# Factors affecting women's participation in cardiovascular research: a scoping review 

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#### Abstract

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#### Abstract

Aims Women are underrepresented in cardiovascular trials. We sought to explore the proportional representation of women in contemporary cardiovascular research and the factors (barriers and enablers) that affect their participation in cardiovascular studies.

\section*{Methods} and results

\section*{Conclusion}

Registration

Multiple electronic databases were searched between January 2011 and September 2021 to identify papers that defined underrepresentation of women in cardiovascular research and/or reported sex-based differences in participating in cardiovascular research and/or barriers for women to participate in cardiovascular research. Data extraction was undertaken independently by two authors using a standardised data collection form. Results were summarised using descriptive statistics and narrative synthesis as appropriate.

From 548 identified papers, 10 papers were included. Of those, four were conducted prospectively and six were retrospective studies. Five of the retrospective studies involved secondary analysis of trial data including over 780 trials in over 1.1 million participants. Overall, women were reported to be underrepresented in heart failure, coronary disease, myocardial infarction, and arrhythmia trials, compared to men. Barriers to participation included lack of information and understanding of the research, trial-related procedures, the perceived health status of the participant, and patient-specific factors including travel, childcare availability, and cost. A significantly higher likelihood of research participation was reported by women following a patient educational intervention.

This review has highlighted the underrepresentation of women in a range of cardiovascular trials. Several barriers to women's participation in cardiovascular studies were identified. Researchers could mitigate against these in future trial planning and delivery to increase women's participation in cardiovascular research.

The protocol was published on the public Open Science Framework platform on 13th August 2021 (no registration reference provided) and can be accessed at https://osf.io/ny4fd/.


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## Graphical Abstract

## Factors affecting women's participation in cardiovascular research: A scoping review

Women are underrepresented in cardiovascular disease (CVD) research


## Aim

Explore the evidence in CVD research on (a) underrepresentation of women (b) sex-based differences in participation © barriers for women to participate

(10) Papers


Met eligibility and
were included


10 Papers
Included 780 trials and over 1.1 million participants


Underrepresented in heart failure, coronary disease, myocardial infarction and arrhythmia trials

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-morors Barriers
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Lack of information; trial-related procedures perceived health status; travel costs; childcare


Educational interventions; sex-specific trial materials; flexibility of appointments; financial reimbursement

## Novelty

- This review is the first formal critical appraisal of the evidence of the underrepresentation of women in cardiovascular trials and the barriers and facilitators to their participation.
- Women particularly report a lack of information and understanding of the research, trial-related procedures, the perceived health status of the participant and patient-specific factors including travel, childcare availability, and cost as barriers to participation.
- This study offers valuable insight into optimising the recruitment and participation of women in cardiovascular trials and recommends that research protocols should consider educational interventions, sex-specific trial materials, flexibility of appointments, and financial reimbursement for time and travel.
- We 'call to action' funding bodies, journal editors, and researchers to be required to demonstrate actions and outcomes to optimise sexrepresentation of CVD research as well as consider sex-specific research to increase the evidence specifically for women.


## Introduction

Globally, cardiovascular disease (CVD) is the leading cause of death for women, responsible for over a third of all deaths. ${ }^{1}$ Women also account for $52 \%$ of those living with CVD in Europe. ${ }^{2}$ Despite the substantial burden of CVD on women, considerable cardiovascular health inequalities exist between men and women ${ }^{3}$ culminating in the understanding that women are 'underrecognised, underdiagnosed and undertreated.' ${ }^{1}$ This is undoubtedly affected by the fact that women are also consistently 'understudied' ${ }^{1}$ and so there is a lack of sex-specific evidence on which to base practice. This is extensive across a range of cardiovascular specialties (for example, coronary artery disease, acute coronary syndrome, heart failure, and device trials), where less than a third of trial participants have been found to be women. ${ }^{4,5}$

There is a recognised need to address the sex-based research inequality in cardiovascular care. However, there are a myriad of factors contributing to the underrepresentation of women in cardiovascular clinical trials, all of which require attention. ${ }^{6}$ A key
influence is the recruitment and retention of women to cardiovascular studies, since men have a $15 \%$ greater willingness to participate than women. ${ }^{7}$ Recently, there have been many opinion papers regarding the underrepresentation of women and the potential barriers to participating in clinical trials. ${ }^{8,9}$ However, the existing evidence to date has not been formally scrutinised using a robust methodological approach. By doing so, an evidence-base will be provided on which to develop and implement solutions to aid the recruitment and retention of women to cardiovascular research. Thus, we sought to scope, collate, and explore the evidence for factors (barriers and enablers) that affect women's participation in cardiovascular research.

## Methods

## Protocol and reporting guidelines

A scoping review was undertaken to enable the mapping of the literature related to this area. The scoping review protocol was designed in
accordance with the Johanna Briggs Institute recommendations, ${ }^{10}$ was published on the public Open Science Framework (OSF) platform on 13th August 2021 (no registration reference provided) and can be accessed at https://osf.io/ny4fd/. This review is reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta Analyses extension for Scoping Reviews. ${ }^{11}$

## Eligibility criteria

Papers were included if they met the following criteria: Population: female sex (adult or paediatric) Intervention: medical or interventional treatment for CVD; Control: not applicable for this review; Outcome: studies (any design excluding case studies, discussion papers, editorials and systematic reviews) that reported sex-based differences in participation in cardiovascular research, and/or addressed solutions to barriers to participation, and/or defined underrepresentation of women in cardiovascular research. Papers published within the last 10years were included (1st January 201117th September 2021) to reflect contemporary relevant factors and influences. Only full-text papers published in English were included and studies were not excluded on the basis of quality.

## Information sources and search strategy

A search of MEDLINE, EMBASE, EMCare, Cumulated Index of Nursing and Allied Health Literature (CINAHL), NICE Evidence Search, and clinicaltrials.gov was undertaken on 17th September 2021. No grey literature was searched as only primary research studies were included. The electronic search strategy is detailed in the Supplementary material.

## Selection of sources of evidence

The review for selection was undertaken in Covidence, a literature review management system (https://www.covidence.org), which is a core component of Cochrane's review production toolkit. Two rounds of screening occurred. First, a title and abstract review was undertaken followed by a full paper review of those included from the first screening. All screening was undertaken independently by two authors, in accordance with the inclusion and exclusion criteria. Discrepancies were resolved through discussion until a consensus was reached.

## Data charting processes

A modified and standardised data extraction template was developed in Covidence to extract data from each paper. Key data extraction variables included primary author, date of publication, country of study, study design, definition of underrepresentation, population description, and specific enablers and barriers to women participating in research. All data were extracted independently by two authors, with differences resolved through discussion until consensus was achieved.

## Synthesis of results

Results were summarised using descriptive statistics, tables, and narrative synthesis, as appropriate. Interpretation of the analysis was discussed and agreed by all authors.

## Results

## Study selection

A total of 548 papers were identified prior to deduplication, after which point 414 papers were subjected to title and abstract screening. One hundred and ten papers underwent independent full-text assessment (see Figure 1 below). This resulted in 10 papers being included for data extraction and analysis.

## Study characteristics

The main characteristics of the 10 included papers are detailed in Table 1 (full table as supplementary material). In summary, the vast majority of papers were led in the United States of America or Canada ( $n=9,90.0 \%$ ), although five (50\%) included trials recruiting participants
from various countries. All studies were undertaken on adults, including a range of cardiovascular conditions, with one study conducted in the United Kingdom (UK) on pregnant women at risk of pre-eclampsia. ${ }^{19}$ There was a relatively even split between studies conducted retrospectively ( $n=6,60.0 \%$ ) and prospectively ( $n=4,40.0 \%$ ), with the majority of the retrospective studies involving the secondary analysis of trial data ( $n=5,83.3 \%$ ). Overall, these five studies contained over 780 trials conducted between 2005 and 2017, including more than 1.1 million participants. Of the prospective studies, all were cohort studies and collectively included 2147 participants.

## Proportion and underrepresentation of women

The proportion of women participating in the included studies, compared to men, is detailed in Table 1. Across all 10 studies, the proportion of women included ranged from $33.7 \%{ }^{14}$ to $61.3 \%{ }^{16}$ with two studies focusing specifically on women's perceptions of participating or refusing to in CVD studies. ${ }^{15,19}$ Of the five secondary trial analysis studies, women comprised approximately one third of all participants [range $33.7 \%{ }^{14}$ to $38.2 \%$, ${ }^{4}$ although this was higher in the Get With The Guidelines-Heart Failure registry study $\left(48.8 \% .^{18}\right)$ ].

Overall, underrepresentation of women was defined in five of the 10 studies. ${ }^{4,14,17,19,20}$ In three, refusal to participate was used as a proxy for participation and representation. ${ }^{14,19,20}$ In both the two largest secondary analysis studies, comprising $224417^{17}$ and $862652^{4}$ participants, respectively, underrepresentation of women was defined using a participation to prevalence ratio (PPR). The PPR is defined as the representativeness of women in a trial relative to their representation in the disease population (percentage of women among trial participants/women among disease population), where a PPR $<0.8$ is considered underrepresented (Table 2). Both studies reported reasonable or over representation of women in pulmonary hypertension and hypertension trials, but underrepresentation of women was found to have occurred in heart failure, coronary disease, and acute coronary syndrome/myocardial infarction trials. Small differences were observed in arrhythmia studies with Scott and colleagues reporting reasonable representation to overrepresentation of women in atrial fibrillation trials. ${ }^{17}$ However, Jin and colleagues observing that women were underrepresented in arrhythmia trials overall. ${ }^{4}$ Women were also found to be underrepresented in stroke trials, in government sponsored research, trials where the average age was between 61-65 years, in procedure interventions and in trials conducted in the Western Pacific region. ${ }^{4}$

## Barriers and enablers to women participating in clinical trials

The barriers and enablers to women participating in cardiovascular clinical trials identified from seven of the included papers are collated Table 3. These factors were identified from a variety of methods including exploring reasons for refusal to participate, ${ }^{12,14,19,20}$ surveys to elicit perspectives, ${ }^{15,16}$ and opinions after a patient educational intervention to improve research participation. ${ }^{13}$ Barriers and enablers were themed into trial-related, medical-related, and patient-related factors.

Trial-related barriers were predominant and specifically concerned a lack of information and understanding of the research, trial-related procedures (for example, not knowing what treatment will be received, additional procedures and tests, side-effects of medications as well, and the time commitment to the trial), and patient views regarding being a 'test subject', ${ }^{20}$ or that 'only terminally ill patients participate in clinical trials'. ${ }^{16}$ The perceived health status of the patient, ${ }^{14}$ whether too sick or too well, ${ }^{14}$ were barriers to participation and the cost, ${ }^{15}$ time, ${ }^{19}$ travel, ${ }^{14}$ availability of childcare, ${ }^{15}$ and family issues ${ }^{14}$ were also obstacles. Conversely, receiving information about the study was considered an important factor for participation, ${ }^{13,15,19}$ whether this


Figure 1 PRISMA flow chart of literature selected scoping review.
be from the patients' doctor, ${ }^{15,16}$ someone who had already participated ${ }^{15}$ or via the web or social media. ${ }^{15}$ On a practical level, reminder calls for appointments, ${ }^{15}$ positive reinforcement from a trusted professional or significant other, ${ }^{19}$ payment or reimbursement for travel and participation, ${ }^{15}$ as well as having available childcare were considered to aid participation. ${ }^{15}$
While it was reported that women appeared to be more risk averse ${ }^{20}$ and less likely to consent than men, ${ }^{12,20}$ significant differences in willingness to participate by sex were not always evident. ${ }^{16}$ There were also no differences found in the main reasons for refusal between men and women which included not interested, too busy, travel is a burden and too sick. ${ }^{14}$ Importantly, a significantly higher likelihood of research participation was observed following a patient educational intervention consisting of a personal health information passport and an introduction to web-based resources. ${ }^{13}$

## Discussion

This review was undertaken to explore the proportional representation of women in contemporary cardiovascular trials and to scope, collate, and explore the evidence on the barriers and enablers that affect women's participation in cardiovascular research. Ten papers were identified published in the last 10 years. Collectively, these papers
contain data from over 780 trials including more than 1.1 million participants with a further 2147 included from the four prospective studies. A consistent underrepresentation of women was reported in a range of cardiovascular specialties (heart failure, coronary disease, and acute coronary syndrome/myocardial infarction, arrhythmia, and stroke), in government sponsored studies, in procedure intervention trials, and trials conducted in the Western Pacific region. Particular barriers to participation reported in the studies were related to a lack of information, trial-related activities and their burden, patient views of research, patient health status, and logistic factors relating to finance, time, and family issues. Conversely, the reverse of those barriers were reported as enablers to the willingness to participate in cardiovascular trials.
There are four key findings to note. Firstly, the perceived risks and benefits of participation are known to affect women's willingness to participate in cardiovascular trials. ${ }^{7}$ Since less than half of women recognise CVD as the primary cause of death for their sex, ${ }^{21}$ there is less recognition of CVD as a health concern and, as a consequence, they do not see CVD research as important. Our findings confirm this, with particular concerns raised with the randomisation process and not knowing what treatment they would receive, alongside having concerns regarding the medications and their side effects are particular barriers for women to participate in CVD trials. Furthermore, women also have misconceptions about research with many believing CVD trial participants are treated like a guinea-pigs, only terminally ill patients
Table 1 Study Characteristics

| Author Year | Country | Study Design | Setting (number of sites) | Population | Sample size | Proportion of women | Recruitment Period |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Martin $2013{ }^{12}$ | USA | Secondary trials analysis Retrospective | Hospital (1) | Mixed cardiovascular | 655/667 (98.2\%) | Overall: 227 (34.6\%) | $1^{\text {ST }}$ December 2005-28 $8^{\text {TH }}$ February 2011 |
| Valente $2013{ }^{13}$ | USA | Pre/post-test Cohort study <br> Prospective | Clinics (12) | Congenital heart disease | 992 | 520 (57.5\%) | $\begin{gathered} 1^{\mathrm{ST}} \text { January 2009-31 }{ }^{\mathrm{ST}} \\ \text { December } 2010 \end{gathered}$ |
| Harrison $2016{ }^{14}$ | USA | Secondary trials analysis Retrospective | Clinics or general practices (4 studies in 4 states) | Heart failure | $\begin{aligned} & \text { 288/300 (96.0\%) } \\ & \text { eligible } \end{aligned}$ | Overall: 97 (33.7\%) | Not stated. |
| Zanni $2017{ }^{15}$ | USA | Cross-sectional Survey Prospective | Community-based educational support group (1) | Women with or at risk for HIV | 40 | 40 (100\%) | April 2015 |
| Gruca $2018{ }^{16}$ | USA | Prospective Online Survey | Community | Patients with CVD and other chronic conditions | 504/4439 (11.4\%) | 309 (61.3\%) | 15-23rd February 2013 |
| Scott $2018{ }^{17}$ | USA | Secondary trials analysis Retrospective | 36 US FDA approved trials | Mixed cardiovascular | 224417 | Overall: 75862 <br> (33.8\%) | 1st January 2005-15th September 2015 |
| Greene $2019{ }^{18}$ | USA | Secondary trials analysis <br> Retrospective | USA centres affiliated the GWTG-HF registry or the ASCEND-HF RCT | Heart failure patients | ```ASCEND-HF RCT: 72506 GWTG-HF registry: 4 9 0 6 3``` | ASCEND-HF: 887 (35.4\%) <br> GWTG-HF: 23949 <br> (48.8\%) | May 2007-August 2010 |
| Nikčević $2019{ }^{19}$ | UK | Qualitative <br> Prospective | Hospitals (2) | Pregnant women at high risk of PE | 14/255 (5.5\%) | 14 (100\%) | Not stated |
| O'Neill $2019{ }^{20}$ | Canada | Cohort Study <br> Retrospective | Vancouver Stroke Program | Patient with or at risk of AF and stroke | 235 | 101 (42.9\%) | Retrospective-June <br> 2015-April 2017. <br> Prospective—May 2017- <br> March 2018 |
| Jin $2020{ }^{4}$ | USA | Secondary trials analysis Retrospective | 740 completed cardiovascular trials registered on ClinicalTrials.gov | Mixed cardiovascular | 862652 | 329633 (38.2\%) | 1st January 2010-31st December 2017 |

[^1]Table 2 Underrepresentation of women in cardiovascular trials
$\left.\begin{array}{lcc}\hline \begin{array}{l}\text { Trials by disease } \\ \text { type }\end{array} & \begin{array}{l}\text { Scott et al. 2018 }{ }^{\mathbf{1 7}} \\ \text { Participation to } \\ \text { prevalence ratio } \\ \text { (PPR) }\end{array} & \begin{array}{c}\text { Jin et al. 2020 }\end{array} \\ \text { Participation to } \\ \text { prevalence ratio } \\ \text { (PPR) }\end{array}\right\}$

Participation to prevalence ratio (PPR) is the representativeness of women in a trial relative to their representation in the disease population. A PPR $<0.8$ is considered underrepresentation.
participate in clinical trials and almost a quarter believe clinical studies only involve experimental treatments. ${ }^{16}$ Thus, it is essential that efforts to increase women's understanding of the impact of CVD on women, and the benefits of participation in CVD research, ${ }^{1}$ are made if increasing the number of women to consent to CVD trials is to occur. Secondly, but linked to the previous point, is the requirement for information by women. Many of the barriers pertained to lack of information and understanding of the research. Women reported that being able to talk to either their own doctor, talk to someone who had done the study, or by watching a video or reading a flyer were considered likely to be most helpful. This suggests that sex-specific trial information may be beneficial to aid women's recruitment into trials, a conclusion also shared by Jin and colleagues. ${ }^{4}$ Lastly, is the issue of eligibility. Women reported they did not qualify to participate due to age or multi-morbidity. This is not uncommon. A recent review highlighted that heart failure trials consistently have upper age limits, excluded women of childbearing age and those with multi-morbidities. ${ }^{22}$ Historically, women have been excluded from drug studies due to these factors, as well as other sex-specific issues for safety reasons (for example, contraception use, menopause), resulting in a paucity of evidence relating to drug efficacy and effectiveness in women. ${ }^{23}$ Therefore, not only are women-only research studies needed to redress the lack of evidence for their sex, but a revision of exclusion criteria to avoid age limits and other physiological and social factors that will predominantly exclude women, is needed. Finally, there are practical issues for women who are otherwise eligible to consent that prevent them from participating. Reasons include financial, time, travel, and childcare and family issues. Globally, there are more elderly women now living alone and on low incomes ${ }^{24}$ and women undertake up to 10 times more caring work than men. ${ }^{24}$ At the last UK census, a quarter of women aged $50-64$ had caring responsibilities. ${ }^{25}$ Therefore, to enable more women to participate in CVD trials consideration is needed regarding the time required to participate and the distance needed to travel to appointments, providing or permitting flexibility with childcare or other caring responsibilities, and providing financial reimbursement for time and travel.

Table 3 Barriers and enablers for women to participate in CVD research

| Barriers for women to <br> participate in CVD research | Enablers for women to <br> participate in CVD research |
| :--- | :---: |
| Trial-related factors | Trial-related factors |

Table 3 Continued

| Barriers for women to participate in CVD research | Enablers for women to participate in CVD research |
| :---: | :---: |
| Trial-related factors | Trial-related factors |
| Only terminally ill patients participate in clinical trials $(89.1 \%)^{16}$ |  |
| All clinical research studies involve experimental treatments $(24.6 \%)^{16}$ |  |
| Views of significant others' and trusted professionals ${ }^{19}$; daughter doesn't approve $(0.3 \%)^{14}$ |  |
| Conflict of interest of pharmaceutical companies $(28.4 \%)^{16}$ |  |
| Privacy concerns $(1.4 \%)^{14}$ <br> c) Other factors |  |
| The treating physician's attitude towards the tria ${ }^{20}$ |  |
| Not interested (56.6\%) ${ }^{14}$ |  |
| Too nervous (0.3\%) ${ }^{14}$ |  |
| Medical-related factors | Medical-related factors |
| Too many medical conditions, on too many medications ${ }^{15}$ | None |
| Health status: too sick $(13.2 \%)^{14}$; Doing well right now $(0.3 \%)^{14}$ |  |
| Patient-specific factors | Patient-specific factors |
| Don't have enough money (5\%) ${ }^{15}$ | Payment/reimbursement for participation ${ }^{15}$ |
| Not having childcare (5\%) ${ }^{15}$ | Reimbursement for transportation $(55 \%)^{15}$ |
| Lack of time ${ }^{19}$; too busy ( $\left.22.2 \%\right)^{14}$ | Having childcare available ${ }^{15}$ |
| Travel is a burden (17.4\%) ${ }^{14}$ |  |
| Family problems (4.9\%) ${ }^{14}$ |  |

Valente 2013: enablers were identified after an educational intervention to improve heart disease knowledge and research participation; Martin 2013, Harrison 2016, O’Neill 2019 and Nikčević 2019 reasons for refusal to participate; Zanni 2017 and Gruca 2018: proportion of respondents to survey highlighting each factor.

Findings from this review suggest a culture shift is required. It can no longer be convention that the 'male norm' or that 'women are too difficult to study ${ }^{\prime 26}$ is accepted. Several strategies have been introduced over the last two decades to prioritise the representation of women in trials [for example, the National Institute for Health Revitalisation Act 1993 and the Canadian Institute for Health Research 2009 sex and gender-based analysis policy (https://cihr-irsc.gc.ca/e/50833.html)], but this scoping review suggests that more needs to be done. Recent initiatives, like the New England Journal of Medicine's inclusion in the instructions for authors for all clinical trials to be representative of the patients affected by the condition, are certainly welcomed. If researchers are required to demonstrate this for publication then more focus on delivering it will occur. Given that educational interventions, sex-specific trial materials, flexibility of appointments, and the
reimbursement for time and travel are offered solutions to increase the recruitment and retainment of women in CVD trials, funding bodies should consider that trials may require more funding and time to implement these strategies. Similarly, making this a requirement for funding proposals will inevitably provide incentive to researchers to design the trials in a more inclusive manner. ${ }^{6}$

Although the underrepresentation of women in CVD research and the challenges to their participation have been commented on previously, ${ }^{8,9}$ to our knowledge this is the first scoping review to collate and present the evidence concerning barriers and enablers to women participating in CVD trials. This methodologically robust scoping review has identified areas for consideration in the development and delivery of future research to optimise the participation of women. However, this work does have three main limitations. Firstly, only studies conducted in the last 10 years were included. Women's role in society and the socio-economic factors that influence it are continuously evolv$\mathrm{ing}^{27}$ and so it was decided to focus on the most contemporary barriers that would benefit from targeted strategies to mitigate or eliminate their influence in future studies. That said, some trials included in the studies identified were conducted from 2005, providing a wider timeframe of included evidence. Equally, further examination of some studies conducted prior to 2011 highlighted that barriers for women's participation have remained consistent. ${ }^{7,28}$ Thus, we do not believe restricting the time-period of the review has been detrimental to the findings. Secondly, only full-text English language publications were included. This was part of the search criteria and although we do not anticipate that this would have affected many papers, we are unclear exactly how many papers were excluded from this review as a result. Language is often a barrier to accessing healthcare ${ }^{29}$ and participating in trials ${ }^{30}$ and so additional barriers relating to language may be important to consider. Finally, this review has focused on the barriers and enablers at point of screening and inclusion into CVD research for women. However, it is known that there are other factors impacting on women participating in CVD research that fall outside the remit of this review. For example, the opportunity to participate is reduced as women with CVD are underdiagnosed and undertreated ${ }^{1}$ and experience delay to both referral and treatment. ${ }^{3}$ Equally, the lack of women in academic cardiology ${ }^{31}$ and in clinical trial leadership positions ${ }^{32}$ is also likely to be a factor, with the expectation that greater visibility of women in these roles will enhance the recruitment of women into CVD research.

## Conclusion

This scoping review has highlighted not only the consistent underrepresentation of women in a range of cardiovascular specialties, but a number of considerations that researchers could use to increase women's participation in future CVD research. We would welcome the use of the findings from this review to inform future trial planning and delivery by researchers. Furthermore, we recommend that funding bodies acknowledge, actively encourage and prioritise the funding of research that explicitly demonstrates a considered approach to ensuring CVD research is sex-representative and that more publishers and journals revise their publication policies to ensure researchers can demonstrate the representativeness of their research. If grant and publication success were dependent on demonstrating representation, there would be greater incentive for researchers to address the stated challenges. ${ }^{6}$ Ultimately, this is essential to improve the evidence of CVD prevention, diagnosis, treatment and outcome of women, and to redress the CVD health inequalities that women have consistently endured.

## Supplementary material

Supplementary material is available at European Journal of Cardiovascular Nursing online.

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## Data availability

The data underlying this article will be shared on reasonable request to the corresponding author.

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[^1]:     Controlled Trial; UK: United Kingdom; USA: United States of America.

