**Transitions of care for patients with HFpEF and Assessment of their Carers’ needs and support required**

**STUDY PROTOCOL**

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## 1.1 Study Summary

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| --- | --- | --- |
| **Trial Title** | **Transitions of care for Patients with Heart Failure with Preserved Ejection Fraction (HFpEF) and Assessment of their carers’ needs and support required.** | |
| **Short Title** | Optimise-HFpEF Work Package 2c | |
| **Trial Design** | This is a multi-method programme of research culminating in the development of an optimised programme of management for patients with heart failure with preserved ejection fraction (HFpEF). This protocol details one work package (Part 2C) of a larger programme of research. A mixed methods approach that includes quantitative (validated tools) and qualitative (semi-structured interviews) methods will be used prospectively to determine patients’ perceptions about (re)hospitalisation and transitions in care over one year from enrolment, carers’ needs immediately post hospitalisation of their relative, and the medium and longer-term support carers of HFpEF patients require. | |
| **Trial Participants** | Patients with a confirmed diagnosis of HFpEF and their reported informal carer/s enrolled in the Optimise HFpEF cohort study (NREC 17/LO/2136). | |
| **Planned Sample Size** | Patients with confirmed HFpEF and their reported informal carers recruited from an on-going cohort study.   * For sub-study 1, Assessing Transitions of Care, a purposive sample of 20 (re)-hospitalised patients and 20 carers will be interviewed as soon as possible post hospitalisation and their on-going needs. | |
| **Follow-up Duration** | Patients will be followed for 12 months from enrolment in the Optimise-HFpEF cohort study. Those in the cohort study will be contacted regarding participation in Work Package 2C, if they agree to participate one face to face interview will be conducted with them +/- their carer subject to their consent.. | |
| **Planned Trial Period** | 1 year | |
| **Objectives** | The hypothesis of the parent Optimise-HFpEF study is that outcomes of patients with HFpEF can be improved through an optimised management programme which would be based in primary care, in collaboration with specialist services. To develop this programme our study will seek better understanding of the needs and experiences of patients with HFpEF, their management in primary care and their transition of care and important outcomes. The objectives for these sub-studies (work package 2C) are to:   1. Determine patients’ perception of reasons for hospitalisation and re-hospitalisation over one year. 2. Determine the perspectives of carers on their roles in providing care for patients with HFpEF, the challenges they face, and the support needed for them as carers.   Findings from the sub-study will be integrated with findings from the larger OPTIMISE HFpEF research programme to develop a programme of optimised management that will be relevant and acceptable to patients and their carers. | |
| **Funder** | * National Institute for Health Research/National School for Primary Care Research (NHIR SPCR). Grant Ref no: 384 * National Institute for Health Research/National School for Primary Care Research (NHIR SPCR). Grant Ref no: 393 | |
| **Sponsor(s)** | Cambridge University Hospital NHS Foundation Trust and the University of Cambridge | |
| **Chief Investigator** | Professor Christi Deaton  Florence Nightingale Professor of Clinical Nursing Research , University of Cambridge | |
| **Co-Investigators** | Professor Jonathan Mant (co-PI) |  |
| Dr Duncan Edwards | Susana Borja Boluda |
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| **Collaborators** | Dr Morag Farquhar | Dr Gail Ewing |
| Professor Gunn Grande |  |

## 1.2 Abbreviations

|  |  |
| --- | --- |
| **CSNAT** | Carer Support Needs Assessment Tool |
| **HCP** | Health Care Providers |
| **HES** | Hospital Episode Statistics |
| **HFSN** | Heart Failure Specialist Nurse |
| **HF** | Heart Failure |
| **HFpEF** | Heart Failure with preserved Ejection Fraction |
| **HFrEF** | Heart Failure with reduced Ejection Fraction |
| **LTC** | Long Term Conditions |
| **LOS** | Length Of Stay |
| **LVSD** | Left Ventricular Systolic Dysfunction |
| **NIHR SPCR** | National Institute for Health Research School for Primary Care Research |
| **NYHA** | New York Heart Association |
| **PID** | Patient Identifiable Data |
| **CTM** | Care Transitions Measure |

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## 2.0 Plain English Summary

Heart failure (HF) is a condition in which the heart does not work well to pump blood around the body. About half of all people with HF have a type in which the heart is very stiff called heart failure with preserved ejection fraction or HFpEF. The Optimise-HFpEF research programme includes talking to patients and providers about HFpEF, a cohort study that will identify and follow a group of patients with this type of HF for a year to better understand their HF, and exploring patients’ thoughts about hospitalisation and care between hospital and home, and its impact for both patients and their carers. To explore hospitalisation and the needs of informal carers (usually a family member or friend) a small substudy (Work Package 2c) is proposed that will 1) interview patients and carers about what they think led to them being admitted, and their experience in hospital and after discharge and 2) exploring the needs of carers of patients with HFpEF to establish what support they require. We will also explore their views on a tool that helps carers assess support needs.

Interviews with patients and carers will be confidential, held in a place of the participant’s choosing, audio-recorded and then typed out. This information will help us to plan better care and develop a programme of management for patients with HFpEF and their carers involving primary care and specialist services. The final agreed optimised management programme will be tested in future studies to see whether it improves patients’ care and health outcomes.

## 2.1 Abstract

Heart failure (HF) accounts for 5% of emergency hospitalisations, and 2% of NHS expenditure. Patients with HF with preserved ejection fraction (HFpEF) are older, have more comorbidities, have similarly poor or worse outcomes compared to patients with reduced ejection fraction (HFrEF), and currently lack an evidence base for treatment. Developing an optimised programme of management for patients with HFpEF has to take into consideration the uncertain trajectory of HF, changes in needs for support associated with HF exacerbation or hospitalisation due to comorbid conditions, and high readmission rates post discharge. Reducing high (re)hospitalisation rates requires accurate information about reasons for admissions, and patients’/carers’ perceptions and experiences of transitions of care such as going from hospital to home. In addition, the vital role of carers is also important to recognise. Informal carer information is especially important given their roles as co-workers providing practical and emotional support to patients including medication management. Supporting their needs enables them to support patients as well as looking after themselves. Unfortunately carers are rarely identified and their needs and support required seldom assessed or addressed. This is the void that this project will address. These additional data will enhance the information from the cohort study (Optimise-HFpEF), which will inform the next phase of Optimise-HFpEF to develop an optimised programme of management.

## 2.2 Background and Rationale

Around 900,000 people in the UK have heart failure (HF) (1), which accounts for 2% of NHS expenditure, and causes or complicates 5% of emergency hospitalisations (2). HF a heterogeneous clinical syndrome characterised by fatigue and dyspnoea, around half of patients with HF have a preserved ejection fraction (HFpEF) rather than a reduced ejection fraction (HFrEF) also known as left ventricular systolic dysfunction (LVSD) (3, 4). Patients with HFpEF are usually older, female and more likely to have multiple comorbid conditions such as obesity, hypertension and diabetes (4, 5).

Patients with HFpEF face substantial challenges related to under diagnosis, poor outcomes and sub-optimal management (6-8). In contrast to LVSD, there is only a limited evidence base on which to base treatment. Perhaps as a result of this, programmes of care have lagged behind (7). Accordingly, it has been termed a stealth syndrome and a clinical crisis (8, 9). Yet HFpEF has remained neglected as a focus for study.

## 2.3 Sub-optimal Management Strategies

Management of people with HFpEF has proven to be especially challenging. While patients with LVSD have historically benefitted from pharmacologic and device treatments, that have been proven to have a positive outcome, the same is not true for HFpEF (10). The mainstays of treatment are management of comorbidities and fluid status, requiring patients to monitor fluid retention, optimise blood pressure and potentially blood glucose, and manage symptoms, medications, diet and physical activity. Treatment burden for HFpEF is thus high, yet patients characterised by ageing, comorbidities, and frailty are especially challenged by self-management, and need pro-active support and timely communication with familiar health care providers (HCPs) especially across transitions in care (i.e. hospital to home) (11). Informal carers, normally family members, have an important role in helping HFpEF patients manage their conditions.

## 2.4 The role of the Informal Carers

Patients with HFpEF have a higher comorbidity burden than those with LVSD, and these conditions have a greater impact on functional class and physical health status in patients with HFpEF compared to LVSD (12). Patients with HFpEF reported greater consequences of HF on their lives, more symptoms and the same or worse quality of life than those with LVSD (10, 11). In a large clinical trial of patients with HFpEF (n = 3406) there was substantial impairment in quality of life, and 27% of patients had moderate to severe depression scores (13). Thus patients are likely to need substantial support from family carers as well as from familiar health care providers (HCPs) (14). In a national survey of people at or near retirement age, those with HF (3.9%) were almost twice as likely to receive informal caregiving as those who did not have HF (15). The burden for carers of providing that care has been found to be affected by a higher number of patient co-morbidities, poorer mental health, more symptoms of depression, and a lower level of perceived control over the heart disease of the partner (16).

Most of the studies of carers of those with HF have focused on advanced heart failure, end of life, and the HF itself. Common themes include need for understandable information, good, consistent communication with HCPs, support across multiple domains, and symptom management (17, 18). Few studies have addressed the challenges of managing multiple conditions. In interviews with carers we will incorporate the framework of Burden of Treatment as a sensitising framework for interviews.

## 2.5 Transitional Care in HFpEF

Carson, et al. (19) found an 18% rate of readmission in 30 days for patients with HFpEF in a large clinical trial, and post-hospitalisation events were highest in the first 30 days and returned toward baseline after 6 months. Importantly, many readmissions are due to non-cardiac causes (19,20). Ensuring that patients hospitalised for HF are identified and followed-up is essential: in a recent linked database analysis, patients hospitalised for HF but without a matched primary care record of HF had a 5-year estimated survival of 22% (21). Transitional care interventions can be effective in preventing readmission, although a review and meta-analysis of transitional care after hospitalisation for HF found that high-intensity interventions (home visits combined with telephone follow-up, clinic visits or both) were the most effective (22).Hospitalisation comprises the greatest proportion of health service costs attributable to heart failure (HF) – estimated to be 2% of NHS expenditure – and HF causes or complicates 5% of emergency hospitalisations (1, 2). Data from the US demonstrate a trend toward increasing hospitalisation for patients with heart failure with preserved ejection fraction (HFpEF) and decreasing hospitalisation for those with reduced ejection fraction (also known as left ventricular systolic dysfunction [LVSD]) (23).

In a study of newly diagnosed patients with HFpEF (n = 193), 33% had a HF hospitalisation or cardiovascular death at mean follow-up of 22 + 13 months (24). Hospitalisation is associated with adverse outcomes in patients with HFpEF, and a history of recent hospitalisation (< 6 months) is associated with a more than twice the risk of subsequent hospitalisation or cardiovascular death (25). In-hospital mortality for HFpEF in studies is estimated at 2.5-6.5%, with 6 month mortality rates of 14-16%, similar to LVSD (26). A study of 679 elderly patients with first hospitalisation for HFpEF found a 25% likelihood of death in one year, with age and pulmonary artery systolic pressure as independent predictors of mortality (27). Rehospitalisation rates of 29% within 60-90 days have been found in patients with HFpEF (23), and results from the I-PRESERVE trial (28) found a 18% rate of readmission in 30 days for patients with HFpEF. Similarly an analysis of re-hospitalisation of 3631 patients hospitalised for HFpEF found a 19% rate of readmission at 30 days, and 58% at one year. Outpatient and emergency visits were slightly higher in patients with HFpEF compared to those with LVSD (29). Given the high co-morbidity burden in patients with HFpEF, many hospitalisations and re-hospitalisations are due to or complicated by non-cardiac causes (28,30). In a review it was noted that over 50% of hospitalisations in community studies of patients with HFpEF are due to non-cardiovascular causes (31). In a large study analysing repeated hospitalisations in 8948 patients hospitalised for HF and discharged alive, less than half (46%) had a measurement of EF and among these, 27.5% had HFpEF. Over a median follow-up of 1003 days a mean of 3.5 and median of 2.0 hospitalisations occurred per patient, with 27% of these being for HF. The presence of each additional comorbidity increased the risk of readmission by 11% (RR 1.11; 95% CI 1.10-1.12; p<.001). The association of age, diabetes and COPD with increased risk for readmission was consistent across 5 re-hospitalisation episodes (32).

In addition to the admission and discharge diagnoses associated with hospitalisation on medical records, patients and carers may have a different understanding of the cause or problem leading to hospitalisation. Understanding patients’ and carers’ perspectives is important in terms of self-management, education and support. Patient behaviour may be driven by their perception of the reason for decompensation and hospitalisation, or patients and carers may feel overwhelmed by the illness and powerless to prevent problems leading to need for hospital admission. Some patients after hospitalisation report more social, psychological and existential needs than physical ones (33).

## 3.0 Towards an optimised programme of care for patients with HFpEF.

Our starting point is the assumption that management of patients with HFpEF may be improved through a patient-centred, multi-professional team approach that includes comorbidity management, a flexible diuretic regimen, support for self-management, a healthy lifestyle, and timely specialist input when needed. Any programme of care will need to take into account potential treatment burden on the patient, and ensure that patient preferences are respected and patients are well supported. Implementation of a programme of management also needs to be feasible within primary care with programme components based on evidence, and an understanding of the mechanisms of effect. This component of the programme of research will focus on understanding the characteristics, needs, management and illness trajectory of patients with HFpEF as well as assessing those of their carers.

Work Package 2c will contribute to the overall Optimise-HFpEF programme; this project builds on work done by School for Primary Care Research (SPCR) members on the organisational management of heart failure and other long-term conditions (LTC), the implications of living with HF and LTCs, diagnostic studies in HF, organisation of services in primary care, assessment of frailty, collaborative care, and management of chronic illness. The specific areas it adds are 1) a more in-depth assessment of hospitalisation in this patient group from both patients’ and their cares’ perspectives, and 2) assessment of overall carer perspectives and needs given their essential roles in supporting patients and risks of poor health outcomes. Transitional care (i.e. hospital to home and within hospitalisation) is an important component when developing an optimised management plan for patients with HFpEF, and we need robust information regarding hospitalisations, readmissions, and patient/carer perspectives of their transition needs. Adding the carer perspective contributes an additional dimension to optimising patient management, and in itself provides an essential foundation for further studies of supporting carers, and adapting an existing carer support needs intervention to carers of people with HFpEF.

## 4.0 Description of Work Package 2c

The Work Package will employ validated tools and qualitative interviews that will be integrated into and complement data collection in the Cohort Study of the Optimise-HFpEF programme. Initially, a purposive sample of (re)hospitalised patients from the cohort and their carers will be invited for interviews to explore their perspectives on reasons for hospitalisation, support needed and received, and follow-up after discharge. These interviews will be informed by a tool specifically designed to assess Transitions of Care, the Care Transitions Measure (CTM). Carers who participate in the above interviews may be invited to participate in a further interview, subject to their consent, that will explore their needs in more detail. The Carer Support Needs Assessment Tool (CSNAT) will be used as a framework for discussion during this interview. Ideally, some interviews will be conducted in the absence of the ‘patient’ to ensure the carer does not feel inhibited, however, a pragmatic approach will be employed that will aim to achieve the best balance between participant burden, practicalities of multiple interviews and ensuring the best quality data possible is obtained.

## 4.1 Design

Work Package 2c will use multiple methods to complement the work being done in the Optimise-HFpEF study. These will include qualitative semi-structured interviews and relevant tools and surveys to add information to the qualitative data.

## 4.2 Sample size and settings

Within Work Package 2c we will recruit patients enrolled in the OPTIMISE-HFpEF Cohort Study who have HFpEF confirmed by a consultant cardiologist. A sub-sample of confirmed HFpEF patients and their carers in the Cambridge/East of England cohort will be approached and invited to take part in our study. The Cambridge/East of England Cohort Study (NREC 17/LO/2136) will consist of approximately 100 patients, assessed at baseline, 6 and 12 months after enrolment.

Patients who state that they have been hospitalised at some point due to their heart condition or comorbidities will form the sampling frame for the qualitative patient interviews. We estimate that over a year approximately 25% of patients will be hospitalised, and of those, up to 50% will be readmitted in a year. We will purposively sample from this group, recruiting 20-25 Cambridge hospitalised patients and their carers. Carers will be invited to reflect on their needs during the above interview and if possible, be invited to attend a further interview without their respective loved one to ensure uninhibited discussion regarding care provision and carers needs. An additional interview will be explored on a case by case basis in order to limit the burden of participation.

## 4.3 Work Package 2c Methods

Assessing Transitions of Care: The cohort study will provide us with accurate information regarding hospitalisation, discharge diagnosis, readmission and length of stay. As these data will be collected retrospectively we will also ask patients in the East of England cohort whether they have experienced an episode of hospitalisation related to their heart failure (HF) or comorbidities at some point. We will purposively sample patients based on stated reason for hospitalisation (HF or other condition), sex (male and female), and index (from baseline) or re-hospitalisation. We will explore their perspectives on the reasons for hospitalisation, support needed, and follow-up after discharge using semi-structured interviews conducted in the patient’s home or by telephone and digitally recorded. The interviews will be transcribed verbatim, and NVivo software will be used to organise and manage the data.

-Support Needs for Carers: Carers will be identified through the patients recruited into the Cohort Study. We will explore the carer role with the patient and ask them to consider whether they have someone that supports them in the community. If they do, we will ask them if they are willing to take part in the interview or provide information and an expression of interest form which they can pass on. An additional interview exclusively exploring their needs will be discussed during the interview with patients regarding their hospitalisation. As hospitalisations are often associated with an element of enhanced support from family and friends, many of the carers’ needs will likely be discussed when exploring transitions of care. However, an additional interview with the carer alone will be explored on a case by case basis in order to capture unfiltered carers views. Carers who participate in either interview will be asked to complete ademographic characteristics form and the 5 step CSNAT tool. The CSNAT tool will be completed at the end of the interview. A semi-structured interview schedule will guide the carers’ interview.

## 4.4 Analysis

Analysis of the qualitative data will use a framework approach, with the following steps: Transcripts will be read as they are completed, first to become familiar with the data (stage 1), then to develop an initial thematic framework (stage 2) and begin indexing data (stage 3). Thematic charts (stage 4) will allow patterns to be explored and reviewed; and in stage 5 data will be mapped and interpreted. Analysis will be data driven, and initial themes and key ideas will be shared and discussed by the research team. The CTM will be analysed and scored according to its instructions manual. The information obtained from the self-reported CSNAT will inform the focus of the interview with carers. Qualitative interviews will be digitally recorded, transcribed verbatim, and analysed using a framework approach as described above. NVivo software will be used to organise and manage the data. The data will be discussed with our expert collaborators in the field of carer support to determine similarities and differences with experiences of carers for patients with other LTCs. This will establish whether the CSNAT intervention can be adapted for carers of patients with HFpEF, and how that might be incorporated into practice. For both patients and carers, demographic data will be analysed using descriptive statustics.

## 4.5 Identifying Participants

Participants will be patients with confirmed HFpEF enrolled in the Optimise HFpEF cohort study who have experienced at least one episode of hospitalisation due to their HF or comorbidities.

Carers will be approached via patients already recruited in the cohort study either face to face (carers often attend the clinical assessments in the cohort study) or formally via a mailout that includes an expression of interest form.

## 4.6 Patients Inclusion and Exclusion Criteria

Adult patients recruited in the Optimise-HFpEF cohort study with a confirmed diagnosis of HFpEF (defined as: patients diagnosed with non-valvular HF that are i) not diagnosed with left ventricular systolic dysfunction or have a documented ejection fraction < 50%; or ii) do have a reported ‘normal’ or preserved EF, documented EF > 50%, or reported diastolic dysfunction without moderate to severe systolic dysfunction). Participants who do not report any previous or do not experience a subsequent hospitalisation due to HF or comorbidities during the study will not be approached.

## 4.7 Carers Inclusion and Exclusion Criteria

Adult informal carers\* of HFpEF patients will be approached either face to face if they attend follow-up visits or formally via a mail out that includes an expression of interest form. To be eligible they must be:

* ≥18 years of age
* Able to communicate in English (both verbally and in writing)
* Identify themselves as informal carers

Informal carers who happen to work in the Health care setting/care team that provides regular care for the patient regarding his/hers HFpEF will be excluded. E.g. spouse caring for HFpEF patient at home is also a healthcare professional employed in the hospital that the patient receives care.

\*Informal Carers definition includes those who provide care to HFpEF patients. The care provided has to be directly or indirectly related to the needs that emerge from the HFpEF condition regardless if they receive monetary compensation for the care they provide.

## 5.0 Data Collection and Storage

Data will be collected and stored in a number of methods:

Electronic transfer by computer network: All forms and tools and data in the study will be shared using only the patient's study identification number (therefore no identifiable data will be held in this system).

Personal Identifiable Data (PID): PID (names, addresses, telephone number, emails) belonging to participants is required to enable contact during the study. PID will be kept securely in a password protected database overseen by the Chief Investigator at Cambridge. The areas that hold PID are locked down to enable only the authorised and authenticated members of the Research teams to access and maintain the data.

Manual files: Paper forms with PID or research data (expression of interest forms, paper questionnaires or consent forms) will be identifiable by a unique participant study ID number and stored in a locked filing cabinet in a locked room in the Institute of Public Health, University of Cambridge.

University computers: Electronic PID will be held using the Secure Data Hosted Service (SDHS) managed by the University of Cambridge Clinical School Computing Service. The SDHS is located on a firewall protected network (LAN) certified to ISO29001 security. The security policy can be accessed here: <https://www.medschl.cam.ac.uk/research/information-governance/information-governance-policy/>. Once uploaded to SDHS, access to PID will be accessible only by the research team using a 2-step authentication (password and security fob). Other data without personal identifiers will held on password-protected University Networked servers.

## 6.0 Study Timetable

Initial preparations will include from:

* June 2018 onwards training of research staff in relevant study methodology, training and applying for any specific IT requirements to comply with regulations.
* September 2018 submission of HRA ethics and governance application(s).

Recruitment will be guided by the rate of recruitment in the Optimise-HFpEF study which began recruiting in July 2018. Carers will be approached through patients already recruited in the cohort study.

## 7.0 List of Tools

The Carer Support Needs Assessment Tool (CSNAT) is an evidence-based tool that facilitates support for carers (family members and friends) of adults with life-limiting conditions. The research underpinning this tool was informed by carers and practitioners. It comprises 14 domains (broad topic areas) in which carers commonly say they require support. Carers may use this tool to indicate further support they need in relation to enabling them to care for someone at home, as well as support for their own health and well-being within their caregiving role. It is short and simple to use for both carers and practitioners.

The Care Transitions Measure 3 and 15 (CTM-3 and CTM-15) are tools designed to assess the transitions of care once patients have been admitted to hospital, when they are about to be discharged and about the follow up appointments and medication. In this study we will use CSNAT, CTM-3 and CTM-15 as a sensitizing framework to guide the qualitative interviews, keeping it open to reflect carers and patients’ views. They should tell their stories.

## 8.0 References

1. Guidance NIfHaCE. Chronic Heart Failure: National Clinical Guideline for Diagnosis and Management in Primary and Secondary Care. London: Royal College of Physicians (UK)

National Clinical Guideline Centre.; 2010.

2. National Heart Failure Audit. April 2014 - March 2015.

3. Borlaug BA. The pathophysiology of heart failure with preserved ejection fraction. Nature reviews Cardiology. 2014.

4. Lam CS, Donal E, Kraigher-Krainer E, Vasan RS. Epidemiology and clinical course of heart failure with preserved ejection fraction. European journal of heart failure. 2011;13(1):18-28.

5. Pedrotty DM, Jessup M. "Frailty, thy name is woman": syndrome of women with heart failure with preserved ejection fraction. Circulation Cardiovascular quality and outcomes. 2015;8(2 Suppl 1):S48-51.

6. Deaton C, Benson J. Time for correct diagnosis and categorisation of heart failure in primary care. The British journal of general practice : the journal of the Royal College of General Practitioners. 2016;66(652):554-5.

7. Simmonds R, Glogowska M, McLachlan S, Cramer H, Sanders T, Johnson R, et al. Unplanned admissions and the organisational management of heart failure: a multicentre ethnographic, qualitative study. BMJ open. 2015;5(10):e007522.

8. Banerjee P. Heart failure with preserved ejection fraction: A clinical crisis. International journal of cardiology. 2016;204:198-9.

9. Clark AM, Flynn R, Hsu ZY, Haykowsky M. Heart failure with preserved ejection fraction: health services implications of a stealth syndrome. European journal of cardiovascular nursing : journal of the Working Group on Cardiovascular Nursing of the European Society of Cardiology. 2013;12(4):316-7.

10. Ponikowski P, Voors AA, Anker SD, Bueno H, Cleland JG, Coats AJ, et al. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure: The Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC)Developed with the special contribution of the Heart Failure Association (HFA) of the ESC. European heart journal. 2016.

11. Fry M, McLachlan S, Purdy S, Sanders T, Kadam UT, Chew-Graham CA. The implications of living with heart failure; the impact on everyday life, family support, co-morbidities and access to healthcare: a secondary qualitative analysis. BMC family practice. 2016;17(1):139.

12. Deaton C. Unpublished data from Greater Manchester and Cambridgeshire practice records.

13. Glogowska M, Simmonds R, McLachlan S, Cramer H, Sanders T, Johnson R, et al. Managing patients with heart failure: a qualitative study of multidisciplinary teams with specialist heart failure nurses. Annals of family medicine. 2015;13(5):466-71.

14. Gallacher K, May CR, Montori VM, Mair FS. Understanding patients' experiences of treatment burden in chronic heart failure using normalization process theory. Annals of family medicine. 2011;9(3):235-43.

15. Joo H, Fang J, Losby JL, Wang G. Cost of informal caregiving for patients with heart failure. American heart journal. 2015;169(1):142-48.e2.

16. http://liu.diva-portal.org/smash/get/diva2:1055919/FULLTEXT01.pdf

17. Bekelman DB, Nowels CT, Retrum JH, Allen LA, Shakar S, Hutt E, et al. Giving voice to patients' and family caregivers' needs in chronic heart failure: implications for palliative care programs. Journal of palliative medicine. 2011;14(12):1317-24.

18. Hupcey JE, Fenstermacher K, Kitko L, Fogg J. Palliative Needs of Spousal Caregivers of Patients with Heart Failure Followed at Specialized Heart Failure Centers. Journal of hospice and palliative nursing : JHPN : the official journal of the Hospice and Palliative Nurses Association. 2011;13(3):142-50.

19. Carson PE, Anand IS, Win S, Rector T, Haass M, Lopez-Sendon J, et al. The Hospitalization Burden and Post-Hospitalization Mortality Risk in Heart Failure With Preserved Ejection Fraction: Results From the I-PRESERVE Trial (Irbesartan in Heart Failure and Preserved Ejection Fraction). JACC Heart failure. 2015;3(6):429-41.

20. O'Carroll GW, D.; O'Connell, E.; O'Hanlon, R.; Kenny, C.; McDonald, K. Re-admission patterns in patients following first admission for heart failure: Heart failure with preserved ejection fraction as compared with heart failure with reduced ejection fraction. Embase European Heart Journal. 2015.

21. Koudstaal S, Pujades-Rodriguez M, Denaxas S, Gho JM, Shah AD, Yu N, et al. Prognostic burden of heart failure recorded in primary care, acute hospital admissions, or both: a population-based linked electronic health record cohort study in 2.1 million people. European journal of heart failure. 2016.

22. Vedel I, Khanassov V. Transitional Care for Patients With Congestive Heart Failure: A Systematic Review and Meta-Analysis. Annals of family medicine. 2015;13(6):562-71.

23. Oktay AA, Rich JD, Shah SJ. The emerging epidemic of heart failure with preserved ejection fraction. Current heart failure reports. 2013;10(4):401-10.

24. Dalos D, Mascherbauer J, Zotter-Tufaro C, Duca F, Kammerlander AA, Aschauer S, et al. Functional Status, Pulmonary Artery Pressure, and Clinical Outcomes in Heart Failure With Preserved Ejection Fraction. Journal of the American College of Cardiology. 2016;68(2):189-99.

25. Soren L. Kristensen, Pardeep S. Jhund, Lars Kober, Robert S. McKelvie et al. Relative Importance of History of Heart Failure Hospitalization and N-Terminal Pro–B-Type Natriuretic Peptide Level as Predictors of Outcomes in Patients With Heart Failure and Preserved Ejection Fraction. JACC:Heart Failure. 2015;3(6).

26. Chan MM, Lam CS. How do patients with heart failure with preserved ejection fraction die? European journal of heart failure. 2013;15(6):604-13.

27. Perez de Isla L, Canadas V, Contreras L, Almeria C, Rodrigo JL, Aubele AL, et al. Diastolic heart failure in the elderly: in-hospital and long-term outcome after the first episode. International journal of cardiology. 2009;134(2):265-70.

28. Carson PE, Anand IS, Win S, Rector T, Haass M, Lopez-Sendon J, et al. The Hospitalization Burden and Post-Hospitalization Mortality Risk in Heart Failure With Preserved Ejection Fraction: Results From the I-PRESERVE Trial (Irbesartan in Heart Failure and Preserved Ejection Fraction). JACC Heart failure. 2015;3(6):429-41.

29. Gregory A. Nichols, Kristi Reynolds, Teresa M. Kimes and Wing Chan, Kaiser. Resource Use One Year Following Hospitalization for Acute Heart Failure: A Comparison of Patients with Preserved versus Reduced Ejection Fraction. JACC(2015);65(10S)

30. O'Carroll GW, D.; O'Connell, E.; O'Hanlon, R.; Kenny, C.; McDonald, K. Re-admission patterns in patients following first admission for heart failure: Heart failure with preserved ejection fraction as compared with heart failure with reduced ejection fraction. Embase European Heart Journal. 2015.

31. S M. Dunlay, V L. Roger & M M. Redfield. Epidemiology of heart failure with preserved ejection fraction. Nature Reviews Cardiology (2017); 14, pages 591–602.

32. J R, Braga, V R, Tu, P C Austin, R Sutradhar, H J Ross and D S Lee. Recurrent events analysis for examination of hospitalizations in heart failure: insights from the Enhanced Feedback for Effective Cardiac Treatment (EFFECT) trial. European Heart Journal Quality Care and Clinical Outcomes 2018 Jan; 4(1): 18–26.

33. Unmet needs following hospitalization with heart failure: implications for clinical assessment and program planning. PM, Davidson, J Cockburn, P J Newton. Journal of Cardiovascular Nursing. 2008 Nov-Dec; 23(6):541-6