DIGITAL PLATFORMS TO SUPPORT CARDIAC REHABILITATION

[GID-HTE10060]: FINAL PROTOCOL

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Medical Technologies Evaluation Programme

Final Protocol

April 2025

PROJECT TITLE

Digital platforms to support cardiac rehabilitation

1.1 Plain English Summary

Cardiac rehabilitation is a treatment approach that involves exercise and education for people with cardiovascular disease These conditions are responsible for around a quarter of all deaths in the UK as well as around £12 billion of healthcare costs per year. Only just over half of people with cardiovascular disease take up the offer of cardiovascular rehabilitation. Funding difficulties also mean it is not currently possible to offer this treatment to all people who would likely benefit from it. Digitally supported cardiac rehabilitation may address capacity concerns and facilitate greater adherence to treatment.

This assessment considers whether digitally supported cardiac rehabilitation is beneficial and safe for adults with cardiovascular diseases, and whether these technologies represent good value for money for the National Health Service (NHS). Thirteen digitally supported cardiac rehabilitation therapies will be compared with alternative treatment options offered by the NHS.

1.2 Decision Problem

1.2.1 Purpose

The topic has been identified by NICE for early value assessment (EVA). The objective of an EVA is to identify promising technologies in health and social care where there is significant need and enable earlier conditional access while informing further evidence generation. The evidence developed will demonstrate if the expected benefits of the technologies are realised and inform a final NICE evaluation and decision on the routine use of the technologies in the NHS.

1.2.2 The interventions

This EVA is on digitally supported cardiac rehabilitation for cardiovascular disease, where the treatment has at least six weeks duration and facilitates the delivery of a supported cardiac rehabilitation programme (see Section 1.2.3). Thirteen interventions will be included. They are:

- Activate Your Heart (University Hospitals of Leicester NHS Trust) – a web-based cardiac rehabilitation platform for a range of cardiac conditions.
- Beat Better (Avegen Limited) - an app-based cardiac rehabilitation platform for people who have had a myocardial infarction or coronary artery bypass graft.
- Datos Health - AI Driven Hybrid Care Platform (Datos health Ltd) - a digital remote monitoring AI-enabled platform for delivering cardiac rehabilitation.
- D REACH-HF (Health & Care Innovations Ltd) – a digital version of a paper manual developed for people with heart failure that can be accessed via a website.
- Digital Heart Manual (NHS Lothian) - a digital version of the Heart Manual Programme (NHS Lothian) that can be accessed via a website.
- Get Ready – Solution (Medtronic) – a patient management, remote monitoring and patient engagement platform that can be accessed via website or app for people with a wide range of conditions.
- Gro Health HeartBuddy (DDM health) – an app-based cardiac rehabilitation platform for people.
- KiActiv (Ki Performance Lifestyle Limited) – a digital platform that can be accessed via a website or app to deliver personalised exercise-based cardiac rehabilitation programmes.
- Luscii Vitals (Luscii healthtech B.V.) – an app designed to help people manage their condition following discharge from hospital.
- myHeart (my mhealth Limited) – an app and web-based cardiac rehabilitation platform.
- Pumping Marvellous Cardiac Rehab Platform (Pumping Marvellous Foundation) – a web-based online cardiac rehabilitation platform for people with heart failure.

- R Plus Health (RPlusHealth Limited) – an app and web-based platform that provides exercise prescription and heart rate monitoring for people with a chronic heart condition.
- Sword Move (Sword Health) – an app-based cardiac rehabilitation platform.

1.2.3 Care pathways

Cardiovascular disease is managed by a multidisciplinary team. Treatment approaches mainly involve risk factor modification, controlling symptoms and preventing progression. These approaches may include medication, surgery, devices, behaviour change and cardiac rehabilitation services. Specific cardiovascular diseases considered in this appraisal are listed in Section 1.2.4

NICE Guideline NG185[1] on acute coronary syndrome recommends that people who have had a myocardial infarction should be given advice about and offered a cardiac rehabilitation programme with an exercise component. NG106[2] recommends that people with heart failure should be offered personalised, exercise-based cardiac rehabilitation programme unless their condition is unstable. The British Association for Cardiovascular Prevention and Rehabilitation (BACPR) Standards and Core Components for Cardiovascular Disease Prevention and Rehabilitation 2023[3] says that all eligible people should be offered cardiac rehabilitation before discharge from hospital and providers should make contact within 5 working days of referral . It is known that there are challenges meeting clinical guideline recommendations due to resource and funding difficulties.[4] It is noted that commissioning of services is complex and different from national decision making and that the challenges in reaching cardiac rehabilitation uptake targets are different for each region.[4]

Cardiac rehabilitation programmes are delivered according to six standards (see Scope at https://www.nice.org.uk/guidance/indevelopment/gid-hte10060/documents for full details)[5] . Standard four is the delivery of the programme. It should start as soon as possible after the initial assessment, deliver evidence-based interventions, and address the individual's needs across all core components.[6] The core intervention components are health behaviour change and education, lifestyle risk factor management, psychosocial health, medical risk management, and long-term strategies. SCM advice will elucidate the role of each of these components.

More details about the scope and the place of digitally supported therapies in the cardiac rehabilitation care pathway for the purposes of this EVA can be found on the Final Scope[5] document on the NICE website.

1.2.4 Population

Adults aged 18 years and over who are eligible for cardiac rehabilitation (full criteria shown on the Final Scope[5] on the NICE website), prioritising those with a confirmed diagnosis of acute coronary syndrome, coronary revascularisation and heart failure, although studies assessing cardiac rehabilitation without specifying the underlying cohort will be considered for inclusion. . If the evidence allows, the following populations can be considered: stable angina, pre- and post-implantation of cardiac defibrillation and resynchronisation devices, post-heart valve repair/replacement, post-heart transplantation and ventricular assist devices, adult congenital heart disease, atrial fibrillation, non-obstructive coronary artery disease, peripheral artery disease, spontaneous coronary artery dissection.

1.2.5 Comparators

The comparator is:

- Standard cardiac rehabilitation programme where digital tools are not offered as an option

1.2.6 Healthcare settings

Community

1.2.7 Outcomes to be examined

Outcome measures for consideration may include:

- Adherence (concordance) rates for intervention and long-term strategies
- Intervention uptake rates
- Intervention completion rates
- Attrition (dropout) rates
- Hospital readmissions, referral to specialist services, clinic visits
- Mortality
- Exercise capacity or performance (e.g. 6 Minute Walk Test, incremental shuttle walking test)

- Cardiovascular risk profile (systolic blood pressure, body mass index, serum triglycerides, HDL cholesterol, total cholesterol, blood glucose, and peak oxygen uptake)
- Health-related quality of life
- Nutrition status (e.g. Mediterranean Diet Score Tool)
- Medication adherence
- Time from post-discharge referral to start of core cardiac rehabilitation programme
- Usability and acceptability of the platform
- Behavioural change.

1.2.8 Subgroups to be examined

If the evidence allows, the following subgroups may be considered:

- Age
- Sex
- Socioeconomic status
- Ethnicity
- Cardiovascular condition
- Presence of comorbidities
- Previous involvement with cardiac rehabilitation

1.3 Objective

The purpose of the EVA is to summarise and critically appraise existing evidence on the clinical effectiveness and cost-effectiveness of digitally supported cardiac rehabilitation for people with cardiovascular disease. A review will be conducted to identify relevant evidence for the included interventions in the target population. Where feasible, a simple *de novo* economic model will also be developed to explore the potential cost-effectiveness of the included interventions. The following objectives are proposed:

1.3.1 Clinical Effectiveness

- Identify and assess evidence relating to the use and clinical effectiveness of the included technologies as it pertains to the scope
- Report on any potential safety issues
- Report the evidence gaps, highlighting what data may need to be collected to inform these gaps
- If evidence is included that is not directly related to the scope, outline the potential generalisability and limitations of the evidence

1.3.2 Cost-Effectiveness

- Identify and assess economic evidence relating to the use of the included technologies within the scope
- Subject to sufficient evidence, develop a conceptual economic model related to the scope, that can be used to inform future research and data collection
- Report available model inputs and evidence gaps
- Report on the technologies' costs and effects, and an early assessment of whether there is a *prima facie* case for their use to be a cost-effective alternative to standard care in the NHS.

1.4 Evidence review

A review to identify evidence for the clinical and cost-effectiveness of included interventions will be undertaken following the general principles published by the Centre for Reviews and Dissemination (CRD)[7] at the University of York. A systematic literature review (SLR) to comprehensively search for all relevant evidence for the appraisal is beyond the scope of an EVA. However, the review methods, including the literature search strategy and evidence synthesis, will be high quality and conducted in a transparent manner, with the aim to produce a comprehensive overview of the relevant literature. Based on initial scoping searches, the EAG does not expect there to be a large body of evidence for the included technologies, and that this evidence base should be identified through our planned searches. However, if the evidence base identified is large, the EAG will prioritise the inclusion of evidence that is of the best quality and most pertinent to the objectives of the EVA, for example RCTs, UK studies, studies with larger sample sizes and longer follow-up.

At study commencement, the NICE will request the manufacturers supply any evidence they wish to be considered and reviewed by the EAG.

1.4.1 Search strategy

Searches for clinical and cost-effectiveness will be conducted in one strategy, without any study type filters, to reduce screening burden. An exemplar search strategy for MEDLINE is provided in Appendix 1.

The searches will include the following sources:

- Electronic databases: MEDLINE (inc In-Process), EMBASE, and Cochrane.
- Economics sources, such as HERC and CEA Registry.
- Manufacturer websites.
- The WHO International Clinical Trials Registry Platform (ICTRP) and the US National Library of Medicines registry at clinicaltrials.gov.
- MHRA field safety notices and the MAUDE database will be searched for adverse events.
- In addition, any industry submissions to NICE, as well as any relevant systematic reviews identified by the search strategy, will be scrutinised to identify additional relevant studies.
- Relevant clinical guidelines from NICE, SIGN and INAHTA, especially for economic modelling

In addition to the above searches, a targeted search of the broader literature on people with cardiovascular disease will be undertaken to identify the evidence base on HRQoL (i.e. health state utility values), resource use and costs for treatment and side-effects (UK studies only if available), and the methods available for the modelling of cardiovascular disease to inform cost-effectiveness analyses.

The search strategies employed will be reported in full, findings will be presented in a table of results and the methods will be described in narrative text.

1.4.2 Clinical evidence to be included

This assessment will look across a range of evidence types including RCTs and real-world evidence. Systematic reviews meeting the inclusion criteria will also be included. Studies

may report either quantitative or qualitative evidence (the latter likely to be mainly on usability and acceptability of the platform). The following evidence types will be excluded:

- Animal models
- Pre-clinical and biological studies
- Narrative reviews, editorials, opinions
- Meeting abstracts, for studies where full-text papers are available. If studies are only available as meeting abstracts, inclusion will depend on sufficient information being available to offer meaningful critique.
- Studies not available in the English language.

1.4.3 Economic evidence to be included

Full economic evaluations, costing studies and studies reporting health related quality of life measures that inform either the design of the EAG's own analysis or provide a source of input data will be included where they meet the inclusion criteria set out for the review of clinical effectiveness (see section 1.2). Priority will be given to more recent studies and those with a UK NHS setting.

1.4.4 Study selection

The abstracts and titles of references retrieved by the searches will be screened against the inclusion criteria for relevance. Full publications of potentially relevant studies will be obtained. The retrieved articles will be assessed for inclusion by one reviewer (10% check by a second reviewer).

1.4.5 Quality assessment strategy

Formal risk of bias assessment will not be conducted, as it is not required in the EVA process. Discussion will be included in the EAG report on potential biases in key studies and how the risk of bias could affect key outcomes. The report will explicitly detail the potential sources of bias such as the main confounding factors and will comment on the generalisability of the results to clinical practice in the NHS.

1.4.6 Data extraction strategy

Data will be extracted from included studies into a bespoke database by one reviewer (10% check by a second reviewer). Data points to be extracted include information about the study

reference and design, the population and intervention characteristics, relevant outcomes and their measurement.

1.4.7 Methods of analysis / synthesis

Clinical data will be tabulated and narratively synthesised.

Methods and findings from included economic evaluations will be summarised in a tabular format and synthesised in a narrative review. Economic evaluations carried out from the perspective of the UK NHS and Personal Social Services (PSS) perspective will be presented in greater detail.

Key sources of risk of bias will be discussed. The generalisability of findings to clinical practice in the NHS will be considered.

1.5 Economic modelling

1.5.1 Overview of approach

If data allow, an economic model will be constructed either by adapting an existing model or developing a new model using available evidence and following guidance on good practice in conduct and reporting of decision analytic modelling for HTA.[8-10] If data do not allow construction of a model, the EAG will describe the appropriate characteristics of the model that would be required (e.g. structure, setting, input parameters and ideal sources of data).

The structure of any model will be determined based on research evidence and clinical expert advice (from specialist committee members) about:

- appropriate assumptions to make where no suitable data are identified for effectiveness for some of the interventions,
- appropriate assumptions to make if there are data gaps in the information available to populate resource use or quality of life information per health state.

All assumptions applied in the modelling framework will be clearly stated. All data inputs and their source will be clearly identified.

Costs will be considered from an NHS and Personal Social Services perspective. Costs for consideration may include:

- Cost of the technologies including device, license fees and staff training

- Cost of other resource use (e.g. acute events, suspected acute events, hospital presentations, adverse events, or complications)
- Healthcare appointments in primary, secondary and community care
- Medication use and adverse events
- Occupied bed days

Where appropriate, and if data allow the model will be analysed probabilistically. The use of probabilistic analysis involves sampling of parameter inputs from distributions that characterise uncertainty in the mean estimate of the parameter. The approach is used to characterise uncertainty in a range of parameter inputs simultaneously, to consider the combined implications of uncertainty in parameters and provides a base case based on expected costs and outcomes. Sensitivity analyses will be undertaken to explore uncertainty. These may include one-way and multi-way sensitivity analyses, and value of information analyses where modelling permits. Value of Information analysis helps identify where future research can be most efficiently targeted to reduce uncertainty.

Where probabilistic modelling is undertaken, results will be presented as expected costs and outcomes, with uncertainty represented using cost-effectiveness planes and/or cost-effectiveness acceptability curves/frontier (CEACs/CEAF).

1.5.2 Specifics

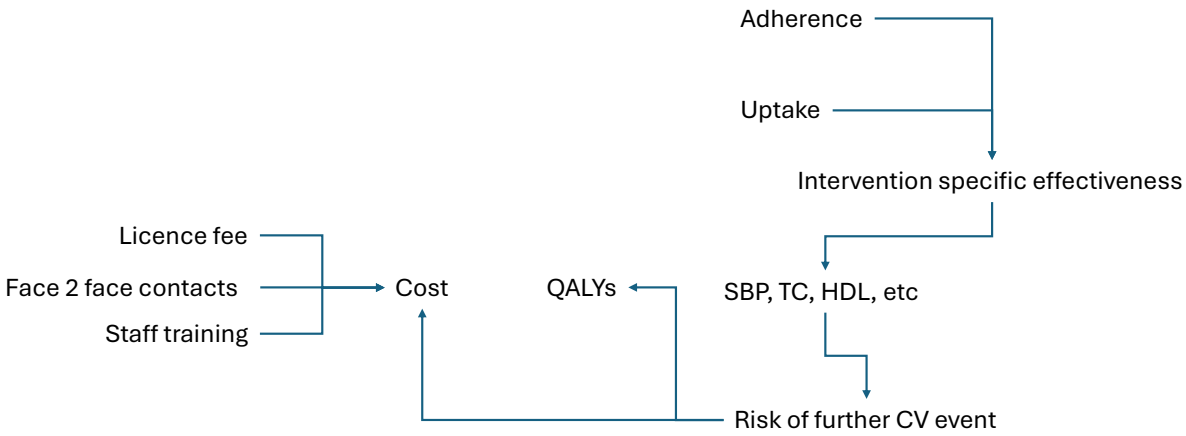
The analysis will compare offer of one or other of the digital rehab products with treatment as usual (TAU). If data allow, the analysis will compare TAU vs digital rehab vs digital rehab + TAU (i.e. digital rehab in place of face-to-face rehab or non-digital home-based rehab and digital rehab as adjunct to face to face).

A draft conceptual model of the analysis is in Figure 1. Key elements of cost will comprise licence fee of products, face to face contacts and staff training, as well as cost associated with future CV events. Key variables affecting outcomes are anticipated to be uptake, adherence/completion, and product-specific effectiveness. These factors affect biomarkers such as blood pressure, cholesterol and triglycerides which then change the risk of a future CV event, which affects expected lifetime QALYs.

The EAG anticipates drawing on existing models linking changes in biomarkers to risk of further CV event (eg Q-RISK[11]), and future events to Quality Adjusted Life Expectancy. Evidence on differences in adherence, uptake and intervention specific effectiveness will be

extracted from the literature. As this is an EVA with evidence at an early stage, the EAG anticipates this to be a key element of uncertainty.

Figure 1 Conceptual model



1.6 Gap Analysis

Evidence gaps identified pertaining to the intermediate and final outcomes from the scope and those pertaining to the economic modelling will be summarised in tabular and narrative form. If appropriate, a 'traffic light' scheme will be used to highlight relative importance of the gap. Key areas for evidence generation will be summarised in tabular form. Narrative text will also address missing clinical evidence for other parts of the scope, such as population, setting and comparators.

1.7 Handling the company submissions

Data received from the company will be appraised and, where consistent with the decision problem, will be extracted and quality assessed in accordance with the procedures outlined in this protocol. Data provided (e.g. cost and resource use data) will be assessed against NICE's manual (2022),[8] reasonableness of assumptions made and appropriateness of the data used.

Any academic or commercial in confidence data taken from a company submission will be marked up as appropriate in the report. The final date after which the EAG cannot consider new data is Friday 9th May 2025.

1.8 Competing interests of authors

Saul Stevens worked with Health & Care Innovations Ltd in an unrelated area more than one year ago.

1.9 References

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Appendix 1 Sample Search Strategy

Ovid MEDLINE(R) ALL <1946 to April 21, 2025>

1 ("Activate Your Heart*" or "Datos Health" or "AI Driven Hybrid Care Platform*" or "Reach?HF*" or "Reach HF" or "Health and Care Innovation*" or "Digital Heart Manual*" or "Gro Health" or HeartBuddy* or "Heart Buddy*" or "DDM Health" or HealthMachine or "Health Machine" or "Beat Better" or Avegen or KiActiv* or "Ki Performance Lifestyle" or "Luscii Vital*" or "Luscii Healthtech" or myHeart* or "my Heart*" or "my mHealth" or "Pumping

Marvellous" or "R Plus Health" or RPlusHealth or "Sword Move" or "Sword Health" or "Get Ready").tw. 1199

2 (rehab* or coronar* or cardia* or cardio* or heart*).tw. 2524510

3 1 and 2 537

4 (digital* or online or app or apps or web or website* or internet or electronic or ehealth or e-health or mhealth or m-health or ai or artificial intelligen*).ti. 293726

5 (coronar* or cardia* or cardio* or heart*).ti. 1184922

6 (rehab* or reabl* or re-abl* or recover*).ti,ab. 1100047

7 4 and 5 and 6 371

8 *Cardiac Rehabilitation/ 3795

9 4 and 8 127

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11 limit 10 to english language 884