Digital Health for Heart Health Priority Setting Partnership

PROTOCOL 20 September 2023 Version 3.0

1. Purpose of the PSP and background

The purpose of this protocol is to clearly set out the aims, objectives and commitments of the Digital Health for Heart Health Priority Setting Partnership (PSP) in line with James Lind Alliance (JLA) principles. The Protocol is a JLA requirement and will be published on the PSP's page of the JLA website. The Steering Group will review the Protocol regularly and any updated version will be sent to the JLA.

The JLA is a non-profit making initiative, established in 2004. It brings patients, carers, and healthcare professionals together in PSPs. These PSPs identify and prioritise the evidence uncertainties, or 'unanswered questions', that they agree are the most important for research in their topic area. Traditionally PSPs have focused on uncertainties about the effects of treatments, but some PSPs have chosen to broaden their scope beyond that. The aim of a PSP is to help ensure that those who fund health research are aware of what really matters to patients, carers and healthcare professionals. The National Institute for Health and Care Research (NIHR – www.nihr.ac.uk) coordinates the infrastructure of the JLA to oversee the processes for PSPs, based at the NIHR Coordinating Centre (NIHRCC), University of Southampton.

Cardiovascular diseases (CVD) are the leading cause of death globally and encompass a range of conditions including coronary artery disease, arrhythmias, heart failure, valvular disease, congenital heart issues, and cardiomyopathy. In 2016, the global prevalence of CVD was estimated to be approximately 470 million and there were approximately 17.6 million deaths due to CVD worldwide (1,2). In the UK, it is estimated that 7.6 million people have CVD, resulting in over 160,000 deaths annually (3). CVD is estimated to cost UK healthcare £9 billion per annum and the UK economy £19 billion. Disparities in CVD mortality and morbidity are also well documented, highlighting the significant impact of socioeconomic status, ethnicity, and gender on the distribution of CVD risk and poorer long-term outcomes (4). Notably, the burden of CVD is often disproportionately borne by underserved societal groups. Solutions are required that will aid diagnoses and improve secondary care for those living with CVD, in addition to narrowing inequalities.

Digital health includes different tools and devices that use technology to help with healthcare. Some examples of digital technology are online learning, monitoring patients from a distance (like through video calls or devices), telephone support, participating in consultations with healthcare professionals online, using health-related mobile apps, and wearing devices that track health data (5). Such digital technology can bring big changes to heart healthcare by connecting patients, services, and health information in new and exciting ways. However, substantial gaps exist in the evidence base underlying the utility of these technologies in the prevention and management of CVD. To close this gap, it's important to involve patients and healthcare professionals in evaluating digital health uses in heart health. This way, we can make sure digital technologies meet people's needs, gain public trust, and

improve CVD healthcare for patients, their carers, and their healthcare teams. The PSP leads are both clinical and digital technology academics and passionate about improving patient care through relevant and effective research. This Digital Health for Heart Health PSP has enabled the formation of a multi-disciplined steering group of individuals who have experience of CVD and the uses of digital health either from a personal or professional perspective.

2. Aims, objectives and scope of the PSP

The aim of the Digital Health for Heart Health PSP is to identify the unanswered questions about the use of digital technology in the prevention and management of cardiovascular disease (CVD) from patient, carer and clinical perspectives and then prioritise those that patients, carers and healthcare professionals agree are the most important for research to address.

This PSP focuses on identifying uncertainties related to the positive and negative impacts of using digital technologies for managing cardiovascular disease (CVD) in adults. We are particularly interested in exploring how digital technology can address the unmet healthcare needs of individuals living with CVD and their caregivers. This PSP will focus on the use, or potential use, of digital technology in the prevention and management (physical, psychological, social, and societal) of heart disease and the direct impact on patients and their families.

For the purposes of this PSP, we define 'digital technologies' as a broad range of interventions, tools, and services that utilise information communications technology (ICT) to benefit and improve people's heart health. This includes, but is not limited to, remote care delivery, treatment support, monitoring, and self-management, as well as innovative approaches such as virtual reality, avatars and artificial intelligence. Examples of digital technology devices include the internet, personal computers, laptops, tablets, social media platforms, mobile phone applications (apps), and wearable devices. These digital technologies can be used either alongside or independently of heart health services. We are excluding from this PSP technologies that people with lived experience cannot access directly and interact with themselves, such as, electronic health records and other healthcare administrative systems. In addition, we will not focus on technology integration or healthcare workforce capacity to use such technologies to care for people with heart disease.

For the purposes of this PSP, CVD (or heart disease) refers to a broad range of conditions that affect the heart and its function. The most common type of heart disease is coronary artery disease, which occurs when the coronary arteries, which supply blood to the heart muscle, become narrowed or blocked by a build-up of plaque. This can lead to chest pain (angina), heart attack, or even death. Other types of heart disease include arrhythmias, heart failure, valvular heart disease, congenital heart disease, and cardiomyopathy.

In this PSP, 'people with lived experience' refers to adults who have been diagnosed with CVD and people who informally care for and support friends and family with CVD.

Given the number of exclusions to the scope of this PSP, we will monitor the nature and volume of responses on these issues, and if required, will adjust the scope of the PSP (by agreement of the Steering Group) and/or work with project partners to identify ways in which these questions can be incorporated into other priority setting processes.

The objectives of the Digital Health for Heart Health PSP are to:

- Work with patients, carers and healthcare professionals to identify uncertainties about the use of digital technology for the prevention and management of heart disease and heart conditions
- To agree by consensus a prioritised list of those uncertainties, for research
- To publicise the results of the PSP and process
- To take the results to research commissioning bodies to be considered for funding

The scope of the Digital Health for Heart Health PSP is defined as:

- The use of digital technologies by those diagnosed with heart disease or a heart condition, and their carers, in the prevention and management of heart disease or heart conditions
- The use of digital technology to support heart disease patients and their carers (e.g. long-term support for patients prevention of future complications and access to services and social support)
- The use of these digital technologies by those residing in the United Kingdom of Great Britain and Northern Ireland and the Republic of Ireland
- The perspectives of patients with heart disease or a heart condition, their carers/close family and healthcare professionals who work with heart disease or heart condition patients

The PSP will exclude from its scope questions:

- By those under 18 years of age
- By those not residing in the United Kingdom of Great Britain and Northern Ireland and the Republic of Ireland
- About diagnosis and treatment of heart disease and heart conditions
- About integration of digital technologies into healthcare environments
- About workforce needs and capacity building to be able to use digital technology to manage care for patients with heart disease and heart conditions
- About stroke. This is due to another PSP, completed in 2021, having focused on stroke

The Steering Group is responsible for discussing what implications the scope of the PSP will have for the evidence-checking stage of the process. Resources and expertise will be put in place to do this evidence checking.

3. The Steering Group

The Steering Group includes membership of patients and carers and healthcare professionals[1], as individuals or representatives from a relevant group.

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[1] In some cases, it has been suggested that researchers are represented on the Steering Group, to advise on the shaping of research questions. However, researchers cannot participate in the prioritisation exercise. This is to ensure that the final prioritised research questions are those agreed by patients, carers, and healthcare professionals only, in line with the JLA's mission.

The Digital Health for Heart Health PSP will be led and managed by a Steering Group involving the following:

PSP executive team:
Lis Neubeck, Professor of Nursing at Edinburgh Napier University, PSP lead
Alistair Lawson, Associate Professor of Computing at Edinburgh Napier University, PSP lead
Susan Dawkes, Professor of Nursing at Robert Gordon University, PSP lead
Coral Hanson, Senior Research Fellow at Edinburgh Napier University, PSP lead
Nicola Straiton, Research Fellow, St Vincent's Health Network, Sydney, information specialist
Simon Nichol, Senior Research Fellow at Robert Gordon University, information specialist.

Patient and carer representatives:
Richard Mindham. Patient Representative on the European Society of Cardiology Patient Forum.
Jill Mclaggan, Advanced Clinical Massage Therapist and SCAD patient.

Clinical representatives:
Amanda Pitkethly, Lecturer at Edinburgh Napier University
Amitava Banerjee, Clinical Data Scientist at University College London, and Honorary Consultant
Cardiologist at University College London Hospitals and Barts Health NHS Trusts
Donna Fitzsimons, Professor of Nursing at Queens University Belfast
Ian David Jones, Senior Cardiac Nurse and Academic at Liverpool John Moores University
Nick Mills, British Heart Foundation Chair of Cardiology and Consultant Cardiologist at University of Edinburgh
Rani Khatib, Consultant Pharmacist in Cardiology and Cardiovascular Research at Leeds Training Hospital NHS Trust
Rakesh Modi, Welcome trust PHD Fellow and member of the Department of Public Health and Primary Care at University of Cambridge.

Professional / partner representatives:
David McColgan, Head of the British Heart Foundation Scotland
Fiona Strachan, Chief Operating Officer for the Innovative Healthcare Delivery Programme at University of Edinburgh
Jane-Claire Judson, Chief Executive Officer of Chest Heart and Stroke Scotland
Joanne Boyle, Head of engagement at the Digital Health & Care Innovation Centre
Mary McAuley, Network manager at NHS Research Scotland for Cardiovascular Health.

Project coordinator:
Graeme Simpson, Research Assistant, Edinburgh Napier University

James Lind Alliance Adviser and Chair of the Steering Group:
Dr Louise Dunford

The Steering Group will agree the resources, including time and expertise that they will be able to contribute to each stage of the process, with input and advice from the JLA.

4. Partners

Organisations and individuals will be invited to be involved with the PSP as partners. Partners are organisations or groups who will commit to supporting the PSP, promoting the process and encouraging their represented groups or members to participate. Organisations which can reach and advocate for these groups will be invited to become involved in the PSP.

Partners represent the following groups:

- people who have heart disease or a heart condition
- carers of people who have heart disease or a heart condition
- health and social care professionals with experience of managing heart disease and heart conditions

Exclusion criteria
Some organisations may be judged by the JLA or the Steering Group to have conflicts of interest. These may be perceived to potentially cause unacceptable bias as a member of the Steering Group. As this is likely to affect the ultimate findings of the PSP, those organisations will not be invited to participate. It is possible, however, that interested parties may participate in a purely observational capacity when the Steering Group considers it may be helpful.

5. The methods the PSP will use

This section describes a schedule of proposed steps through which the PSP aims to meet its objectives. The process is iterative and dependent on the active participation and contribution of different groups. The methods used in any step will be agreed through consultation between the Steering Group members, guided by the PSP's aims and objectives. More details of the method are in the Guidebook section of the JLA website at www.jla.nihr.ac.uk where examples of the work of other JLA PSPs can be seen.

Step 1: Identification and invitation of potential partners
Potential partner organisations will be identified through a process of peer knowledge and consultation through the Steering Group members' networks. Potential partners will be contacted and informed of the establishment and aims of the Digital Health for Heart Health PSP.

Step 2: Awareness raising
PSPs will need to raise awareness of their proposed activity among their patient, carer, and healthcare professional communities, in order to secure support and participation. Depending on budget, this may be done by a face-to-face meeting, or there may be other ways in which the process can be launched, e.g. via social media. It may be carried out as part of steps 1 and/or 3. The Steering Group should advise on when to do this. Awareness raising has several key objectives:

- to present the proposed plan for the PSP
- to generate support for the process
- to encourage participation in the process
- to initiate discussion, answer questions and address concerns.

Step 3: Identifying evidence uncertainties

The Digital Health for Heart Health PSP will carry out a consultation to gather uncertainties from patients, carers and healthcare professionals. A period of 18 months will be given to complete this exercise (which may be revised by the Steering Group if required).

The Digital Health for Heart Health PSP recognises that the following groups may require additional consideration:

- People from underserved populations and communities
- People with pre-existing or concurrent cognitive or physical disabilities
- People who are at risk of, or experiencing homelessness
- People who have been imprisoned

The Steering Group will use the following methods to reach the target groups

- A dedicated Digital Health for Heart Health PSP website
- Link to online survey on JLA Digital Health for Heart Health social media accounts (X/facebook/Instagram)
- Link to online survey on JLA Digital Health for Heart Health website
- Representatives within the steering group to disseminate information within their clinical and professional environments and forums
- Online and paper resources available
- Formation of a system of champions from underserved communities to advise and recommend relevant platforms of communication
- Involvement of charitable organisations within steering group and partners
- Link to online survey and paper options hosted on CVD and heart condition charity websites
- Link to online survey and paper options promoted on UK relevant CVD, academic and health X accounts
- Link to online survey on the James Lind Alliance website

Existing sources of information about uncertainties for people with lived experience and health and social care professionals will be searched. These can include outputs from other identification processes involving patients, carers, and healthcare professionals, such as workshops, hack days, innovation labs; research recommendations in systematic reviews and clinical guidelines; protocols for systematic reviews being prepared and registers of ongoing research. In additional, previous, or current heart disease and heart condition-related, or digital technology focussed PSPs will be reviewed. The starting point for identifying sources of uncertainties and research recommendations is NHS Evidence: www.evidence.nhs.uk.

Step 4: Refining questions and uncertainties
The consultation process will produce 'raw' questions and comments indicating patients', carers' and healthcare professionals' areas of uncertainty. These raw questions will be categorised and refined by information specialists, Simon Nichols and Nicola Straiton, into summary questions which are clear, addressable by research, and understandable to all. Similar or duplicate questions will be combined where appropriate. Out-of-scope and 'answered' submissions will be compiled separately. The Steering Group will have oversight of this process to ensure that the raw data is being interpreted appropriately and that the summary questions are being worded in a way that is understandable to all audiences. The JLA Adviser will observe to ensure accountability and transparency.

This will result in a long list of in-scope summary questions. These are not research questions and to try and word them as such may make them too technical for a non-research audience. They will be framed as researchable questions that capture the themes and topics that people have suggested.

The summary questions will then be checked against evidence to determine whether they have already been answered by research. This will be done by Simon Nichols and Nicola Straiton. The PSP will complete the JLA Question Verification Form, which clearly describes the process used to verify the uncertainty of the questions, before starting prioritisation. The Question Verification Form includes details of the types and sources of evidence used to check uncertainty. The Question Verification Form should be published on the JLA website as soon as it has been agreed to enable researchers and other stakeholders to understand how the PSP hasdecided that its questions are unanswered, and any limitations of this.

Questions that are not adequately addressed by previous research will be collated and recorded on a standard JLA template by Simon Nichols and Nicola Straiton. This will show the checking undertaken to make sure that the uncertainties have not already been answered. The data should be submitted to the JLA for publication on its website on completion of the priority setting exercise, taking into account any changes made at the final workshop, in order to ensure that PSP results are publicly available.

The Steering Group will also consider how it will deal with submitted questions that have been answered, and questions that are out of scope.

Step 5: Prioritisation – interim and final stages
The aim of the final stage of the priority setting process is to prioritise through consensus the identified uncertainties about the use of digital technologies in the prevention and management of heart disease and heart conditions. This will involve input from patients, carers and healthcare professionals. The JLA encourages PSPs to involve as wide a range of people as possible, including those who did and did not contribute to the first consultation. There are usually two stages of prioritisation.

1. Interim prioritisation is the stage where the long list of questions is reduced to a shorter list that can be taken to the final priority setting workshop. This is aimed at a wide audience and is done using similar methods to the first consultation. With the JLA's guidance, the Steering Group will agree the method and consider how best to reach and engage patients, carers, and healthcare professionals in the process. The most highly ranked questions (around 25) will be taken to a final priority setting workshop. Where the interim prioritisation does not produce a clear ranking or cut off point, the Steering Group will decide which questions are taken forwards to the final prioritisation.

2. The final priority setting stage is generally a one-day workshop facilitated by the JLA. With guidance from the JLA and input from the Steering Group, up to 30 patients, carers and healthcare professionals will be recruited to participate in a day of discussion and ranking, to determine the top 10 questions for research. All participants will declare their interests. The Steering Group will advise on any adaptations needed to ensure that the process is inclusive and accessible

6. Dissemination of results

The Steering Group will identify audiences with which it wants to engage when disseminating the results of the priority setting process, such as researchers, funders, and the patient and clinical communities. They will need to determine how best to communicate the results and who will take responsibility for this. Previous PSPs' outputs have included academic papers, lay reports, infographics, conference presentations and videos for social media.

It should be noted that the priorities are not worded as research questions. The Steering Group should discuss how they will work with researchers and funders to establish how to address the priorities and to work out what the research questions are that will address the issues that people have prioritised. The dissemination of the results of the PSP will be led by the PSP leads.

The JLA encourages PSPs to report back about any activities that have come about because of the PSP, including funded research. Please send any details to jla@soton.ac.uk.

7. Agreement of the Steering Group

The Digital Health for Heart Health PSP Steering Group agreed the content and direction of this Protocol on 20/09/2023.

8. References

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