Technology-enabled remote monitoring for heart failure: rapid scoping to inform evaluation of the Managing Heart Failure @home programme

Study protocol

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Abstract

Background

Given the significant impact of heart failure on both the healthcare system and patient outcomes, the Managing Heart Failure at Home programme (MHF@home programme) was developed by NHS England in 2022, following an initial five-site demonstration pilot in 2021. The MHF@programme aims to help improve heart failure management and population outcomes, being primarily designed to reduce hospital admissions and readmissions related to heart failure and to improve quality of life for people living with heart failure. While the initial pilot included ten sites over 2023/2024, seven of the ten sites have continued the programme in 2024/2025, in addition to 18 new sites. The proposed rapid evaluation seeks to understand data availability and implementation approaches for the seven pilot sites continuing with the MHF@home programme in 2024/2024. Evaluation activities will inform a potential future evaluation which would build on the current limited evidence on programme impacts, while providing rich detail on implementation approaches across sites.

Aims, objectives and research questions

The aim of the proposed scoping phase evaluation is twofold:

- To understand data availability in terms of the types of data needed to assess the uptake and impact of care pathways as part of the MHF@home programme; and
- To begin to identify the diversity of implementation approaches across MHF@home sites, including considerations of equity and inclusion, in order to inform the design of a full evaluation of the MHF@home programme post-pilot phase.

The objectives are as follows:

1) To confirm to extent to which data elements identified in the MHF@home data collection framework are being collected across continuing pilot sites and to identify any issues associated with data collection that impact completeness and quality
2) To explore the feasibility of sites to provide comparator data for patient reported outcomes data and healthcare resource use
3) To understand at a high-level the implementation approaches and core components of MHF@home care pathways across implementation sites, including considerations of equity and inclusion
4) To identify potential study designs for a fuller evaluation, given what we learn about the availability of data and about the nature of care pathways in this scoping phase

Design and methods

This evaluation will take a multi-site, qualitative approach. Facilitated by the MHF@home team as our policy customer, our work will focus on two areas: (i) examining data collection by sites/availability of data that would be needed for a quantitative evaluation of patient reported outcome measures and measures of healthcare resource use and (ii) beginning to understand the nature of care pathways and implementation approaches at the seven sites.

Our core methods includes both semi-structured interviews and document review. We will conduct up to 15 interviews, which include interviews with up to two representatives from each of the seven continuing pilot sites (one with the identified data lead and one with the site lead or named replacement) and one interview with a member of the NHS England MHF@home team. We will also analyse key documents

from each pilot site on their MHF care pathway, and MHF@Home programme documents with a specific focus on data/metrics frameworks and theory of change.

Timelines for delivery

Evaluation activities will start October 2024 and last five months, to be completed by the end of February 2025.

Anticipated dissemination and impact

Outputs will include a final report with executive summary, which will include recommendations related to the feasibility and design of a potential full evaluation. The final report and executive summary will be made freely available through the DECIDE website. A lay summary will also be made available with the support of a project PPIE group.

Background and rationale

The health system and policy context

The burden of heart failure in the UK is increasing with population growth and ageing, and is now similar to the four most common causes of cancer combined[1]. The National Institute for Health and Care Excellence (2018) estimate that there are currently around 920,000 people in the UK with heart failure[2]. It is particularly prevalent among older adults, with the average age of diagnosis being around 77 years. **A high amount of NHS resources are directed towards treating heart failure, including hospital admissions and re-admissions.** Heart failure is responsible for 5% of all emergency hospital admissions and 2% of the overall NHS budget, making it a critical focus area for healthcare resource allocation[2].

Given the significant impact of heart failure on both the healthcare system and patient outcomes, it was included as a priority in the 2019 NHS England (NHSE) Long Term Plan, which outlined key areas of improvement:

- **Earlier detection and more proactive identification of heart failure** to allow for timely interventions that can prevent the progression of the disease, improve patient outcomes, and reduce the need for hospitalizations;
- **Integration of multidisciplinary team support through primary care networks** (PCNs), to support a team-based approach to address patients' medical, lifestyle, and psychosocial needs is also being prioritised. Improved integration of care across primary, secondary, and community settings is expected to enhance early diagnosis and provide continuity of care throughout the healthcare system;
- **Improved access to heart failure nurses** on admission to hospital, to allow for specialist care and advice;
- **Improved access to and uptake of cardiac rehabilitation**, to improve quality of life and reduce hospital admissions[3].

The Managing Heart Failure at Home programme (MHF@home programme) in NHS England was developed starting 2022, following five demonstrator sites being funded in 2021 to implement approaches to supported self-management and remote monitoring[4]. The programme aims to help improve heart failure management and population outcomes, being primarily designed to reduce hospital admissions and readmissions related to heart failure and to improve quality of life for people living with heart failure[5]. Based on information from the MHF@home team, the MHF@home is comprised of three core elements:

- **A personalised care approach** which empowers individuals to have control over their care, tailored to their unique needs, strengths, and preferences. This approach includes shared decision-making, personalised care planning, advance care planning, social prescribing, and supported self-management, all aimed at improving health outcomes and quality of life.
- **Remote support and monitoring** to facilitate the tracking of physiological measures and symptoms, enabling timely interventions and better communication between patients and healthcare providers.
- **Integrated care** to enhance the coordination of care across various healthcare settings, leveraging multi-disciplinary teams to identify and support high-risk patients, improve

outcomes, and reduce costs. This involves sharing information across organisational boundaries and communication between primary, community, and secondary care providers.

These three components are interdependent and with overlapping elements, but point to a programme which seeks to enable the use of technology-enabled remote monitoring, as part of wider efforts to support personalised and integrated care, and enable service users to better manage their condition and prevent deterioration.

The MHF@home programme is focused on all people living with heart failure, whether newly diagnosed or those with existing diagnoses of heart failure. The programme is for patients whose heart failure presents as heart failure with reduced ejection fraction (HFrEF), heart failure with preserved ejection fraction (HFpEF) and people with heart failure with mildly reduced ejection fraction (HFmREF). The programme seeks to provide patients with support to better manage their condition in the person's home or place of residence. The services are provided remotely and then supplemented with in face-to-face interactions as necessary/appropriate. Patients are admitted to the MHF@home programme and then are 'discharged' from the service as appropriate back to primary care.

NHS England supported a pilot consisting of 10 sites over fiscal year 2022/2023, lasting 12 months. While all sites included some level of all three core elements, the sites varied in the extent to which they implemented each[6], although further detail is needed to understand the diversity of care pathways and implementation approaches and their evolution in practice.

The programme specified criteria for each element of the programme are summarised in Table 1 below.

Personalised care	**Remote monitoring**	**Integrated care**
Shared decision making	Physical observations • Weight • Blood pressure • Heart rate • Heart rhythm • Oxygen saturation	Comprehensive care pathways across care settings
Personalised care and support planning:	Self-reported health status	Multidisciplinary team meetings
Advance care planning	Lung congestion: Thoracic impedance, dielectric sensing	Use of multidisciplinary care plans
Social prescribing and community-based support	Haemodynamics: Pulmonary artery pressure, left arial pressure	Patient self-management education provided by a multidisciplinary team
Supported self-management		Liaison between primary and secondary care services for planned admission and discharge
		Early (<14 days) and medium-term (6 months) post-discharge follow-up
		Shared professional education

Table 1. Criteria included in each of the three core elements of the MHF@home programme.

The pilot ended May 2024 after which seven of the ten pilot sites applied for and received additional funding for fiscal year 2023/2024 to participate in an additional year-long extension of the programme. The seven continuing pilot sites are as identified below:

- East and North Hertfordshire Health and Care Partnership
- University Hospitals of North Midlands
- Frimley Health NHS Foundation Trust
- Haringey GP Federation
- North Tees and Hartlepool NHS Trust
- University Hospital Coventry and Warwickshire NHS Trust
- University Hospital Southampton NHS Foundation Trust

Alongside the continuing pilot sites, there are 18 new sites starting implementation of the MHF@home programme this year (though they are not the focus of the study). Each site is expected to recruit 50 patients as part of the additional programme which runs July 2024 to June 2025.

The study will focus only on the seven continuing pilot sites – to understand their ongoing data collection and implementation of the MHF@home programme. The work will inform the design of a potential full evaluation which will answer questions about scaling up of the programme, i.e. growing the programme to care for more patients, or provide more robust evidence on the impacts of the programme on patient report outcomes and healthcare resources use, i.e. through a controlled analysis. Findings will be of interest to national policymakers and regional decisionmakers (e.g. at the integrated care system level). The findings may also be of interest to an international audience of both scholars and health system decisionmakers, given the global burden of heart failure.

Rapid evidence review for managing heart failure

In this section we review some key insights from the literature on managing heart failure, with a view to taking stock of relevant learning for informing this rapid scoping project. This is based on a targeted review of 16 papers based on a PubMed search and the NHS Futures MHF@home website. The review has helped to inform this protocol and is proportionate to the exploratory nature of the proposed project. (A fuller and more systematic literature review could be considered if this rapid scoping project confirms the need for and feasibility of a fuller evaluation of the MHF@home programme).

We consider key insights related to evidence from prior evaluations of the MHF@home programme. We also examine evidence from the wider literature on managing heart failure more generally, that sheds light on three key components of care pathways in the MHF@home programme, these being *self-management* (one of the key criteria within the personalised care element in the MHF@home programme), *remote monitoring* and *integrated care*. We do this to draw out some learning of relevance to understanding the core elements of care pathways in the MHF@home programme, including in the context of interactions between digital and non-digital elements of care pathways.

In terms of scope, the insights we present stem from literature on heart failure-specific programmes/interventions. (It is important to note that we do not include evidence for general virtual wards that can include patients with heart failure under the remote monitoring section for example, but that are not specifically designed for heart-failure care as this is outside the scope of the current focus of work).

By self-management we mean multidimensional strategies that patients employ to cope with chronic illness in their daily lives[7, 8]. Self-management can include activities such as symptom management and understanding when and how to take action when deterioration begins. By remote monitoring, we employ DECIDE's definition of technology-enabled remote monitoring, as that involving 'the use of digital tools, devices or apps to support people to monitor and manage their health and well-being, ill-health, disability or limiting long-term physical or mental health conditions, in ways appropriate to them. Such technologies enable the remote exchange of information, primarily between the user and health or care professionals, and to assist diagnosis, monitoring and management of health, care and wellbeing.' Finally by integrated care we mean activities used to promote joined up and coordination of care across healthcare settings – care that is 'coordinated across professionals, facilities, and support systems; continuous over time and between visits; tailored to the patients' needs and preferences; and based on shared responsibility between patient and caregivers for optimizing health'[9]. Technology can play a role in all of these aspects (e.g. self-management, remote monitoring and integrated care) but it does not have to be involved in all aspects and when involved, is accompanied by other non-technological activities and conditions. In this rapid scoping study, we will be particularly interested in understanding the interfaces and relations between tech-enabled remote monitoring and other aspects of the managing heart failure care pathway (i.e. self-management, integrated care).

Evidence on the MHF@home pilot programme

Evidence from a recent evaluation of the MHF@home pilot programme suggests positive impacts on health status and coordinated care, as reported by patients, as well as decreases in various measures of resource use; however, the single evaluation was based on a pre-/post- analysis of a single group. The lack of a controlled analysis limits our understanding of programme effects and the moderate strength of evidence limits the acceptability of the evaluation in the UK and internationally.

A 2024 evaluation of the MHF@home pilot programme conducted by Mtech Access included 571 patients and explored both patient-reported outcome measures and healthcare resource use. The evaluation found that the MHF@home programme was associated with improvements over time in health status (as measured by the EQ-5D-5L, a patient reported measure of health-related quality of life), improvements in the clinical summary, quality of life and self-efficacy subscales based on the patient completed Kansas City Cardiomyopathy Questionnaire (KCCQ), and improved person-centred and coordinated care (as measured by the Person-Centred Coordinated Care Experience Questionnaire (P3CEQ))[10]. Analysis also showed statistically significant decreases over time in GP, community and district nurse, and secondary care contacts. The multiple regression analyses were a single group pre-/post- analyses, i.e. not controlled, but adjusted for gender, age, type of heart failure at baseline and number of comorbidities. Missing data was cited as a limitation of the analysis, though a description data missingness and how missing data were handled was not provided (a sensitivity analysis of complete observations was conducted)[10].

One of the sites in the pilot programme provided data for non-MHF@home patients, and a matched analysis (matching based on age, heart failure type, time since diagnosis, baseline left ventricular ejection fraction (LvEF) score, baseline patient status (on treatment/support), baseline New York Heart Association (NYHA) classification score that reflects the extent of heart failure (I, II or III)) was conducted over baseline and three month follow up time periods. Though limited by small sample size (n=50 for each group) the analysis showed statistically significant differences in changes in score between the MHF@home and control groups in health status (as measured by the EQ-5D-5L), quality of life (KCCQ), person-centred and coordinated care (though very small effect size, via the P3CEQ)

but not in the clinical summary or self-efficacy scores of the KCCQ.[10] For healthcare resource use (in terms of the volume of contacts with different types of services), the study found significant differences in the magnitude of the change between the MHF@home and control groups for GP and secondary care contacts, but no significant differences for nurse or NHS 111 contacts.

Evidence from the wider literature on managing heart failure

Self-management:

The evidence base on the impacts of interventions to support self-management of heart failure is mixed. The interventions themselves vary widely. Some studies report benefits on mortality, readmissions and readmissions and quality of life, but overall the evidence base is mixed. Below we include a summary of a UK-based home-based intervention as well as digitally focused self-management interventions.

In the UK, Rehabilitation EnAblement in CHronic Heart Failure (REACH-HF), was a trial of a home-based, self-management rehabilitation programme for heart failure, which took place over 12 weeks and was conducted by trained healthcare professionals[11]. The programme plus usual care was found to improve clinical effectiveness in terms of health-related quality of life and patient self-care, compared to usual care[12], and was also found to be beneficial specifically for heart failure patients with preserved ejection fraction[13].

The body of evidence on digital health tools to support self-management of heart failure at home has been rapidly growing in the recent years. A 2022 international systematic review of studies focusing on the use of mobile apps for self-management (including components such as patient education, symptom monitoring, medication review and physical activity support) identified a total of 28 articles, reporting on 23 apps[14]. These studies reported mixed results, which, together with somewhat limited size and quality of the studies, prevents making robust conclusions on the effectiveness of such interventions. However, a 2022 meta-analysis of eHealth interventions, which more broadly included information and communication technologies for self-management of heart failure (n=24), suggested that eHealth self-management interventions can improve primary and secondary outcomes in patients with heart failure, with significantly lower all-cause mortality, all-cause readmissions and heart failure-related readmissions[15].

Remote monitoring:

The evidence for remote monitoring to support management of heart failure is promising with meta-analyses showing that remote monitoring reduces the risk of morality and hospitalisation.

A 2015 Cochrane review (n=17) observed that remote monitoring reduced the risk of all-cause mortality by 20% [16]. A 2022 meta-analysis of remote monitoring (n=8) also showed a 17% reduction in the risk of cardiovascular mortality. For hospitalisation related to cardiovascular disease, the studies with short-term (but not long-term) follow up showed a risk reduction of 29% for remote monitoring. Such improvements were not observed in studies that simply provided remote access to health care professionals without the monitoring of patient data; improvements were not significant for all cause mortality[17].

However, a randomised controlled trial of seven sites in the UK compared self-monitoring of heart failure patients versus those engaged in active remote monitoring, of which the latter involves sharing the monitoring information with their GP, with regular feedback[18]. The study did not find significant differences in patient-related outcomes such as recommended treatment adherence or in patient reported physical well-being outcomes after 6 months, although the intervention was shown

to be feasible and acceptable for patients. Further qualitative analysis found that the implementation differed widely across sites[19].

In the grey literature, Birmingham and Solihull CCG were involved in an earlier NHS@home pilot involving five sites, which included remote monitoring and self-management support for heart failure patients through education from heart failure specialty nurses. An unadjusted, non-controlled analysis showed a reduction in in-person appointments for the heart failure specialty nurses and general patient satisfaction with the service, with all patients (n=17) showing improvements in blood pressure control and pulse rates[20].

Integration of care:

While case studies from the grey literature reports benefits of interventions targeted toward improving care integration, such as reduced secondary resource use, the evidence is weak and there is a need for further robust evaluations.

There were a few English examples in the grey literature of activities and related evidence of improving care integration for heart failure patients. In general the strength of evidence is low, with either single group analyses or matched analyses that lack detail on how the comparison groups were formed. Various tools to support integration are discussed in the different reports (e.g. digital health tools, virtual meetings, integrated care pathways).

Based on a report on The North Midlands NHS Trust, improved integration between secondary and community health was enabled by using digital health tools focused on patient education (Recap Health) and self-assessment (Flo)[21]. This intervention focused on patients admitted or recently admitted to hospital with heart failure and was run by telehealth coordinators. The evaluation found evidence of some reduction of all cause readmissions at 3- and 6-months post discharge, though it is unclear who made up the usual care comparison group[21]. Results also pointed to observed increases in patient reported KCCQ self-efficacy score over the 9-month pilot[21].

In Liverpool, virtual multi-speciality meetings helped to improve integration across community, secondary and tertiary care. The meetings included participation from heart failure cardiologists from the community, secondary care and tertiary care, heart failure specialist nurses from the community and hospital, pharmacist and other specialist consultants. In a pre-/post- study (with average 13.9 months follow up), the meetings were associated with a reduction in outpatient appointments and all-cause hospitalisations[22].

Two case studies described implementing integrated heart failure pathways. Imperial College Healthcare NHS Trust developed a pathway across primary and secondary care[23] supported by a smartphone software application for remote monitoring, self-assessment (symptom and quality of life questionnaires) and patient education smartphone application with Lucsii[24]. The remote monitoring involved once daily, weekday readings and was targeted to chronic stable outpatients, managed by the heart failure specialist nurses and pharmacists. A nonrandomised matched analysis showed a reduction in unplanned hospital admissions and A&E attendances, with no increase in outpatient resource use[25]. Additionally, South Tees NHS Foundation Trust developed an integrated care pathway for heart failure patients, which is largely community based but allows the heart failure speciality nurse to see patients who are admitted to hospital. The intervention included clustering patients in a specialty unit to provider more intensive monitoring from specialist staff. Benefits described include provision of timely discharge instructions and education to patients and upskilling

of nursing staff in heart failure disease process and management, though no further specifics are provided[26].

In summary, the review of targeted literature showed mixed results for interventions related to self-management, remote monitoring and integration of care for heart failure. The UK-based evidence for self-management is promising though we did not find rigorous studies related to remote monitoring and integrated care. The current evaluation activities would inform a potential future evaluation which would build on the currently limited evidence using a strong or moderately strong research design, while providing rich detail on implementation approaches across sites.

EVALUATION PLAN

AIM, OBJECTIVES & RESEARCH QUESTIONS

The aim of the proposed scoping phase evaluation is twofold:

- To understand data availability in terms of the types of data needed to assess the uptake and impact of care pathways as part of the MHF@home programme; and
- To begin to identify the diversity of implementation approaches across MHF@home sites, including considerations of equity and inclusion, in order to inform the design of a full evaluation of the MHF@home programme post-pilot phase.

The objectives are as follows:

1) To confirm to extent to which data elements identified in the MHF@home data collection framework are being collected across continuing pilot sites and to identify any issues associated with data collection that impact completeness and quality
2) To explore the feasibility of sites to provide comparator data for patient reported outcomes data and healthcare resource use
3) To understand at a high-level the implementation approaches and core components of MHF@home care pathways across implementation sites, including considerations of equity and inclusion
4) To identify potential study designs for a fuller evaluation, given what we learn about the availability of data and about the nature of care pathways in this scoping phase.

EVALUATION ACTIVITIES

Our evaluation activities are focused on learning from the seven continuing pilot sites that have continued with the MHF@home programme about data and implementation, and using this to inform design of a potential full follow up evaluation of the MHF@home programme.

Facilitated by the MHF@home team as our policy customer, our scoping and feasibility work will be conducted with each of the seven continuing pilot sites. Activities will focus on two areas: (i) examining data collection by sites/availability of data that would be needed for a quantitative evaluation of patient reported outcome measures and measures of resource use and (ii) beginning to understand the nature of care pathways and implementation approaches at the seven sites.

Our core methods are:

- **Online interviews**: Evaluation activities will include up to 15 semi-structured interviews, including interviews with up to two representatives from each of the seven continuing pilot sites (one with the identified data lead and one with the site lead or named replacement)

and one interview with a member of the NHS England MHF@home team. Interviews will last up to 60 minutes, will take place online via MS Team, and will be digitally recorded.

- **Scoping document review**: We will collect and analyse up to 10 documents, to include at least one key document from each pilot site on the MHF care pathway, and 2-3 MHF@Home programme documents with a specific focus on data/metrics frameworks and theory of change.

Collection and analysis of interview and documentary data will be guided by our specific focus on the following two areas.

Understanding data collection by sites and availability of needed data for quantitative evaluation

NHS England's desired data collection framework to be used with pilot sites has been shared by the MHF@home team and agreed to by all seven sites. Our interviews will focus on understanding the degree to which sites will be able to provide data according to the data collection framework and any issues around specific data elements, including any issues that may impact completion or accuracy of data provided. The framework includes patient characteristics, including demographics and clinical information (such as NYHA, LvEF, comorbidities); patient reported outcomes (EQ-5D-5L, KCCQ, P3CEQ); patient-reported healthcare utilisation; measures of secondary care utilisation; programme data such as number of staff trained, number of patients referred to cardiac rehabilitation, number of patients referred to social prescribing, etc.

Findings from the 2024 pilot evaluation conducted by Mtech Access will partially inform our questions in this area, such as for example insights on key / critical measures to focus on. For example, the earlier evaluation[10] combined secondary care resource use into a single measure which included 11 categories of secondary care contacts (see Appendix 1). Depending on data availability and in discussion with the MHF@home team, future evaluation may focus on specific measures of secondary care resource use, e.g. all-cause 30-day re-admissions to hospital or heart failure related 30-day readmissions, or all-cause/heart failure-related A&E visits.

The MHF@home team is particularly interested in understanding whether sites are able to provide anonymised, patient-level comparator data, i.e. data of patients with heart failure meeting specific criteria who are NOT admitted to a MHF@home programme. With the MHF@home team we will first outline what the comparator group would likely look like, i.e. high-level inclusion/exclusion criteria so that during interviews we could provide this description to site data leads. The data that we would be interested in for any future comparative analysis would largely follow the data elements in the existing data collection framework already agreed with sites (see above). We would be interested in knowing the extent to which the variables are manually or automatically coded to understand whether the data are routinely collected or require more effort to collect.

In terms of information governance, NHS England had deemed, for the earlier 2024 pilot evaluation, that NHSE approval was sufficient and as such approvals at the integrated care system (ICS) level were not necessary. Following this, we will not ask specifically about information governance requirements for the ICS, but rather focus on data availability and logistics surrounding data provision. However, we will seek to understand and clarify the information governance requirements and ethics approvals necessary (including the Data Sharing Agreement and Data Protection Impact Assessment) between NHSE and DECIDE/University of Oxford for this evaluation.

Understanding implementation approaches at sites including core care pathway elements

The second area of focus will be on implementation approaches and core care pathway elements at all seven continuing pilot sites.

From existing NHSE documentation we already have a limited indication of what has been implemented within each site, according to the three core elements (personalised care approach, remote support and monitoring, integrated care)[6], i.e. which of the criteria in Table 1 each site would self-report as having implemented.

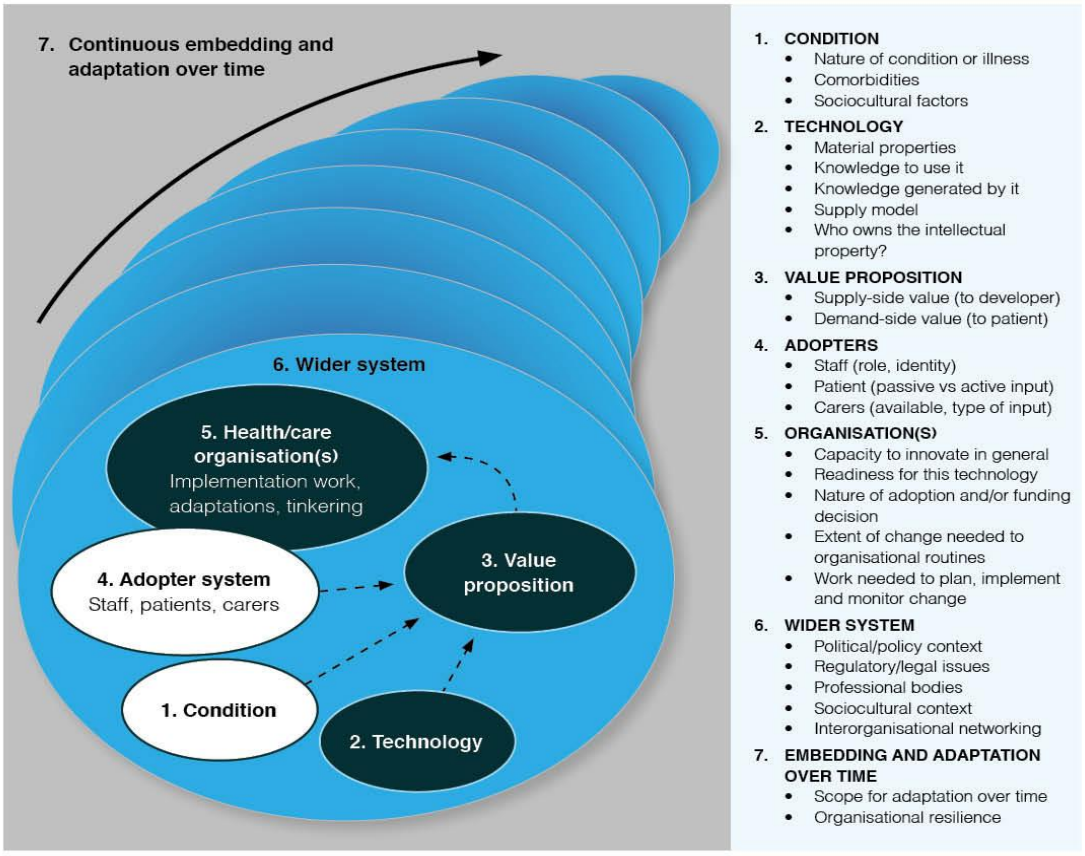
We will in the scoping interviews seek to better understand:

- Constituent components and activities within the care pathway, including as they relate to these three core elements of personalised care approach, remote support and monitoring, integrated care
- Characteristics of the workforce (specialty and grade) delivering the pathway
- How core elements and activities in the pathway (across personalised care approach, remote support and monitoring and integrated care) relate to each other
- Whether the care pathway and implementation approaches have changed in any way and if so why, i.e. beginning to examine what the original intervention logic was and how it evolved and why

We are interested to understand the extent to which MHF@home core elements are implemented in similar or different ways and the to what extent the approaches are comparable, i.e. whether core elements are similar enough to be included in a single analysis, or whether there aspects of sites' implementation approaches that are different enough from each other such that conceptualising the programmes as the same is not meaningful.

The NASSS (non-adoption, abandonment and challenges to scale up, spread and sustainability) framework (see Figure 1 below) will be used to sensitise us to the types of questions of interest for understanding implementation.

The qualitative data will be analysed thematically, guided by the NASSS framework in the first instance.



Note: Adapted from Greenhalgh T, et al. 'Beyond adoption: a new framework for theorizing and evaluating nonadoption, abandonment, and challenges to the scale-up, spread, and sustainability of health and care technologies'.[1]

Figure 1. NASSS Framework

Data collection tools

We will develop two semi-structured interviews guides, with input from the NHSE MHF@home team. The first of these will be developed around ongoing quantitative data collection using the data collection framework and will include questions around existing data collection for patients that do not take up MHF@home, as described above. The second guide will be focused on programme implementation, understanding to what extent the seven continuing pilot sites have implemented aspects of personalised care, remote monitoring and integrated care.

The research team will develop project information sheets to describe the aim and activities of this initial scoping work as well as consent forms for interview participants. We plan to obtain written informed consent for all interviews.

Service user group involvement

We will convene an online meeting at inception, including 2-3 service users or individuals representing patient groups including people with heart failure. We plan to include the patient who currently sits on the MHF@home steering group, a member from DECIDE's existing User Advisory Group, and an individual from the Pumping Marvellous patient group. In the meeting we will seek members' thoughts on what will be useful to ask sites leads from a patient and public perspective, so that their ideas can inform design of the interview guide.

Towards the end of the project, we will convene a second online meeting with a larger group of up to ten service users, which will be drawn from the initial group as described above, the Pumping Marvellous patient group as well as patients from the continuing pilot sites themselves, to share insights and ask about implications for what would be important to further consider in a fuller evaluation.

ANTICIPATED OUTPUTS, IMPACT AND PLANS FOR DISSEMINATION

Reporting

We will produce a final report with executive summary, which will include recommendations related to the feasibility and design of a potential full evaluation. The final report and executive summary will be freely available through the DECIDE website. A lay summary will also be produced and made available on the website with the support of the project PPIE group.

In addition, we will share emerging insights with the NHSE MHF@home team halfway through the study, via a prepared slidedeck. We will also share emerging insights from the project advisory group (see Project Management and Quality Assurance section below) for external input.

We will maintain open lines of communication and engage with the MHF@home team at regular intervals to provide updates and feed back emerging insights.

PROJECT TIMELINES

Evaluation activities will start October 2024 and last five months, to be completed by the end of February 2025.

Table 2: Project timetable

Month	Oct	Nov	Dec	Jan	Feb	Mar	Apr
Ethics, data and R&D governance							
Develop data collection instruments							
Document review							
Conduct interviews							
Synthesis/report writing							
Service user engagement							
Client engagement							
Project management and administration							
Project end							
Final report to NIHR							

PROJECT MANAGEMENT AND QUALITY ASSURANCE

Project management

We see project management as an important and continuous effort in performing this evaluation, and have established both staff roles, processes and structures to support effective delivery.

The project leader at RAND Europe (Dr Frances Wu) will lead on ensuring effective delivery to time and budget, with project management support (Dr Agne Ulyte). Overall project delivery will also be supported by oversight by centre leads for DECIDE at RAND Europe (Dr Sonja Marjanovic) and from Oxford (Prof Sara Shaw).

We will hold meetings at regular intervals between the research team and policy customer (NHSE MHF@home team) to update on the progress of the project and next steps for the research. We will also establish an expert advisory group for this project which will comprise 2-3 individuals drawn from DECIDE's Steering Committee.

Quality Assurance

The study may be monitored, or audited by the Sponsor or funder in accordance with the current approved protocol, relevant regulations and standard operating procedures.

PLANS FOR SERVICE USER AND PUBLIC INVOLVEMENT

See 'Service user group involvement' section above under Evaluation Plan.

RESEARCH TEAM

Table 2 presents the team members and their corresponding roles and expertise.

Table 2. Study team members

Team member	Role/contribution	Relevant expertise
Dr Frances Wu (RAND Europe)	Lead researcher. Project conception, design, data collection, analysis and synthesis. Writing of reports/dissemination.	Experienced in conducting mixed-method and embedded research and evaluation, including quantitative analysis using administrative, electronic health record and survey-based quantitative data.
Dr Agne Ulyte (RAND Europe)	Project design, data collection, and analysis. Writing of reports/dissemination	Experienced in health services research and quantitative methods such as multilevel modelling and survey methodologies
Prof Sara Shaw (PI for Decide, Professor at Oxford University);	Project conception, writing of reports/dissemination.	Highly established academic bringing expertise on technology-enabled health care, qualitative, case study and mixed methods design and delivery, and knowledge exchange/impact. Experienced in rapid evaluation and oversight of large research projects and evaluations; overall oversight of all projects under NIHR DECIDE centre.
Dr Sonja Marjanovic (RAND Europe)	Project conception, data collection, writing of reports/dissemination.	Experienced in health services and healthcare innovation research and evaluation of complex interventions; wide ranging portfolio of work on role of innovation in service delivery; experienced in leading large and rapid projects involving public, third sector and industry stakeholders and collaborative research partnerships.

ETHICAL, REGULATORY AND GOVERNANCE CONSIDERATIONS

Risks and their management

See Table 3 below for our assessment of potential risks and mitigation strategies

Risk	Impact	Likelihood	Mitigation
Demand pressures on local staff and system stakeholders and associated challenge to capacity to engage in timely ways	High	Medium	The evaluation requires support from the policy customer and sites on diverse grounds such as helping recruit interviewees, and where applicable timely access to relevant data. We will be adaptive to the schedules and constraints on staff during fieldwork, including the timing and modality of interviews.
Loss of key staff on project	High	Low	Oxford and RAND Europe's staffing model allows for flexibility such that in the event of project staff turnover, we can tap into wider expertise. Senior staff at both Oxford and RAND have extensive experience needed to deliver on the evaluations. The short duration of the project mitigates against this risk.
Delays in R&D approvals	High	Medium	We have been working with the NHSE MHF@home team to understand requirements. We understand that site level agreements are not necessary but a data sharing agreement and data protection impact assessment between NHSE and the University of Oxford will be required.

Ethical issues and required approvals

This project has been reviewed by the Oxford Joint Research Office classification committee, which determined that this is service evaluation

If and as required, we will put agreements in place with individual sites participating in this piece of work. These agreements will include clauses that cover activities to be undertaken at the site, including (but not limited to) recruitment of participants, transfer of funds, physical access to the site, and access (and use and subsequent storage of) data required to support outcome findings.

The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

Informed consent

All participants will have capacity to provide informed consent. The participant must personally sign and date the latest approved version of the Informed Consent form before any study specific activities are undertaken.

Written and verbal versions of the Participant Information and Informed Consent will be presented to the participants detailing the nature of the study, what it will involve for the participant, the implications and constraints of the protocol, and any risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, and with no obligation to give the reason for withdrawal.

The participant will be allowed as much time as wished to consider the information, and the opportunity to question the study evaluation team or other independent parties to decide whether they will participate in the study. Written Informed Consent will then be obtained by means of

participant dated signature and dated signature of the person who presented and obtained the Informed Consent. The person who obtained the consent must be suitably qualified and experienced, and have been authorised to do so by the Chief/Principal Investigator. A copy of the signed Informed Consent form will be given to the participant. The original signed form will be retained at the study site.

During the course of the study a participant may choose to withdraw early at any time. This may happen for several reasons, including but not limited to:

- The occurrence of significant distress during study interviews
- Inability to comply with study procedures
- Participant decision

Discontinuation/withdrawal

Participants may withdraw their consent at any time. Options for participants wishing to withdraw will be explained in the information sheet.

1) Participants may withdraw from all study communication but allow the study team to continue to access their medical records and any relevant data that has been recorded as part of routine standard of care and is held by the study team; i.e., disease progression data, routine patient reported outcome data and quality of life questionnaire data etc.

2) Participants can withdraw from the study but permit data obtained up until the point of withdrawal to be retained for use in the study analysis. No further data would be collected after withdrawal.

3) Participants can withdraw completely from the study and withdraw the data collected up until the point of withdrawal. The data already collected would not be used in the final study analysis*.

*In cases where data have already been incorporated into analysis it will not be possible to exclude these data. It is also not possible to exclude data collected from any group discussions as an individual's data will likely be directly related to that of other participants.

The reason for withdrawal by researcher (and by participant, if this information is volunteered) will be recorded in a study file.

Data management and storage

Data Recording and Record Keeping

Datasets collected and collated for this service evaluations will include:

- Our interviews will generate interview recordings which may be audio only (conducted using digital recorder devices or Teams), or audio-visual (e.g., Teams). Interview data will be collected by a small number of the DECIDE centre team (~1-2). Electronic files will be saved on password-accessible areas of the University of Oxford network and remote access to these files will be granted to members of the DECIDE centre team as required. The original recordings will be deleted when transcribed files have been checked and there is no further need for the original recording.
- DECIDE will may also collect contact details for key personnel involved in the evaluation where this information is required to arrange interviews or similar. This will consist of name, email address, and phone number. These data will be stored in the University of Oxford

network files and remote access will be granted as required to those within the DECIDE team.

Data will be collected and stored in accordance with the University of Oxford (Sponsor) data policies.

The University of Oxford requires all projects to register project data sets as 'information assets'. The DECIDE programme reference is IAR 561. This register supports obligations under General Data Protection Regulation (GDPR) and links to 'data protection by design' policies which include initial screening to confirm the level of data protection documentation required. Results of the screening will indicate that either a Data Protection Assessment (DPA) or, for data sets that include special category data, or where activity is likely to result in high risk to those individuals whose personal data are being processed, a Data Protection Impact Assessment (DPIA) form needs to be completed.

Any data generated from this piece of work will be processed in line with this protocol and stored in secure environments at the University of Oxford and RAND Europe. These secure environments are hosted within each institution and are accessible through a dual-authentication password process. As the primary award holder, the University of Oxford will act as the data controller for DECIDE. The University of Oxford data storage servers will therefore be the primary repository for all data. Members of the team who are employed by RAND Europe will be granted remote access to these files. As per any data storage clauses in the individual site agreements, RAND Europe may also store data files pertaining to this piece of work.

Participant Confidentiality

The study will comply with the General Data Protection Regulation (GDPR) and Data Protection Act 2018, which require data to be de-identified as soon as it is practical to do so. The processing of the personal data of participants will be minimised by making use of a unique participant study number only on all study documents and any electronic database(s). All documents will be stored securely and only accessible by study staff and authorised personnel. The study staff will safeguard the privacy of participants' personal data.

Access to data

Data will be accessible to the immediate team. This includes employees of The University of Oxford and RAND Europe who will be collecting and analysing the data for this evaluation.

Direct access to the data will also be granted as required to authorised representatives from the Sponsor or host institution for monitoring and/or audit of the study to ensure compliance with regulations.

Archiving

Identifiable personal data will be deleted as soon as it is practical to do so. De-identified (pseudonymised) data will be stored for a minimum of three years after the end of the project in line with University of Oxford data management and storage policies.

Sponsorship, indemnity and insurance

The University of Oxford will act as the main sponsor and guarantor for this study.

The University of Oxford maintains Public Liability and Professional Liability insurance, which will operate in this respect.

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Appendix 1. Categories of secondary care

The previous MHF@home evaluation examined the following eleven types of secondary care resource use:

- All-cause outpatient contacts
- HF-related outpatient contacts
- All-cause accident and emergency (A&E) contacts
- HF-related A&E contacts
- All-cause non-elective inpatient contacts
- HF-related non-elective inpatient contacts
- All-cause elective inpatient contacts
- HF-related elective inpatient contacts
- All-cause 30-day re-admissions to hospital and A&E
- HF-related 30-day re-admissions to hospital and A&E
- Appointments with a HF specialist