

Title: What services are currently provided to people with HFpEF in the UK and what are their components? A protocol for a scoping literature review

Short Title: [HFpEF Services, a UK scoping review](#)

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Aim: Heart failure with preserved ejection fraction (HFpEF) is increasing in incidence and is increasingly the most common heart failure (HF) diagnosis. Patients with HFpEF are often excluded from specialist HF services which has negative impacts on their healthcare experiences and health-related outcomes. As emerging evidence-based treatments are being incorporated into clinical guidelines, it is timely to focus on the management of this phenotype. This review aims to explore literature around care provision for HFpEF in the United Kingdom; to characterise and assess HFpEF care pathways against current standards, and to generate evidence to create an optimised framework of care.

Methods & Results: A scoping review of the evidence from six databases will be performed, alongside a search of grey literature search and consultation with relevant experts. Given expected heterogeneity, multiple lines of synthesis are anticipated. Data analysis will follow best practice guidelines for the synthesising methodologies selected. Patient and public representatives will assist with analysis and in identifying priority components for HFpEF clinical services

Conclusion: This scoping literature review will enable an in-depth examination of the current health service provision for those with HFpEF in the UK. Synthesis of key components of services and illumination of challenges and barriers will inform current and future practice. There is a long history of specialist HF care in the UK, including seminal work on nurse-led care. Therefore, evidence derived from this review will likely be useful to HF services across Europe. The proposed combination of the search across both peer-reviewed literature and grey literature, combined with patient and public involvement will identify the key components of a framework of care for those with HFpEF.

Registration: This scoping review protocol was published on the public Open Science Framework platform (no registration reference provided) and can be accessed at: <https://osf.io/5gufq/>

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Graphical abstract

What services are currently provided to people with HFpEF in the United Kingdom and what are their components? A protocol for a scoping literature review

HFpEF accounts for 50% of all heart failure cases, however patients with HFpEF are often excluded from specialist HF services, which has negative impacts on their healthcare experiences and health-related outcomes.

AIM To explore literature around care provision for HFpEF in the United Kingdom to establish 1) services offered; 2) service characteristics; 3) services provided versus guideline recommendations; 4) a framework of components for a future intervention

METH. A scoping review of the evidence from six databases will be performed, alongside a search of grey literature search and consultation with relevant experts. Multiple lines of synthesis are anticipated, and relevant guidelines will be followed.

RES. The formulation of a robust scoping review process will enable an in-depth examination of the current understanding of HFpEF health service provision. A systematic approach, using scientific methodologies to synthesise extracted data, will inform and develop a matrix of care components.

- This review will enable: a description of current services that are provided to those with HFpEF; a framework of clinical components for a heart failure service designed specifically for people with HFpEF; details of barriers and facilitators, identified by people both delivering and receiving care.
- Combined, these findings will promote discussion around effective organisation of care and facilitate change that will deliver better outcomes for people with HFpEF.

What services are currently provided to people with HFpEF in the United Kingdom (UK) and what are their components? A protocol for a scoping literature review

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Method A scoping review of the evidence from six databases will be performed, alongside a search of grey literature search and consultation with relevant experts. Multiple lines of synthesis are anticipated, and relevant guidelines will be followed.

Results The formulation of a robust scoping review process will enable an in-depth examination of the current understanding of HFpEF health service provision. A systematic approach, using scientific methodologies to synthesise extracted data, will inform and develop a matrix of care components.

- This review will generate:
- A description of current services that are provided to people with HFpEF in the UK;
 - A matrix of clinical components for a heart failure services, designed for people with HFpEF;
 - Details of barriers and facilitators, identified by people both delivering and receiving care.

Novelty Box

- Recent advances in the pharmacological management of patients with HFpEF necessitates a review of the organisation of care.
- This review will characterise care being delivered and assess this against guideline recommendations.
- Summarising care provision and its relative strength/weaknesses, will drive improvement in care.
- Given the established history of HF care in the UK, evidence derived from the review will be useful for, and transferable to, new or less well established services across Europe.

What services are currently provided to people with HFpEF in the UK and what are their components? A protocol for a scoping literature review

Introduction

Heart failure with preserved ejection fraction (HFpEF), defined as symptoms of heart failure within the context of a left ventricular ejection fraction $\geq 50\%$, structural remodelling and/or diastolic dysfunction plus abnormal biomarkers,⁽¹⁾ accounts for 50% of all heart failure (HF) cases and is growing in prevalence.⁽²⁻⁴⁾ Within the United Kingdom (UK), care for people with HFpEF is usually embedded within services designed around the needs of people with heart failure with reduced ejection fraction (HFrEF).⁽⁵⁾ Recent advances in the pharmacological management of HFpEF,^(6, 7) has refocused attention on management and led some to question the suitability of current services.^(3, 8, 9)

Much of the previous research exploring care provision in HFpEF, has described barriers to optimum care.^(5, 10-12) Key amongst these are: low awareness of HFpEF,^(5, 13) scepticism around the validity of HFpEF as a diagnosis,^(14, 15) physical barriers to diagnosis and management such as high natriuretic peptide levels;⁽¹⁶⁾ funding restrictions that limit support from specialist services;⁽¹⁷⁾ clinical inertia due to perceptions around treatability⁽¹⁸⁾ and; uncertainties around responsibilities.⁽¹⁹⁾ For people living with HFpEF, these barriers can result in protracted diagnostic experiences and unsatisfactory levels of treatment and support.⁽¹⁰⁾ Whilst there is consensus amongst the HF community that change is needed;^(20, 21) there is little literature characterising and assessing 'real world' HFpEF clinical services to help drive improvements.

Rationale

The 2021 European Society of Cardiology (ESC) guidelines states that those with HFpEF should receive multi-disciplinary team (MDT) care that includes the management of co-morbidities, relief from congestion, support with self-management, and referral to cardiac rehabilitation.⁽¹⁾ Similar recommendations are included in National Institute for Health and Care Excellence (NICE)⁽²²⁾ guidelines in England and Scottish Intercollegiate Guidelines Network (SIGN) in Scotland.⁽²³⁾ Recent research has demonstrated that novel pharmacological treatments can reduce symptoms and hospital admissions and improve quality of life in HFpEF.⁽²⁴⁻²⁶⁾ In response, guidelines have issued updates recommending the initiation of the Sodium-Glucose co-Transporter-2 (SGLT2) inhibitors (Dapagliflozin and Empagliflozin) in HFpEF.⁽²⁷⁻²⁹⁾

Previous research has shown that supportive care for those with HFpEF is not always available and is beset by challenges.^(10, 30, 31) Subsequently, patients with HFpEF are at risk of missing out on new pharmacological agents. There are few reports describing what services currently deliver in terms of

care for people with HFpEF, and even fewer describing how new therapies will be implemented within existing structures. Questions about capacity and capability to deliver additional care have already been raised.^(32, 33) There is also emerging evidence that suggests expansion of HF services to include HFpEF, may lead to dilution of care for people with HFrEF.⁽³⁴⁾ Given these challenges, sharing information on effective organisation and delivery of care is essential to improve outcomes. As the UK has a long history of delivering HF care, and has led the way in delivering heart failure specialist nurse driven care,^(35, 36) information generated will likely be valuable and transferable to other settings. In summary, this scoping review will be the first to explore and synthesise what clinical services are available in the UK for people with HFpEF and to report and evaluate what features of care are being delivered.

Objectives

The review has four aims: 1) to establish what service are currently offered to patients with HFpEF in the UK; 2) to analyse and synthesise the characteristics of HFpEF services; 3) to explore services provision against guideline recommendations; 4) to generate knowledge that would contribute to a framework that would guide a future clinical intervention.

Patient and public involvement: A patient and public involvement and engagement (PPIE) group advised on this protocol and will continue to participate in this programme of work. Following synthesis, data will be circulated amongst the PPIE group, and they will be asked to contribute towards the interpretation of the data. Opportunities for more in-depth involvement will be offered throughout(i.e. as co-investigator.) The PPIE group will then be invited to evaluate the proposed new framework that is developed from the synthesis of the review.

Methods

This report has been structured in line with the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist.⁽³⁷⁾

Protocol and registration

This scoping review protocol was published on the public Open Science Framework platform (no registration reference provided) and can be accessed at: <https://osf.io/5gufq/>.

Eligibility criteria

We will consider publications of any type that: 1) are published in the English language; 2) describe or evaluate the content of HFpEF services within the UK; 3) have a publication date \geq 2013. A description

of detailed inclusion principles based on SPIDER (Sample, Phenomenon of Interest, Design, Evaluation, Research type)⁽³⁸⁾ criteria is provided in **Table 1**.

Table 1: SPIDER Criteria

Criterion	Description
Sample	People with diagnosed HFpEF seen in both community or hospital clinics. HF services often treat all HF phenotypes; we will consider reports only when identification of HF phenotype is possible. HFpEF definitions and diagnostic criteria have rapidly evolved, therefore, non-explicit papers will be considered to determine presence of HFpEF. <u>Mixed samples (i.e. HFpEF/HFrEF) will be included if there is sufficient detail parsing the phenotypes. No other exclusion criteria will be applied.</u>
Phenomenon of Interest	Any healthcare service which provides supportive care to people with HFpEF with a focus on the management of their illness.
Design	Any publication that refers to 'real world' management of HFpEF; including but not limited to: retrospective case reviews, poster abstracts, retrospective observational studies, registry analyses, case reports, narrative descriptions, audits, charitable organisation reports.
Evaluation	Descriptions of the healthcare services provided will be examined for the following factors: type of services, referral criteria, services offered, follow-up schedules, patient reported outcome measures (PROMs) collected and staffing metrics.
Research Type	All type of research articles together with grey literature will be included if published in English and since 2013.

Information sources

Search terms were developed in conjunction with an information specialist (IK). Search terms for HFpEF will be based on previous reviews conducted by the authors.^(39, 40) These terms reflected historical and continued debate over terminology related to HFpEF.⁽⁴¹⁾ We did not add search terms relating to clinical interactions (e.g. HF clinic, HF unit, outpatient etc.) as pilot searches demonstrated these negatively impacting search specificity and sensitivity.

Searches were performed in six bibliographic databases based on the recommendations from Bramer *et al.*⁽⁴²⁾ (MEDLINE [via Ovid], Embase [Via OVID], EMCARE [via Ovid], CINAHL [via EBSCO], Cochrane

Library, Web of Science). Databases were searched separately, rather than multiple databases being searched on the same platform. The search syntax was adapted for each database, and to account for variation between thesaurus terms/controlled vocabulary across each database. UK filters have been adapted from Ayiku et al.^(43, 44) Results were imported to Endnote by IK for deduplication, using established methods.⁽⁴⁵⁾ The search strategy was evaluated against the PRISMA-S guidelines.⁽⁴⁶⁾ Searches included the period 01 January 2013 to 23 August 2023; to ensure only contemporary practice is included (prior to 2013, there was less consensus around the definition and diagnostic criteria of HFpEF). The searches will all be rerun prior to submission in order to include any papers published between the initial searching, and submission for peer review.

Grey literature searches will be conducted in Google Scholar. The first 500 Google Scholar results will be screened and unique reports identified by consensus. Additionally, we will search information published by charities and National Health Service (NHS) bodies responsible for commissioning, managing or evaluating HF care. We anticipate data of interest may be published locally as 'spotlights', local pathways of care, cases or internal reports (charitable/governmental). Appeals for HF specialists to share details on current clinical services that support those with HFpEF will be made through our individual networks, national heart failure networks and social media. Backwards and forwards citation tracking will be performed.

Search

Searches have been run and the full electronic searches are presented in the supplementary material.

Selection of sources of evidence

The digital platform Rayyan⁽⁴⁷⁾ will be used to manage the screening of the search results. This will be performed blinded and in duplicate, by a team of researchers who have previous experience of conducting systematic, mixed methods and scoping reviews; as well as meta-analysis. The team includes four heart failure specialist nurses and a practising cardiologist who bring the necessary expertise in assessing and evaluating care. In addition, team members come from a wide geographical area, which will facilitate access to data across a broad range of networks.

First-level screening will confirm eligibility based on title and abstract, possible inclusion of HFpEF in the sample, and whether clinical practice is or potentially described. Disagreements will be discussed between screeners and adjudicated by a third reviewer if necessary. Any publication included after first-level screening will undergo full-text review. Full-text review will also be performed blinded and in duplicate.

Data charting process

Before charting begins, multiple reports relating to the same service will be aggregated, in line with best practice.⁽⁴⁸⁾ The data extraction template will be piloted and modified as needed following extraction of the first five reports included in the review. Various tools will be employed to manage data extraction including Microsoft Excel⁽⁴⁹⁾ and NVivo software.⁽⁵⁰⁾ The charting process will be informed by established guidelines, including but not limited to: Cochrane,⁽⁴⁸⁾ Joanna Briggs Institute,⁽⁵¹⁾ Systematic Review without Meta-Analysis (SWiM).⁽⁵²⁾ Extraction will be performed independently by one researcher, a sub-section of extracted data will be checked by a second investigator. Authors of the original reports will be contacted to provide missing data or to clarify descriptive data if required.

Data items

A broad range of data will be considered in this review. Data extraction fields and descriptions are detailed in **Table 2** below.

Table 2: Data extraction fields and descriptions

Data field	Description
Administrative	Title, author, acronym, year, country, design (main), design (sub-type), sample details (if any), will be both summarised and considered for meta-analysis.
HFpEF Population	Details of the HFpEF population (e.g., clinical characteristics), will be extracted if described. For example, age, gender, ejection fraction, other echocardiographic variables, comorbidities, socio-demographic factors, frailty data, medication data.
Service characteristics	Staff, type of service (outpatient/inpatient), referrals, clinic sessions, follow-up, triage, tele-health, medication management, titration details, rehabilitation, additional services. The TIDieR ⁽⁵³⁾ (template for intervention description and replication) framework will be used to organise and report service characteristics.
Results/findings	<i>Quantitative articles/reports:</i> primary outcome, secondary outcome, follow-up schedule, follow-up time point used in analysis, raw outcome data if any, authors' conclusions.
	<i>Qualitative articles/reports:</i> All published data along with the analysis of the data will be examined for descriptive details of the clinical encounter, details around the patient experience of the clinical interaction, met/unmet needs, clinician experiences and reflections, services offered, subsequent outcomes/referrals, etc. Of particular interest will be authors' suggestions for the structure of a service aimed at this population.
	<i>Mixed-methods articles:</i> Data from quantitative and qualitative data will be extracted and disaggregated accordingly.

Critical appraisal of individual sources of evidence

Critical appraisal is not a requirement of scoping reviews; however, we consider this a necessary step that will inform the weighting we apply to results within the analysis. Study quality will be assessed using a relevant tool that corresponds to reported study design. Given the wide variety of potential methods employed, we anticipate using the following: the Joanna Briggs Institute Critical Appraisal Skills Programme,⁽⁵⁴⁾ Cochrane Risk of Bias assessment tool,⁽⁴⁸⁾ Mixed Method Appraisal Tool (MMAT)⁽⁵⁵⁾ and/or risk of bias in observational studies of interventions (ROBINS-I).⁽⁵⁶⁾ Grey literature will most likely be evaluated using the Joanna Briggs Institute methodology of systematic reviews of text and opinion.⁽⁵⁷⁾ However, each article retrieved will be evaluated on a case by case basis, depending on the data collected and analysis methods utilised

Synthesis of results

We expect this review will generate mixed data (qualitative and quantitative reports). Therefore, the synthesis will vary depending on the type and heterogeneity of the data. Guidelines that informed the charting process (Cochrane,⁽⁴⁸⁾ Joanna Briggs Institute,⁽⁵¹⁾ SWiM)⁽⁵²⁾ will also be used to guide the synthesis methods. Qualitative synthesis and analysis will follow the principles of abductive analysis;⁽⁵⁸⁾ as a means of theorising reports to create a framework of components for supportive care in HFpEF. Quantitative data, if of sufficient quantity, will be assessed for suitability for meta-analysis.⁽⁴⁸⁾ If, as is anticipated, there is insufficient data for meta-analysis, quantitative data will be reported in line with SWiM guidelines.⁽⁵²⁾ Given the scope of the potential data we will retrieve, the exact synthesis methods will only be clear after extraction. Updated methods will be summarised in the online protocol hosted on the Open Science Framework platform⁽⁵⁹⁾ and during the reporting of the review.

Results of analysis

The formulation of robust search strategies will enable an in-depth examination of the current understanding of HFpEF health service provision in the UK. A systematic approach, using scientific methodologies to synthesise extracted data, will inform and develop a matrix of care components for those with HFpEF. This matrix will then be presented to PPIE groups and stakeholders for refinement, as a part of a larger piece of work to inform the development of a clinical intervention for those with HFpEF. The PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) extension for scoping reviews will be utilised for reporting the review conduct.⁽⁶⁰⁾ We expect to create various reports including a peer reviewed publication and patient focussed outputs which we will co-design with the PPIE group. In addition, we anticipate sharing the matrix of components with the heart failure specialist nursing community, for their critical appraisal and revision.

Discussion

HFpEF is a growing challenge that health services need to address. The adoption of new evidenced based treatments for those with HFpEF is a welcome addition for clinicians who may often struggle to manage these individuals. This will be the first review to synthesise data enabling an initial description of current services provided to those with HFpEF. It will also be the first to provide a framework of clinical components for a heart failure service designed specifically for people with HFpEF. Further, it will collate barriers and facilitators, identified by people both delivering and receiving care. Together, these data will promote discussion around effective organisation of care and provide services with the information they need to facilitate change that will deliver better outcomes for people with HFpEF.

Conclusion

It is anticipated the results of this review will be beneficial for the informing of clinical services for those with HFpEF within the UK and beyond. Findings may inform the creation of supportive interventions and care pathways for this currently under served population of patients.

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Data Availability: data, once available, will be made upon reasonable request.

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