future research needs.(55) An evidence map is broad in scope,  
35  
36 but systematic in its approach to synthesize the evidence.(55) Evidence mapping is useful in directing  
37  
38 future research, including systematic reviews.(56, 57) We are collaborating with women with lived  
39  
40 experience (Goodenough, Robert) and the Canadian Women's Heart Health Alliance (CWHHA) and  
41  
42 using the Strategy for Patient-Oriented Research (SPOR) Capacity Development Framework,(58)  
43  
44 SPOR Patient Engagement Framework,(59) and the Individual and Family Self-Management  
45  
46 Theory(60, 61) to describe peer support interventions used for women with CVD (IHD, stroke, heart  
47  
48 failure). The Individual and Family Self-Management Theory(62) consists of three dimensions:  
49  
50 context, process, and outcomes. We have used this in a previous integrated mixed methods systematic  
51  
52 review to guide processes related to defining patient-reported outcome variables and variables used for  
53  
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1  
2 data extraction.(63) This theory depicts self-management within the broader context of people and  
3  
4 other influences (e.g., ethnicity, racism, healthcare access, institutionalized gender).(64) The Individual  
5  
6 and Family Self-Management Theory(62) has provided a platform for testing clinical interventions that  
7  
8 have included the Arthritis Self-Management Program (ASMP)(65) and the Diabetes Self-Management  
9  
10 Program.(66) This model highlights the role of social influence (e.g., peer support) and the value of  
11  
12 emotional, informational, and appraisal support (*Figure 1*).(62, 67)  
13  
14

15  
16 -Insert Figure 1-  
17

18 We used the Preferred Reporting Items for Systematic reviews and Meta-Analyses for Protocols  
19  
20 2015 (PRISMA-P 2015) checklist when preparing this manuscript (Supplementary Table 1).(68)  
21  
22 Additionally, the Guidance for Reporting Involvement of Patients and the Public – Long Form (GRIPP  
23  
24 2 - LF) was used to document the engagement of women with lived experience (Supplementary Table  
25  
26 2).(69) We will also use a patient partner compensation rate structure described in the  
27  
28 Recommendations on Patient Engagement Compensation – Prepared by the SPOR Networks in  
29  
30 Chronic Diseases and the PICHI Network(70): each woman with lived experience will receive a one-  
31  
32 year honorarium of \$1000 that will include compensation for 4-hours of training and assistance across  
33  
34 all other activities of the project (i.e., screening, knowledge translation and exchange [KTE] activities).  
35  
36  
37

38  
39 We will not register our evidence map on PROSPERO, the international prospective register of  
40  
41 systematic reviews, as evidence mapping does not meet the inclusion criteria for this registry.  
42  
43 However, to manage records and promote transparency, we have registered our project on the Open  
44  
45 Science Framework (DOI 10.17605/OSF.IO/E7KQ3).(71) Assessment of risk of bias, meta-bias(es), or  
46  
47 strength of the evidence will not be undertaken. We will follow methods described by the Evidence for  
48  
49 Policy and Practice Information (EPPI) and the Coordinating Centre at the Institute of Education,(57,  
50  
51 72-75) using six steps utilized in performing previous broad maps of the literature(76): 1) identify the  
52  
53 scope of the evidence map, 2) define key variables, 3) establish a comprehensive search strategy, 4)  
54  
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1  
2 identify clear eligibility criteria, 5) systematically retrieve, screen and classify the evidence, and 6)  
3  
4 report the findings in an evidence map.  
5

### 6 **Identify the scope of the evidence map**

7  
8  
9 The initial scope of the work was defined by the research team to focus on the most common causes of  
10  
11 CVD mortality in women(1, 2): IHD, stroke and heart failure. The research question, key variables, and  
12  
13 eligibility criteria were discussed with women with lived experience (Goodenough, Robert). Our  
14  
15 overarching review question was established: *What is known about peer support interventions used for*  
16  
17 *women with CVD (IHD, stroke, and heart failure)?* This question can be answered by a broad range of  
18  
19 evidence that includes RCTs, cohort and cross-sectional studies, case control studies and case  
20  
21 series/reports across reported from urban and rural settings across the globe.  
22  
23  
24

### 25 **Define key variables**

26  
27 We used the PICO framework to focus our research question and also to inform our broad search of the  
28  
29 literature.(77) The PICO elements included the population, intervention, comparison and outcomes.  
30  
31 Keywords and the National Library of Medicine's Medical Subject Headings (MeSH) were combined  
32  
33 under two of the PICO categories: (P) women with CVD (IHD, stroke and heart failure) and (I) peer  
34  
35 support. We did not search using a comparator or by outcome so that we could maintain breadth and  
36  
37 reduce bias in our search strategy. Women with lived experience (Goodenough, Robert) collaborated to  
38  
39 identify and confirm search terms as there is evidence that this may increase the number of citations  
40  
41 retrieved by 34%.(55, 78) The draft MEDLINE search strategy (*Table 1*) was also informed by  
42  
43 searches of existing reviews(79, 80) and executed by a library scientist (Visintini).  
44  
45  
46  
47

### 48 **Establish a comprehensive search strategy**

49  
50 The literature on peer support interventions used for women with CVD (IHD, stroke, and heart failure)  
51  
52 will be systematically and comprehensively searched using subject headings and keywords in  
53  
54 accordance with the search syntaxes in each bibliographic databases. As noted, the search was drafted  
55  
56 in MEDLINE via Ovid (*Table 1*) by a library scientist. Prior to finalization and execution, the draft  
57  
58  
59

MEDLINE search strategy will be peer reviewed by another librarian(81). It will then be translated and run from inception in the remaining databases: CINAHL (EBSCO), EMBASE (Ovid), APA PsychInfo (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 (ICTRP). 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 Covidence(82) for duplicate elimination and screening.

**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 gangli*) 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

### 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 minimize 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 (i.e., worsening of the condition, etc.) and HRQoL (i.e., perceived wellbeing measured using the Minnesota Living with Heart Failure, Kansas City Cardiomyopathy Questionnaire, SF-12, EuroQoL 5D-3L, etc.).<sup>(83)</sup> Estimating direct and indirect costs of peer support using a cost-effectiveness analysis (CEA), incremental cost-effectiveness ratio (ICER), or quality-adjusted life years (QALYs) will be included.<sup>(84)</sup>

**Table 2. Inclusion and exclusion criteria**

Include if study involves:	Exclude if study involves:
<input checked="" type="checkbox"/> Women <ul style="list-style-type: none"> <li><input type="checkbox"/> Including cis and trans women</li> <li><input type="checkbox"/> Also include if sex/gender is not specified</li> </ul> <input checked="" type="checkbox"/> Adults aged 18 and older <input checked="" type="checkbox"/> One or more of the following diagnoses:	<input checked="" type="checkbox"/> Men only <input checked="" type="checkbox"/> Exclusively the following diagnoses (if none of the inclusion diagnoses on the left are also present): <ul style="list-style-type: none"> <li><input type="checkbox"/> Peripheral arterial disease</li> <li><input type="checkbox"/> Peripheral vascular disease</li> </ul>

<ul style="list-style-type: none"> <li>○ Heart disease</li> <li>○ Ischemic heart disease</li> <li>○ Coronary heart disease</li> <li>○ Coronary artery disease</li> <li>○ Acute coronary syndrome</li> <li>○ Myocardial infarction</li> <li>○ Unstable angina</li> <li>○ MINOCA (myocardial infarction with non-obstructive coronary arteries)</li> <li>○ Spontaneous Coronary Artery Dissection (SCAD)</li> <li>○ Microvascular coronary disease</li> <li>○ Coronary artery spasm</li> <li>○ Coronary embolism</li> <li>○ Kounis syndrome</li> <li>○ Congestive Heart failure <ul style="list-style-type: none"> <li>▪ Cardiomyopathy</li> <li>▪ HFrEF (heart failure with reduced ejection fraction)</li> <li>▪ HFpEF (heart failure with preserved ejection fraction)</li> <li>▪ Takotsubo syndrome</li> </ul> </li> <li>○ Stroke or Cerebrovascular accident</li> <li><input checked="" type="checkbox"/> A support intervention led by a peer(s)</li> <li>○ Could be <ul style="list-style-type: none"> <li>▪ Individual (1:1) support or group programs</li> <li>▪ Virtual/online programs</li> <li>▪ The provision of emotional, appraisal, and/or informational assistance</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>○ Heart valve diseases <ul style="list-style-type: none"> <li>▪ Stenosis</li> <li>▪ Regurgitation/leaky valve</li> </ul> </li> <li>○ Arrhythmias <ul style="list-style-type: none"> <li>▪ Atrial Fibrillation</li> <li>▪ Atrial Flutter</li> <li>▪ Supraventricular tachycardia</li> <li>▪ Palpitations</li> </ul> </li> <li>○ Hypertension</li> <li>○ Risk factors for cardiovascular disease (e.g., physical inactivity or sedentary lifestyle, smoking, depression), but no diagnosis of a cardiovascular disease</li> <li><input checked="" type="checkbox"/> Support programs led by health care professionals, and not peers with lived experience</li> <li><input checked="" type="checkbox"/> Informal social support from family, friends, or caregivers, and not peers with lived experience</li> <li><input checked="" type="checkbox"/> Systematic reviews and meta-analyses, scoping reviews (these types of studies should be flagged and documented in a group Google doc for reference)</li> <li><input checked="" type="checkbox"/> 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)</li> </ul>
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### 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) one-hour of training on screening titles and abstracts, 2) one-hour of training on screening full-text reviews, and 3) two-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 two-hour meeting to establish title and abstract screening accuracy and confirm understanding of the inclusion and exclusion criteria.(85) Title, abstract, and full-

1  
2 text articles will be screened by two independent reviewers. Disagreements or conflicts will be resolved  
3  
4 by a third reviewer (Parry or Mullen). Data from included studies will be extracted to include article-  
5  
6 level data (e.g., author/country, publication year) and study-level data (e.g., sample size, percent  
7  
8 women, study design, population [e.g., context], intervention and outcomes). Contextual factors will  
9  
10 include participant characteristics as guided by the Individual and Family Self-Management Theory  
11  
12 (e.g., sex, gender [roles, relations, identity and institutionalized], ethnicity, racism, age).(62) We will  
13  
14 use the Template for Intervention Description and Replication –TIDieR)(86) to extract peer support  
15  
16 intervention details that will include intervention procedures, peer background and training, modes of  
17  
18 delivery (i.e., face-to-face, group), location of delivery (i.e., in-person, virtual), number of times the  
19  
20 intervention was delivered over what period of time (i.e., duration, intensity, dose), and intervention  
21  
22 fidelity. Social facilitation details including type of support (emotional, informational, and appraisal  
23  
24 support) will also be captured in our data extraction. Outcomes will include health status, HRQoL, and  
25  
26 healthcare costs. To ensure transparency and rigor, we will describe our methods of locating relevant  
27  
28 unpublished and grey literature in a systematic way,(73, 87, 88) following processes used in our  
29  
30 previous broad map of the literature.(76)  
31  
32  
33  
34  
35

### 36 **Report findings in an evidence map**

37  
38 The findings of all studies meeting the eligibility criteria will summarized narratively. This will include  
39  
40 a description of the participants, settings, and peer support interventions. The Individual and Family  
41  
42 Self-Management Theory will guide specific descriptions by context, process, and outcomes. Bubble  
43  
44 plots (i.e., weighted scatter plots), geographic heat/choropleth maps, and infographics will be used to  
45  
46 graphically illustrate peer support intervention elements by category of CVD (i.e., IHD, stroke, and  
47  
48 heart failure). Analyses will be performed using R, a software environment for statistical computing  
49  
50 and graphics.(89)  
51  
52  
53

### 54 **Patient and public involvement**

1  
2 Two women living with CVD (Goodenough, Robert) are members of our investigative team and  
3  
4 members of the CWHHA, a volunteer organization of over 130 health professionals and women living  
5  
6 with CVD. The mission of the CWHHA is to support patients, clinicians, scientists, and decision-  
7  
8 makers to implement evidence, transform clinical practices, and impact public policy related to  
9  
10 women's cardiovascular health. CWHHA members, and the 16 patient advocate members, voted in the  
11  
12 Fall 2020 strategic planning session to pursue a project focused on peer support for women with CVD.  
13  
14 This evidence map review is direct guidance from women who live with CVD. We are using the SPOR  
15  
16 Capacity Development Framework(58) and the SPOR Patient Engagement Framework(59) to ensure  
17  
18 the perspectives of women living with CVD are integrated into all steps of this broad map of the  
19  
20 literature, including developing the research question/objectives, key variables, and eligibility criteria,  
21  
22 defining search terms, screening titles/abstracts and full text papers, evaluating results, and  
23  
24 disseminating findings. The GRIPP 2 - LF(69) has been utilized to document patient engagement  
25  
26 activities and we have used the patient partner compensation rate structure described in the  
27  
28 Recommendations on Patient Engagement Compensation – Prepared by the SPOR Networks in  
29  
30 Chronic Diseases and the PICHI Network.(70) The guiding principles of co-build, inclusiveness,  
31  
32 support, and mutual respect underpin all patient engagement activities in this study.(59)  
33  
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40

## 41 **ETHICS AND DISSEMINATION**

42  
43 Ethics approval has been granted from the University of Toronto (42608, April 28/2022). It is not  
44  
45 necessary to obtain informed consent for this review. Knowledge will be disseminated through  
46  
47 publication, presentation/public forums, and social media.  
48  
49  
50  
51

52 **Contributors:** The PI (Parry) and Co-PI (Mullen) conceived the study. Kapur and Parry drafted and  
53  
54 revised the manuscript prior to submission. Co-authors (Adreak, Colella, Dancey, Gomes, Goodenough,  
55  
56 Hay, Johnston, Kapur, Liblik, Liu, Mullen, Noble, O'Hara, Robert, Tang, Visintini) will contribute to all  
57  
58  
59



1  
2 steps of the review. One co-author (Wong) will be responsible for coordinating administrative aspects  
3  
4 of the review. Most authors (Adreak, Colella, Dancey, Goodenough, Hay, Johnston, Kapur, Liblik, Liu,  
5  
6 Mullen, Noble, Parry, Robert, Tang, Visintini) are grant holders. We thank the two women with lived  
7  
8 experience (Goodenough, Robert) from the CWHHA who are Co-Is. Parry finalized the Research Ethic  
9  
10 Board (REB) submission. The Co-PIs (Parry, Mullen) will provide day-to-day oversight of the review.  
11  
12 Most authors (Adreak, Colella, Dancey, Goodenough, Hay, Johnston, Kapur, Liblik, Liu, Mullen, Noble,  
13  
14 Parry, Robert, Tang, Visintini) assisted to build and approve content for the funding application. All  
15  
16 authors (Adreak, Colella, Dancey, Gomes, Goodenough, Hay, Johnston, Kapur, Liblik, Liu, Mullen,  
17  
18 Noble, O'Hara, Parry, Robert, Tang, Visintini, Wong) approved the final manuscript prior to  
19  
20 submission. All authors (Adreak, Colella, Dancey, Goodenough, Hay, Johnston, Kapur, Liblik, Liu,  
21  
22 Mullen, Noble, O'Hara, Parry, Robert, Tang, Visintini, Wong) are also accountable for all aspects of  
23  
24 ensuring the accuracy and integrity of the work across all steps of the review.  
25  
26  
27  
28

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30  
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32  
33 470800).  
34  
35

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37

38 **Supplemental material:** PRISMA-P and GRIPP 2 – LF checklists.  
39

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For peer review only

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3 **FIGURE TITLE**

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6 **Figure 1. Individual and Family Self-Management Theory model**  
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For peer review only



**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
<b>ADMINISTRATIVE INFORMATION</b>			
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
<b>INTRODUCTION</b>			
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
<b>METHODS</b>			
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 <sup>2</sup> , 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.

<b>Section and topic</b>	<b>Checklist item</b>	<b>Included</b>
<b>Section 1: Abstract of paper</b>		
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
<b>Section 2: Background to paper</b>		
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
<b>Section 3: Aims of paper</b>		
3: Aim	Report aims of study	Yes
<b>Section 4: Methods of paper</b>		
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
<b>Section 5: Capture or measurement of PPI impact</b>		
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
<b>Section 6: Economic assessment</b>		
6: Economic assessment	Report method used for economic assessment of PPI	N/A
<b>Section 7: Study results</b>		
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
7e: 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
<b>Section 8: Discussion and conclusion</b>		
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