Longitudinal effects of self-care (and baseline quality of life) on caregiver burden and quality-of-life outcomes in patients with heart failure and their family caregivers

Robert Thomson

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DECLARATION

I hereby declare the work in this thesis to be my own, except where otherwise stated.

R [illegible] Thomson

Robert Thomson
University of Stirling, 2021

DEDICATION

"It's like growing old overnight, without gradual ageing giving you the chance to get used to it."

Heart Failure Patient (Pumping Marvellous Charity)

This thesis is dedicated to my Mum, Dad and big brother, David, who would have been incredibly proud of this huge achievement, and to my Aunt May, who, like many of the patients in this thesis, bravely battled with the debilatating symptoms and poor quality of life that is associated with the syndrome of Heart Failure.

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Along this journey, precious time has been lost with my wife Nicola and my two daughters, Isla and Emily. Thanks for your patience, understanding and endless love along the way – I will make it up to you! Emily, dad has in fact, completed this before he retires!

Finally, thank you to the many patients and their family caregivers who agreed to take part in this study. Without them, the progression of HF dyadic knowledge and understanding would not be possible.

ACRONYMS/ABBREVIATIONS

ACEI:	Angiotensin-converting enzyme inhibitor
ACS:	Acute Coronary Syndrome
ADLs:	Activities of Daily Living
AF:	Atrial Fibrillation
AMI:	Acute Myocardial Infarction
ARB:	Angiotensin Receptor Blocker
ARNI:	Angiotensin Receptor Neprilysin Inhibitor
CAD:	Coronary Artery Disease
CCU:	Coronary Care Unit
CIBIS II:	Cardiac Insufficiency Bisoprolol Study II
CONSENSUS:	Cooperative North Scandinavian Enalapril Survival Study
COPERNICUS:	Carvedilol Prospective Randomized Cumulative Survival
DCM:	Dilated Cardiomyopathy
ECG:	Electrocardiogram
ECS:	Emotional Component Score
EF:	Ejection Fraction
EMPHASIS-HF:	Eplerenone in Mild Patients Hospitalization and Survival Study in Heart Failure
EPHESUS:	Eplerenone Post-Acute Myocardial Infarction Heart Failure Efficacy and Survival Study
ESC:	European Society of Cardiology

HCM:	Hypertrophic Cardiomyopathy
HF:	Heart Failure
HFmrEF:	Heart Failure with Mid-range Ejection Fraction
HFpEF:	Heart Failure with Preserved Ejection Fraction
HFrEF:	Heart Failure with Reduced Ejection Fraction
HFSN:	Heart Failure Specialist Nurses
IHD:	Ischaemic Heart Disease
LV:	Left Ventricular/Left Ventricle
LVEF:	Left Ventricular Ejection Fraction
LVSD:	Left Ventricular Systolic Dysfunction
MCS:	Mental Component Score
MLwHFQ	Minnesota Living with Heart Failure Questionnaire
MRA:	Mineralocorticoid Receptor Antagonist
NYHA:	New York Heart Association
PARADIGM-HF:	Prospective Comparison of ARNI with ACEI to Determine Impact on Global Mortality and Morbidity in Heart Failure Trial
PCS:	Physical Component Score
RCT:	Randomized Controlled Trial
T1:	Time-point one
T2:	Time-point two
Val-HeFT:	Valsartan Heart Failure Trial

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ABSTRACT

Background: Heart Failure (HF) is a complex, progressive syndrome which is recognised as being disabling and deadly; and it impacts on the patient's ability to self-care. Caregivers are pivotal in supporting patients' self-care, but often their own health is affected. The burden associated with caregiving is often influenced by certain patient and caregiver sociodemographic and personal characteristics, as well as the patient's engagement and the caregiver's contribution to self-care. With the interdependence of the patient–caregiver relationship, it is therefore essential to examine self-care, quality of life and caregiver burden. To date there is limited empirical evidence that examines specifically the nature in which HF patients and their caregivers influence each other. Previous studies have been cross-sectional and have either compared health outcomes for patients as a group or caregivers as a group. No known studies in Scotland have looked at the association between self-care and quality-of-life outcomes in HF patients and caregivers over time.

Aims: To explore longitudinally: 1) the effects of patients' and caregivers' baseline characteristics and self-care on caregiver burden at 6 months' follow-up (TP2); and 2) the effects of self-care on quality-of-life outcomes in patients with HF and their family caregivers (dyads) at 6 months' follow-up (TP2).

Design and methods: A multifactorial, exploratory longitudinal study was carried out. A survey approach was used to collect data from patient and family caregiver dyads at two time-points: following hospital discharge (TP1) and again at six months (TP2). Patients completed the SF-12 version 2 Health Survey, the Minnesota Living with Heart Failure Questionnaire, and the Self-Care of Heart Failure Index. Caregivers completed the same questionnaires, as well as the Zarit Caregiver Burden Interview Questionnaire. Dyadic data were analysed using the Actor-Partner-Interdependence Model.

Results: There were statistically significant differences between patients' and caregivers' physical and emotional quality of life (SF-12 PCS, MLwHFQ total score, MLwHFQ PCS and ECS) at time-point one and time-point two. These differences were accounted for by the patients' poorer physical and emotional

health at both TP1 and TP2. However, the patients' and caregivers' mental health (SF-12 MCS) was similarly affected and the results for both were below that of the general population. There were statistically significant differences between patients' and caregivers' self-care maintenance at TP1, but not at TP2. These differences were accounted for by the patients contributing more to self-care maintenance than their caregivers were assisting them with at TP1 (research question one).

Caregiver burden scores did not change significantly from time-point one to time-point two. Patients' lower physical activity levels, caregivers' emotional health and caregiver burden at TP1 significantly predicted caregiver burden at TP2 (research question two).

Quality of life was associated with patients' self-care and caregivers' contribution to self-care (*actor effects*). Patients' baseline self-care confidence significantly predicted their own mental (SF-12 MCS) at TP2. Patients' baseline self-care maintenance and self-care confidence significantly predicted their quality of life (MLwHFQ total score) at TP2. Patients' baseline self-care confidence significantly predicted their physical quality of life (MLwHFQ PCS). Patients baseline self-care management, maintenance and confidence significantly predicted their emotional health (MLwHFQ ECS) at TP2. The caregivers' baseline contribution to self-care maintenance and self-care confidence significantly predicted their physical (SF-12 PCS) and mental (SF-12 MCS) health at TP2. Caregivers' baseline contribution to self-care maintenance and self-care confidence significantly predicted their quality of life (MLwHFQ total score) and their emotional health (MLwHFQ ECS) at TP2 (research question 3).

Patient's baseline self-care significantly predicted the caregiver's quality of life at TP2 and vice-versa (*partner effects*). Patient's baseline self-care management significantly predicted the caregiver's physical health (SF-12 PCS) at TP2. Patient's baseline self-care maintenance significantly predicted the caregiver's emotional health (MLwHFQ ECS) at TP2. The caregiver's baseline self-care management significantly predicted the patient's physical health (SF-12 PCS) at TP2. Caregiver's baseline self-care management and self-care maintenance significantly predicted the patient's mental health (SF-12 MCS) at TP2.

Caregiver's baseline self-care maintenance significantly predicted the patient's overall quality of life (MLwHFQ total score), physical health (MLwHFQ PCS) and emotional health (MLwHFQ ECS) at TP2 (research question 3).

Conclusion: Patients physical and emotional health was poorer than their caregivers at both TP1 and TP2. The perceived mental health of both patients and caregivers were similar at both TP1 and TP2. Statistically significant differences were found for self-care maintenance at TP1, but not at TP2, which is accounted for by the patients contributing more to self-care maintenance than their caregivers were assisting them with. Confidence was gained, in that, clinicians can rely on family caregivers to support patients in their self-care, without increasing the level of caregiver burden. Early assessment of emotional health in the patient is needed to prevent a deterioration later in the clinical trajectory.

This longitudinal study has found that self-care maintenance, management and confidence influence quality of life outcomes in both members of the dyad. Indeed, the mutual dyadic effect of self-care maintenance on the emotional quality of life of the dyad supports the need for early assessment of emotional health and consideration of an early clinical psychology referral.

CHAPTER 1

OVERVIEW OF THE THESIS

This chapter provides an overview of the organisation of the thesis, as well as a justification for selecting this area of enquiry. The research undertaken in this doctoral thesis aims to explore longitudinally: 1) the effects of patients' and caregivers' baseline characteristics and self-care on caregiver burden at 6 months' follow-up (TP2); and 2) the effects of self-care on quality-of-life outcomes in patients with HF and their family caregivers (dyads) at 6 months' follow-up (TP2).

An evolving body of evidence is emerging regarding the unique relationship bond that develops between partners in a committed personal relationship during chronic illnesses (Lewis et al., 2006). However, very little attention has been given to patient–caregiver pairs (i.e., dyads), when, in effect, important dynamic and interpersonal influences occur at dyadic level. Caregiver burden is recognised as being high for carers within the population of people affected by HF, but inconsistencies exist within the literature, as well as ambiguity regarding patient and caregiver predictors (including patient and caregiver contribution to self-care) of caregiver burden (Agren et al., 2010; Chung et al., 2010). Also, previous studies conducted on HF caregiver burden tend to be unidimensional, despite recommendations outlined in theoretical and research literature suggesting the use of multiple constructs (Bayen et al., 2017; Li et al., 2017). Shamali et al. (2019) recognise the importance of the dyadic relationship and suggest that, with interdependence theory, greater recognition is given to the interactive nature of individuals in a close relationship, and to the impact of the close relationship on each other's outcomes during periods of chronic illness. Whilst interdependence between individuals in a committed relationship has been recognised in the literature, a paucity of studies have been identified that explore specifically heart failure patients and their family caregivers from a dyadic perspective (Chung et al., 2009; Vellone et al., 2014). Furthermore, no known dyadic heart failure studies were identified that explored longitudinally the effects of self-care on the quality of life (outcome) of patients diagnosed with HF and their family caregivers.

As a previous Charge Nurse in Coronary Care, I observed the unpredictability associated with the syndrome and the "revolving door scenario" that frequently occurred with many patients diagnosed with HF. Furthermore, I observed the impact that the variability of symptoms had on the patients' ability to self-care, which ultimately impacted on their overall quality of life. It was evident that quality-of-life outcomes differ depending on the level of support available to the patient on hospital discharge; some patients lived alone, and some patients had the support of a family member, friend or neighbour. From personal experience, a close family member was diagnosed with HF during the early stages of the thesis, and, as a carer, I watched how quickly the symptom burden affected her overall quality of life. After several episodes of de-compensation, medical staff made the decision to withdraw all therapy. This personal experience enhanced my interest in exploring further the influence of self-care on quality-of-life outcomes from a family perspective and indeed caregiver burden.

Throughout my clinical career, I have been involved in nursing patients affected by cardiovascular disease (CVD) and have witnessed significant changes in the management of HF. The NHS Scotland (2009) *Better Heart Disease & Stroke Action Plan* postulates that this is a result of improved survival rates following myocardial infarction (MI) as well as the demographics of an ageing population. It is recognised that HF is becoming more prevalent and is commonly associated with other co-morbidities (McMurray et al., 2012). The deadly and devastating nature of HF affects patients, family caregivers and healthcare systems globally (McMurray et al., 2012). The severity of the syndrome is recognised by NHS Quality Improvement Scotland (NHS QIS, 2010), who report that up to 50% of patients will sadly die within 5 years of diagnosis; 6% within the first month of diagnosis; 11% within 3 months, and 14% within 6 months. HF also places a significant burden on the NHS and the "revolving door" scenario is a common feature of advanced HF, accounting for a large proportion of healthcare expenditure (NICE, 2018). Furthermore, NICE (2010) document that admissions associated with HF are projected to rise by 50% over the next 25 years – predominantly as a result of the ageing population.

The National Institute for Clinical Excellence (NICE, 2010) indicate that approximately 26 million people worldwide are living with the syndrome. In the UK, HF is increasingly common and affects around 920,000 people, with an estimated 66,000 new cases being diagnosed annually in the UK (BHF, 2019). France et al. (2010) suggest that the true prevalence of patients living with HF in Scotland is often underestimated by Quality Outcomes Frameworks – presumably due to the unknown proportion of undiagnosed patients. However, the Information Statistics Division Scotland (ISD, 2016) estimate that the number of those living with the syndrome, is around 100,000 in Scotland – comparable with UK estimates.

Ponikowski et al. (2016) acknowledge this burden and highlight that HF is often referred to as a “malignant” disease, with a prognosis worse than several cancers. Further, Lesman-Leegte et al. (2009) and Bekelman et al. (2009) substantiate this claim and their studies have demonstrated that the patients’ quality of life is worse than many patients affected by cancer or patients diagnosed with other chronic diseases. This is in part due to the unpredictable disease trajectory and in part due to the high symptom burden of dyspnoea, fatigue, oedema and depressive symptoms, which impacts on patients’ exercise tolerance and ability to socialise.

There is inconsistent evidence regarding the association between effective engagement in self-care and improvements in quality of life. Lainscak et al. (2011), Lee et al. (2011), Wang et al. (2012), Kato et al. (2013), Tsuchihashi-Makaya et al. (2013) and Auld et al. (2018) suggest that health-related quality of life in patients diagnosed with HF is associated with their level of engagement in self-care. For example, greater symptoms were associated with improved emotional health when engagement with self-care maintenance and management were high. On the other hand, other studies concluded that no strong inferences could be reached regarding the associations between self-care engagement and quality of life (Seto et al., 2011; Nesbitt et al., 2014; Buck et al., 2015; Lee et al., 2015a), and these studies concur with the findings from Grady’s

(2008) systematic review, but the cross-sectional designs prevented temporal or causal relationships being reached. Despite self-care being the cornerstone of effective HF management, it remains suboptimal, and the reasons for this are inconsistent within the literature (Jaarsma et al., 2013; Riegel et al., 2009; Moser et al., 2012). Further, Cocchieri et al. (2015) highlight that only 20% of patients diagnosed with HF perform self-care effectively. The chronic nature of HF requires patients to be diligent in the identification of signs of decompensation, as well as to adopt certain behaviour changes, including minimising sodium intake, complying with medication and up-titration of doses when required, monitoring weight, and restricting their fluid intake – all of which have been reported to be burdensome (Gallagher et al., 2011). As the patients' functional status changes, their ability to maintain adequate self-care declines, and, as a consequence, they become reliant on the support of an informal caregiver – often reported to be the spouse (Luttik et al. 2007a; Vellone et al., 2014). The detrimental effects of being a caregiver are also recognised, that is to say, caregiver burden, as is the impact on their physical and psychological quality of life, as well as the potential benefits to patients (Kikto & Hupcey, 2013; Saunders, 2009; Luttik et al., 2007a; Molloy et al., 2005; Malik et al., 2013; Yeh and Bull, 2012). This thesis is designed to highlight the need to address caregiver burden and the needs of both patients diagnosed with HF and their caregivers. The literature to date has been limited in that it has mostly compared either health outcomes for patients as a group, or family caregivers as a group. Whilst the relationship effect of HF has been described in patients diagnosed with HF and their caregivers, no known study has examined how patients' and caregivers' self-care may influence quality-of-life outcomes in patient–caregiver dyads as well as the patient and caregiver factors that influence caregiver burden (outcome) over time, as this research has, and as presented in this thesis.

Chapter 2 presents the literature on caregiver burden, self-care in HF, and quality of life in HF. The limitations of current research are highlighted, and recommendations are made for further research, which helped inform the aims of this study. In addition, the lack of longitudinal studies identified through the literature review informed the selection of predictor and outcome variables. In this study, caregiver burden was used as an outcome variable. Patients' and caregivers' baseline self-care subdomain scores (management, maintenance and confidence) were used to predict caregiver burden and health-related quality of life; the majority of studies used self-care as an outcome variable. The literature relating to self-care and quality of life is scant and is limited by the frequent use of cross-sectional designs. Baseline physical and mental component scores (SF-12 and MLwHFQ) were used to predict quality of life at 6 months' follow-up (time-point 2 (TP2)), as there is an overall lack of longitudinal dyadic studies that have assessed these outcomes.

Chapter 3 discusses the design of the study and justifies its selection. Three research questions were identified to achieve the aims of the study. Several validated measures were used to collect, as far as possible, parallel data from patients and their family caregivers. In addition, the statistical tests employed to analyse the data are presented.

Chapters 4, 5 and 6 present the results of the thesis in relation to the study aims: to explore longitudinally: 1) the effects of patients' and caregivers' baseline characteristics and self-care on caregiver burden at 6 months' follow-up (TP2); and 2) the effects of self-care on quality-of-life outcomes in patients with HF and their family caregivers (dyads) at 6 months' follow-up (TP2). Three research questions were identified, namely: 1) Are there differences between patients' and family caregivers' self-care and quality of life at TP1 (after diagnosis) and TP2 (6 months later)? 2) What patient and family caregiver characteristics and self-care at TP1 (baseline) predict caregiver burden at 6 months (TP2)? 3) What are the effects of patient self-care and family caregiver contribution to self-care (at TP1) on their own and their partner's quality of life at 6 months (TP2)?

Chapter 7 provides the main discussion of the study findings and comparisons are made to previous research. The strengths and limitations of the study are highlighted. From this, practice-based recommendations are made, as well as those to promote the advancement of longitudinal dyadic research methods in HF care.

CHAPTER 2

LITERATURE REVIEW

2.1 Introduction

This chapter presents the empirical literature that relates to caregiver burden, self-care and quality-of-life outcomes, as well as dyadic studies of patients diagnosed with HF and their family caregivers. The chapter concludes with a summary of the salient issues drawn from the literature review.

2.2 Search strategy

The following electronic databases were systematically searched in line with the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) (Moher et al., 2015): OVID, MEDLINE, Medline in Process, CINAHL and PsychINFO. The databases were searched for studies reported between the years of 2005 and 2020, and a thorough review of the studies was undertaken in relation to their relevance to the study research questions, methodological strengths, study results and their relevance to clinical practice.

As the clinical doctorate was undertaken part-time, the literature review process was ongoing, from 2013 until 2020. The following combination of search terms were used: “caregiver burden”; “caregiver strain”; “caregiver health”; “self-care”; “self-care behaviour”; “self-care management”; “lifestyle”; “heart failure”; “chronic heart failure”; “congestive heart failure” and “quality of life”. In addition, the terms “carer”; “caregiver”; “partner” and “spouse” were included in the search strategy. Finally, these key themes were combined with the following terms: “dyads” and “dyadic relationships”. Alternative searches included the use of Google Scholar and reviewing the reference lists of relevant articles. The use of parentheses and Boolean operators, such as “AND”, “OR” and “NOT” were used. When the key terms were combined (“heart failure”; “caregivers”; “dyads”; “quality of life” and “self-care”) with limitations set from 2005 – 2020 a total of n=572 papers were available. Appendix 1 shows the initial search strategy and screening process employed, and a summary of the search strategy is provided within the PRISMA diagram presented in Figure 1.

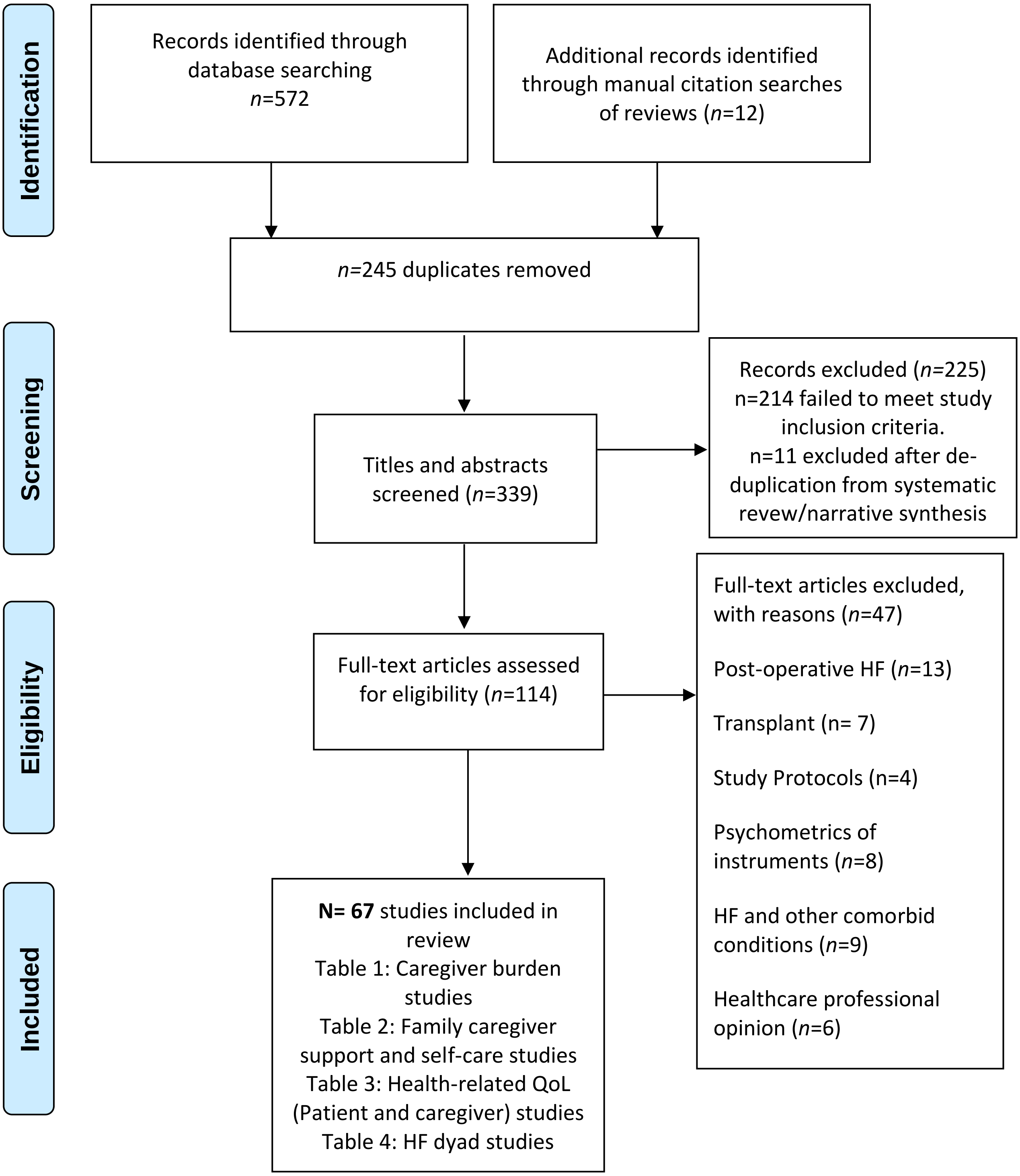

Figure 1: PRISMA 2009 Flow Diagram (Moher et al., 2009)

2.2.1 Study selection

The inclusion criteria for this review were all peer reviewed studies that were based on adult patients with a diagnosis of HF, HF family caregivers, and studies published in English. In addition, the studies included within the review were those that included measures of self-care, caregiver contribution to self-care, and assessment of caregiver burden, and studies that included patient and caregiver reported outcome measures (PROMS) to assess quality of life. Any duplicates were removed, and the exclusion of studies was based on those not having HF as the primary diagnosis, and those including non-family caregivers, as the research was particularly interested in spousal or partner relationship effect. In addition, study protocols, editorials, healthcare professional opinion and studies that focused solely on palliative care needs were excluded. All titles and abstracts were screened individually by the researcher but were discussed with academic supervisors to ensure transparency of the selection process and reliability of the results.

2.2.2 Study characteristics

On reviewing the original research publications, specific attention was given to the methods and results sections of each of the studies. The number of participants included in the study (patients and caregivers) and their sociodemographic and clinical details (NYHA classification, and ejection fraction), were also taken into account. Additional data that were of interest included the recruitment setting, country and the data collection tools used to assess the studies outcomes. The cross-sectional studies were appraised using the AXIS tool (Downes et al., 2016) (Appendix 2) and the Cochrane's bias assessment tool (Sterne et al., 2020) (Appendix 3) was used for the other studies. Appendix 2 and Appendix 3 also present the quality appraisal of the studies using these individual tools.

After combining the key search terms, 67 publications were included in the review and constituted: 4 systematic reviews; 1 meta-analysis; 2 integrative reviews; 1 narrative review; 1 prospective cohort study; 2 secondary analyses; 3 qualitative studies; 2 randomised controlled trials; 17 longitudinal studies; and 34 cross-sectional studies. For all studies, data were extracted using a template designed for the study on the following study features: study design/country of origin, study characteristics, findings/results, and limitations. The studies were then grouped as caregiver burden (Table 1), family caregiver support and self-management (Table 2), health-related quality of life (patient and caregiver) (Table 3), and heart failure dyads (Table 4). The study findings were then discussed in themes within each section.

2.3 Caregiver burden

2.3.1 Caregiver burden overview

A total of 11 caregiver burden studies were reviewed. This included 1 systematic review, 1 narrative review, 1 qualitative analysis, 6 cross-sectional, and 2 longitudinal studies (Table 1). The caregiver studies were largely carried out in the USA and Italy. There was a clear cultural imbalance regarding other countries publishing in the field. Variation was found in the instruments being used to measure caregiver burden, and some were not specific to the HF population.

The majority of the studies were cross-sectional, which limits the findings to associations between variables at one point in time. Three studies were longitudinal, which can enable the identification of causal relationships. Both the systematic and narrative review consisted largely of cross-sectional studies. Across the studies, most caregivers were female, which is typical of most HF caregiver studies, and the caregivers age ranged from 53 – 67 years. Variation was found in the sample size of the studies, which ranged from 50 to 505. The sample size/power analysis was discussed in only two of the studies, although one study acknowledged that, by not carrying out a sample size calculation, statistical power was limited. Eight of the studies used convenience sampling, with one study not reporting the sampling method used. The potential for sampling bias was reported in two of the studies, as the sample was selected from outpatient clinics in one region, which fails to represent the broad-based HF population. Six of the studies failed to acknowledge whether confounders had been considered, which increases the accusation of confounding bias. However, three studies recognised this within their limitations section.

Further, selection bias due to missing data was identified in seven studies, where the researchers did not mention whether any data from the instruments was missing and, if so, what measures were taken to deal with this. One longitudinal study indicated that 16% of the caregivers were unable to complete the data collection at follow-up, but did not provide any reasons for this, and the authors did not indicate whether the non-responders were drawn from a specific group, giving rise to a shift in the baseline data away from that group.

Overall, pertinent clinical data were reported in each of the studies. Two studies reported that greater than half of the patients were within NYHA class 1-2, indicating no limitation to slight limitation in physical activity. Six studies reported that a greater number of patients were within NYHA class 3–4, indicating marked limitation or unable to carry out any physical activity without discomfort. Two studies did not mention the NYHA classification. EF was reported in eight studies and ranged from 20.8 – 44.5%. These clinical features are largely consistent with other HF studies, which enhances the generalisability of the results.

Table 1: Caregiver Burden – review and analysis

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
Strömberg and Luttik (2015)	Systematic review of 24 studies.	Aim: To Identify the latest research on the risk and consequences of the burden that may be imposed on informal caregiver of persons living with HF.	Caregivers are important partners in care and their lives are often seriously affected by the condition of advanced HF. Studies on the longitudinal effects of the caregiving role on caregiver's QOL and caregiver contributions to patient outcomes are still scarce.	The majority of the studies were conducted in North America. A cultural imbalance with regard to the countries publishing in the field is noteworthy, impacting on the generalizability of the review findings.
Luttik et al. (2007)	Cross-sectional study. The Netherlands Patients *n* = 357 Caregivers *n* = 357	Aim: To assess the determinants of caregiver burden in partners of HF patients. Demographic and clinical data were assessed. Patients and partners completed questionnaires on caregiver burden, caregiving tasks performed, physical and mental health,	The physical health status of HF patients was only significantly associated with two domains of caregiver burden, "disruption of daily schedule" ($p<0.01$) and "loss of physical strength" ($p<0.01$). No associations were found with age, comorbidity and LVEF. All domains of the CRA were mainly associated with the partner's own mental health ($p<0.01$) and with providing personal care to HF patients ($p<0.01$). Gender differences were found with regard to the domain of "feeling a lack of family support". The assessment of caregiver burden	Cross-sectional design limits the findings to the associations between variables. It is unclear whether caregiver burden impacts on health status or impaired health status impacts on caregiver burden. A further limitation may be in relation to the lack of instrument validity measuring caregiver burden in the HF population; a generic instrument was used. Like other studies, the caregivers consisted mainly of females.

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
		and quality of the marital relationship. Tools: Caregiver Reaction Assessment; RAND -36; Cantril's Ladder of Life; Dutch Objective Burden Inventory (DOBI).	should focus on the mental strength of partners.	
Hooley et al. (2005)	Cross-sectional study *n* = 50 patients *n* = 50 caregivers	Aim: to describe levels of caregiver burden and depressive symptoms and to correlate this with patient QoL and depression in a HF outpatient clinic. Tools: Patients and caregivers completed the Beck Depression Inventory (BDI); patients also completed the	The mean quality-of-life score was 35 and 26% had a BD I-II score > 10. The mean ZCB score was 16 and the MLWHQ questionnaire, BDI-II and Zarit CB scores were all associated with lower ejection fraction, need for hospitalisation, increased number of medications, and comorbidities. Caregiver burden was correlated with both caregiver BDI-II and patient BDI-II. Death or hospitalisation at 6 months was associated with greater caregiver burden and depressive symptoms. Caregivers of patients diagnosed	The sample consisted of only stable HF patients visiting the CHF clinic with their caregiver. The sample was a selected cohort, and the sample size was relatively small. The sample consisted of only out-patients with family caregivers. Confounding variables such as medications could not be assessed.

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
		MLwHFQ and caregivers completed the Zarit Burden Interview questionnaire.	with HF experience high caregiver burden.	
Chung et al. (2016)	Cross-sectional study, USA *n* = 102 patients *n* = 102 caregivers	Aim: to examine differences in caregivers' outcomes (i.e., caregiving burden), between caregivers who take care of HF patients with depressive symptoms and without depressive symptoms. Tools: Patients completed the Beck Depression Inventory; Caregivers completed the Caregiving Outcomes Questionnaire and	Family members caring for patients diagnosed with HF with depressive symptoms had significantly higher levels of caregiving burden and worse quality of life compared to those caring for patients without depressive symptoms.	The cross-sectional design limits the ability to establish causality between patient depression and caregiver outcomes. There was the potential for sampling bias as the sample was selected from outpatient clinics from one region, using convenience sampling. The generalisability of the results was decreased by the fact that it was unclear whether participating caregivers had depressive symptoms or were taking antidepressants prior to commencing the caregiver role. More than half of the patients were in NYHA class I-II.

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
		the Oberst Caregiving Burden Scale.		
Albert et al. (2018)	Correlational longitudinal, Cleveland *n* = 132 patients *n* = 132 caregivers	Aim: to evaluate caregiver burden (outcomes) at baseline and 3 months.	Caregivers believed they spent more time dealing with patient depressive symptoms and monitoring patient condition changes, compared to the patients. Stability in patient symptoms at 90 days was not associated with improvements in the level of caregiver burden or quality of life. Caregiver burden was also noted to be higher when patients' symptoms were stable.	It is unknown whether the results reflected the type of care patients received, i.e., during periods of stability, the caregiver may have been the person the patient relied on, or if symptoms deteriorated, if the patients contact their healthcare professional. It was not clear which instrument was used to measure caregiver burden.
Pressler et al. (2013)	Longitudinal, Michigan, US *n* = 63 patients *n* = 63 caregivers	Aim: to evaluate changes in caregiver burden and to determine differences in perceptions between caregivers of patients with high and low symptoms based on NYHA.	Caregivers who completed the study had significant improvements in perceived time spent on and difficulty of caregiving tasks from baseline to 4 and 8 months. Caregivers of patients with high symptoms are in need of interventions to reduce time and difficulty of caregiving tasks and improve their physical QoL.	Relatively small sample size. 16% of caregivers did not complete the data collection at 8 months. Changes to patients' health status were not measured in the study over time. Caregivers' perceptions of the quality of care they provided was not measured. Multiple statistical tests were used, which could have impacted or influenced the results.

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
		Tools: The Oberst Caregiver Burden Scale, The Brief Symptom Inventory Anxiety Subscale, The Bakas Caregiving Outcomes Scale, Charlson Comorbidity Index, Family Assessment Device and the SF-12 PCS and MCS scores.		
Durante et al. (2019)	Cross-sectional study, Italy *n* = 505 patients *n* = 505 caregivers	Aim: to identify patient and caregiver predictors of caregiver burden in HF, and to identify whether caregiver contribution to self-care increases caregiver burden. Tools: Caregiver Burden Inventory; Caregiver	Caregiver predictors of higher caregiver burden were older age, female gender, fewer caregiving hours and poor social support. Patient predictors of higher caregiver burden were older age, better education, taking fewer medications and higher quality of life. Caregiver contribution to self-care maintenance and management were not significant predictors of caregiver burden.	It was a convenience sample from a cross-sectional study. Generalisability to other countries is reduced, as it was conducted in only one European country.

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
		Contribution to Self-Care of Heart Failure Index; Charlson Comorbidity Index; SF-12 Health Survey.		
Kitko & Hupcey (2013)	Secondary qualitative analysis of in-depth interviews *n* = 20 caregivers	Aim: to describe the types of work in long-term spousal caregiving of older adults with HF. Tools: Interviews.	Caregiving in HF was always present, even when patients were clinically stable. The caregiving tasks and intensity of the tasks varied throughout the trajectory. Six key themes emerged: providing care; navigating the system; maintaining self; managing the household; vigilance; and normalcy.	Limitations included the homogenous sample – the majority of the participants were Caucasian females. All participants reported a happy and healthy marriage, which does not capture the variations in marital relationships across all HF patients and their spouses.
Agren et al. (2010)	Descriptive cross-sectional study, Sweden *n* = 135 patients *n* = 135 caregivers	Aim: to describe the levels and identify predictors of caregiver burden in partners of HF patients. Tools: Caregiver Burden Scale; SF-36; Beck	The caregiver burden was perceived as being medium in 30% of the caregivers. Patients' PCS scores and the caregivers' MCS scores and perceived control accounted for 39% of the variance in the level of caregiver burden.	The cross-sectional design prevented causal conclusions being reached. The sample size was relatively small, which was partly associated with the large number of screened patients not having a partner. The sample was quite homogenous, as it consisted of mostly moderate-severely ill

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
		Depression Inventory; Control Attitude Scale; Knowledge Questionnaire (RAND); Charlson Comorbidity Index.		patients, which precludes generalisations being made to mildly ill or patients with advanced heart failure.
Hooker et al. (2018)	Cross-sectional study, USA n=99 patients n=99 caregivers	Aim: to examine associations among mutuality, patient self-care confidence and maintenance and caregiver burden.	Patients and caregivers who had greater mutuality were more confident in performing self-care. The regression models identified that greater mutuality was associated with less burden.	The main limitations were in relation to the primarily male patients and female caregivers but is a recognized limitation in other HF patient–caregiver studies. Other limitations include the cross-sectional design and self-reported self-care behaviour. It was also unclear whether the patients and caregivers completed their questionnaires independently of each other.
Whittingham et al. (2013)	A narrative review of 16 studies	Aim: to explore the specific dimensions that impact on caregiver burden and QoL in caregivers of	The review highlighted that HF caregivers face many challenges, which impact on their physical and mental well-being. External factors influence caregiver burden, i.e.,	The search strategy was a recognised limitation; because of limited time and resources, hand-searches were not completed and, as a result, some studies may have been missed. The studies

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
		patients with HF; to highlight both the positive and negative aspects associated with caregiving. Tools: Beck Depression Inventory; SF-36; Zarit Burden Interview; European QoL, HADs; Cantril’s Ladder of Life, Brief Symptom Inventory; The Centre of Epidemiological Studies Short Depression Scale.	NYHA and recent hospital discharge.	predominantly included measures that assessed the negative aspects associated with caring for HF patients.

2.4 Caregiver burden – review and analysis

Patients' functional status, comorbidities, symptom burden/disease severity, age and self-care emerged as key issues in relation to caregiver burden.

2.4.1 Patients' functional status

Whittingham et al.'s (2013) review found a correlation between patient factors and caregiver burden, which included poor functional status, higher symptom burden and frequent hospitalisations. The association between functional status and caregiver burden was also recognised in Luttick et al.'s (2007a) study that suggested patients' physical health impacted significantly on two areas of caregiver burden: "disruption of daily schedule" and "loss of physical strength". Similarly, the association between poorer physical function in the patient and increased caregiver burden was also recognised in Agren et al.'s (2010) and Hooley et al.'s (2005) cross-sectional studies. The association between poor functional status and caregiver burden is not surprising, as it would be logical to assume that patients with greater limitations (i.e., poor mobility or physical inactivity) place a greater demand on their caregiver, resulting in the "loss of physical strength".

2.4.2 Patients' comorbidities, symptom burden and disease severity

The association between higher symptom burden and caregiver strain was identified in Whittingham et al.'s (2013) narrative review and Pressler et al.'s (2013) longitudinal study. Hooley et al.'s (2005) cross-sectional study found similar results but also reported that a lower ejection fraction and greater comorbidities predicted greater caregiver burden. However, Luttick et al.'s (2007a) and Agren et al.'s (2010) studies reported no association between ejection fraction and comorbidities on the level of caregiver burden experienced. Further, Whittingham et al.'s (2013) and Chung et al.'s (2016) studies reported that patients with mental health issues (specifically depression) was associated with increased burden in the caregiver. Further, Albert et al. (2018) reported that caregivers spent more time dealing with patient depressive symptoms, which was also recognised in Durante et al.'s (2019) study, where the mental health-related quality of life of the patient predicted all caregiver dimensions as well as the total level of caregiver burden.

2.4.3 Patients' and caregivers' age

The association between advancing age and caregiver burden was inconsistent in the literature. Saunders' (2009) and Durante et al.'s (2019) studies found that advancing age influenced the level of caregiver burden encountered, whilst Luttick et al.'s (2007a) and Agren et al.'s (2010) studies found no such association between age and caregiver burden.

The findings for caregivers' age and the level of burden experienced was also inconsistent in the literature. Caregivers' age was not associated with the level of burden experienced in the studies conducted by Agren et al. (2010) and Luttick et al. (2007a), but Saunders' (2009) study found older carers were at greater risk of caregiver burden, which might be expected, due to increasing comorbidities.

2.4.4 Self-care and caregiver contribution to self-care

Caregivers' contribution to patients' self-care maintenance and management was identified in Durante et al.'s (2019) study, but these domains did not predict caregiver burden. An explanation for this may be related to the positive aspects experienced in providing care. However, these findings contrast with those of Albert et al.'s (2018) study, which reported that caregivers' contribution to self-care was even greater in patients who were clinically stable at 90 days, with a resultant increase in the level of caregiver burden being reported. This finding supports those of Kitko et al.'s (2013) study, which suggest that HF caregiving is constant – even during periods of clinical stability – and the contribution to self-care varies throughout the clinical trajectory. Further, Hooker et al.'s (2018) cross-sectional study found associations between patient self-care and caregiver burden. This study found that greater relationship mutuality is associated with less caregiver burden and improved confidence in patient self-care.

In summary, the above studies have demonstrated that certain patient and caregiver characteristics can influence the level of caregiver burden experienced. It is evident that inconsistencies exist between the various designs of the studies, the caregiver burden instruments used, and within sample sizes. Such variation makes it difficult to generalise the study findings. Future studies could incorporate caregiver burden instruments that have been tested in the HF population and have been found to have good internal validity. Further, adopting longitudinal designs with larger sample sizes, as well as considering the impact of known confounders, would also be advantageous.

2.5 Family caregiver support and self-care management

2.5.1 Family caregiver support and self-care management overview

A total of 24 HF support and self-care studies were reviewed in this section. These studies included 4 systematic reviews, 1 integrative review, 2 RCTs, 3 secondary analysis studies, 1 qualitative study, 10 cross-sectional studies, and 3 longitudinal studies. Further, the systematic reviews consisted largely of cross-sectional studies. Of the longitudinal studies, selection bias was reduced, as they each reported attrition rates and response rates. A significant proportion of the studies was carried out in the USA, therefore limiting the generalisability to other countries, as patients and caregivers in these populations may have differing cultural views on engaging in self-care and in the amount of support being offered. The sampling method of choice in most studies was convenience, and, whilst this is consistent with other HF studies, the limitations of this method were recognised. Further, the majority of studies were patient-related, which highlights the growing need for studies to consider both the patient and the caregiver.

Across the studies, there were more male than female patients, and a greater number of caregivers were female; findings that are largely comparable with other HF studies. The average age of patients was 75 years, which confirms the association with HF and advancing age. Table 2 highlights the wide range in sample sizes (62 – 5964), with Jaarsma et al.'s (2013) study recruiting patients from 15 countries worldwide. The statistical power was limited in six of the studies, which failed to mention the sample size/power analysis used. Five of the studies failed to acknowledge whether confounders had been considered, which increases the risk of confounding bias. However, recognition of this was given in two of the studies. Selection bias was introduced in 12 of the studies as they failed to mention whether missing data was an issue and how it was handled. Variation was found in the instruments being used to measure self-care and the results were largely subjective due to self-reporting of the level of self-care and efficacy of patient self-care engagement.

Overall, pertinent clinical data were reported in each of the studies. Fourteen studies used the NYHA classification scale, with significantly more patients being within NYHA class III, indicating marked limitation on physical activity. Nine studies mentioned the EF, which ranged from 26–43%. These clinical features are largely consistent with other HF studies, which enhances the generalisability of the results.

Table 2: Family caregiver support and self-care management

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
Buck et al. (2015)	Systematic Review, USA *n* = 40 studies (*n*= 17 qualitative; *n* = 23 quantitative)	Aim: To identify what specific activities caregivers contribute to patents' self-care in heart failure; and to identify the maturity of the science of caregiver contribution of self-care.	Importance of caregiver role in heart failure self-care identified. However, research is needed to examine the impact of caregiving on HF patients' self-care.	The authors acknowledge that some studies may not have been captured by their search. A further potential limitation was the inclusion of multiple papers from one study. Other theoretical conceptualisations of HF self-care may have had different findings.
Clark et al. (2014)	Systematic Review Alberta, Canada *n* = 49 qualitative studies	Aim: To examine the views and needs of patients and their caregivers regarding the nature and determinants of effective self-care.	Identification of key drivers of effective self-care, i.e., capacity of patients to successfully integrate self-care practices with their preferred normal daily life patterns and responding to HF symptoms in a timely manner.	It was unclear to what degree self-care factors were pursued during data collection, which was carried out in wealthy countries with different healthcare systems, limiting generalisability to poorer economic and deprived areas. Further, there was no reporting of patients' NYHA classifications.

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
Kessing et al. (2016)	Systematic review, Netherlands. *n*= 65 quantitative studies.	Aim: To describe the current evidence concerning psychological determinants of self-care in patients with HF.	Depression, self-efficacy and mental well-being were significantly associated with self-care. Anxiety was not associated with either self-reported or objective self-care.	There was a high degree of selection bias in the studies reviewed, and future studies should minimise this by providing information relating to attrition rates, statistical power and characteristics of non-responders. Further, consideration should be given to the role of covariates and whether they are confounders or whether they are serving as mediators instead.
Kessing et al. (2017)	Longitudinal, Tilburg, Netherlands *n* = 459 patients Follow-up at 6, 12 and 18 months.	Aim: To examine the association of (changes in) self-care with HRQOL while adjusting for psychological distress. Tools: European Self-care Behaviour Scale; MLwHFQ.	Self-care was significantly associated with better disease specific HRQOL in patients with HF, which was fully accounted for by controlling for depression and partially accounted for by anxiety and Type D personality.	There was the risk of systematic biases as a result of the self-reporting of self-care. There was also some missing data. No conclusions could be drawn regarding the causality of relationships as a result of the observational nature of the study design.
Shahriari et al. (2013)	RCT, Iran	Aim: To evaluate the effects of family support intervention on the self-care	Self-care behaviour scores in the experimental group and control group were 47.2 and 28.4, respectively, and independent *t*-tests	A limitation was in relation to the short follow-up period after the intervention. It would have been useful to have followed this up at

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
	n = 62 patients with HF	behaviours in patients with HF. Tools: Self-care Behaviours' Questionnaire.	revealed the difference was statistically significant. Findings suggest that engaging family caregivers can be an effective method for improving the self-care behaviours in patients with HF.	different time-points to assess efficacy. The reasons for not continuing in the study were not detailed. It was unclear whether the self-care tool had been used in previous HF studies.
Gallagher et al. (2011)	Secondary analysis of cross-sectional data. Multi-site trial Netherlands *n* = 333 patients.	Aim: To determine the types of social support provided to HF patients and the impact of differing levels of social support on HF patients' self-care.	Patients with a high level of support reported significantly better self-care (*p*=0.002) than those with low or moderate levels of support. In addition, patients with a high level of support were more likely to consult with a healthcare professional, for example: weight gain (*p*=0.011) and fluid reduction (*p*=0.002), and to comply with their heart failure medication (*p*=0.017) compared to those with medium or low levels of support. Social support provided by partners needs to be of a quality and content that match HF patients' perceptions of need to influence self-care. Caregivers (especially partners), should be integral to the treatment of and care of HF patients.	The study was a secondary analysis and not designed specifically to detect the role of social support. It was likely that other important factors that influence HF self-care were not addressed, as the multivariate model using the variables outlined in the study was not adequate.

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
Clark et al. (2009)	Qualitative study, semi-structured interviews Alberta, Canada. *n* = 42 patients *n* = 30 caregivers (63% spouses)	Aim: To identify Individual and contextual factors influencing self-care.	Links between knowledge of HF and self-care were weak and long delays in seeking health professional care were frequent. Knowledge of HF and its management is a necessary though not sufficient determinant of self-care. Individual and contextual factors influence willingness to undertake effective HF self-care.	The study findings were based on subjective perceptions of influences of self-care. Objective measurements of self-care determinants may have yielded different results if matched pairs were used or they were interviewed together.
Cocchieri et al. (2015)	Cross-sectional design, Italy. *n* = 1192 patients	Aim: To describe self-care in adults with heart failure and to identify sociodemographic and clinical determinants of self-care. Tools: Self-care of Heart Failure Index; Charlson Comorbidity Index;	Three areas of self-care ranged from 53.18 to 55.26; few people were adequate in self-care (14.5% to 24.4% of the sample). Self-care behaviours were low for symptom monitoring, exercise, use of reminders to take medicines and symptom recognition. Confidence in the ability to keep oneself free of symptoms and relieve symptoms was also low. Taking fewer medications, poor cognition, older age, having a caregiver, being male and having HF for a shorter time	Despite data being collected in several centres across Italy, convenience sampling was used, and the study was cross-sectional. The cognitive screening tool used was less sensitive to mild degrees of cognitive impairment than other measurement tools. It would have been useful to see how the self-care behaviours changed over time.

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
		Mini Mental State Exam.	predicted poor self-care maintenance. Poor cognition, not being employed, being male and having worse NYHA class predicted poor self-care management. Poor cognition, taking fewer medications, older age, and male gender predicted poor self-care confidence.	
Seto et al. (2011)	Cross-sectional design, Canada *n* = 100 patients.	Aim: To investigate self-care and quality of life of patients attending a heart function clinic; to explore the relationship between self-care and quality of life. Tools: Self-care of Heart Failure Index; MLwHFQ.	Patients performed poorly in self-care (< recommended 70 threshold). Patients reported moderate quality of life using MLwHFQ. Higher self-care confidence was associated with improved quality of life.	A recognised limitation was that most of the data was self-reported; participants may have reported greater self-care than in reality. There may have been participant bias as 1/3 were called to remind them to complete/return the questionnaire; 11% declined participation.
Nesbitt et al. (2014)	RCT REMOTE HF, Northern California.	Aim: To test an education and counselling intervention to	Measures of self-care behaviours, literacy and barriers to accessing healthcare had no influence on quality of life. A very weak	There was no urban control group – only targeting a rural population – which consisted of mainly white patients. The recruitment from the

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
	n = 612 patients.	improve self-care in HF patients. Tools: MLwHFQ; Charlson Comorbidity Index; European Heart Failure Self-care Behaviour Scale; Control Attitude Scale; Brief Symptom Inventory.	association between self-care and quality of life was found. Higher NYHA classification, depression/ anxiety and some sociodemographic factors were associated with reduced QOL.	three rural sites may not be reflective of all the rural populations in the US.
Buck et al. (2015)	Cross-sectional, Italy *n* = 628 patients	Aim: To test the contribution of comorbidity to HF self-care behaviours and outcomes (hospitalisation, QOL) and to assess whether comorbidity is a moderator of the relationship between self-efficacy and HF self-care.	Higher comorbidity weakened the strength of the relationship between self-efficacy and self-care maintenance. Higher levels of self-care maintenance were associated with better quality of life and lower hospitalization.	This was a secondary analysis of cross-sectional data. The study only included symptomatic patients, which resulted in a much sicker population and fails to represent the range of trajectories in HF.

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
		Tools: Charlson Comorbidity Index; Self-care of Heart Failure Index; MLwHFQ.		
Lee et al. (2015)	Longitudinal (6 months), USA *n* = 146 patients.	Aim: To measure changes in self-care and HRQOL over 6 months. Tools: Self-Care of Heart Failure Index; Kansa City Cardiomyopathy Questionnaire.	Patients with greater physical symptoms at enrollment (odds ratio (OR) =1.04, *p*=0.037), larger left ventricles (OR=1.50, *p*=0.044), and ischemic heart failure (OR=3.84, *p*=0.014) were more likely to have the declining trajectory of self-care management.	The study design was observational. Future studies are required to provide greater insight into the relationship between HF self-care management and HRQOL. The use of a single-centre, younger age group and low percentage of women, as well as those with ischaemic aetiology limit the generalizability of results to other HF patients.
Riegel et al. (2009)	Cross-sectional study, USA *n* = 2082 patients.	Aim: To identify determinants of self-care in developed and developing countries. Tools: Self-Care of Heart Failure Index.	The results of the study demonstrate that self-care is poor in all four countries. Lower NYHA (or better NYHA) was a determinant of better self-care maintenance. Determinants of self-care management were younger age, more comorbid conditions and country. Determinants of self-care	Limitations include the secondary analytic approach. The differences in sampling may have influenced the results (i.e., most were consecutive samples and 1 was both consecutive and random).

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
			confidence were younger age, less comorbid conditions, and higher education, as well as lower NYHA class.	
Jaarsma et al. (2013)	Secondary analysis of self-care data from 15 countries *n* = 5964 patients.	Aim: To describe self-care behaviours of patients from 15 countries across three continents. Tools: Self-Care of Heart Failure Index; European Heart Failure Self-care Be haviour Scale.	Self-care behaviours were sub-optimal. Most of the patients reported taking their medication as prescribed, but exercise and weight monitoring were found to be low.	A limitation was the secondary analysis of the existing data, where the studies applied different inclusion and exclusion criteria. The pooled data were drawn from two different instruments. The two tools that were used described self-care behaviours differently, which resulted in variation in the results and failed to capture the full picture of self-care.
Hadjuk et al. (2013)	Cross-sectional, USA *n* = 577 patients.	Aim: To examine associations between cognitive impairment and self-care adherence. Tools: European Heart Failure Behaviour Scale;	79% of the patients were impaired in at least one of the cognitive domains. No differences were found between adherence to self-care activities in patients with global cognitive impairment and those without impairment. Greater cognitive impairment was associated with lower self-care scores (p= 0.006) in the multivariate models.	Study sample was restricted to patients without a diagnosis of dementia, potentially reducing the generalizability of the study findings. The self-care behaviour scale used did not have established cut-off scores to determine adequate from inadequate self-care.

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
		Montreal Cognitive Assessment Battery.		
Currie et al. (2014)	Systematic Review and Narrative Synthesis. *n* =10 observational, correlation studies. Scotland, UK	Aim: To identify the evidence for an association between mild cognitive impairment and self-care in patients who have a HF diagnosis.	There is growing evidence to suggest the association between mild cognitive impairment and self-care in HF, specifically in relation to mediation adherence or more general self-care activities. A significant negative correlation was found in one study, suggesting that worse cognitive function was associated with improved self-care.	Limitations include the small number of studies reviewed, small convenience samples, and recruitment from single sites.
Zavertnick (2014)	Integrative Review, USA (qualitative, quantitative, RCTs and mixed-methods) *n* = 9 studies.	Aim: To examine self-care in older adults with HF.	The review identified three themes: patient-related factors; patient education and telemonitoring. Patients' age, cognitive factors and social issues were identified as self-care barriers. Patient education was related to self-care knowledge and the use of telemonitoring augmented symptom recognition. The use of telemonitoring in older adults was an appropriate self-are enhancer, which was surprising.	The small number of studies included in the review were limited by the small sample sizes. The majority of the studies included predominantly male patients.

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
Sayers et al. (2008)	Cross-sectional study, USA *n* = 74 patients.	Aim: To investigate the effects of social support among patients with HF. Tools: Blessed Test; Medical Care Questionnaire; Multidimensional Scale of Perceived Social Support; Self-Care of Heart Failure Index; Medication Non-adherence; Eating Behaviour Questionnaire.	The spouse was most involved in the patient's care. Self-care was generally poor. Greater perceived social support was associated with better medication adherence and dietary adherence (B = -0.28 SE B 0.13, β =-0.41*; B = 1.95, SE B 0.9, β = 0.39**). Daily weighing was also better.	The study included a predominantly male sample of patients. Like many of the other studies, self-care behaviours were measured by self-report. A relatively large number of measures were used given the sample size.
Chung et al. (2006)	Cross-sectional comparative study, USA *n* = 68 patients.	Aim: To determine gender differences in adherence to sodium restricted diet, knowledge about sodium restriction and HF self-care and perceived barriers to	Women were more adherent to a sodium restriction than men and were able to recognise signs of excess sodium (p=0.001) in the diet and oedema (p=0.01). Overall, females had a better understanding of self-care measures. No gender differences were identified in	Data were only collected at one time-point, which does not reflect patients' long-term dietary adherence. The sample of patients was relatively small, and they were healthy in comparison to the general HF population.

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
		following a sodium restricted diet. Tools: Urinary Sodium Excretion measurement; Dietary Sodium Restriction Questionnaire.	perceived barriers to following a sodium restricted diet.	
Seid et al. (2019)	Cross-sectional study, Ethiopia *n* = 310 patients.	Aim: To assess HF patients' adherence to self-care recommendations and its associated factors. Tools: Self-care Behaviours Data Collection Tool; Heart Failure Knowledge Scale.	Only 22.3% of patients reported good adherence to the recommended self-care (95% CI, 17.4%–26.8%). Self-care adherence was positively associated with male gender (AOR = 2.34, 95% CI:1.18–4.62), knowledge and understanding and (AOR = 2.49, 95% CI: 1.276–4.856) and being free of chronic comorbid conditions (AOR = 2.57, 95% CI:1.28–5.14)	The use of self-report data and recall bias may affect the study. The absence of multi-centre data may limit generalisation of the findings to the general population.
Chuang et al. (2019)	Cross-sectional study, Taiwan	Aim: To examine how depressive symptoms, social support, e-Health literacy and HF	Self-care confidence mediated the relationship between depressive symptoms, social support and HF knowledge, as well as the outcome variables (self-care maintenance	The authors advised caution when generalising the findings to similar patients across other regions. Self-report may give an inaccurate account of self-care behaviours.

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
	n = 141 patients.	knowledge directly and indirectly affect self-care. Tools: Health Questionnaire; Multidimensional Scale of Perceived Social Support; e-Health Literacy Scale; Heart Failure Knowledge Scale; Self-care of Heart Failure Scale.	and management). Depressive symptoms negatively affected self-care maintenance, whereas e-Health literacy had a significant and direct effect on self-care management and knowledge of HF.	Consideration of certain confounders should have been considered in the analysis, i.e., educational level and age. The cross-sectional design limits inferences about causal relationships being made.
Heo et al. (2008)	Cross-sectional study, USA *n* = 122 patients.	Aim: To identify the factors related to self-care behaviours in patients with HF. Tools: Self-care of Heart Failure Index (SCHFI); Beck Depression Inventory (BDI-II); Control Attitudes Scale–Revised; HF Knowledge and	Patients did not engage sufficiently in self-care behaviours; mean scores were < the recommended threshold of 70. In male patients, increased self-care confidence, perceived control and knowledge were related to better self-care. In the female patients, increased self-care confidence and poorer functional status were associated with greater self-care behaviours.	The cross-sectional design limits the inferences about causal relationships that can be made. The data on self-care were collected using self-report measures, which may not represent the actual behaviour of the patients.

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
		Barriers to Adherence Scale; Duke Activity Status Index; Multidimensional Scale of Perceived Social Support; Charlson Comorbidity Index.		
Heo et al. (2014)	Cross-sectional, USA *n* = 71 patients.	Aim: To examine the types of social support associated with physical and depressive symptoms and HRQoL in patients with HF and the mediating effects of symptoms on the relationship between social support and HRQOL. Tools: MLwHFQ; Symptom Status Questionnaire-HF; Patient Health	Emotional support was significantly related to physical symptoms and depressive symptoms in the general linear model analysis (R^2 = .568 and 540, respectively, p = .003 and p = .009, respectively). Physical and depressive symptoms mediated the relationship between emotional support and HRQoL.	Most patients were Caucasian and social support and its relationships to symptoms and HRQOL may be different to other races. The quality of the social relationship was not measured. All the interactive effects (i.e., social support and physical and depressive symptoms) could not be assessed due to the small sample size.

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
		Questionnaire (PHQ-9).		
Wu et al. (2013)	Longitudinal, USA *n* = 218 patients. Follow-up 3.5 years	Aim: To explore the combined influence of medication adherence and perceived social support for prediction of cardiac event-free survival in patients with HF. Tools: Medication Adherence Device (MEMS); Multidimensional Perceived Social Support Scale.	Medication adherence and perceived social support were independent predictors of cardiac event-free survival (*p* = .006 and .021, respectively). In the group of patients who were non-adherent lower perceived social support resulted in a 3.5 times greater risk of cardiac events than those who adhered and had adequate support.	Different types of perceived social support were not measured, such as practical and emotional support, and family cohesiveness and conflict. These confounders may have influenced medication adherence and outcomes differently. It is possible that the rates of adherence were inflated, given the fact the patients were being monitored.

2.6 Family caregiver support and self-care management – review and analysis

The definition of self-care, barriers to effective self-care, facilitators of self-care and consequences of poor self-care emerged as key issues in relation to support and self-care management.

2.6.1 Definition of self-care

Self-care is defined as *"the decisions and strategies undertaken by the individual in order to maintain life, healthy functioning and well-being"* (Jaarsma et al., 2013 p. 114). This suggests that patients need to actively participate in the management of their own HF to reduce the risk of potential decompensation and the "revolving door" scenario that many HF patients face. Self-care remains suboptimal (Jaarsma et al., 2013; Riegel et al., 2009; Moser et al., 2012) and is implicated as the reason for 20–60% of HF readmissions (Moser & Watkins, 2008).

Further, Dickson et al. (2007) usefully conceptualises self-care within the context of HF and describe self-care as a combination of self-care maintenance, self-care management and self-care confidence. Self-care maintenance involves symptom monitoring and treatment adherence (i.e., daily weights and checking ankles for oedema). Self-care management involves evaluation of symptoms (i.e., reducing salt and taking an extra diuretic in response to dyspnoea and ankle swelling). Self-care confidence involves greater engagement in symptom monitoring, implementation and evaluation (i.e., being able to recognise changes in symptoms associated with HF and being able to confidently do something to relieve the symptoms (MacInnes, 2008). Figure 2 presents the self-care of HF model as depicted by Riegel et al. (2009). These 3 elements of self-care are examined in self-care measurement tools, such as the Self-Care of Heart Failure Index (SCHFI), which can be found in Table 2 (Cocchieri et al., 2015). The limitations of these tools include the use of self-report, which may differ from the actual self-care behaviours.

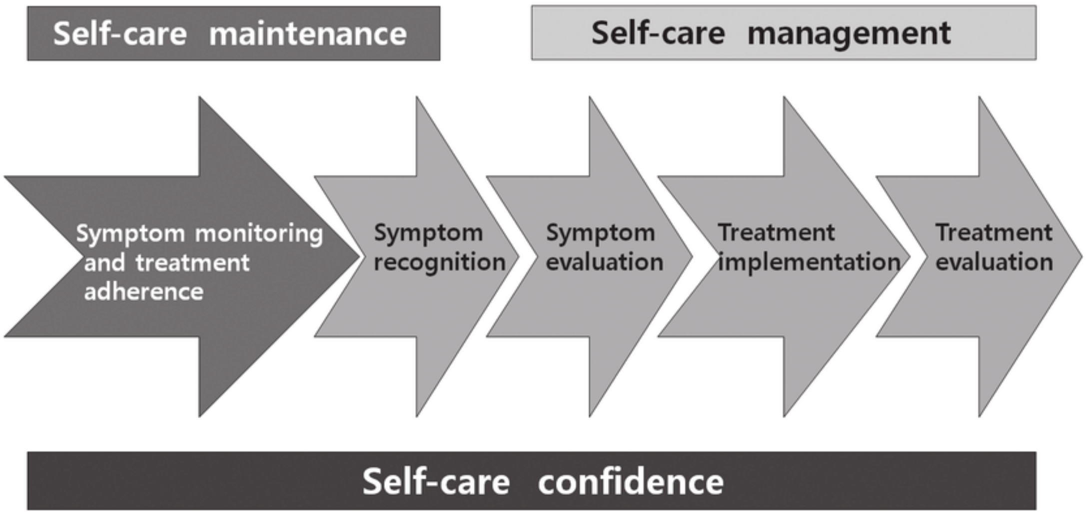

Figure 2: Self-Care of Heart Failure Model (Riegel et al., 2009)

2.7 Barriers to effective self-care

Patients diagnosed with HF are a heterogenous group, as they present with their own challenges. They can present with differences in aetiology, functional status, social support, cognitive impairment as well as a range of other comorbidities and symptoms that significantly impact on their ability to engage in effective self-care (Riegel et al., 2009). In addition, advancing age and poor medication adherence were also offered as potential barriers to poor engagement in self-care (Cocchieri et al., 2015).

2.7.1 Age

The association between age and engagement in self-care is inconsistent in the HF literature. Older age was a determinant of poor self-care maintenance and confidence in the study by Cocchieri et al. (2015), but, conversely, older age was found to correlate with better self-care maintenance in Seto et al.’s (2011) study. The association between older age and poorer self-care may be related to cognitive decline, which impairs patients’ self-care abilities. This association was recognised in Clark et al.’s (2013) systematic review, which reported that older patients often misattribute HF symptoms to other clinical conditions, which is a significant challenge, particularly in the domains of self-care maintenance and management. The findings identified in Seto et al.’s (2011) study may be explained by older patients having more time in their retirement to develop their knowledge and engage in self-care behaviours more frequently. Interestingly, age was not strongly associated with self-care adherence in Gallagher et al.'s (2011) and Seid et al.'s (2019) studies. This highlights the importance of measuring self-care over time, especially in older patients diagnosed with HF.

2.7.2 Comorbidities

Several inconsistencies were found in the literature in relation to comorbidities and their impact on self-care. Comorbidities reported included: hypertension, diabetes, anaemia, stroke, previous acute coronary syndrome, and peripheral vascular disease – all common comorbidities associated with HF. Comorbidities that resulted in physical limitations were associated with lower self-care (Cocchieri et al., 2015; Kessing et al., 2017; Lee et al., 2015). Interestingly, Cocchieri et al.'s (2015) and Lee et al.'s (2015) studies found that those comorbidities that had an impact on physical functioning were associated with poorer self-care management, and Buck et al.'s (2015) study found that patients with a greater number of comorbidities in general also had an impact on lower levels of engagement in self-care management. Conversely, Gallagher et al. (2011) reported that the presence of comorbid conditions was not associated with engagement in self-care behaviours, whilst Seid et al.'s (2019) study found that patients diagnosed with no comorbidities were more adherent to self-care management than those with comorbidities.

2.7.3 Cognitive function

The impact of cognitive function was also recognised in the HF literature as a barrier to effective self-care. Indeed, Cocchieri et al. (2015) found that poor cognition was associated with poor self-care, and it was a consistent determinant in all self-care domains (maintenance, management and confidence). Similarly, Zavertnik's (2014) integrative review reported that reduced cognition negatively affected HF patients' functional status and their ability to engage in effective self-care, whilst memory impairment was statistically significantly correlated with lower self-care scores (p = 0.006) in the European Heart Failure Self-care Behaviour Scale (Hadjuk et al., 2013). It seems logical to assume that patients with poor cognition will understandably have poor knowledge and understanding of HF, which will ultimately limit their ability to engage in effective self-care. Conversely, Currie et al.'s (2014) systematic review and narrative synthesis concluded that there is limited evidence to support the association between cognition and self-care ability in the HF population. These differences in each study's findings may be attributed to the different self-care behaviour tools used.

2.7.4 Depression

Kessing et al. (2017) found that patients who were poor at performing self-care had increased levels of depression, and depression fully explained the relationship between self-care and all health-related quality-of-life domains. Chuang et al.'s (2019) study found that depressive symptoms directly and negatively affect self-care maintenance, whereas Lee et al.'s (2015) study found that increased depression did not predict a decrease in self-care management over time, although different self-care domains were examined. Heo et al. (2008) and Gallagher et al. (2011) found that depression was not associated with self-care engagement. It can therefore be assumed that depression has an impact on self-care decision-making, and, especially within the self-care maintenance and management domains, patients may struggle to learn about their diagnosis, perceive symptoms, and judge the severity of their symptoms.

2.8 Facilitators of self-care

2.8.1 Caregiver social support

Shahriari et al. (2013) showed that self-care behaviours in HF patients improved when support was available from a family member. Similarly, Gallagher et al. (2011) reported greater self-care management (p=0.002) when supported, as well as having the confidence to contact their health professionals sooner regarding symptom changes. Chuang et al.'s (2019) study reported that the presence of social support correlated positively with self-care maintenance and self-care management. In contrast, Heo et al. (2008) found that social support, when entered into the regression model, was not statistically significantly related to self-care behaviours. Surprisingly, Cocchieri et al. (2015) found that having support through a caregiver was associated with poor self-care engagement. Further research is required to explain this paradox, however, it may be explained by the increased comorbidities and the number of functionally compromised patients in this study.

2.8.2 Heart Failure knowledge

The association between HF knowledge and self-care was reported in Chuang et al.’s (2019) study, where increased knowledge regarding HF positively correlated with greater engagement in self-care maintenance and management. This was not a surprising finding, as patients who have been educated regarding their symptoms are expected to be able to relate increasing oedema and dyspnoea to worsening HF. However, it was also identified in the literature that having knowledge about HF is not sufficient on its own to change behaviour – a finding reported by Clark et al. (2009). Having greater HF knowledge had a positive impact on self-care in Heo et al.’s (2014) and Seid et al.’s (2019) studies; patients were 2.5 times more likely to be adherent to self-care than patients who had a poor understanding of HF.

2.9 Consequences of poor self-care

2.9.1 Medication and non-adherence

It is recognised that a major challenge to HF self-care is the use of “polypharmacy” (pharmacological and non-pharmacological), a treatment course which is necessary to control symptoms, halt the progressive nature of the syndrome, and resolve poor adherence to prescribed regimes. This has been linked to increased mortality in HF patients (Chung et al., 2006). Poor self-care was linked to medication non-adherence in Clark et al.’s (2009) study and (2014) systematic review. Further, the association between lack of social support and poor medication adherence was also recognised in Gallagher et al.’s (2011), Sayer’s et al.’s (2008) and Wu et al.’s (2013) studies. Interestingly, Wu et al. (2013) reported that patients who lacked support and were non-adherent to medication were 3.5 times more likely to experience a cardiac event compared to those who were adherent and had high levels of social support. Surprisingly, Cocchieri et al. (2015) identified that poor self-care maintenance and confidence was associated with taking fewer medications. This paradox is difficult to explain, without further research, but Cocchieri et al. (2015) did attempt to explain this association with the number of medicines being considered as a surrogate for the number of comorbid conditions.

2.9.2 Poor quality of life

The associations between self-care and health-related quality of life are inconsistent from the literature reviewed. Kessing et al.'s (2016) systematic review found that poor self-care was associated with increased psychological distress. Similarly, Kessing et al.'s (2017) later study found that poor self-care predicted poor overall health-related quality of life, as well as poor physical and emotional health. Auld et al. (2018) suggest that health-related quality of life in patients diagnosed with HF is associated with their level of engagement in self-care and, if performed well, it can improve physical and mental quality-of-life outcomes, suggesting the opposite if performed poorly. Specifically, increased self-care maintenance was associated with better quality of life in Buck et al. (2015). Whilst poor self-care management was not associated with health-related quality of life (Lee et al., 2015), Nesbit et al.'s (2014) and Seto et al.'s (2011) studies found no association between self-care and health-related quality of life.

Whilst the crucial role of perceived support and self-care has been identified in previous sections, the empirical research is still scant with respect to the exact contributions of caregivers in promoting patient self-care, as well as caregivers' determinants in contributing to patient self-care in HF. This highlights the need for further research to evaluate caregivers' contributions to self-care and their influence on their own and their partner's quality of life. More longitudinal studies are needed to examine whether self-care predicts patient and caregiver quality-of-life outcomes in heart failure, as well as UK studies that shift the cultural imbalance identified in the literature reviewed (Table 2).

2.10 Health-related Quality of Life in Heart Failure Patients and Caregivers

2.10.1 Introduction

A total of 22 patient and caregiver health-related quality-of-life studies were reviewed in this section. This included nine cross-sectional studies, one RCT, ten longitudinal studies, one meta-analysis and one narrative review (Table 3).

Of the ten longitudinal studies, selection bias was found in four of the studies, as they failed to mention attrition and response rates. Bias was identified in two of the studies as a result of not addressing confounders. Further, selection bias was high in thirteen of the studies, as the authors failed to mention the percentage of missing data. Twelve of the studies examined patients' quality of life, two studies examined caregivers' quality of life and eight of the studies examined patients' and caregivers' quality of life. Unlike the caregiver burden and support and self-care studies, a greater variation in the country of origin was found within the quality-of-life literature. The studies presented in Table 3 originate from the USA, Canada, the Netherlands, Sweden, Greece, Taiwan and the UK. Heterogeneity was found in the instruments being used across the studies, each of which examined quality of life in patients and caregivers, which limited comparability.

Consistent with other HF studies, most patients were male, and they ranged in age from 60–72 years. Similarly, the caregivers were predominantly female, and they ranged in age from 60–67 years. Variation was found in the sample size of the patient and caregiver studies, which ranged from 50–661. Only two of the studies documented a sample size calculation (with one of the studies basing their sample size on previous research), which limits the overall statistical power for these studies. Convenience sampling was the main sampling method used within the studies, although in two of the studies, the sampling method was unclear.

Overall, pertinent clinical data were reported in most of the studies. NYHA classification was reported in 15 of the studies, indicating patients' marked limitation in physical activity. The EF was reported in 13 of the studies and ranged from moderate to severe left ventricular dysfunction.

Table 3: Health-related Quality of Life (Patient and Caregiver)

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
Årestedt et al. (2013)	Cross-sectional, Sweden *n* = 349 patients	Aim: To investigate whether age, gender, cohabitation, finances, and disease severity are associated with social support in older adults and whether social support is associated with HRQOL. Tools: MLwHFQ; SF-12 Health Survey; Social Interaction Schedule.	Male gender, living alone, finances and high disease severity (NYHA) were associated with lower support. Social support was largely associated with HRQoL, particularly emotional HRQoL.	Increased number of non-participants. The use of self-reported questionnaires was used, which introduces reporting bias.
Audi et al. (2017)	Cross-sectional, Athens, Greece	Aim: To identify the factors affecting HRQOL in hospitalized HF patients.	Patients not receiving anxiolytics had lower QOL, compared to patients who received them. Patients with prior hospitalization had lower QOL. Similar results were	The cross-sectional design prevented determination of causal relationships and the use of convenience sampling was a limitation.

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
	n = 300 patients	Tools: MLwHFQ.	observed for physical and mental QOL.	
Gallagher et al. (2019)	Cross-sectional, London, UK *n* = 163 patients	Aim: To invesitgate the acceptability and feasibility of using HRQOL instruments in HF clinics and to examine the impact of patient characteristics on HRQOL. Tools: MLwHFQ; Kansas City Cardiomyopathy Questionnaire; E1-5D-3L.	The patients' HRQOL significantly correlated with NYHA classification. Within each of the NYHA classes, there was a range of HRQOL scores. The study found no association between LVEF, BNP or renal function and HRQOL for any of the QOL tools used.	A convenience sample was used within an urban population in a single tertiary centre, which limits the generalisability of the results.
Heo et al. (2014)	Cross-sectional, USA *n* = 71 patients	Aim: To examine types of social support associated with physical, depressive symptoms and HRQoL in patients with HF and the mediating effects of	Emotional support was significantly related to physical symptoms and depressive symptoms in the general linear model analysis (R^2 = .568 and 540, respectively, *p* = .003 and *p* = .009, respectively.	Most patients were Caucasian and social support and its relationships to symptoms and HRQOL may be different to other races. The quality of the social relationship was not measured. All the interactive effects (i.e., social support, physical and depressive symptoms) could not be

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
		symptoms on social support and HRQOL. Tools: MLwHFQ; Symptom Status Questionnaire-HF; Patient Health Questionnaire (PHQ-9).		assessed due to the small sample size.
Hoekstra et al. (2013)	Prospective Longitudinal, Netherlands *n* = 661 patients	To examine whether self-rated disease-specific and generic quality of life predicts long-term mortality. Tools: Ladder of Life; RAND 36; MLwHFQ.	Physical and depressive symptoms mediated the relationship between emotional support and HRQoL.	The follow-up period for assessing mortality was a limitation; 3 years was considered relatively short. Only hospitalised HF patients were included in the study, which limits the generalizability of the results.
Nesbitt et al. (2014)	RCT REMOTE HF, Northern California	Aim: To test an education and counselling intervention to	Measures of self-care behaviours, literacy and barriers to accessing healthcare had no influence on quality of life. A very weak association between self-care and	There was no urban control group – only targeting a rural population. The population consisted of mainly white patients. The recruitment from the

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
	n = 612 patients	improve self-care in HF patients. Tools: MLwHFQ; Charlson Comorbidity Index; EHFSCBS; Control Attitude Scale; Brief Symptom Inventory.	quality of life was found. Higher NYHA classification, depression/ anxiety and socio-demographic factors were associated with reduced QOL.	three rural sites may not be reflective of all the rural populations in the US
Saunders (2009)	Cross-sectional, Southeast Michigan, USA *n* = 50 caregivers	Aim: To identify indicators of and perceptions of caregiver burden, depression, patient disease severity and HRQOL. Tools: Centre for Epidemiological Studies Short Depression Scale (CES-D10); Caregiver Reaction Scale; QoL Index.	Caregiver burden explained 62% of the variance in caregiver HRQL, adjusted $R^2 = 0.58$, $F(5, 44) = 14.54$, $p<0.01$. Caregiver depressive symptoms explained an additional 2% of variance in HRQL. Significant indicators of caregiver HRQL were in caregiver health and caregiver finances.	A number of recognised limitations were evident: non-random sampling, cross-sectional design, small sample size, and self-report data.

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
Hu et al. (2016)	Cross-sectional descriptive design, Southwest China *n* = 226 patients *n* = 226 caregivers	Aim: To investigate quality of life and the factors (characteristics of patients and caregivers, caregiver burden, self-efficacy, and social support) related to QOL in HF. Tools: Social Support Rating Scale; Zarit Burden Interview Scale; General Self-Efficacy Scale.	Multivariate analysis showed higher NYHA class, more caregiving hours per day, more readmissions in the last 6 months, higher caregiver burden, and lower social support were associated with poorer physical and mental QOL. Lower self-efficacy was also associated with poorer physical QOL.	The cross-sectional design makes it difficult to determine causal relationships. A convenience sample from three hospitals may limit the representativeness of the sample. The study did not address coping strategies or emotional distress of caregivers.
Grigorovich et al. (2017)	Longitudinal cohort study, Toronto, Canada *n* = 50 patients	Aim: To examine changes in caregivers' well-being over time and to identify patient and caregiver factors associated with positive and	Caregivers' negative and positive emotions did not change significantly over time. Depression symptoms were associated with higher participation restriction in caregivers. Positive affect was associated with more personal gain and higher social support. Patients' health-related	The duration of the follow-up period may not have been sufficient to detect emotional outcomes. Race or ethnicity were not considered in relation to caregivers' approaches to care and changes in health

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
	n = 50 caregivers	negative QoL outcomes. Tools: Caregiver Completed the Centre for Epidemiological Studies Depression Scale; Caregiver Impact Scale; Caregiver Assistance Scale; Medical Outcomes Study Social Support Survey. Patients completed: MLwHFQ.	quality of life and their behavioural and psychological symptoms were not significantly associated with caregivers' emotional outcomes.	outcomes. Relatively small sample size of patients and caregivers.
Bidwell et al. (2017a)	Meta-analysis Oregon, Portland 15 studies	Aim: To quantitatively synthesize the relationships between caregiver well-being and patient outcomes.	Higher caregiver strain was associated with greater patient symptoms (Fisher's *z* = 0.22, *p*<0.001) and was significantly associated with lower patient quality of life (Fisher's *z* = -0.36, *p*< 0.001)	The studies used differing measures (i.e., psychological distress and QoL outcomes). This resulted in substantial heterogeneity in the analysis. The literature pre-dominantly focused on patients or caregivers as a group. Some

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
				relevant studies may not have been included in the analysis.
Kessing et al. (2017)	Longitudinal, Tilburg, Netherlands *n* = 459 patients Follow-up at 6, 12 and 18 months	Aim: To examine the association of (changes in) self-care with HRQOL while adjusting for psychological distress. Tools: European Self-care Behaviour Scale; MLwHFQ.	Greater self-care was significantly associated with better disease specific HRQOL in patients with HF, which was fully accounted for by depression and partially accounted for by anxiety and Type D personality.	There was the risk of systematic biases in self-reporting of self-care. There was a small percentage of missing data. No conclusions can be drawn regarding the causality of relationships as a result of the observational nature of the study design.
Chung et al. (2013)	Cross-sectional, USA *n* = 362 patients	Aim: To determine the nature of the relationships (direct, mediator and moderator) among depressive symptoms, social support and quality. of life in HF patients. Tools: Beck Depression Inventory; Perceived	Less social support and greater depressive symptoms independently predicted patients' poorer quality of life, having controlled for known confounding factors: age, gender, NYHA.	The cross-sectional nature limits the determination of causality. The MLwHFQ does not fully address depressive symptoms, which might be a significant contributor of the variance in the QoL in the study. The study also had a low participation rate, thus affecting the generalizability of the results.

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
		Social Support Scale; MLwHFQ.		
Goodman et al. (2013)	Longitudinal study, London, UK *n* = 88 patients Follow-up at 2 and 6 months	Aim: To examine the association between illness perception, self-care behaviour and quality of life in patients admitted to hospital with HF. Tools: The Revised Illness Perception Questionnaire; the SCHFI; HAD and MLWHFQ.	HF symptoms improved over time (MLWHFQ co-efficient (95% CI) –0.915 (-1.581–0.250) $p<0.001$). Patients believed that many causes of their illness were outwith their control. Self-care maintenance (daily weighing) improved over time but not self-care management. Self-care confidence was lower in those who reported negative emotional impact of their illness, but higher in those who had high scores on illness coherence.	Observational study, which only allows for reporting of associations and changes over time. Relatively small sample size, which limited the type of analysis done. Recruitment was problematic due to the high symptom burden and mortality associated with HF, giving rise to the high attrition rate at follow-up.
Hwang et al. (2014)	Cross-sectional correlational, Taiwan *n* = 133 patients	Aim: To understand the effects of socio-demographics, disease severity, physical symptoms and depression on QOL of HF patients.	Age, HF duration, NYHA, as well as physical symptoms and depression significantly impacted on HF patients QOL.	The authors did not acknowledge the studies limitations, i.e., cross-sectional design and the use of convenience sampling. A further limitation was the use of HF patients attending an outpatient clinic, which is not representative of the wider HF population.

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
		Tools: MLwHFQ; Pulmonary Function Status and Dypsnea Questionnaire (PFSDQ-M); and the BSI Depression subscale.		
Pressler et al. (2013)	Longitudinal, Michigan, US *n* = 63 patients *n* = 63 caregivers Follow-up at 4 and 8 months	Aim: to evaluate changes in caregiver burden and differences in perceptions between caregivers of patients with high and low symptoms based on NYHA. Tools: The Oberst Caregiver Burden Scale, The Brief Symptom Inventory Anxiety Subscale, The Bakas Caregiving Outcomes Scale; Charlson Comorbidity Index,	Caregivers showed significant changes in perceived time spent on, and difficulty of, caregiving tasks, indicating greater caregiver burden Caregivers of patients with high symptoms are in need of interventions to reduce time and difficulty of caregiving tasks and improve their physical QoL.	Relatively small sample size; 16% of caregivers did not complete the data collection at 8 months. Changes to patients' health status was not measured in the study over time. Caregivers' perceptions on the quality of care they provided was not measured. Multiple statistical tests were used which could have impacted or influenced the results.

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
		Family Assessment Device and SF-12.		
Iqbal et al. (2010)	Longitudinal, Edinburgh, UK *n* = 179 patients *n* = 131 caregivers	Aim: Assessment of factors affecting HRQOL in CHF patients and caregivers and the impact on clinical outcomes. Tools: EQ-5D Generic QOL; and MLwHFQ.	Patients' overall QOL was independently predicted by NYHA, lack of an informal carer, and socio-economic deprivations. Caregivers' overall QOL was independently predicted by severity of HF, anaemia and a cancer comorbidity.	Relatively small sample and lack of biochemical markers including BNP. Only patients with LVSD were included, which limits the generalizability of the findings to other HF patients, i.e., patients with preserved systolic dysfunction.
Pressler et al. (2009)	Prospective Longitudinal, Indiana, US *n* = 63 patients *n* = 63 caregivers	Aim: To determine predictors of family caregiver outcomes among caregivers of patients with HF. Tools: Bakas Caregiving Outcome Scale; SF-12 Health Survey; The Family Assessment Device; Control Attitudes Scale; Patient	Moderately poor physical and emotional health was found in the caregivers. Caregivers' medical conditions were predictors of their physical health-related QOL; depressive symptoms were predictors of caregivers' emotional quality of life.	The use of convenience sampling was a limitation, and the small sample size. A further limitation was the lack of matched patient–caregiver pairs.

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
		Health Questionnaire – 8; Brief Symptom Inventory.		
Whittingham et al. (2013)	A narrative review of 16 quantitative studies, UK Patient–caregiver dyads and informal carers	Aim: To explore what impacts caregiver burden and QoL in caregivers of patients with HF; to highlight the positive and negative aspects associated with caregiving. Tools: Beck Depression Inventory; SF-36; Zarit Burden Scale; European QoL, HADs; Cantril's Ladder of Life, Brief Symptom Inventory; Centre of Epidemiological	The review highlighted that HF caregivers face many challenges, such as managing unstable patients, dealing with frequent hospital admissions, which impacts on them physically and emotionally. External factors influence caregiver burden, i.e., patients' NYHA and recent hospital discharge.	The search strategy was a recognised limitation; because of limited time and resources, hand-searches were not completed and, as a result, some studies may have been missed. The studies predominantly included measures that assessed the negative aspects associated with caring for HF patients.

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
		Studies Short Depression Scale.		
Holland et al. (2010)	Longitudinal, UK *n* = 293 patients Follow-up at 6 months	Aim: To test whether patients' self-assessment of functional status by NYHA class predicts hospital admissions, quality of life, and mortality Tools: EQ-5D13 and Minnesota Living with Heart Failure Questionnaire (MLHFQ).	Higher NYHA class at baseline predicted patients' worse quality of life at 6 months' (*p* = .002 for MLHFQ; *p* = .047 for EQ-5D) and was associated with higher mortality rate (adjusted hazard ratio 1.84; 95% CI 1.10–3.06; *p* = .02).	The follow-up period was relatively brief (limited to 6 months). A further limitation was in relation to the study measure (self-assessed NYHA): it was not validated against objective measures of functional capacity.
Trivedi et al. (2016)	Longitudinal Feasibility study, USA *n* = 17 patients *n* = 17 caregivers	Aim: To develop and test a pilot programme that targets the needs of self-management support among HF patients and their caregivers.	Poor QOL was reported at baseline for patients and there was clinically significant depressive symptoms and inadequate self-care. The quality of life of patients and caregivers declined over time.	The main limitation was a feasibility study and the small sample size, limiting a reliable change in scores over time. The results may not be generalizable to non-veteran patients or non-heterosexual couples.

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
	Follow-up period not clear	Tools: Health Behaviour Change Model; Semi-structured interviews.		
Tsai et al. (2014)	Longitudinal study, Taiwan *n* = 122 patients Follow-up 3 at 3 and 12 months	Aim: To determine individual symptom trajectory effects of dyspnoea and fatigue on disease outcomes. Tools: Modified Pulmonary Functional Status and Dyspnoea Questionnaire; MLwHFQ.	Dyspnoea-fatigue trends were identified as “constant good”, “recovery”, and “getting worse”. The cumulative incidence of a first cardiac event in both dyspnoea and fatigue groups had similar results. The QOL score for “getting worse” was significantly higher than that of “constant good” and “recovery” groups. Increased fatigue over time was related to a worse event-free survival when compared to lower and stable levels of fatigue.	A limitation was in relation to the time-points used for data collection; may not be sufficient to confirm the symptom trajectory. A significant proportion of quality-of-life data was missing at one or two measurement points; this resulted in a total of 68 patients’ data being analysed in the study from an initial sample of 122.
Hooley et al. (2005)	Cross-sectional study, Canada *n* = 50 patients *n* = 50 caregivers	Aim: To describe caregiver burden and depressive symptoms and correlates with patients’ and caregivers’ QoL and	The mean patient quality-of-life score was 35 and 26% had a BD I-II score > 10. The mean ZCB score was 16 and the MLWHQ questionnaire, BDI-II and Zarit CB scores were all associated with lower ejection fraction, need for	The sample consisted of only stable HF patients and caregiver pairs. The sample was relatively small. The sample consisted of only out-patients with family caregivers; therefore, the results do not apply to patients who do not require

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
		depression in a HF outpatient clinic. Tools: Patients and caregivers completed the Beck Depression Inventory (BDI); Patients also completed the MLwHFQ and caregivers completed the Zarit Burden Interview questionnaire.	hospitalisation, increased number of medication and comorbidities. Caregiver burden was correlated with both caregiver BDI-II and patient BDI-II. Death or hospitalisation at 6 months was associated with greater caregiver burden and depressive symptoms. Caregivers of patients diagnosed with HF experience high caregiver burden.	supportive care. Confounding variables such as medications were not assessed. A further limitation was in relation to the cross-sectional design.

2.11 Health-related quality of life in HF patients and caregivers – review and analysis

Predictors of patients' health-related quality of life and predictors of caregivers' health-related quality of life (with sub-themes) emerged as key issues in the HF quality of life literature.

2.11.1 Health-related quality of life definition

According to Nesbitt et al. (2014), quality of life is the subjective perception of an individual's general health status, which encompasses physical, mental and emotional aspects, which will be the focus of the research reported in this thesis. In addition to these characteristics, clinical and social support have also been recognised as being influential in affecting quality of life (Gallagher et al., 2019). Within the literature, a number of well-validated generic and disease-specific quality-of-life tools have been developed for HF (Table 3), but there appears to be no consensus on the most appropriate one to use in clinical practice.

2.12 Predictors of patients' health-related quality of life

2.12.1 Physical symptoms

The association of physical symptoms in HF (i.e., dyspnoea, oedema, chest pain and difficulty sleeping) was recognised in Heo et al.'s (2014) and Hwang et al.'s (2014) studies, with more physical symptoms significantly predicting poorer health-related quality of life. Similarly, Tsai et al. (2014) highlighted that the presence of dyspnoea correlated significantly with patients' overall poorer health-related quality of life, and Iqbal et al. (2010) reported that greater symptoms predicted worse overall health-related quality of life. The physical symptoms reported by Audi et al. (2017) were associated with worse quality of life in patients who had been living with HF for 6–10 and 11–15 years, respectively – a similar finding to that identified in Hoekstra et al.'s (2013) study (Table 3). The association between time and poorer health-related quality of life is not surprising, as it would be logical to assume that, as time passes, the patient with HF will become more symptomatic and may be diagnosed with additional comorbidities.

2.12.2 NYHA classification

The association between NYHA classification was recognised in five of the studies presented in Table 3. Iqbal et al. (2010), Nesbitt et al. (2014) and Gallagher et al. (2019) reported that increased NHYA independently predicted worse health-related quality of life, whilst Heo et al. (2014) reported that NYHA classes II and III specifically were significantly associated with poor health-related quality of life. Unsurprisingly, NYHA classification III was a predictor of subjective health-related quality of life, as patients in this category may experience a marked limitation in physical activity. Holland et al.'s (2010) RCT found that NHYA classification was a significant predictor of worse health-related quality of life at 6 months, and, interestingly, that patients' self-assessment of their NYHA classification was also a predictor of worse health-related quality of life, as measured by the MLwHFQ total, physical and emotional scores.

2.12.3 Mental health and anxiety

The association between mental health and worse health-related quality of life was recognised in six of the studies presented in Table 3. Heo et al. (2014) and Nesbitt et al. (2014) reported that anxiety and depression was significantly associated with overall health-related quality of life, as measured by the MLwHFQ total score, and Chung et al.'s (2013) study found that greater depressive symptoms independently predicted poorer health-related quality of life. Audi et al. (2017) and Hwang et al. (2014) found that time since diagnosis predicted worse mental and emotional health-related quality of life, with Hwang et al. (2014) reporting depression as a dominant predictor of worse overall health-related quality of life. Clinically significant depressive symptoms were associated with worse health-related quality of life (Trivedi et al., 2016), with a statistically significant deterioration in mental health-related quality of life at follow-up.

2.12.4 Social support

The association between perceived social support and patients' health-related quality of life was reported in four studies (Table 3). Årestedt et al. (2013) reported that the presence of social support for patients was generally high and was associated with improved health-related quality of life, specifically in the emotional domain. Similarly, Iqbal et al. (2010) reported that the presence of a caregiver independently predicted improved health-related quality of life. Conversely, Chung et al.'s (2013) study reported that less social support independently predicted poorer health-related quality of life. Whilst emotional support was significantly correlated with health-related quality of life in Heo et al.'s (2014) study, when physical and depressive symptoms were added to the regression model, it was no longer significant, suggesting that physical and depressive symptoms mediated the relationship between emotional support and improved health-related quality of life.

2.13 Predictors of caregivers' health-related quality of life

2.13.1 Patients' physical symptoms and comorbidities – impact on caregivers

The association between patients' symptoms and comorbidities on caregivers' health-related quality of life was reported in six of the studies presented in Table 3. Iqbal et al. (2010), Pressler et al. (2009) and Hu et al. (2016) reported similar findings, in that the severity of the patients' HF and presence of comorbidities were independently linked to lower health-related quality of life in the caregiver. In contrast, patient disease severity was not a significant predictor of caregiver health-related quality of life in Saunders' (2009) study. Specifically, the physical health of the patient was associated with poorer health-related quality of life in caregivers in Pressler et al.'s (2013) study and in Whittingham et al.'s (2013) narrative review. These findings are not surprising, as, generally, one would expect a change in caregivers' health-related quality of life when caring for someone with advanced disease and functional limitations. Conversely, Luttick et al. (2009) found no statistically significant effects of patients' physical functioning and role limitations on the caregivers' health-related quality of life. Not surprisingly, the caregivers did report lower general health, when compared to the partners of healthy individuals.

2.13.2 Patient predictors of caregivers' mental and emotional health

Four of the studies presented in Table 3 focused on caregivers' mental and emotional health. Hu et al. (2016) found that patients' NYHA classification and unstable symptoms were associated with the caregivers' poorer mental health-related quality of life, and Hooley et al. (2005) found that patient depression was associated with poorer caregivers' emotional health. In contrast, Bidwell et al.'s (2017) meta-analysis reported that patient symptoms and quality of life were not significantly associated with caregivers' psychological distress. Similarly, Grigorovich et al. (2017) found no association between patients' behaviour and psychological symptoms on the caregivers' emotional health-related quality of life, which may be explained by the short follow-up period.

2.13.3 Caregivers' predictors of health-related quality of life

Five of the studies presented in Table 3 focused on caregivers' physical, mental and emotional health-related quality of life. Caregivers with greater illness and comorbidities had lower health-related quality of life (Saunders et al., 2009) and caregivers' greater comorbidities at baseline predicted their significantly worse physical health-related quality of life (Pressler et al., 2009, 2013). It may be that the caregivers in these studies neglected their own health by missing health checks, avoiding taking their medication and not sleeping properly. However, Grigorovich et al. (2017) found that the caregivers' emotional well-being impacted on their mental health-related quality of life, more than any patient-related factors, whilst Pressler et al. (2009) reported that caregivers' depression was a statistically significant predictor of their emotional health-related quality of life at follow-up. Hu et al. (2016) found that increased caregiver burden was associated with poorer physical and mental health-related quality of life in caregivers. Further, caregivers' time spent on providing care was significantly associated with their emotional health-related quality of life (Pressler et al., 2013).

In summary, the study findings presented in Table 3 underscore the need to examine further patients' and caregivers' physical, mental and emotional health-related quality of life. In addition, the patients' and caregivers' relationships ought to be carefully considered, given the interdependence and the possibility that the reactions (emotions) of caregivers may serve to enhance or impede the patients' quality of life and vice versa. Thus, simultaneous exploration of patient and caregiver quality of life, informed by the study of patient–caregiver pairs (dyads), is both necessary and justified.

2.14 Heart Failure Dyads

2.14.1 Introduction

A total of 19 HF patient and caregiver dyadic studies were reviewed in this section. These included 1 meta-analysis, 1 integrative review, 13 cross-sectional studies, 2 longitudinal studies, and 2 qualitative studies (one of which was longitudinal). The studies examined in Table 4 were largely carried out in the USA and Italy, which highlights the existence of a clear cultural imbalance regarding countries publishing in the field.

Selection bias was minimised in one quantitative longitudinal study, as the authors considered and clearly discussed the attrition and response rates. Lack of consideration to confounders was recognised in four of the studies, which could give rise to confounding bias. Further, selection bias was high in thirteen of the studies, as the authors did not address the percentage of missing data. Heterogeneity was found in the instruments being used across the studies, each of which examined patient and caregiver dyads, which limited the overall comparability of findings between studies. Only three of the dyadic studies used the Actor Partner Interdependence Model (APIM) to determine how outcomes are influenced by both members of the dyad, i.e., patient and spousal caregiver. This suggests the need for further studies that explore specifically the complex interactions between patients and their caregivers, using such techniques to enhance and develop our understanding of dyadic relationships.

Consistent with other HF studies, most patients were male, and the mean ages ranged from 61–75 years. Similarly, the caregivers were predominantly female, and mean ages ranged from 56–69 years. Variation was found in the sample size of patients and caregivers, which ranged from 19–515. Only four of the studies mentioned their sample size calculation, which increases their overall statistical power. Convenience sampling was the main sampling method used, which introduces the risk of participation bias and questions the representativeness of the sample to the entire population. However, most authors recognised the limitations of using convenience sampling.

Overall, pertinent clinical data were reported for the patients in most of the studies. NYHA classification was reported in 16 of the studies, with most patients falling within NYHA classification III, indicating marked limitation in physical activity. The EF was reported in eight of the studies and ranged from moderate to severe left ventricular dysfunction, although one study demonstrated preserved systolic function. Only two of the studies reported caregivers' clinical characteristics.

Table 4: Heart Failure Dyads

Author/Year	Study Design/Country	Study Characteristics	Findings/Results	Limitations
Agren et al. (2011)	Cross-sectional study, Sweden *n* = 135 patients *n* = 135 caregivers (dyads)	Aim: To compare HRQOL, depressive symptoms, perceived control and knowledge in patients with HF and their partners (2). To compare HRQOL and QALY weights in their partners. Tools: SF-36; Beck Depression Inventory; Control Attitude Scale; European Heart Failure Behaviour Scale.	Patients had lower HRQOL in all dimensions (*p*<0.001) except for mental health and lower QALY weights, compared with their partners (*p*<0.001). Mental health scores were lower in partners compared with age and sex matched references (*p*<0.001). The study confirms that partners of patients with HF have markedly diminished mental health.	No causal conclusions can be drawn because of the cross-sectional design and relatively small sample size. Potential bias was introduced as data collection spanned over 4 years. There was no guarantee that the dyads completed the questionnaires independently of each other. The validity and reliability of the knowledge scale was questionable. There was an unequal sex distribution between men and women (patients and partners).
Chung et al. (2009)	Cross-sectional descriptive study, Kentucky, USA *n* = 58 patients	Aim: To examine the effects of patients' and partners' depressive symptoms and anxiety on QoL in	Actor effects (*p*<0.001) were identified in both members of the dyad for depressive symptoms, indicating that mental health effects both members equally and only a partner effect (*p*<0.05) of patients on QoL.	Marital quality and perceived social support were not measured, although marital quality is a known predictor of quality of life but was not part of the study's aim. The study was cross-sectional which does not allow for any inferences of causality

	n = 58 caregivers (dyads)	patient-spousal dyads. Tools: The Actor-Partner-Interdependence Model (APIM); MLwHFQ; Brief Symptom Inventory.		to be drawn between psychological distress and QoL. It is unknown whether spousal caregivers' distress impacts on patients' long-term QoL. The study sample size was also relatively small, and only the MLwHFQ total score was used.
Durante et al. (2019)	Cross-sectional study, Italy *n* = 505 patients *n* = 505 caregivers	Aim: To identify caregiver and patient predictors of caregiver burden in HF, to evaluate whether caregiver contribution to HF self-care maintenance and management increases caregiver burden. Tools: Charlson Comorbidity Index; Mini Mental State Exam; Caregiver Burden Index; Caregiver Contribution to Self-	Caregiver predictors of increased levels of caregiver burden include being older, female gender, fewer caregiving hours and less social support. Patient predictors of increased caregiver burden were being older, better educated, less medication and higher quality of life. Caregiver contribution to self-care maintenance and management was not statistically significant.	A convenience sample from a cross-sectional study was used. Second, the generalisability of the study findings to other countries should be done with caution as it was conducted in only one European country.

		care Heart Failure Index.		
Cameron et al. (2017)	Cross-sectional study, Australia *n* = 25 patients *n* = 25 caregivers (dyads)	To examine whether HF patient–carer dyads who disagree about the division of illness management tasks (incongruent) experience poorer psychosocial health and self-care, than those who agree (congruent). Tools: Heart Failure Care Assessment Scale; Depression Anxiety Stress Scale; Self-Anchoring Stiving Scale; Revised Dyadic Adjustment Scale; Self-care Heart Failure Index; Caregiver Reaction Assessment Scale.	No significant differences were found between congruent (*n*=16) and incongruent (*n*=9) dyads in CHF illness management, although patients in incongruent dyads tended to have been diagnosed more recently. The authors conclude that HF dyads incongruence exists even for patients with relatively mild HF symptoms. The findings indicate that dyadic incongruence in illness management might not affect high-functioning heart failure patients or their carers.	Relatively small sample of (*n*=25) patient caregiver dyads. Dyads were predominantly in a patient-spousal relationship, which precludes generalisations of the study results being made to others, i.e., partners, children and other family members.
Vellone et al. (2014)	Cross-sectional study, Italy	Aim: To analyse the way adults with HF and their caregiver	Both actor and partner effects were found for patients and caregivers. Higher self-care was associated with	Limited by cross-sectional nature of the study. Although the analysis was conducted to identify the relationship

	n = 138 patients *n* = 138 caregivers (dyads)	influence each other's self-care behaviours and quality of life. Tools: Self-care Heart Failure Index/Caregiver Contribution to Self-Care; SF-12.	their lower physical QoL in both members of the dyad (*actor effects*). Greater self-care maintenance in patients was associated with improved mental health in the caregiver (*partner effects*).	effect. The true dynamics are difficult to discern without the use of longitudinal studies. A further limitation was the lack of power calculation before data collection.
Vellone et al. (2015)	Cross-sectional study, Italy *n* = 515 patients *n* = 515 caregivers	Aim: To describe the caregivers' contribution to HF patients' self-care and identify its determinants. Tools: CCSCHFI.	The caregivers' contribution to self-care was low in weight monitoring, and physical activity, but higher in checking ankles, advising on low salt foods and medicines compliance. Caregiver confidence in the ability to contribute to patient self-care explained a significant amount of variance in the caregiver's contribution.	Whilst the study was a multi-centre study, a convenience sample was used and the design was cross-sectional, allowing only for the correlates or determinants of self-care. Generalisability to other countries should be used with caution as caregivers in the Italian population may have different cultural views on caregiving than other countries.
Lyons et al. (2015)	Cross-sectional study, Italy *n* = 329 patients	Aim: To identify individual and dyadic determinants of self-care confidence in HF dyads.	Patient and caregiver levels of confidence were significantly associated with > patient reported relationship quality and better mental health of the caregiver. Patients' greater self-care confidence was associated with being female, non-spousal caregiver dyads, poor	The cross-sectional design limits the discussion relating to directional effects. It is unclear whether the results will generalise beyond the Italian population. The patient sample was relatively healthy, which

	n = 329 caregivers (dyads)	Tools: Self-care/Caregiver Contribution to Self-Care; Mini Mental Sate Exam; MLwHFQ; SF-12; COPE Index; Caregiver Burden Inventory.	caregiver health, and low levels of caregiver burden. Caregiver gender was more balanced compared to other studies reporting a higher percentage of female caregivers.	resulted in variability in the levels of strain experienced.
Kitko et al. (2015)	Longitudinal Qualitative study, USA *n* = 100 patients *n* = 100 caregivers (dyads)	Aim: To determine the prevalence of incongruence between HF patient–caregiver dyads. Tools: Semi-structured interviews.	47 dyads were found to be incongruent. Three major themes were identified: illness management; healthcare issues; and end-of-life care. Incongruent dyads reported more issues relating to mental health and distress individually and within the dyad.	Limitations include racial and ethnic homogeneity; the sample consisted mainly of non-Hispanic, Caucasian participants, which limits the generalizability of study findings to wider ethnic groups. The semi-structure interview did not include questions relating to relational quality, which would have enabled a more in-depth analysis of the dyad.
Lum et al. (2014)	Cross-sectional study, USA *n* = 19 patients *n* = 19 caregivers	Aim: To determine whether relationship quality is associated with caregiver benefit/burden and the influence of depression.	Relationship quality was positively associated with caregiver benefit (r =0.45, p =0.005) and negatively associated with burden (r = -0.80, p=<0.0001) and depression (r = -0.77, p = 0.0001).	The main limitation was the small sample size, which prevented control of potential confounders, i.e., age, number of caregiving hours and depressive symptoms. A further limitation was the cross-sectional

		Tools: Mutuality Scale; Zarit Burden Inventory; Benefit Finding Scale; Patient Health Questionnaire.		design, which prevents causality of relationships between variables.
Bidwell et al. (2017a)	Meta-analysis Portland, OR, USA 15 studies	Aim: To quantitatively synthesize the relationships between caregiver well-being and patient outcomes.	Higher caregiver strain was associated significantly with greater patient symptoms (Fisher's z = 0.22, *p*<0.001) and higher caregiver strain was associated significantly with lower patient quality of life (Fisher's z = -0.36, *p*< 0.001)	There was a lack of integrated studies that used differing measures (i.e., psychological distress and clinical outcomes). This resulted in substantial heterogeneity in the analysis. There was an overall lack of dyadic studies; the literature predominantly focused on either patients or caregivers. Some relevant studies may not have been in the analysis.
Bidwell et al. (2017b)	Secondary analysis of subset of data with longitudinal follow-up, USA Patients and Caregivers followed up at 1 year	Aim: To quantify the influence of patient and caregiver characteristics of patient clinical event risk. Tools: Caregiver Burden Inventory; SF-12 MCS; Mini	Higher caregiver strain in the caregiver, caregiver improved mental health, as well as increased caregiver contributions to HF self-care maintenance were statistically significantly associated with patients' better event-free survival. In addition, patients' worse functional class and increased caregiver contribution to self-care manage-	The relatively small sample size limited the number of known predictors of clinical event risk that could be included. The self-report data may not reflect the reality of the actual behaviours. The single-country sample limits the generalisability of the results outside of Italy.

		Mental State Exam; SCHFI; CCSCHFI.	ment were associated with worse patient-event free survival.	
Bidwell et al. (2015)	Cross-sectional study, USA *n* = 364 patients *n* =364 caregivers (dyads)	Aim: To identify determinants of patient and caregiver contribution to self-care. Tools: SF-12; MLwHFQ; Barthel Index; Mini Mental State Exam; Caregiver Burden Inventory; Caregiver Perceived Social Support; Self-care/Caregiver Contribution to Self-care of Heart Failure Index.	Both patients and caregivers reported low levels of HF self-care maintenance and management behaviours. A range of significant individual and dyadic determinants were identified, i.e., gender, QoL, burden, cognition and hospitalization, HF duration and relationship quality. For patients, male gender and higher caregiver physical QOL were associated with worse self-care management. For caregivers, greater patient comorbidities was associated with fewer contributions to patient self-care management, where better caregiver perceived social support, better caregiver reported relationship quality were all associated with greater contributions to patient self-care management. Multi-level dyadic analysis was used.	The cross-sectional data prevents conclusions being drawn about directionality and cause of relationships. Only caregivers who attended the appointment with patients were asked, limiting the recruitment of the caregiver population. The sample was limited to a single European country, which limits generalisability to other countries.
Hooker et al. (2018)	Cross-sectional study, USA *n* = 99 patients	Aim: To examine associations between mutuality, patient self-care	The path model used demonstrated statistically significant *actor effects*, but no *partner effects.* The *actor effects* included: patients and	The sample consisted primarily of male patients and primarily female caregivers. Other limitations include the cross-sectional design and self-

	n = 99 caregivers	confidence and maintenance, caregiver confidence in and maintenance of patient care and perceived caregiver burden. Tools: Kansas City Cardiomyopathy Questionnaire; Zarit Burden Interview; Self-Care of Heart Failure/Caregiver Contribution to Self-Care of HF;15 Item Mutuality Scale, APIM.	caregivers with better mutuality were more confident in their self-care (*p*<0.05). Caregivers who had greater mutuality reported less perceived caregiver burden (*p* <0.01).	reported self-care. Further, it was unknown whether the patients and caregivers completed their questionnaires together, despite being asked to complete them independently.
Vellone et al. (2018)	Cross-sectional study, Italy *n* = 366 patients *n* = 366 caregivers (dyads)	Aim: To evaluate the influence of mutuality on patient caregiver dyadic self-care. Tools: Actor Partner Interdependence Model; Self-Care of Heart Failure/ Caregiver Contribution to Self-	The total mutuality scale had an *actor effect* on patient self-care maintenance as well as caregiver self-care confidence. The total mutuality score for patients showed a *partner effect* on caregiver's self-care management. The specific domains of the mutuality scale had different *actor* and *partner* effects on patient and caregiver self-care. The study concluded that interventions	Despite the multi-centre recruitment, the sample was restricted by the use of convenience sampling. Patients were excluded if they were in NYHA class I or had severe cognitive impairment. A further limitation was the cross-sectional design of the study which precludes causal relationships being identified.

		Care of Heart Failure; Mutuality Scale.	that focus specifically on mutuality of patient–caregiver dyads, may serve to improve patients' and caregivers' contribution to self-care.	
Sebern & Riegel (2009)	Cross-sectional study, USA *n* = 75 patients *n* = 75 caregivers (dyads)	Aim: To explore background characteristics associated with supportive relationships (2) the contribution of supportive relationships to HF self-care. Tools: Self-care of Heart Failure Index; SCI-3 Shared Care; Perceived Health Subjective Question	Patients who were older and perceived their health to be better reported greater shared care communication. Spousal dyads perceived greater reciprocity in the relationship than non-spousal dyads. Shared care decision-making was significantly related to HF self-care maintenance ($r = 0.65$) and self-care confidence ($r = 0.52$). Patient communication and reciprocity were related to self-care confidence. In caregivers, decision making ($r = 0.29$) contributed to self-care maintenance. Also, caregiver decision-making ($r = 0.37$) and reciprocity ($r = 0.35$) contributed to self-care confidence.	The main limitation was in relation to the relatively small sample size and cross-sectional design, which prevents the direction of the study relationships and causality to be assumed. The majority of participants were non-Hispanic white, therefore, evaluation with other ethnic groups is required.
Retrum et al. (2013)	Qualitative study, USA *n* = 17 patients	Aim: To examine for congruence and incongruence between HF patients and their family caregivers.	Congruence, incongruence and lack of communication between patients and caregivers were identified. The areas where this was problematic were in relation to illness management, perceived care needs,	The limited sample size prevented the examination of relationships between dyadic characteristics and congruence. The interview focused specifically on the needs of the dyad in relation to HF challenges, which

	n = 17 caregivers (dyads)	Tools: Interviews	future perspectives and end-of-life care. There was variation between the dyads: 7 dyads were congruent; 4 were incongruent; and 6 dyads demonstrated aspects of congruence and incongruence. Congruence affected areas of self-care, advanced care planning and communication.	may have resulted in the positive aspects that influence congruence being uncovered. Not all of the interview schedule was published.
Hooker et al. (2015)	Integrative Review, USA *n* = 13 articles.	Aim: To synthesise the literature on the associations between HF patient–caregiver relationship quality, communication and patient and caregiver health outcomes.	The review included cross-sectional, longitudinal and qualitative studies. The majority of studies were cross-sectional. One longitudinal study found that better relationship quality between HF dyads was associated with a reduced risk of mortality in patients. The other types of studies reported that better relationship quality and communication were related to reduced mortality, improved health status, reduced distress as well as lower levels of caregiver strain.	The studies all included married patient and caregiver dyads, which limits the generalisability to other non-spousal dyads. The studies included in the review had small sample sizes and the majority of patients were male.
Rohrbaugh et al. (2006)	Longitudinal follow-up, USA *n* = 189 patients	Aim: identify whether psychosocial factors, perceived social support and	Lower NYHA class was a strong predictor of patient survival during the 8-year follow-up. Patient survival was unrelated to age, education, race, religion, household income or	The limitations outlined in the study were in relation to all patients being married and tended to be younger on average than other community HF patients. As a result of only

	n =189 caregivers	marital quality have prognostic significant for morbidity and mortality after a HF diagnosis. Tools: Life Orientation Test; Hopkins Symptom Checklist; Videotaped marital discussion	years since diagnosis. In the Cox regression analysis, marital quality was strongly related to the 8-year patient survival. Patient gender and marital quality contributed more to the survival of females than males. Whilst marital quality was significant for both males and females, it only predicted 8-year survival in females. Only perceived self-efficacy was close to predicting the 8-year survival, whilst controlling for NYHA classification.	completing assessments at baseline, there was no way of identifying the dynamics of close relationships and their influence on cardiac health status.
Lee et al. (2015)	Cross-sectional study, Italy *n* = 509 patients *n* = 509 caregivers (dyads)	Aim: To characterise naturally occurring archetypes of patient–caregiver dyads with respect to their contributions to HF self-care (2) To identify patient–caregiver and dyadic level determinants thereof. Tools: Self-Care of Heart Failure Index; Caregiver Contribution Heart	3 distinct archetypes were identified: novice and complementary (24% of dyads); inconsistent and compensatory (56.4% of dyads); expert and collaborative (21.2% of dyads). Novice archetypes contributed to different aspects of self-care, which was generally poor. Inconsistent archetypes – caregivers reported greater contribution to self-care that patients were insufficient in. Expert archetypes were caregivers who contributed to all aspects of self-care and patients were generally the sickest.	The cross-sectional data and patients and their primary caregivers were relatively healthy compared to other studies of HF dyads, which limits the ability to comment on the changing nature of dyadic contributions to HF self-care and how these patterns may be related to quality of life or caregiver burden. Given the cultural differences in the Italian population, the results may not be generalizable to other countries.

		Failure Self-Care Index; Charlson Comorbidity Index; Mini Mental State Exam; MLwHFQ; SF-12; Caregiver Burden Inventory		

2.15 HF Dyads – review and analysis

Correlations and associations of supportive relationships in contributing to self-care and correlations and association between self-care and caregiver burden emerged as key issues in the HF dyad literature. Further, the association between self-care and quality-of-life outcomes emerged as key issues and underscored the interdependence of the patient–caregiver relationship.

2.15.1 Supportive relationships and patent and caregiver self-care: correlations, associations

The associations between supportive relationships and self-care were reported in five of the studies presented in Table 4. Sebern and Riegel (2009) reported that support and positive communication were significantly correlated with HF self-care confidence in the patient. Similarly, Lee et al. (2015) found that having the support of a caregiver resulted in greater patient engagement in their routine self-care behaviours, with caregivers assuming a greater role in responding to changes in heart failure symptoms. This indicates that the patients were unable to recognise and/or respond to symptom changes independently and required the support of their caregiver to manage the more challenging aspects of self-care. Bidwell et al. (2017b) also recognised the supportive role of the caregiver and reported that caregivers' engagement in the day-to-day self-care adherence behaviours (i.e., self-care maintenance) may be associated with a reduction in clinical events, whilst greater engagement in response to symptoms (i.e., self-care management) may be associated with episodes of HF decompensation. Lyons et al. (2015) found that greater caregiver perceived support was significantly associated with increased self-care confidence in the caregivers. Interestingly, Bidwell et al. (2015) recognised that perceived caregiver social support impacted on both members of the dyads' contribution to self-care, underscoring the unique relationship that exists between patients and their caregivers.

2.15.2 Self-care and caregiver burden: correlations, associations

The associations between self-care and caregiver contribution to self-care and caregiver burden were reported in four studies (Table 4). Bidwell et al. (2015) found no association between caregiver strain and either patient or caregiver contribution to self-care, and, similarly, Durante et al. (2019) found no association between caregiver contribution to self-care maintenance and management on caregiver burden. Of note, the lack of association between self-care and caregiver strain in Bidwell et al.'s (2015) study may be attributed to the measure used to assess caregiver strain, which had not previously been tested in the HF population. In contrast, Lee et al. (2015) found that caregivers contributed more to self-care than patients, which was associated with lower caregiver strain. One would have expected the opposite effect to have occurred, but Lee et al. (2015) suggest that lower strain was explained by better patient–caregiver relationship quality. However, the association between patient self-care confidence and lower caregiver strain reported by Lyons et al. (2015) was not surprising. It is logical to assume that, if patients have greater confidence in self-care, they will be actively participating in the self-care domains, which should lessen the involvement of the caregiver and subsequent strain.

2.15.3 Congruence/incongruence

The idea of HF congruence and incongruence was identified in three of the studies presented in Table 4. Cameron et al. (2017) reported that around one-third of dyads were incongruent, and these dyads were more likely to have had a recent diagnosis, compared to congruent dyads, who had been living with HF for much longer. Surprisingly, there were no statistically significant differences between congruent and incongruent dyads in terms of depression, anxiety, quality of life or self-care. These findings may be explained by the relatively stable sample of HF patients, who were predominantly in NYHA class II. It may be that incongruence has more of a significant impact on patients' and caregivers' physical and mental health in more advanced disease. Unlike Cameron et al. (2017), Kitko et al. (2015) found that incongruence was associated with poorer illness management, more health care issues and decisions about end-of-life care. Incongruent dyads reported greater mental health-related issues associated with increased conflict and stress. Likewise, Retrum et al. (2013) found that incongruence was associated with tension and distress in the caregiver, patient or both. However, their study also found that congruence was associated with collaborative working and solidarity, with both patients and caregivers agreeing on aspects relating to advanced care planning and self-care.

Notably, the patients in both Kitko et al.’s (2015) and Retrum et al.’s (2013) studies reported more symptoms than did Cameron et al.’s (2017).

2.16 Interdependence in patient–caregiver dyads

2.16.1 Self-care and quality-of-life outcomes in patient–caregiver dyads (APIM)

Associations between self-care and quality-of-life outcomes using the APIM were found in only one study (Table 4). Vellone et al. (2014) found both *actor* and *partner effects* for self-care and caregiver contribution to self-care on their own and their partner’s quality of life. Patients’ higher self-care maintenance and management were associated with their lower physical quality of life (*actor effects*). Only increased caregiver contribution to self-care maintenance was associated with their lower physical quality of life (*actor effect*). Only one *partner effect* was found for caregivers’ increased self-care confidence on the patient’s lower physical quality of life (*partner effect*). No *actor* effects were found for patients’ self-care on their own mental quality of life. However, caregivers’ increased self-care confidence was associated with their better mental quality of life (*actor effect*). Patients’ increased self-care maintenance was associated with the caregivers’ better mental quality of life (*partner effect*). The negative relationship identified for patients’ increased self-care on poorer physical health may be explained by motivation to engage in more self-care to prevent further deterioration in physical health. The negative relationship identified for caregivers may be explained by the physical demands placed on some caregivers to provide direct “hands-on” care and the associated exhaustion impairing their physical quality of life. The relationship between increased caregiver self-care confidence and poorer physical health in the patient (*partner effect*) is not so easily understood; it may be that caregivers assume greater responsibility during periods of physical decline. The final *partner effect* is more easily understood, as one would expect the caregiver’s anxiety and burden associated with self-care is reduced when the patient is actively engaging in their own self-care.

2.16.2 Depression and anxiety and quality-of-life outcomes (APIM)

Only one study that used the APIM to fully account for associations between depression and anxiety on quality-of-life outcomes was identified in Table 4. Chung et al. (2009) reported both *actor* and *partner effects*. Patients and caregivers with greater depression and anxiety had poorer quality of life (*actor effects*). These findings suggest that patients and caregivers experience similar levels of depression and anxiety. However, the impact of increased caregiver depression negatively influenced the patient; increased depression and anxiety were associated with poorer patient quality of life (*partner effect*).

2.16.3 Mutuality and self-care

The association between perceived mutuality and dyadic outcomes was identified in five studies (Table 4). Using the APIM, Hooker et al. (2018) found that mutuality was associated with patient and caregiver confidence (*actor effects*), suggesting that patients who perceived greater quality relationships with their caregivers are more confident in their abilities to engage in self-care behaviours and vice versa. It may that having a quality relationship with a caregiver is a motivator to engage in more self-care behaviours. There were no *partner effects* for mutuality on the patients' and caregivers' self-care confidence, nor did each other's self-care confidence relate to the other's self-care maintenance. Consistent with Hooker et al. (2018), Vellone et al. (2018) found that greater mutuality was associated with patient and caregiver self-care confidence (*actor effect*) and, further, that greater mutuality influenced self-care maintenance (*actor effect*). Unlike Hooker et al. (2018), a *partner effect* was found for patients' total mutuality score on greater caregiver contribution to self-care management, suggesting that higher patient mutuality was associated with greater caregiver contribution to self-care management (Vellone et al., 2018). In addition, greater mutuality was associated with a reduction in patient mortality in Rohrbaugh et al.'s (2006) study. The finding of a reduction in caregiver burden and depression in Hooker et al.'s (2015) integrative review and the association with reduced caregiver burden was extended in their (2018) study, which used APIM.

In summary, there is an absence of research that has examined self-care and quality-of-life outcomes in HF patient–caregiver dyads. In general, there is still a tendency in research to look at what happens between patients and caregivers (i.e., group differences) despite data being collected for both. Also, caregiver outcomes are less frequently reported in the literature compared to patient outcomes. Whilst some studies have adopted the APIM, they have been limited by their use of cross-sectional designs (Chung et al., 2009; Vellone et al., 2014; Hooker et al., 2018; Vellone et al., 2018), which precludes in-depth understanding of the interrelatedness of patient–caregiver dyads' self-care and quality-of-life outcomes over time. Also, self-care was examined mostly as an outcome variable, rather than predictor by outcome, especially quality of life.

To conclude, Chapter 2 has provided a critical review of the literature that relates to caregiver burden, self-care and quality-of-life outcomes in patients diagnosed with HF and their family caregivers. From examination of the caregiver burden literature, a considerable variation exists regarding patient and caregiver factors that predict caregiver burden, including caregivers' mental health, age, comorbidities and left ventricular ejection fraction. Interestingly, caregiver burden was greater when patients' symptoms were stable, and caregiver contribution to patient self-care did not predict caregiver burden. These nuances require further research to support these findings and, in particular, over time.

In the main, the self-care literature showed that social support had a positive relationship on self-care behaviours, when given by a family member. Studies that assessed the influence of patient and caregiver contribution to self-care on quality-of-life (outcomes) are required. The self-care literature that has used self-care as a predictor variable is scant. Further, many of the studies have focused on patients and caregivers as individuals, with few focusing on the dyadic dynamics of the patient and their family caregiver, using the APIM. This would enable greater understanding of important interactions between patient–caregiver dyads. No HF studies of self-care and quality of life were found that used APIM in longitudinal research.

Consistency existed between the reviewed studies in relation to gender, in that a greater number of patients were male, and a greater number of caregivers were female. The studies confirmed that heart failure is a syndrome of advancing age. NYHA classification and ejection fraction were reported in most studies, with a greater number of patients falling within NHYA class III. Limitations within the current evidence lie in the lack of longitudinal studies that examined caregiver burden, self-care and quality of life in HF dyads over time. Also, no identified studies examined all aspects of this research (i.e., caregiver burden, self-care and quality of life) in combination in HF dyads over time. In addition, the use of convenience sampling and non-reporting of missing data were other limitations of the studies examined. Furthermore, a clear cultural imbalance exists regarding other countries publishing in the field, with most research on patient–caregiver dyads coming from Italy and the USA.

CHAPTER 3

METHODS

3.1 Introduction

The aims of this study were to explore longitudinally: 1) the effects of patients' and caregivers' baseline characteristics and self-care on caregiver burden at 6 months' follow-up (TP2); 2) the effects of self-care on quality-of-life outcomes in patients with HF and their family caregivers (dyads) at 6 months' follow-up (TP2). The rationale for selecting this patient group was because of the significant disabling features of HF, i.e., breathlessness, fatigue and lower leg oedema that can affect patients at each stage of the trajectory. This can result in an inability to adequately self-care and limits overall quality of life. Patients become reliant on informal caregivers, often a spouse or partner to meet their care needs. Family caregivers were selected as they are recognised as being pivotal in supporting patients' self-care, but often their own physical and mental health-related quality of life is adversely affected through the burden of being a carer (Luttik et al., 2005; Luttik et al., 2007a). The close relationship between patients diagnosed with HF and their family caregivers has been highlighted in previous research (Vellone et al., 2014; Chung et al., 2009). Despite this, quality-of-life outcomes have mostly been examined separately in either patients or family caregivers. Previous dyadic research in HF has mostly emanated from the United States and Italy, and this has been cross-sectional in design. This chapter will detail the research questions, study design, population, sample and selection process. In addition, it will discuss the process involved in the data collection and the instruments selected for use in the study, and the statistical methods used in the analysis of the data.

3.1.1 Research questions

The following three research questions were proposed to address the overall aims of the study:

Question 1: Are there differences between patients' and family caregivers' self-care and quality of life at TP1 (after diagnosis) and TP2 (6 months later)?

Question 2: What patient and family caregiver characteristics and self-care at TP1 (baseline) predict caregiver burden at 6 months (TP2)?

Question 3: What are the effects of patient self-care and family caregiver contribution to self-care (at TP1) on their own and their partner's quality of life at 6 months (TP2)?

3.1.2 Design of study

This is a longitudinal study of patients diagnosed with HF and their family caregivers who were followed-up at 6 months (TP2). The study adopted a quantitative survey approach to collect data. Data were collected from patients and family caregivers at two time points: following hospital discharge (TP1) and again at 6 months (TP2). Time point one (approximately two weeks post hospital discharge) was chosen as a suitable time, as this enabled early contact with the participants and data collection. This time-point was particularly suitable, as the heart failure specialist nurses (HFSNs) conducted their first home visit around that time and served as additional support regarding the patient's decision to participate in the study. Time-point two was selected, as the literature reported that hospital readmission rates are common during this time period, as, after diagnosis, there is an increased risk of symptom recurrence, complications associated with other comorbidities, and social care problems. (Goodman et al., 2013).

3.1.3 Plan of study

Table 5 outlines the research journey, which I followed from the commencement of data collection until the completion of the research.

Table 5: Research Journey Timeline

Stages in the Research Journey	November 2016	January 2017	February 2017	May 2017	August 2017	Feb 2018	May 2018	September 2018	October 2018	April 2019	May 2019	July 2020
Recruitment of HF patients and family caregivers (time point 1)	▨											
Ongoing recruitment of patients and family caregivers (time point 1) NHS Ayrshire & Arran	▨	▨										
Submit Substantial Amendment to Ethics – Multi-Site			▨									
Reviewing/ Editing Thesis chapters		▨	▨									
Multi-site recruitment commences (time point 1) NHS Ayrshire & Arran & NHS Greater Glasgow & Clyde				▨								
Commence 6-month follow up (time point 2 data)				▨	▨	▨						
Commence data analysis (time point 1 and time point 2)							▨	▨				
Commence write-up of results:									▨	▨		
Final review and write-up											▨	▨

3.1.4 Population, sample and selection process

The study initially started in NHS Ayrshire & Arran, and, after obtaining NHS ethics (Appendix 4) and Research & Development (Appendix 5) approval, patients were recruited from two main hospitals by the cardiac specialist nurses: University Hospital, Crosshouse and University Hospital, Ayr. The study population was made up of all patients registered at these hospitals who received a new diagnosis of HF, confirmed by echocardiography, and patients admitted with an episode of decompensated HF. The two sites were used to draw from a wider population and thus increased the chances of a larger sample size being achieved. The population of Ayrshire and Arran (North, East and South Ayrshire, and Arran) is approximately 367,000 and it is estimated that 350 patients are managed by the Heart Failure Nursing Service per annum. The referral criteria in NHS Ayrshire & Arran to the HF nurse service can be found in Appendix 6.

Recruitment in NHS Ayrshire & Arran was initially slow; from the start of recruitment in November 2016 to January 2017, only two patients were recruited from NHS Ayrshire & Arran. A substantial amendment was therefore made to South East Coast Surrey Research Ethics Committee in February 2017 (Appendix 7) to expand recruitment to NHS Greater Glasgow & Clyde to help improve recruitment rates. Following the submission of the substantial amendment and subsequent NHS ethics (Appendix 8) and Research & Development approval (Appendices 9 and 10), multi-site recruitment commenced in May 2017. NHS Ayrshire & Arran and NHS Greater Glasgow and Clyde became the two recruitment centres. The total board population of NHS Greater Glasgow & Clyde is estimated at 1,203,870, and 1300 patients are managed by the Heart Failure Nursing Service per annum. Appendix 11 highlights NHS Greater Glasgow & Clyde's referral pathway.

The sufficiency of the sample size was determined based on prior research (Chung et al., 2009; Vellone et al., 2014; Thomson et al., 2011) while taking into consideration patient–family-caregiver dyad recruitment and attrition rates. The aim was to approach 140 dyads to allow for the recruitment of 50–70 dyads, which considered possible attrition at TP2. As both the patient and the family caregiver were required to participate in the study at both TP1 and TP2, the following factors were considered: unpredictable disease trajectory, and increased risk of death. NHS Quality Improvement Scotland (NHS QIS, 2010) report that up to 50% of patients who have a diagnosis of HF will sadly die within 5 years; 6% within the first month of diagnosis; 11% within 3 months and 14% within 6 months. Based on these factors (and considering previous dyadic cardiovascular research), an attrition rate of 10% was calculated for this study. While a power analysis algorithm does not currently exist specifically for the APIM, the basis for the technique is modelled on regression. Chung et al. (2009) used a sample size of 40, assuming the alpha level of 0.05, the power of regression F-test to detect a significant prediction model for quality of life was approximately 82% in the presence of a medium size and greater than 95% for a large effect size. Whilst a formal sample size calculation was not conducted prior to recruitment in this study, a retrospective power calculation using G Power* was conducted based on Chung et al.'s (2009) dyadic research. A small, medium and large effect size can be found in Appendices 12–14 for this study.

A total of 52 patient–caregiver pairs (dyads) were recruited over a period of 16 months, using convenience sampling. However, at TP2 46 dyads remained in the study, and the final sample of 46 patient–caregiver pairs (dyads) was used in the data analysis. According to Peacock and Peacock (2011) convenience sampling is a form of non-probability sampling and is recognised as being the method of choice for many healthcare research studies, given its straightforward application and limited rules governing how the sample should be collected. Further benefits of convenience sampling compared to probability sampling are in relation to the cost and time required to obtain the sample. However, since the sampling frame is not known and sample is not chosen at random, the inherent bias associated with convenience sampling suggests that the chosen sample may not be representative of the population being studied, reducing the generalisability of the findings (Peacock and Peacock, 2011). In order to overcome this, baseline characteristics of the sample were collected (Tables 8 and 9) to allow inferences to be made regarding generalisability of the sample. The inclusion and exclusion criteria are outlined in the sections below.

3.1.5 Inclusion criteria

- Patients with a diagnosis of Heart Failure (new or existing) confirmed by echocardiography
- Patients aged between 45 and 90 years of age
- New York Heart Association (NYHA) classification 2-4
- The patient lives with their family caregiver in the same household
- Patient–family caregivers in a marital or cohabiting relationship

3.1.6 Exclusion criteria

- Family caregivers with a personal history of Cardiovascular Disease (CVD)
- Patients or family caregivers unable to read or speak English, or those with psychological or neurological limitations.

The specific inclusion/exclusion criteria ensured the recruitment of a representative sample of participants. The particular age range was specified as the British Heart Foundation (BHF, 2010) estimate the prevalence of HF to be 3% in those over 45 years, 7% in those over 75 years, and 15% in those over 85 years of age. The prevalence of HF rises steeply with age. NYHA class 2-4 was chosen as patients in class 1 may have no symptoms and patients in class 4 are often bed-bound (McDonagh et al., 2011) and have more severe symptoms, which may be of value when exploring the level of caregiver burden experienced. Family caregivers (either married or cohabiting) were selected to ensure a representative sample, as previous research has not always included cohabiting couples. Additionally, Trivedi et al. (2016) recognise the unique role of spousal or cohabiting couples in influencing self-care management. The family caregiver had to live with the patient to help capture a true reflection of the caregiving tasks undertaken by the caregiver, and the possible burden associated with the role. Lewis et al. (2006) recognise that it is often the spouse that adopts the caregiver role, but this can also include children, with each family member adopting a different relationship. The spouse and partner were selected because they are generally viewed as being more connected than formal carers or other family members. The spousal caregiving relationship is generally viewed as being more interdependent than carers or other family members. Patients and family caregivers unable to read or speak English were excluded because of the financial and time constraints placed on this study. It was not possible to offer written materials in other languages or to provide an interpreter. Family caregivers were excluded if they had a recorded cardiovascular disease as having a similar comorbidity to the patients, which could potentially influence their understanding and management of HF. Thomson et al. (2011) suggest that this may also serve as a personal motivator for changing their behaviour.

3.2 Data Collection Procedure

3.2.1 Introduction

Recruitment packs were distributed to the Cardiac Specialist Nurses at both NHS Ayrshire & Arran and NHS Greater Glasgow & Clyde, as they were responsible for the identification of suitable patients, according to the inclusion criteria. The caregiver was recruited via the patient. The recruitment packs contained the following study documentation: Letter of Invitation, Participant Information Sheet, and Consent to Contact Forms (Appendices 15, 16, 17 and 18). The patients who fulfilled the inclusion criteria were initially approached by the Cardiac Specialist Nurses to consider their participation in the study. If both patient and family caregiver pairs (dyads) expressed an interest in the study, they were given two options: to be contacted by me during the patient’s hospital stay; or following discharge from hospital. This enabled me to confirm their suitability based on the inclusion criteria. If the preferred option was to be contacted on discharge, contact was made with the patient and family caregiver on receipt of the two signed Consent to Contact Forms (Appendices 17 and 18).

My initial meeting with the patients and family caregivers provided the opportunity for them to ask questions regarding the study, as well as to discuss any potential concerns or anxieties they had regarding their participation in the study. Reassurance was given that should they wish to withdraw from the study at any point, the quality of current and future care would not be affected. Meeting with the patients and family caregivers in person provided a personalised approach and assisted with improving retention rates 6 months from the initial review. When satisfied that their questions and concerns had been fully answered and they were happy to proceed, I provided them with a separate Consent form

(Appendices 19a and 19b), which they were asked to sign. Only when written consent was given were the patient and family caregiver issued with their questionnaire booklets (Appendices 20a and 20b). They were asked to complete them separately from each other and to return them to the secretaries affiliated with the Cardiac Specialist Nurses.

In order to minimise response burden and possible patient fatigue, the patients were advised that they could complete the questionnaire booklets in stages. In addition, the patients were advised to complete the questionnaire booklets separately from their family caregiver; this was to avoid one influencing the other's answers. The initial meeting also enabled me to collect relevant socio-demographic data from the patient and family caregivers. The General Practitioners (GPs) of all patients who consented to participate in the study were notified in writing (Appendix 21) and they were advised to contact me if they had any concerns.

The questionnaires used at the 6-month follow-up (TP2) were the same questionnaires used at baseline (TP1). Contact was made with the patients and family caregivers before this via telephone, to check for their continued participation. This contact also served as a gentle reminder that the follow-up questionnaires would be sent in the post. The participants were asked to return them, as before, to the secretaries affiliated with the Cardiac Specialist Nurses. Appendix 22 summarises the recruitment and data collection process.

3.2.2 Ethics approval

Ethics approval for the study was granted from the Research and Ethics Committee of the Faculty of Health Sciences and Sport, University of Stirling, in January 2016 (Appendix 23). In addition, as described in Section 3.1.4, NHS ethics approval was granted in June 2016 (Appendix 4), and Research & Development approval from NHS Ayrshire & Arran was granted in August 2016 (Appendix 5). However, due to the recruitment issues mentioned in section 3.1.5, a substantial amendment was submitted to enable multi-site recruitment (Appendix 7). NHS ethical approval was granted in April 2017 (Appendix 8) and Research & Development approval from NHS Ayrshire & Arran was given in May

2017 (Appendix 9). Approval from Greater Glasgow & Clyde was granted in May 2017 (Appendix 10).

3.2.3 Pre-testing of the questionnaires

The Cardiac Specialist Nurses from NHS Ayrshire & Arran identified five patient representatives from the Managed Clinical Network (MCN) for Coronary Heart Disease & Stroke to pre-test the questionnaires that were issued to the HF patients (Appendices 13a and 13b). The five representatives were not included in the recruitment process. The aim of the pre-testing was to minimise the amount of fatigue that the HF patients might experience as a result of completing the questionnaires. In addition, it was an attempt to identify any difficult or ambiguous questions. The questionnaires completed by the representatives included: the UK version of the Medical Outcomes Short-Form 12 Health Survey (SF-12) version 2 (Ware et al., 1998); the Minnesota Living with Heart Failure Questionnaire (Rector, 2004); and the Self-care of Heart Failure Index (Riegel et al., 2009). The results of the pre-testing proved to be particularly useful, as they confirmed that the questionnaires were suitable for self-completion. They also confirmed the importance of highlighting to the HF patients that they could complete the questionnaires in stages to avoid possible fatigue. Pre-testing the questionnaires with caregivers would also have been useful, but this was not feasible because the scope and time of the Cardiac Specialist Nurses was already limited.

3.2.4 Further ethical considerations and potential risks

There were no other significant ethical, legal or managerial issues arising from the research. However, I also considered the relevant ethical principles outlined below.

3.2.4.1 Risks and benefits

There was a small risk of emotional upset for the participants, which could have occurred when asking patients and caregivers about their health status. If this occurred, they were offered the relevant support from the Heart Failure Specialist Nurses (HFSNs). As a further safeguard against risk, they were provided with an independent source of support: the British Cardiac Patients' Association – a charitable organisation run by volunteers – who provide support, advice and information to cardiac patients and carers. Similarly, as part of their usual care, the patients were provided with the web address for the British Heart Foundation (Scotland) (http://patient.info/support/british-heart-foundation) to provide additional information regarding their condition, as well as details of local support groups for them and their family caregiver. I also reminded the participants of these support groups during the first meeting. Further, should the need arise, they could be referred to the appropriate psychological services at local NHS level, as this is already a recognised process for patients diagnosed with HF and their family members within NHS Ayrshire & Arran and Greater Glasgow & Clyde.

In the event that the patient or family caregiver should die during the data collection period, it would be inappropriate, and outwith the aims of the study, to continue without both members of the dyad. The HFSNs agreed that they would notify me of any deaths prior to the follow-up period. If no communication was made, and, as an extra safety measure, I would contact the GP practice to ensure that it was appropriate to make further contact. In the event of a death, the collected data would not be used in any further analysis.

In relation to benefits, participation in the study did not directly help the patients and family caregivers. Nonetheless, through our engagement in the research journey, my knowledge and understanding, and that of the other health professionals, of the complexities associated with caregiver burden, self-care and quality of life from a dyadic perspective has developed significantly. Furthermore, the study offered the opportunity to improve services for HF dyads in the future, providing an indirect benefit to the participants themselves.

3.2.4.2 Confidentiality and anonymity

All patients and family caregivers were advised that participation in the study was entirely voluntary, and that all data that were collected, processed and stored would remain at all times strictly confidential. This assurance was provided in line with the Data Protection Act (1998) and the Principal Investigator's Code of Conduct (NMC, 2018). Regarding data handling, a unique study number was given to each participant, and this was documented on all questionnaires issued to the dyad at both time-points. Once the dyads returned their Consent to Contact Forms, their details were recorded on a spreadsheet and stored separately from any other data gathered during the study. As data were collected longitudinally, the spreadsheet proved useful in keeping track of each stage of the data collection process. The following headings were used within the spreadsheet: entered study; ineligible; refused; time point one; reminder telephone call; time point two; unable to contact; died and no further contact. To avoid the ethical issues associated with accessing patients' medical records, clinical data were obtained directly from the Cardiac Specialist Nurses. This is specifically discussed separately under section 3.4.

All data were stored in a separate locked cupboard within the University of Stirling, and these were only accessible to me and to my academic supervisors. Data analysis was undertaken on a University of Stirling computer, which was password-protected. SPSS for Windows version 24.0 (IBM Corporation, 2016) was the package used to analyse the data. Data will be destroyed after 10 years after the study's completion, in line with the University of Stirling's data retention policy. Destruction of or deleting data will be completed with concern for confidentiality and security (Data Protection Act, 1998).

3.2.4.3 Management Issues

The study sites were separate from the Principal Investigator's own place of work; this ensured separation of the research role and clinical role. A specific screening tool (Appendix 24) was used by the Cardiac Specialist Nurses to recruit eligible patients. As outlined in Section 3.2.4.1, the small risk of emotional upset, which could have occurred when asking patients and caregivers about their health status, was addressed by notifying the Heart Failure Specialist Nurses (HFSNs), who would have provided additional support.

The likelihood of any major risk to me as a researcher was thought to be low. However, issues associated with personal safety regarding visiting the participants in their home were considered. In order to ensure personal safety (and in line with the University of Stirling's lone working policy for researchers) the Principal Investigator kept his mobile telephone with him at all times. In addition, he made contact with the HFSNs prior to any scheduled visit, notifying them where he would be, and immediately following the visit, to reassure them that he was safe.

3.3 Socio-demographic data

During the initial meeting (TP1) with the participants, the Principal Investigator collected data from the patient and family-caregiver relating to their socio-demographic characteristics, including their age, gender, employment, education, occupation and postcode (to determine their social deprivation category).[1] In addition, he recorded information about their physical activity level, alcohol intake and smoking.

3.4 Clinical data

Clinical data were collected that pertained to patients' cardiovascular status and comorbidities. Information relating to the caregivers' health problems were categorised as "no health issues", "one health issue", or "greater than one health issue". The cardiovascular information included the patient's New York Heart Association (NYHA) (Fisher, 1972) classification, Ejection Fraction and any medication used in the management of their HF. This information was collected to develop greater understanding of the complexities associated with the symptom burden of HF and its potential impact on self-care and quality of life. For example, the EF and NYHA classification provide additional details regarding symptomatology than would be provided by the MLwHFQ alone.

3.4.1 New York Heart Association (NYHA) classification

The following table (Table 6) outlines the stages of the NYHA class, illustrating each class of the NYHA and the expected symptoms associated with that class. Ahmed et al. (2006), in their retrospective follow-up study, remind us of the

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[1] In Scotland, social deprivation categories are determined by the Scottish Indicator of Multiple Deprivation (SIMD), which is the a relative measure of deprivation across 6,976 small areas called data zones (Scottish Government, 2020).

importance of the simple risk stratification tool, and how it can assist in tailored management of patients with HF.

Table 6: NYHA Classification

NYHA Class	**Level of clinical impairment**
I	No limitation of physical activity. Ordinary physical activity does not cause undue breathlessness, fatigue or palpitations.
II	Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in undue breathlessness, fatigue or palpitations.
III	Marked limitation of physical activity. Comfortable at rest, but less than ordinary physical activity results in undue breathlessness, fatigue or palpitations.
IV	Unable to carry out any physical activity without discomfort. Symptoms at rest can be present. If any physical activity is undertaken, discomfort is increased

Source: The Criteria Committee for the New York Heart Association (1994), pp. 253–255.

3.4.2 Ejection Fraction

As well as acute and chronic HF, the ESC and the American Heart Association guidelines further categorise the syndrome according to cardiac function (Yancy et al., 2013; Mann & Bristow, 2005; Ponikowski et al., 2016). Historically, HF is described on the basis of measuring the Left Ventricular Ejection Fraction (LVEF) by means of echocardiography. Ponikowski et al. (2016) indicate three types of Ejection Fraction, with the first two consisting of: HF with preserved ejection fraction (HFpEF) – typically considered as an ejection fraction > 50%; HF with reduced ejection fraction (HFrEF) – typically considered as an ejection fraction < 40%. Further, Ponikowski et al. (2016) add that a guideline now exists for patients who fall into an ejection fraction range of 40–49% – previously a “grey area” – and this is now defined as HF with mid-range ejection fraction (HF m-r EF). Information relating to Ejection Fraction was categorised in this study as: LVEF < 40%; LVEF 40–49%; LVEF >50% and “not recorded”. During initial data collection, a significant number (57%) of ejection fractions were not recorded, and the HF nurses highlighted that this was not unusual, given the electronic reporting of echocardiographic results. However, a non-substantial amendment was submitted to South East Coast – Surrey Research Ethics Committee (16/LO/1104/AM02) IRAS 165845) after the initial study period had ended to go back and obtain this information from NHS Ayrshire & Arran. Details regarding this amendment can be found in Appendices 25–27.

3.4.3 Pharmacological management

The principal goals in the management of HF are to relieve symptoms, reduce the number of hospital admissions, and reduce mortality (Johnson et al., 2016). Over the last few decades, HF management has witnessed dramatic changes and increased survival rates for patients diagnosed with HFrEF. The introduction of pharmacological agents have been robustly tested through key RCTs, such as CONSENSUS and Studies of Left Ventricular Dysfunction (SOLVD) using Angiotensin-Converting Enzyme Inhibitors (ACEi), which have demonstrated a relative risk reduction in mortality of 27 and 16%, respectively. Other clinical improvements have been observed, with the introduction of beta-blockers and mineralocorticoid receptor antagonists (MRAs). More recently, Jhund and McMurray (2016) highlight that morbidity and mortality can be improved with the angiotensin receptor blocker neprilysin inhibitor, sacubitril/valsartan. Table 7 highlights the common drugs used in the management of HF (ESC, 2016).

Table 7: Pharmacological agents in the management of HF

Agent	Starting/Initial dose	Target dose
ACE-I	**Starting dose (mg)**	**Target dose (mg)**
Captopril	6.25 *t.i.d.*	50 *t.i.d.*
Enalapril	2.5 *b.i.d.*	20 *b.i.d.*
Lisinopril	2.5–5.0 *o.d.*	20–35 *o.d.*
Ramipril	2.5 *o.d.*	10 *o.d.*
Trandolapril	0.5 *o.d.*	4 *o.d.*
Beta-Blockers	**Starting dose (mg)**	**Target dose (mg)**
Bisoprolol	1.25 *o.d.*	10 *o.d.*
Carvedilol	3.125 *b.i.d.*	25 *b.i.d.*
Metoprolol succinate (CR/XL)	12.5–25 *o.d.*	200 *o.d.*
Nebivilol	1.25 *o.d.*	10 *o.d.*
ARBs	**Starting dose (mg)**	**Target dose (mg)**
Candesartan	4-8 *o.d*.	32 *o.d.*
Valsartan	40 *b.i.d.*	160 *b.i.d.*
Losartan	50 *o.d.*	150 *o.d.*
MRAs	**Starting dose (mg)**	**Target dose (mg)**
Eplerenone	25 *o.d.*	50 *o.d.*
Spironolactone	25 *o.d.*	50 *o.d.*
ARNI	**Starting dose (mg)**	**Target dose (mg)**
Sacubitral/Valsartan	49/51 *b.i.d.*	97/103 *b.i.d*
Loop Diuretics	**Initial dose (mg)**	**Usual daily dose (mg)**
Furosemide	20–40	40–240
Bumetanide	0.5–1.0	1–5
Torasemide	5-10	10–20
Thiazide	**Initial dose (mg)**	**Usual daily dose (mg)**
Bendroflumethiazide	2.5	2.5–10
Hydrochlorothiazide	25	12.5–100
Metolazone	2.5	2.5–10
Indapamide	2.5	2.5–5.0
Potassium -sparing diuretic	**Initial dose (mg)**	**Usual daily dose (mg)**
	+ACE-I/ARB - ACE-I/ARB	**+ACE-I/ARB - ACE-I/ARB**
Spironolactone/eplerenone	12.5–25 50	50 100–200
Amiloride	2.5 5.0	5-10 10–20
Triamterene	25 50	100 200

Source: ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure, 2016 (Ponikowski et al., 2016).

3.5 Measures

Following receipt of written consent, data collection commenced in December 2016. The following measurement tools were used: the Zarit Burden Caregiver Index (Hooley et al., 2005); the UK version 2 of the Medical Outcomes Short-

Form 12 Health Survey (SF-12) (Ware et al., 1998; Jenkinson & Layte, 1997); the Minnesota Living with Heart Failure Questionnaire (Rector, 2004); the Self-care of Heart Failure Index (Riegel et al., 2009); and the Caregiver Contribution to Self-care in Heart Failure Index (Vellone et al., 2014). The family caregiver was asked to complete the questionnaires independently to avoid the possibility of the participants influencing each other's answers.

3.5.1 Zarit Caregiver Burden Interview Scale

Caregiving can be burdensome and there is strong evidence to suggest that it can affect the quality of life of the caregiver (Luttik et al., 2007; Molloy et al., 2005; Saunders, 2009). The Zarit Caregiver Burden Interview scale was selected for use in the study, as the questions reflect much of the issues raised within the HF caregiver literature (Molloy et al., 2005; Luttik et al., 2007a; Saunders, 2009). The questionnaire has 22 questions, each of which use a 5-point Likert scale to address emotional quality-of-life, physical quality-of-life and social quality-of-life. Each question is scored ranging from - never to nearly always present. A score may range from 0 (low burden) to 88 (high burden). The developers of the Zarit Caregiver Burden Interview scale proposed the use of cut-offs to include the following: 0–21 little or no burden; 21–40 mild–moderate burden; 41–60 moderate–severe burden; and 61–88 severe burden. Saunders (2009) reports that the measure is user-friendly and is a reliable and valid measure of caregiver burden. Al-Rawashdeh et al.'s (2016) US study tested the psychometric properties of the Zarit Burden Caregiver Interview in HF caregivers and confirmed that it is a reliable and valid measure, with a very strong Cronbach's alpha (0.921). The alpha co-efficient in this study was 0.75, which indicates a strong positive correlation. Data at TP1 and TP2 was reviewed for completeness, and both time-points had complete data.

3.5.2 SF-12 Health Survey

The SF-12 Health Survey was used to measure both patients' and family caregivers' perceived health status (Ware et al., 1998; Jenkinson & Layte, 1997). The survey was chosen for the short completion time of 2 minutes, compared to the SF-36 survey, which can take up to 10 minutes to complete. Although SF-12 version 2 is a brief measure of perceived physical and mental health, it has been referred to frequently in the general cardiovascular literature and has also been used within HF cross-sectional studies (Vellone et al., 2014). Ware et al. (1998) and Thomson et al. (2011) highlight that the validity and reliability of the SF-12 is comparable with the SF-36 survey by the use of alpha coefficients. Furthermore, its recognition in UK health studies (Jenkinson & Layte, 1997) highlight that the Physical Component Score (PCS) and Mental Component Scores (MCS) have similar metrics to the UK SF-36, which reported PCS and MCS alpha-coefficients of 0.86 and 0.77, respectively. In this study, the alpha co-efficient for PCS was 0.72, and for MCS, 0.73. The process of scoring the SF-12 was guided by the instructions in Ware et al.'s (1998) handbook. Once the data were entered into SPSS, four of the items had to be reverse-coded to ensure that higher item values were associated with improved quality of life. The questionnaires were reviewed for completeness at TP1 and TP2. All data at TP1 was complete, however, some questions at TP2 had incomplete data. According to the guidance provided within Ware et al.'s (1998) handbook, missing data was replaced by the mean value. This process is concurred by Perneger and Burnand (2005) who found that the results remained satisfactory when three of the six key items in the SF12 Health Survey was replaced by the mean value.

Ware et al. (1998) advised adding regression weights and a constant to transform both the PCS and MCS; this ensured a mean of 50 and a standard deviation of 10 was reached. According to Ware et al. (1998), any participants who scored below 50 were classified as being below the population average. A recognised limitation of the SF-12 health survey is that the PCS-12 AND MCS-12 scores have fewer items, which limits the amount of information that can be gained when compared to a disease-specific quality-of-life tool (Ware et al., 1998; Bilbao et al., 2016).

3.5.3 Minnesota Living with Heart Failure Questionnaire (MLwHFQ)

In order to measure patient-specific symptoms and quality of life in HF, the Minnesota Living with Heart Failure Questionnaire (MLwHFQ) was chosen for use in this study because it was disease-specific (Rector, 2004) and, unlike the SF-12 survey, it would assess the patients' perceptions of HF and establish how it affects their physical, socioeconomic and psychological needs. The questionnaire has 21 items and uses a six-point Likert scale, which ranges from 0–5; 0 suggesting no impact on quality of life, and 5 suggesting that quality of life is significantly impacted. Rector (2004) summarises the questionnaire and indicates that the total score for the 21 items can range from 0–105; a higher score indicates that the HF symptoms have a negative impact on a patient's quality of life. The Physical Component Score (PCS) ranges from (0–40) and the Emotional Component Score (ECS) ranges from (0–25), and, like the overall score, a higher score indicates poorer quality of life. The total MLwHFQ score has been demonstrated to be reliable by estimates of the correlation (*r*) between repeated baseline assessments, as well as measures of internal consistency, such as Cronbach's alpha coefficient (Whittingham et al., 2013). The internal reliability has been reported in several HF studies (Lee et al., 2014; Goodman et al., 2013; Heo et al., 2005), as well as in patient–caregiver pairs (dyads) (Thomson et al., 2020a). According to McMurray et al. (2012), the measure is as valid as other scales that assess quality-of-life and health outcomes in HF. An advantage of the MLwHFQ is that it discriminates between patients diagnosed with CHF and patients who have symptomatic left ventricular dysfunction (McMurray et al., 2012). A disadvantage of the scale is its inability to clearly distinguish between the different severities of HF, as well as patients' difficulties in separating the symptoms experienced from HF to other co-morbidities.

In order to use the questionnaire with caregivers, the wording of some of the questions had to be altered to ensure that their answers reflected their own situation and not those of their partner. The alpha co-efficient for the patients in this study was 0.78, which indicates a strong positive correlation. The alpha co-efficient for caregivers also demonstrated a strong positive correlation of 0.79. However, HF studies from the USA and UK that used patient–caregiver pairs (dyads) also demonstrated good internal consistency with very strong alpha co-efficients being reported (Chung et al., 2009; Thomson et al., 2020a). Missing data were handled by following the instructions outlined in the MLwHFQ handbook (Rector, 2004). On reviewing the TP1 and TP2 data, a small number of questions were incomplete.   In order to minimise bias associated with missing values, the data missing at baseline was assigned a zero and was subsequently carried forward to the TP2 questions (Rector., 2004). For the questionnaires that had no missing values at TP1, but had missing values at TP2, the baseline response was carried forward to complete the missing values.

3.5.4 The Self-Care of Heart Failure Index (SCHFI)

The Self-Care of Heart Failure Index (SCHFI) was used to measure self-care in HF patients (Riegel et al., 2004; Riegel et al., 2009), and consists of three sub-scales: self-care maintenance, self-care management, and self-care confidence. Within the self-care maintenance scale, 10 items measure the patients' self-monitoring and treatment compliance, for example, monitoring weight on a daily basis and ensuring compliance with medication and dietary advice. The self-care management scale has six items, which measures patients' ability to respond promptly to deteriorating symptoms. In addition, it measures treatment implemented after the identification of symptoms and the evaluation of such treatment. The self-care confidence scale (six items) primarily measures the level of confidence that patients have with regards to symptom recognition. The measure has a 4-point self-report scale; 1 = never or rarely, and 4 = always or daily to perform the self-care activity (i.e., weighing or checking ankles for signs of oedema). Total scores range from 0–100, with higher scores indicative of better self-care; self-care adequacy in each of the sub-scales was assessed using a cut-off score of >70 (Riegel et al., 2009). The SCHFI has demonstrated adequate psychometric properties in the US population (Riegel et al., 2009) and, similarly, in the Italian population (Vellone et al., 2013). The alpha co-efficient in this study was 0.81, which indicates a very strong positive correlation. Missing data were handled by the use of series means, as advised by Riegel et al. (2009). Other caregiver measures were considered (European Self-care Behaviour Scale), however, given that the SCHFI had previously been used in dyadic research (Vellone et al., 2014), which also explored self-care and quality-of-life outcomes, this was the instrument that was chosen in this study. Table 8 provides an overview of each of the self-care domains that patients with HF are encouraged to engage in.

3.5.5 Caregiver Contribution to Self-care Heart Failure Index (CCSCHFI)

Like the SCHFI for patients, the Caregiver Contribution to Self-Care Heart Failure Index (CCSCHFI) measures the caregiver's contribution to self-care maintenance, management and confidence. The index also has 10 items, which measure the frequency in which caregivers remind patients to monitor their symptoms and the importance of treatment compliance (Vellone et al., 2013). Table 8 gives an example of the domains that the caregiver would be recommending to the patient to engage in. Like the SCHFI, a standardised score of 0–100 is used, with higher scores indicating greater caregiver contribution to patient self-care. The adequacy of the caregivers' contribution to patient self-care in each of the sub-scales is also assessed using a cut-off score of > 70, which indicates adequate contribution (Riegel et al., 2009). The CCSCHFI has demonstrated good validity and reliability in the Italian and US caregiver population, but it is unclear whether the same validity and reliability would be reported in other populations. Chen et al. (2017) report that the CCSCHFI demonstrates very strong internal consistency and test-retest reliability as the co-efficient for both was > 0.80. In this study, the alpha co-efficient was 0.78 for caregivers. Further, the mean scores in Chen et al.'s (2017) study for CCSCHFI maintenance, management and confidence, were 52.41 (9.96), 55.62 (15.36), and 55.27 (16.38), respectively, which suggest that caregiver contribution was sub-optimal. Prior to commencing the data analysis of both the SCHFI and CCSCHFI, the data were reviewed and examined for incomplete questionnaire data. Previous studies that used these questionnaires, handled missing data with simple mean replacement, particularly when the rates of missing data for the questionnaires were less than 7%, and was the case in this study.

Table 8: Self-care domains undertaken by patients

Maintenance	***Management***
• *To check weight* • *To check ankles for swelling* • *To try to avoid getting sick* • *To do some physical activity* • *To keep doctor or nurse appointments* • *To eat a low salt diet* • *To exercise for 30 minutes* • *Try not to forget to take medications* • *To ask for low salt items when eating out* • *To use a pill box reminder system*	• *Recognising difficulty breathing as a symptom of HF* • *Reducing salt in the diet* • *Reducing fluid intake* • *Taking an extra water pill* • *Calling doctor or nurse for guidance* • *Remedies to help with breathing or ankle swelling*
Confidence	
• *Keeping free of HF symptoms* • *Following the given treatment advice* • *Evaluating the importance of symptoms* • *Recognising changes in health as they occur* • *Doing something to relieve symptoms* • *Evaluating the effectiveness of the remedy*	

3.6 Data Analysis

Descriptive and inferential statistics were used to summarise the patients' and caregivers' socio-demographic characteristics. As the data was non-normally distributed, the non-parametric *t* test (Wilcoxon Signed Rank test) was used to assess for differences between patients' and caregivers' self-care and quality of life at TP1 and TP2 (research question 1). The tables within chapter 4 present the median and inter-quartile range (IQR) as part of the descriptive statistics. The IQR was used as it provides the best measure of variability, and when used in conjunction with the measure of central tendency (median), it provides useful information relating to the dispersion of the data (McKenzie, 2013). Multiple linear regression was used to identify the patient and family caregiver characteristics and self-care at TP1 that predicted family caregiver burden at TP2 (research question 2). Field (2013) advises that checks should be carried out to assess linearity and to ensure that the outcome variable (caregiver burden) is related to the predictor variables. Tabachnick and Fidell (2014) suggest that the correlation matrix should be scanned to examine whether any predictor variables are highly correlated, i.e., $r > 0.80$ or 0.90. These correlations can be found in Chapter 5 (see Tables 17 and 19).

For the multiple linear regression, all predictor variables (i.e., TP1 caregiver burden scores, patient and caregiver self-care maintenance, management and confidence; patient and caregiver SF-12 PCS and MCS; MLwHFQ total, MLwHFQ PCS and ECS; and patient physical activity) were entered simultaneously into the model using the Enter method, as supported by Field (2013). The predictor variables with p values of > 0.05 (i.e., non-significant) were removed independently until the model contained only the predictor variables with p-values of < 0.05. The procedure followed Field's (2013) process of fitting a regression model, specifically examining the standardised residuals: normality, independence, homoscedasticity, and linearity. The normality of the outcome variable was demonstrated in a histogram, and independence, homoscedasticity and linearity were identified in P-P plots and scatterplots via ZPRED versus ZRESID, as presented in Appendices 18 and 19.

To address research question 3, longitudinal multi-level dyadic regression modelling, the APIM for distinguishable dyads, was used (Kenny et al., 2006). Two dyad members are considered distinguishable based on their roles, for example, care recipient and caregiver. The APIM approach has been used widely in general health research (Rayens & Svavarsdottir, 2003; Driscoll et al., 2012) and in studies of HF dyads (Chung et al., 2009; Vellone et al., 2014; Thomson et al., 2020a) and patient–partner dyads in Coronary Artery Bypass Grafting (Thomson et al., 2011).

The *actor effect* refers to the impact of an individual's characteristics, i.e., the patient's self-care (or caregivers' contribution to self-care), at baseline on their own quality of life at 6 months (TP2), while controlling for the individual's quality of life at baseline (TP1). The *partner effect* refers to the impact of an individual's characteristics, i.e., the patient's self-care (or caregiver's contribution to self-care) at baseline (TP1) on his or her partner's quality of life at 6 months (TP2), while controlling for quality of life at baseline (TP1). In this study, 15 separate APIM were computed. For example, the physical component score (SF-12) was regressed for each of the three self-care domains (maintenance, management and confidence), controlling for baseline PCS. Similarly, the mental component score (SF-12) was regressed for each of the three self-care domains, controlling for baseline MCS. The MLwHFQ total score was regressed for each of the three self-care domains, controlling for baseline MLwHFQ total score. Also, the MLwHFQ PCS was regressed for each of the three self-care domains, controlling for baseline MLwHFQ PCS. The final model consisted of the MLwHFQ ECS being regressed for each of the three self-care domains, controlling for baseline MLwHFQ ECS. Figure 5 in Chapter 6 demonstrates the MLwHFQ ECS being regressed on each of the self-care domains. It is recognised that, by studying only the *actor effects*, the focus of the research tends to be on an individual. However, when the *partner effect* is included within, it implies that something relational has occurred (Cook & Kenny, 2005), i.e., relational interdependence.

For the multi-level dyadic analysis, the data were reorganised to form a pairwise dyadic data set. In order to achieve the pairwise dyadic data set, Kenny et al. (2006) advise the creation of grand-mean-centred scores, using *z* scores to obtain standardised and unstandardised regression coefficients – a necessary step to ensuring both *actor* and *partner effects.* The *actor* and *partner* effects of the dyadic data are presented in Chapter 6.

This chapter has identified the overall aims of the study and the research questions. It has provided a rationale for the choice of study design, population, sample and selection process, based on the set inclusion/exclusion criteria. The chapter progressed by detailing the data collection procedure, as well as giving due consideration to the relevant ethical issues. The chapter concluded by presenting the relevant statistical tests that were used to obtain the results in Chapters 4 to 6, which will address the following: patients' and family caregivers' sociodemographic characteristics, clinical information and differences for patients' and caregivers' contribution to patient self-care and quality of at TP1 and TP2; caregiver burden and patient and family caregiver baseline factors (including self-care) that predict caregiver burden at TP2, and the effects of baseline self-care management, maintenance and confidence as predictors of quality-of-life outcomes in dyadic relationships.

CHAPTER 4

RESULTS

4.1 Introduction

This chapter presents data on the patients' and family caregivers' socio-demographics and clinical information, and differences between them for self-care and quality of life on hospital discharge (TP1) and six months later (TP2).

4.2 Socio-demographics and clinical information

4.2.1 Background information

Sociodemographic data were collected from 52 patients diagnosed with heart failure (HF) and their family caregivers at baseline (TP1), following hospital discharge. However, 46 patients and their family caregivers remained in the study at 6 months follow-up (TP2); only these patient–caregiver pairs (dyads) were included in the data analysis. Most patients were married (96.2%) and the other 3.8% were in a cohabiting relationship (Table 9). There were statistically significant differences noted in gender; the majority of the patients were male (80.4%) compared to female patients (19.6%). The patients were aged from 40–90 years, of whom 52% were over 70 years old (Table 9). Over two-thirds (73.9%) of the patients were retired. The majority of the family caregivers were female (80.4%), and the greatest number (30.4%) were in the 61–70 age group (Table 9). Statistically significant differences were also noted in education levels; more caregivers studied beyond secondary education, compared to patients (Table 9). The results revealed these patients and family caregivers were within SIMD deprivation categories 1–3, and the remaining were within SIMD deprivation categories 4–5, indicating areas of greater deprivation (Scottish Government, 2016). Statistically significant differences were also found in physical activity levels; twenty-seven (58.7%) patients reported being "not very active – physically inactive", compared to 23.9% of family caregivers who were "not very active – physically inactive" (Table 9). In relation to alcohol intake, eight patients (17.4%) consumed greater than the recommended 14 units per week, consistent with family caregivers (Table 9). Six (13%) of patients were current smokers, compared to 23.9 % of family caregivers (Table 9).

Table 9: Socio-Demographic variables and lifestyle factors for patients and caregivers at baseline (TP1)

Parameter		Patients *n* (%)	Care Givers *n* (%)	*P*-value
Gender	Male	37 (80.4)	9 (19.6)	**<0.0001**
	Female	9 (19.6)	37 (80.4)	
Age	40–50	2 (4.3)	1 (2.2)	0.044
	51–60	7 (15.2)	12 (26.1)	
	61–70	13 (28.3)	14 (30.4)	
	71–80	17 (37.0)	12 (26.1)	
	81–90	7 (15.2)	7 (15.2)	
Employment	Employed	11 (23.9)	13 (28.3)	0.583
	Unemployed	1 (2.2)	0 (0%)	
	Retired	34 (73.9)	33 (71.7)	
Education	Secondary	31 (67.4)	20 (43.5)	**0.008**
	Further Education	6 (13.0)	13 (28.3)	
	University	9 (19.6)	13 (28.3)	
Occupation	Professional to intermediate	11 (23.9)	15 (32.6)	0.095
	Skilled (no manual, manual)	12 (26.1)	19 (41.3)	
	Partly skilled, non-skilled	23 (50.0)	12 (26.1)	
Deprivation	SIMD 1–3	25 (54.3)	25 (54.3)	1
	SIMD 4–5	21 (45.7)	21 (45.7)	
Physical activity	Very – fairly active	19 (41.3)	35 (76.1)	**<0.0001**
	Not very active – physically inactive	27 (58.7)	11 (23.9)	
Alcohol intake	Zero	19 (41.3)	12 (26.1)	0.241
	< 14 units/week	19 (41.3)	26 (56.5)	
	> 14 units/week	8 (17.4)	8 (17.4)	
Smoking	Smoker	6 (13.0)	11 (23.9)	1
	Ex-smoker	24 (52.2)	14 (30.4)	
	Never	16 (34.8)	21 (45.7)	
Health issues	No issues		20 (43.5)	
	1 issue		15 (32.6)	
	> 1		11 (23.9)	
Marital Status (Married)			45 (96.2)	

***SIMD Scottish Index of Multiple Deprivation.**

4.3 Patients' clinical data

Table 10 shows common cardiac drugs prescribed to the study participants that are recommended by the ESC (2016) Guidelines for the diagnosis and treatment of acute and chronic heart failure (Ponikowski, 2016). Fourteen patients (26.9%) were on combined therapy (3 drugs) which included either an Angiotensin Converting Enzyme Inihibitor (ACEi), Angiotenisin Receptor Blocker (ARB) or Angiotensin Receptor Neprilysin Inhibitor (ARNI), with a beta blocker and Mineralocorticoid Receptor Antagonist (MRA). Thirty-two patients (61.5%) were on either an ACE-inhibitor, ARB or ARNI. Twenty-five patients (48.1%) were on a beta-blocker; twenty-five (48.1%) were on a diuretic and seventeen (32.7%) were on an MRA. The ARNI (sacubitril/valsartan) was prescribed in patients with an EF of < 35% with ongoing symptoms, despite optimum ACE-inhibitor or ARB therapy (Jhund & McMurray, 2016).

Table 10 presents the NYHA classifications for the sample. More than half of the patients were NYHA class 3, which indicates a marked limitation of physical activity and ordinary activity that results in dyspnoea, fatigue or palpitations. Two patients (4.3.%) were in NYHA class 4, indicating that symptom burden is significant, and that any physical activity causes discomfort, and symptoms may also be present at rest. Table 10 details information relating to the ejection fraction (EF) of the sample. Thirty-nine (84.8%) of the patients were in the HFrEF category (EF < 40%).

Further, 25 (54.3%) of the patients had a new diagnosis of HF, and 21 (45.7%) had a decompensation.

Table 10: Patients' clinical variables: descriptive statistics

Parameter	*N*=46 (%)
Drugs	
• ACE inhibitor/Angiotensin Receptor Blocker/Angiotensin Receptor Neprilysin Inhibitor	32 (61.5)
• Beta-Blocker	25 (48.1)
• Diuretic	25 (48.1)
• Mineralocorticoid receptor antagonist	17 (32.7)
• Three Drugs (ACEi/ARB/ARNI + Beta Blocker + Mineralocorticoid	14 (26.9)
New York Heart Association Scale (NYHA)	
• 1	0 (0%)
• 2	19 (41.3)
• 3	25 (54.3)
• 4	2 (4.3)
Ejection Fraction	
• LVEF < 40%	39 (84.8)
• LVEF 40–49%	6 (13.0)
• LVEF >50%	0
• Not recorded	1 (2.2)
Presentation	
• New Diagnosis	25 (54.3)
• Decompensation	21 (45.7)

*ACE – Angiotensin Converting Enzyme; *ARB – Angiotensin Receptor Blocker; *NYHA – New York Heart Association classification

4.4 Time-point One: Patient and Family Caregiver Self-care scores

4.4.1 Introduction

Forty-six patients and their family caregivers' data were analysed at time-point one (baseline) and at time-point two (6 months). Table 11 presents the results for the SCHFI for the patient and the family caregiver. The patients' self-care total score median value was 51.00 (IQR 42–57); the median value for the self-care maintenance score was 22.00 (IQR 19–29); the self-care management median value was 13.00 (IQR 10-14); and self-care confidence median score was 14.50 (IQR 10-17). These scores indicate that patient self-care maintenance, management and confidence at TP1 was below the recommended threshold of 70 (Cocchieri et al., 2015). Appendix 28 presents the individual items of the SCHFI. At TP1, the highest rating identified for the patients within the self-care maintenance sub-domain were those related to “seeing the doctor or nurse”; “checking ankles for swelling” and “trying to avoid getting sick”. Items that were rated the lowest (areas given least priority) within the self-care maintenance sub-domain were those relating to “asking for low salt items when eating out” and “exercising for 30 minutes”. In the self-care management sub-domain, the highest rating identified for patients was in relation to “calling the doctor or nurse for guidance” and “reducing fluid intake”. The lowest rating identified at TP1 was in relation to “being sure that a remedy helped or did not help” and “recognising symptoms associated with heart failure.” In the self-care confidence sub-domain, the highest rating identified was in relation to “following the treatment advice given” and “recognising changes in health as they occur”. The lowest ratings were in relation to “keeping free of HF symptoms” and “evaluating the effectiveness of a remedy”.

The family caregivers’ contribution to self-care total median score at TP1 was 48.00 (IQR 42–53); self-care maintenance median score was 19.50 (IQR 15–23); self-care management median score was 14.00 (IQR 11–16); and self-care confidence median score was 14.00 (IQR 11–17) (Table 10). These scores indicate that family caregivers’ knowledge relating to self-care behaviours is insufficient and their contribution to maintenance, management and confidence is inadequate, and also below the recommended threshold of 70. Appendix 29 presents the individual items of the CC-SCHFI. At time-point one, the highest ratings for caregiver contribution to self-care maintenance were those related to “seeing their doctor or nurse” and “trying to avoid them getting sick”. The lowest ratings in relation to caregiver contribution to self-care maintenance were those related to “asking for low salt items when eating out” and encouraging them to “exercise for 30 minutes”. In the caregiver contribution to self-care management sub-domain, the highest ratings were those related to “calling their doctor or nurse for guidance” and “reducing the salt in their diet”. The lowest ratings were in relation to “being sure that a remedy helped or not” and “recognising breathing difficulties as a symptom of heart failure”. In the self-care confidence sub-domain, the highest ratings were in relation to “following treatment advice” and “recognising health changes”. The lowest caregiver contribution ratings were in relation to “preventing heart failure symptoms” and “evaluating how well a remedy works”.

4.4.2 Differences between patients’ and family caregivers’ contribution to self-care at time-point one.

Table 11 demonstrates a statistically significant difference between patients’ and family caregivers’ self-care maintenance at TP1 ($p = 0.015$). These results indicate that the patients were contributing more to self-care maintenance (i.e., weighing themselves daily, observing ankles for swelling, or adhering to a low salt diet) than their caregivers were assisting them with. The differences between the patients’ and caregivers’ self-care total score, self-care management and self-care confidence scores did not reach statistical significance (Table 11).

Table 11: Patient and family caregiver Time Point 1 Questionnaires

Questionnaire	**Patient**		**Family Caregiver**		***P*-value**
	Median	**IQR**	**Median**	**IQR**	
SCHFI/CCSCHFI					
Total score	51.00	(42–57)	48.00	(42–53)	*0.331*
Maintenance	22.00	(19–29)	19.50	(15–23)	***0.015***
Management	13.00	(10–14)	14.00	(11–16)	*0.155*
Confidence	14.50	(10–17)	14.00	(11–17)	*0.928*
SF-12					
Physical Component Scores	34.96	(31–39)	40.39	(38–46)	**< *0.0001***
Mental Component Scores	46.29	(41–51)	47.42	(42–51)	*0.756*
MLwHFQ					
Total	59.50	(51–75)	29.50	(15–39)	**< *0.0001***
Physical Component Score	29.00	(24–34)	9.50	(5–15)	**< *0.0001***
Emotional Component Score	14.00	(10–19)	10.00	(6–15)	***0.001***

4.5 Time-point Two: Patient and Family Caregiver scores

4.5.1 Introduction

Table 12 presents the results for SCHFI and CCSCHFI scores at TP2. The patients' median self-care total score was 53.00 (IQR 47–55); the median self-care maintenance score was 22.00 (IQR 20–27); the median self-care management score was 12.00 (IQR 11–17); and the median self-care confidence score was 15.00 (IQR 13–19). This indicates that the patients' engagement in self-care remained inadequate at TP2. Appendix 28 shows the individual items of the SCHFI at TP2. The highest rating for patients' TP2 self-care maintenance sub-domain was similar to TP1 – "seeing your doctor or nurse"; "checking ankles for swelling" and "trying to avoid getting sick". The lowest rating was for "forgetting to take one of your medicines" and "asking for low salt items when eating out". Items that were rated the highest within the self-care management sub-domain were similar to TP1 – "call your doctor or nurse for guidance" and "reducing your fluid intake". The lowest rating related to "being sure that a remedy helped" and "recognising symptoms as heart failure". Like TP1 – the highest rating for self-care confidence was for "following the treatment advice given" and "recognising changes in your health if they occur". The lowest rating was for "keeping yourself free of heart failure symptoms".

The family caregivers' median total score for CCSCHFI was 54.00 (IQR 46-57); the median self-care maintenance score was 21.00 (IQR 16-24); the median self-care management score was 13.50 (IQR 12-16); and the median self-care confidence score was 15.00 (IQR 12-18). This indicates that caregivers' contribution to self-care at TP2 remains inadequate. Appendix 29 shows the individual items of the CC-SCHFI at TP2. The highest ratings for caregiver contribution to self-care maintenance sub-domain were similar to TP1 - "seeing their doctor or nurse" and "trying to avoid them getting sick". The lowest rating was in relation to "asking for low salt items while eating out". In the caregiver contribution to self-care management scale, the highest scores were similar to TP1 - "calling their doctor or nurse for guidance" and "reducing the salt in their diet". The lowest ratings were in relation to "being sure that a remedy helped or not" and "recognising breathing difficulties as a symptom of heart failure". Within the self-care confidence sub-domain, the highest ratings were similar to TP1 - "following treatment advice" and "recognising health changes". The lowest ratings were for "preventing heart failure symptoms" and "evaluating how well a remedy works".

Table 12: Patient and family caregiver time point two questionnaires

Questionnaire	Patient		Family Caregiver		*P*-value
	Median	IQR	Median	IQR	
SCHFI/CCSCHFI					
Total score	53.00	(47–55)	54.00	(46–57)	*0.640*
Maintenance	22.00	(20–27)	21.00	(16–24)	*0.189*
Management	12.00	(11–17)	13.50	(12–16)	*0.345*
Confidence	15.00	(13–19)	15.00	(12–18)	*0.698*
SF-12					
Physical Component Scores	35.53	(32–39)	40.95	(37–43)	**< *0.0001***
Mental Component Scores	45.09	(40–50)	46.87	(41–51)	*0.516*
MLwHFQ					
Total	66.50	(30–81)	24.00	(5–42)	**< *0.0001***
Physical Component Score	30.50	(20–37)	8.00	(1–17)	**< *0.0001***
Emotional Component Score	17.50	(9–21)	10.00	(2–15)	**< *0.0001***

*****SF-12 Short Form 12 Health Survey
*MLwHFQ – Minnesota Living with Heart Failure Questionnaire
*SCHFI – Self-care of Heart Failure Index

4.5.2 Differences between patients' and family caregivers' contribution to self-care at time-point two

Table 12 demonstrates no statistically significant differences between the patients' and caregivers' self-care total and sub-domain scores at TP2. This indicates that patients and caregivers were contributing to self-care at TP2. It may be that caregivers were contributing more at TP2 because of patient deterioration.

No statistically significant changes were found in patients' self-care scores from TP1 to TP2 (Table 13). Table 14 demonstrates a statistically significant (p = 0.016) change in family caregivers' contribution to self-care (total score) from TP1 to TP2. This suggests that the family caregivers were contributing more to patient self-care at TP2. However, the scores for both patients and caregivers remain below the recommended threshold of 70.

4.6 Time-point One: Patient and Family Caregiver Quality of Life (SF-12)

4.6.1 Introduction

All patients completed the UK SF-12 Short Form Health Survey (UK SF-12) at baseline (TP1) and he 6-months' follow-up (TP2) (Ware et al., 1998). Table 11 presents the results for the SF-12 Physical Component Scores (PCS). The patients' PCS median score was 34.96 (IQR 31-39), which indicates poorer physical health compared to the general population. The family caregivers' PCS score was 40.39 (IQR 38-46) (Table 11). This indicates their perceived physical health status was also below the population average.

4.6.2 Differences between patients' and family caregivers' SF-12 PCS at time-point one

Table 11 indicates there were statistically significant differences between the patients' and the family caregivers' PCS at TP1 (p < 0.0001). This may be explained by the patients' high symptom burden and variations in NYHA and EF.

Table 13: Patients' changes in scores from time-point one to time-point two

Questionnaire	Patient Time Point 1		Patient Time Point 2		*P*-value
	Median	IQR	Median	IQR	
SCHFI					
Total score	51.00	(42–57)	53.00	(47–55)	*0.266*
Maintenance	22.00	(19–29)	22.00	(20–27)	*0.770*
Management	13.00	(10–14)	12.00	(11–17)	*0.073*
Confidence	14.50	(10–17)	15.00	(13–19)	*0.127*
SF-12					
Physical Component Score	34.96	(31–39)	35.53	(32–39)	*0.826*
Mental Component Score	46.29	(41–51)	45.09	(40–50)	*0.692*
MLwHFQ					
Total score	59.50	(51–75)	66.50	(30–81)	*0.974*
Physical Component Score	29.00	(24–34)	30.50	(20–37)	*0.573*
Emotional Component Score	14.00	(10–19)	17.50	(9–21)	*0.757*

*****SF-12 Short Form 12 Health Survey

*MLwHFQ – Minnesota Living with Heart Failure Questionnaire

*SCHFI – Self-care of Heart Failure Index

Table 14: Family caregivers' changes in scores from time point one to time point two

Questionnaire	Family Caregiver Time Point 1		Family Caregiver Time Point 2		*P*-value
	Median	IQR	Median	IQR	
CCSCHFI					
Total score	48.00	(42–53)	54.00	(46–57)	***0.016***
Maintenance	19.50	(15–23)	21.00	(16–24)	*0.235*
Management	14.00	(11–16)	13.50	(12–16)	*0.421*
Confidence	14.00	(11–17)	15.00	(12–18)	*0.323*
SF-12					
Physical Component Score	40.39	(38–46)	40.95	(37–43)	*0.536*
Mental Component Score	47.42	(42–51)	46.87	(41–51)	*0.727*
MLwHFQ					
Total score	29.50	(15–39)	24.00	(5–42)	*0.639*
Physical Component Score	9.50	(5–15)	8.00	(1–17)	*0.885*
Emotional Component Score	10.00	(6–15)	10.00	(2–15)	*0.771*

*****SF-12 – Short Form 12 Health Survey

*MLwHFQ – Minnesota Living with Heart Failure Questionnaire

*SCHFI – Self-care of Heart Failure Index

4.6.3 Patients' and family caregivers' SF-12 MCS at time-point one

The patients' MCS median value was 46.29 (IQR 41–51) at TP1 (Table 11), which is lower than the population average of 51. This indicates that the patients in the sample experienced greater psychological distress and issues relating to role disability due to emotional problems (Ware et al., 1998). Similarly, the family caregivers’ MCS median value was 47.42 (IQR 42–51) which indicates that they were also experiencing poorer perceived mental health (Table 11).

4.6.4 Differences between patients’ and family caregivers’ SF-12-MCS at time-point one

Table 11 shows there were no statistically significant differences between patients and family caregivers for MCS at time point one, which suggests that there may be no important differences between the mental health of the patient and the family caregiver.

4.7 Time-point Two: Patient and Family Caregiver Quality of Life (SF-12)

4.7.1 Introduction

Table 12 presents the SF-12 Physical Component Scores (PCS) at TP2. The patients’ median PCS score was 35.53 (IQR 32–39), indicating poorer physical health than the general population. The family caregivers’ median PCS score was 40.95 (IQR 37–43) (Table 12), which is also below the general population.

4.7.2 Differences between patients’ and family caregivers’ SF-12-PCS at time-point two

Table 12 indicates that the differences between the patients and family caregivers at time point two is significant ($p < 0.0001$), which indicates that the patients’ physical health is poorer than their family caregivers.

There were no significant changes in the patients’ PCS from TP1 to TP2 (Table 13). Likewise, there was no statistically significant change in the family caregivers’ PCS from TP1 to TP2 (Table 14).

4.7.3 Patients’ and family caregivers’ SF-12 MCS at time-point two

The patients’ median MCS was 45.09 (IQR 40–50) and the family caregivers’ median MCS was 46.87 (IQR 41–51), which remained below the population mean value of 51 at follow-up (Table 12).

4.7.4 Differences between patients and family caregivers SF-12-MCS at time-point two

The difference between patients’ and family caregivers’ MCS at TP2 was non-significant (Table 12), suggesting that their perceived mental health status is similar.

The change in patients’ MCS from TP1 to TP2 was non-significant (Table 13). Similarly, the change in family caregivers’ MCS from TP1 to TP2 was non-significant (Table 14).

4.8 Time-point One: Patient and Family Caregiver Quality of Life (MLwHFQ)

4.8.1 Introduction

The patients’ median MLwHFQ (total score) was 59.50 (IQR 51–75). The family caregivers’ median MLwHFQ (total score) was 29.50 (IQR 15–39) (Table 11).

4.8.2 Differences between patients’ and family caregivers’ MLwHFQ total score at time-point one

Table 11 indicates that statistically significant differences between patients’ and family caregivers’ MLwHFQ (total scores) at time-point one ($p < 0.0001$), suggesting that patients have a poorer quality of life at baseline than their family caregivers.

4.9 Time-point Two: Patient and Family Caregiver Quality of Life (MLwHFQ total)

4.9.1 Introduction

The patients’ median MLwHFQ (total score) was 66.50 (IQR 30–81), indicating that their overall quality of life remained poor at TP2 (Table 12). The family caregivers’ median MLwHFQ (total score) was 24.00 (IQR 5–42), indicating that their quality of life was good at TP2.

4.9.2 Differences between patients and family caregivers' MLwHFQ total score at time-point two

Table 12 indicates that the differences between the patients and family caregivers MLwHFQ (total score) at TP2 are statistically significant (p < 0.0001). This indicates that patients' quality of life is much poorer than that of their caregivers.

There were no significant changes between the patients' MLwHFQ (total score) from TP1 to TP2 (Table 13). Similarly, no significant changes were noted between the family caregivers' MLwHFQ (total score) from TP1 to TP2, (Table 14).

4.10 Time-point One: Patient and Family Caregiver Quality of Life (MLwHFQ PCS)

Table 11 presents the result of the physical component scores of the MLwHFQ. The patients' MLwHFQ PCS median value was 29.00 (IQR 24–34) (Table 11). The family caregivers' MLwHFQ PCS median value was 9.50 (IQR 5–15). These results indicate that the patients' physical health is poorer than their caregivers.

4.10.1 Differences between patients' and family caregivers' MLwHFQ PCS at time-point one

Table 11 indicates that the differences between the patients' and family caregivers' MLwHFQ PCS at TP1 were statistically significant (p < 0.0001). These results highlight that patients' physical health-related quality of life is poorer than their family caregivers' physical health-related quality of life at TP1.

4.11 Time-point Two: Patient and Family Caregiver Quality of Life (MLwHFQ PCS)

4.11.1 Introduction

Table 12 presents the results of the MLwHFQ PCS. The patients' median score was 30.50 (IQR 20–37) and the caregivers' MLwHFQ PCS median score was 8.00 (IQR 1–17).

Table 13 indicates that there were no statistically significant changes in the patients' MLwHFQ PCS from TP1 to TP2. Similarly, there was no statistically significant changes in the family caregivers' MLwHFQ PCS from TP1 to TP2 (Table 14).

4.11.2 Differences between patients' and family caregivers' MLwHFQ PCS at time-point two

Table 12 highlights that the difference between patients and family caregivers at TP2 are statistically significant ($p < 0.0001$). The results indicate that family caregivers' physical quality of life is much better than patients' physical quality of life at TP2.

4.12 Time-point One: Patient and Family Caregiver Quality of Life (MLwHFQ ECS)

4.12.1 Introduction

Table 11 presents the patients' MLwHFQ ECS at TP1. The median score was 14.00 (IQR 10–19). The family caregivers' MLwHFQ ECS median score was 10.00 (IQR 6–15) (Table 11), indicating the patients' emotional health was poorer than their caregivers at TP1.

4.12.2 Differences between patients and family caregivers' MLwHFQ ECS at time-point one

Table 11 highlights that the difference between patients and family caregivers MLwHFQ ECS at TP1 were statistically significant (*p* 0.001). This result indicates that the patients' emotional quality of life was much poorer than their caregivers at TP1.

4.13 Time-point Two: Patient and Family Caregiver Quality of Life (MLwHFQ ECS)

4.13.1 Introduction

Table 12 presents the results of the MLwHFQ ECS. The median score was 17.50 (IQR 9–21) for patients and 10.00 (IQR 2–15) for family caregivers, indicating that the caregivers' emotional health was much better than the patients at TP2.

Table 13 shows that there were no statistically significant changes in patients' MLwHFQ ECS from TP1 to TP2, indicating that their emotional health remained much the same at both time points. Similarly, there was no statistically significant changes in the family caregivers' MLwHFQ ECS from TP1 to TP2; their median scores remained the same at both time-points (Table 14).

4.13.2 Differences between patients' and family caregivers' MLwHFQ ECS at time-point two

Table 12 indicates that the difference between patients' and family caregivers' MLwHFQ ECS at TP2 were statistically significant ($p < 0.0001$). These results suggest that patients' emotional quality of life at 6 months (TP2) is significantly poorer than that of their family caregivers.

In summary, Chapter 4 commenced by presenting information relating to the patients' and family caregivers' socio-demographics and clinical data (Table 9 and 10). Tables 11 to 14 reported the results for self-care and quality of life in both patients and caregivers at TP1 and TP2. In addition, the differences in scores from TP1 to TP2 for patients and family caregivers. The results revealed that patients' engagement in self-care was poor at both TP1 and TP2. Family caregivers' knowledge and contribution to self-care was insufficient and less than the recommended score of 70. At TP1, significant differences were noted between patient and family caregiver self-care maintenance scores, indicating that patients were contributing more than their caregivers were assisting them with. At TP2, scores indicated that self-care and family caregiver contribution to self-care remain inadequate. Unlike TP1, no statistically significant differences were found between the patients' and family caregivers' self-care maintenance score, indicating that both were contributing similarly to self-care maintenance. A further significant change was found between the family caregivers' total CCSCHFI score from TP1-TP2, indicating that family caregivers were contributing more to self-care at TP2, which may be as a result of the patients' poorer health status. Furthermore, specific items from the SCHFI and CCSCHFI were identified as being areas where patients and caregivers gave least priority to engaging in. These included dietary adherence, exercise and recognising signs and symptoms associated with a potential episode of decompensation (Appendix 28 and 29).

Quality of life was measured using the SF-12 and the results indicate that the patients' PCS was lower than the general population, suggesting they have poorer physical health. Similarly, their MCS was lower than the average, indicating poorer mental health. The family caregivers' perceived physical health status was also below the population average, and their MCS indicated poorer perceived mental health at TP1. Significant differences were noted between patients' and family caregivers' PCS, with patients experiencing poorer physical health, but no significant differences were noted in relation to MCS. At TP2, the PCS and MCS remained below the general population for both patients and family caregivers. A significant difference was noted between the patients and family caregivers PCS, but not in MCS, suggesting that mental health affects patients and family caregivers equally.

The disease-specific (MLwHFQ) quality-of-life tool showed poor overall quality of life, as well as poorer physical and emotional health in patients at TP1. These differences were also significant at TP2, which indicates that the patients' overall quality of life is poorer than their family caregivers.

The next chapter presents the results of the caregiver burden scores at TP1 and TP2 and the differences between the two time-points.

CHAPTER 5

RESULTS

5.1 Introduction

The previous chapter discussed differences in patients' and family caregivers' self-care and quality of life at baseline (TP1) and at six months (TP2) (research question 1) and changes in these variables from baseline (TP1) to six months (TP2). Following on, this chapter presents the results of caregiver burden and changes in caregiver burden from baseline to six months. It also reports the results on the patient and family caregiver baseline factors that predict caregiver burden (outcome) at six months (research question 2). It was hypothesised that there would be patient and family caregiver baseline factors that predict caregiver burden at 6 months, i.e., personal characteristics, self-care, quality of life (SF-12 and MLwHFQ), patient physical activity, and caregiver burden at TP1.

5.2 Time-point One: Family Caregiver Burden (ZBI Scale)

5.2.1 Introduction

All family caregivers (*n*=52) completed the Zarit Burden Interview at baseline (TP1). The caregiver total mean score was 25.15 (SD 12.99), indicating mild-to-moderate burden, because of some of the following dimensions of caregiving: patient dependence, guilt, self-criticism, psychological burden, and role strain. Figure 3 illustrates the distribution of the Zarit Burden Interview scores at baseline (TP1). The distribution of scores indicates that 21 of the family caregivers reported little or no burden; 26 reported mild–moderate burden; and 5 reported moderate–severe burden. Figure 3 indicates that no family caregivers reported severe burden. The mean scores for caregiver burden are presented in Table 15.

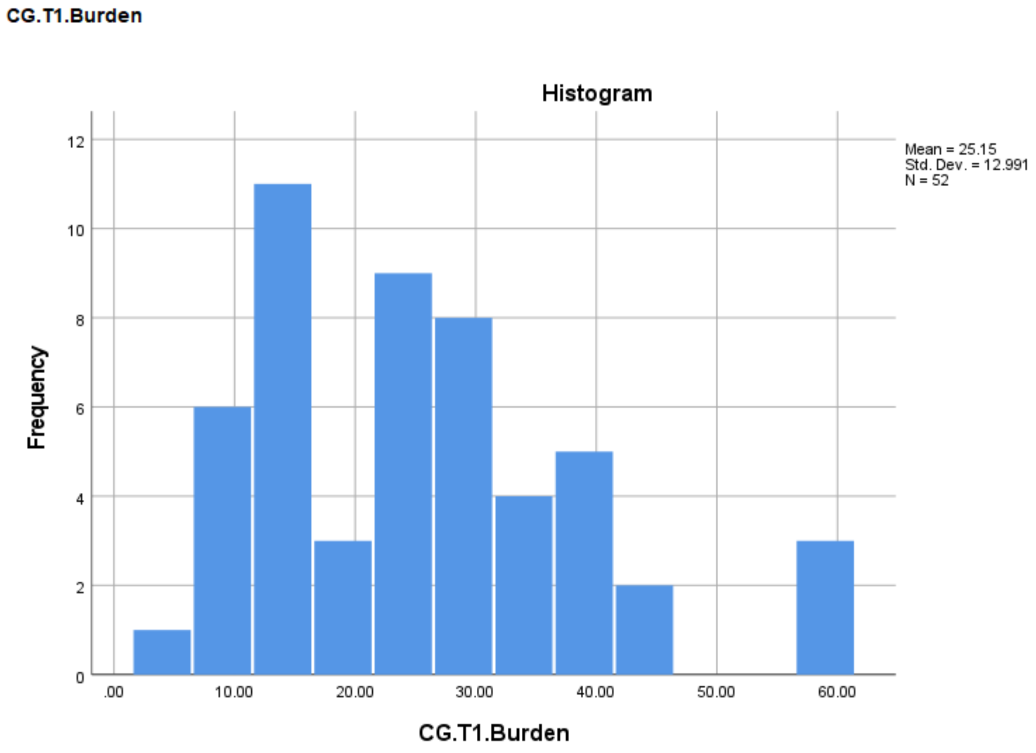

Figure 3: Histogram Distribution of Zarit Burden Interview Total Scores (Family Caregiver T1 Burden scores)

Table 15: Zarit Burden Interview Scores: Differences in scores from TP1 to TP2

Questionnaire	**Family Caregiver TP1**		**Family Caregiver TP2**		***P*-value**
	Mean	SD	Mean	SD	
Zarit Burden	25.15	12.99	26.0	14.88	0.623

5.3 Time-point Two: Family Caregiver Burden (ZBI Scale)

5.3.1 Introduction

Forty-six family caregivers completed the Zarit Caregiver Burden questionnaire at 6 months (TP2). At time point two, the mean total score was similar to the baseline total score, indicating mild-to-moderate burden. Similar to the baseline scores (TP1), no caregivers reported severe burden.

5.3.2 Changes in caregiver burden scores (ZBI Scale) from time-point one to time-point two

The family caregivers' total mean score from TP1 to TP2 is presented in Table 15. This result is higher than the significant level of 0.05, which indicates a lack of evidence supporting the hypothesis of a change from baseline (TP1) to the 6-month follow-up (TP2). However, a very slight increase in the caregivers' total mean score was observed at the 6-month follow-up (TP2), which may be reflective of the caregivers' responses to the patients' increasing symptom burden (Table 15).

5.4 Caregiver Burden and Patient and Family Caregiver Baseline Factors that Predict Caregiver Burden (Outcome)

5.4.1 Statistical analysis

To determine what patient factors (i.e., personal characteristics, self-care and quality of life) at baseline (TP1) were associated with family caregiver burden at the six months follow-up (TP2), a correlation matrix was constructed to test bivariate linear relationships.   Similarly, in order to determine what family caregiver baseline factors were associated with family caregiver burden at 6 months (TP2), a second correlation matrix was constructed to test bivariate linear relationships. Table 16 shows the patient and family caregiver (independent) variables included in the two correlation matrices.

Table 16: Patient and family caregiver baseline variables

Patient	Family caregiver
Self-care	**Contribution to self-care**
• Self-care management • Self-care maintenance • Self-care confidence	• Self-care management • Self-care maintenance • Self-care confidence
SF-12 Scores (perceived health status)	**SF-12 Scores (perceived health status)**
• Physical component score (PCS) • Mental component score (MCS)	• Physical component score (PCS) • Mental component score (MCS)
Minnesota Living with Heart Failure	**Minnesota Living with Heart Failure**
• MLwHFQ Total Score • MLwHFQ Physical component score (PCS) • MLwHFQ Emotional component score (ECS)	• MLwHFQ Total Score • MLwHFQ Physical component score (PCS) • MLwHFQ Emotional component score (ECS)
• Physical activity	• Caregiver Burden at time-point one.

The patient (independent) variables from the first correlation matrix (Table 17) that were statistically significantly correlated with caregiver burden at TP2 (dependent variable) were then tested in multiple linear regression (Model 1). Similarly, the caregiver (independent) variables from the second correlation matrix (Table 19) that significantly correlated with caregiver burden at TP2 (dependent variable) were tested in multiple linear regression (Model 2). The patient and caregiver (independent) variables that significantly correlated with caregiver burden at time-point two were included in the final multiple regression model (Model 3). This procedure was necessary to assess the level of correlation between variables, as a high level of correlation (or multicollinearity) may have led to numerical problems in fitting the model, especially with smaller sample sizes (Schroeder et al., 2017). Appendix 30 shows the assessment of multi-collinearity in the regression models. The variance inflation factor (VIF) and tolerance were used. According to Schroeder et al. (2017) multi-collinearity is found when the VIF is greater than 4 and tolerance less than 0.20. The models used in the regression were not indicative of multi-collinearity.

According to Brace et al. (2016), multiple linear regression or multiple logistical regression are suitable methods when examining relationships between two or more variables, but consideration should be given in determining what variables should be included in the regression model given the sample size. Austin and Steyerberg (2015) suggest that the minimum subjects per predictor variable should be five, while recognising that the ideal would be twenty. This assertion satisfies the number of subjects per variable in this study. Field (2018) indicates that the outcome variable should be normally distributed for conducting multiple linear regression, and, if linearity is not achieved, the model is invalid. In this study, the outcome variable, i.e., caregiver burden at TP2, was approximately normally distributed, as indicated in the regression standardised residual illustrated in Figure 4. In addition, Appendices 31 and 32 present the P-P plot and Scatterplot of caregiver burden (outcome variable) at TP2.

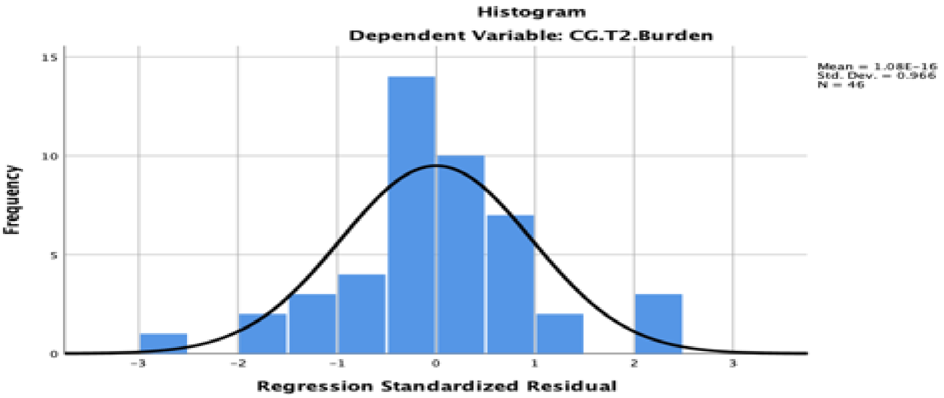

Figure 4: TP2 Caregiver Burden

Table 17 indicates five patient statistically significant correlations with the outcome variable (caregiver burden). These include self-care confidence, SF-12 MCS, MLwHFQ (total score), MLwHFQ ECS, and physical activity. Pearson's Product Moment correlation coefficient was used to quantify the relationship between each of the continuous independent variables. Self-care confidence and the SF-12 MCS were weakly negatively correlated with caregiver burden (outcome). The MLwHFQ total and ECS were weakly positively correlated with caregiver burden. Patients' physical activity was moderately positively correlated with caregiver burden (outcome).

Table 17: Correlation Matrix: Patient TP1 variables that predict Caregiver Burden at TP2 (Dependent Variable)*

Patients – Time Point 1 Independent Variables	***R* and *p* values**
Self-Care Maintenance	
Pearson Correlation	*R* = -0.265
Sig. (2 tailed)	*p* = 0.076
Self-Care Management	
Pearson Correlation	*R* = 0.168
Sig. (2 tailed)	*p* = 0.266
Self-Care Confidence	
Pearson Correlation	***R* = -0.322***
Sig. (2 tailed)	***p* = 0.029**
SF-12 PCS	
Pearson Correlation	*R* = 0.043
Sig. (2 tailed)	*p* = 0.777
SF-12 MCS	
Pearson Correlation	***R* = -0.311***
Sig. (2 tailed)	***P* = 0.035**
MLwHFQ Total Score	
Pearson Correlation	***R* = 0.372***
Sig. (2 tailed)	***p* = 0.011**
MLwHFQ ECS	
Pearson Correlation	***R* = 0.321***

Patients – Time Point 1 Independent Variables	***R* and *p* values**
Sig. (2 tailed)	***p* = 0.029**
MLwHFQ PCS	
Pearson Correlation	*R* = 0.273
Sig. (2 tailed)	*p* = 0.067
Physical Activity	
Pearson Correlation	***R* = 0.545****
Sig. (2 tailed)	***p* = 0.000**

5.5 Model 1: Multiple linear regression of patients' time-point one variables

Table 18 presents the results of Model 1, which was statistically significant (F = 5.788, $p < 0.0001$ using the Enter Method). Forty-two percent of the variance was accounted for by the five variables in the model. The results indicate that there are two statistically significant predictors of caregiver burden at TP2: the patients' mental component score (MCS), and the patients' level of physical activity. The MCS ($\beta = -0.582$, $p = 0.026$) showed a negative beta coefficient, indicating that an increase in patients' MCS at TP1 (i.e., higher MCS is associated with better mental health) is correlated with caregiver burden at TP2 (burden decreases at time-point two). In addition, Table 18 indicates that baseline physical activity ($p < 0.001$) predicts caregiver burden at TP2 (burden increases at TP2).

Table 18: Patients' TP1 variables that predict family caregiver burden at TP2

Model	**SS**	**df**	**F**	***R***	**Adjusted R^2**	**Sig**
1	4724.824	5	5.788	0.410	0.420	0.000

Variables	**Beta**	**T**	**Significance**	**95% CI of Beta Lower**	**95% CI of Beta Upper**
Self-care confidence	-0.398	-0.876	0.386	-1.315	0.520
MLwHFQ Total	0.147	0.806	0.425	-0.222	0.516
SF-12 MCS	-0.582	-2.309	**0.026**	-1.091	-0.072
MLwHFQ ECS	-0.258	-0.445	0.658	-1.430	0.913
Physical Activity	14.817	3.473	**0.001**	6.194	23.440

Table 19 indicates six statistically significant correlations for family caregivers' TP1 variables and caregiver burden at TP2. These correlations were caregiver contribution to self-care maintenance, caregiver self-care confidence, MLwHFQ total score, PCS and ECS and TP1 caregiver burden. The statistically significant correlations ($p < 0.05$) were taken forward and included in the multiple regression model (Model 2). Caregiver contribution to patient self-care maintenance was weakly positively correlated with caregiver burden at TP2 (dependent variable), however, self-care confidence was weakly negatively correlated with caregiver burden. The MLwHFQ total score was moderately positively correlated with caregiver burden. Both MLwHFQ PCS and ECS were strongly positively correlated with caregiver burden. In addition, TP1 caregiver burden was strongly positively correlated with caregiver burden at TP2 (dependent variable).

*Table 19: Correlation Matrix: Family Caregiver TP1 variables that predict Caregiver Burden at TP2 *(Dependent Variable)*

Time-Point 1 Independent Variables (Family Caregivers)	***R* and *p*-values**
Self-Care Maintenance	
Pearson Correlation	***R* = 0.315***
Sig. (2-tailed)	***p* = 0.033**
Self-Care Management	
Pearson Correlation	*R* = 0.172
Sig. (2-tailed)	*p* = 0.254
Self-Care Confidence	
Pearson Correlation	***R* = -0.410****
Sig. (2-tailed)	***p* = 0.005**
SF-12 PCS	
Pearson Correlation	*R* = -0.192
Sig. (2-tailed)	*p* = 0.202
SF-12 MCS	
Pearson Correlation	*R* = -0.128
Sig. (2-tailed)	*p* = 0.398
MLwHFQ Total score	
Pearson Correlation	***R* = 0.597**
Sig. (2-tailed)	***p* = 0.000**
MLwHFQ PCS	
Pearson Correlation	***R* = 0.601****
Sig. (2 tailed)	***p* = 0.000**
MLwHFQ ECS	
Pearson Correlation	***R* = 0.629****
Sig. (2-tailed)	***p* = 0.000**
Caregiver Burden	
Pearson Correlation	***R* = 0.649****
Sig. (2-tailed)	***p* = 0.000**
Physical Activity	
Pearson Correlation	*R* = -0.004
Sig. (2-tailed)	*p* = 0.979

5.6 Model 2: Multiple linear regression of family caregivers’ Time-point One variables

Table 20 presents the results of the multiple regression Model 2. The model was statistically significant (F = 8.056, $p < 0.0001$ using the Enter Method). Forty-eight percent of the variance was accounted for by the six variables. The results indicate that there are two statistically significant predictors of caregiver burden at time-point two: the family caregivers’ MLwHFQ ECS; and TP1 caregiver burden. The MLwHFQ ECS (β 1.438, $p = 0.028$) showed a positive beta coefficient, indicating that an increase in family caregivers’ emotional component score at TP1 (i.e., higher MLwHFQ ECS is associated with poorer emotional health) is correlated with caregiver burden at TP2 (burden increases at time-point two). In addition, the baseline caregiver burden (β = 0.382, $p = 0.047$) shows a positive beta coefficient, indicating that an increased caregiver burden score at TP1 is correlated with increased caregiver burden at TP2.

Table 20: Multiple linear regression of the family caregivers’ TP1 variables that predict family caregiver burden at TP2.

Model	**SS**	**df**	**F**	**R**	**Adjusted R^2**	**Sig**
2	6229.117	6	8.056	0.553	0.485	0.000

Variables	**Beta**	**T**	**Significance**	**95% CI of Beta Lower**	**95% CI of Beta Upper**
Self-care maintenance	0.288	0.835	0.409	-0.410	0.987
Self-care confidence	-0.419	-0.898	0.375	-1.362	0.524
MLwHFQ total score	-0.495	-1.293	0.204	-1.270	0.280
MLwHFQ PCS	0.915	1.292	0.204	-0.518	2.349
MLwHFQ ECS	1.438	2.280	**0.028**	0.162	2.715
Time-point 1 caregiver burden	0.382	2.084	**0.047**	0.005	0.760

5.7 Model 3: Multiple linear regression of patients' and family caregivers' time-point one variables that predict caregiver burden at time-point two

Model 3 multiple linear regression included the statistically significant variables from Model 1 (patient) SF-12 MCS and physical activity, and Model 2 (family caregiver) MLwHFQ ECS, and TP1 caregiver burden (Tables 18 and 20). The model was found to be statistically significant (F = 17.786, *p* = 0.000), using the Enter method (Table 21).

Table 21: Multiple linear regression of patients' and family caregivers' TP1 variables that predict caregiver burden at TP2

Model	SS	df	F	R	Adjusted R^2	Sig.
3	7140.335	4	17.786	0.796	0.599	0.000

Variables	Beta	T	Significance	95% CI of Beta Lower	95% CI of Beta Upper
Patient SF-12 MCS	-0.330	-1.706	0.096	-0.721	0.061
Patient Physical Activity	11.088	3.446	**0.001**	4.590	17.587
Family Caregiver MLwHFQ ECS	0.680	2.138	**0.039**	0.038	1.322
Time-point 1 caregiver burden	0.425	2.926	**0.006**	0.132	0.719

Fifty-nine percent of the variance in the model can be accounted for by the four variables: patients' SF-12 MCS, patients' physical activity, family caregivers' MLwHFQ ECS, and time-point one caregiver burden. The final regression model indicated that patients' physical activity level, family caregivers' MLwHFQ ECS and TP1 caregiver burden remain statistically significant. Patients' physical activity level showed a positive beta coefficient (β = 11.088, *p* = 0.001) indicating that patients who were not very active – physically inactive – increased caregiver burden at TP2. Family caregivers' MLwHFQ ECS showed a positive beta coefficient (β = 0.680, *p* = 0.039), indicating that an increase in caregivers' ECS at TP1 was associated with an increase in caregiver burden at TP2 (i.e., increased MLwHFQ ECS indicates poorer health). In addition, the TP1 caregiver burden showed a positive beta coefficient (β = 0.425, *p* = 0.006), indicating that increased burden at TP1 is associated with increased caregiver burden at TP2 (Table 21).

In summary, the results presented in Chapter 5 indicate that caregiver burden did not change significantly from TP1 to TP2, however, an increase in the caregivers' mean score was observed at TP2, which may be a result of the patients' increasing symptom burden.

Model 1 of the multiple linear regression analysis revealed that caregiver burden at TP2 was predicted by patients' mental component scores (MCS) and level of physical activity at TP1. Increased mental component scores (i.e., higher scores are associated with better quality of life) was associated with a reduction in caregiver burden at TP2. Patients' increased physical inactivity was associated with an increase in caregiver burden at TP2.

Model 2 of the multiple linear regression revealed that caregiver burden at TP2 was predicted by caregivers' emotional component scores (ECS) at TP1. This indicates that family caregivers' poorer emotional status at TP1 predicted greater family caregiver burden at TP2, and also that increased caregiver burden at TP1 was associated with increased caregiver burden at TP2.

The final regression model (Model 3) combined the statistically significant predictor variables from Model 1 and Model 2. Caregiver burden at TP2 was predicted by the patients' lower physical activity levels at TP1, poor caregiver emotional health at TP1 (MLwHFQ ECS), and increased caregiver burden at TP1. Patients' level of physical activity remained overwhelmingly statistically significant as a predictor of caregiver burden at TP2.

The following chapter presents the results of the dyadic data analysis (*actor* and *partner effects*) of baseline (TP1) self-care and caregiver contribution to self-care on quality-of-life outcomes in patient–caregiver dyads at 6 months, using the APIM.

CHAPTER 6

RESULTS

SELF CARE AS PREDICTORS OF QUALITY-OF-LIFE OUTCOMES IN DYADIC RELATIONSHIPS

6.1 INTRODUCTION

This chapter presents information relating to the effects of patient baseline self-care and family caregivers' contribution to self-care on their own and on their family caregiver's quality of life at the 6-month follow-up (TP2). Quality of life was measured by use of the SF-12 Health Survey, which assessed the physical component scores (PCS) and mental component scores (MCS), and by the Minnesota Living with Heart Failure Questionnaire (MLwHFQ), which assessed the MLwHFQ total scores and the MLwHFQ subdomain scores for physical component scores (PCS) and the emotional component scores (ECS). The chapter reports on the effects of baseline self-care (i.e., self-care maintenance, self-care management and self-care confidence) on physical health (PCS, SF-12) and mental health (MCS, SF-12). It will also report on the effects of self-care management, maintenance, and self-care confidence on MLwHFQ total scores, PCS and ECS, highlighting the patient and caregiver *actor effects* and *partner effects* on these quality-of-life outcomes.

The *actor effect* refers to the impact of an individual's characteristics, i.e., the patient's self-care (or caregivers' contribution to self-care), at baseline on their own quality of life at 6 months, while controlling for the individual's quality of life at baseline. The *partner effect* refers to the impact of an individual's characteristics, i.e., the patient's self-care (or caregiver's contribution to self-care), at baseline on his or her partner's quality of life at 6 months, while controlling for quality of life at baseline. In total, 15 separate APIM models were computed, controlling for baseline quality of life as appropriate. Figure 5 presents the APIM model and demonstrates the *actor* and *partner effects* within the model. The results of the APIM models are presented in Tables 22 to 24. The chapter will conclude with an overall summary of the statistically significant *actor* and *partner effects* from the longitudinal dyadic data analysis using the APIM.

Prior to discussing the individual *actor* and *partner effects*, Figure 5 demonstrates the direction of *actor* and *partner effects*. Figure 6 demonstrates a more complex model, which also controls for baseline physical and mental (SF-12-PCS, SF-12 MCS) scores; and baseline total, physical, and emotional (MLwHFQ total, PCS and ECS) scores.

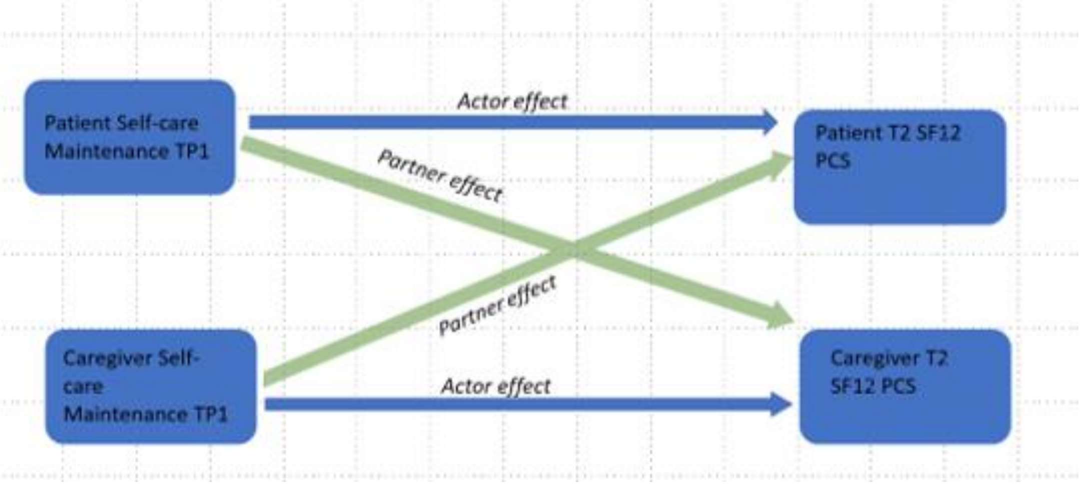

Figure 5: Actor and partner effects APIM example.

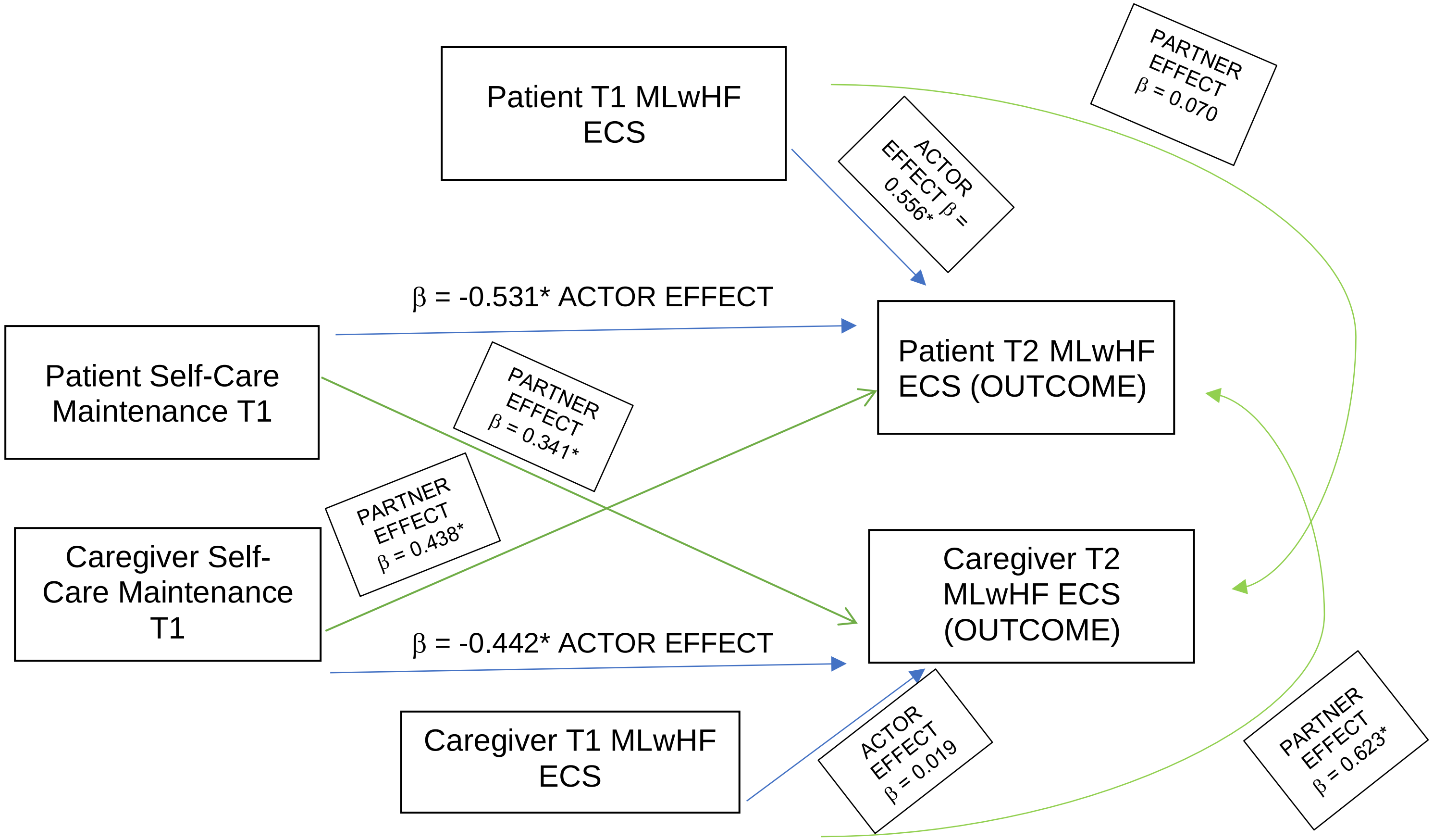

Figure 6: Actor *and* partner *effects of self-care maintenance on time-point two ECS*

6.2 Effects of self-care (management, maintenance and confidence on physical health (SF-12) outcomes

6.2.1 Physical health (PCS, SF-12)

Table 22 shows there were no statistically significant *actor effects* of patients' baseline self-care management, self-care maintenance or self-care confidence on their physical health (SF-12) outcomes at the 6-month follow-up (TP2), which suggests their level of engagement in symptom monitoring, treatment adherence and their evaluation of treatment had no impact on their physical health status at the 6-month follow-up (TP2). However, there were statistically significant *actor effects* for caregivers' baseline self-care maintenance (β = -0.358, *t* = -3.194, ***p* = 0.002**) and self-care confidence (β = -0.410, *t* = -2.641, ***p* = 0.010**). This suggests that **greater** caregiver contribution to symptom monitoring and treatment adherence resulted in a decrease in their own physical quality of life at TP2. The self-care confidence subdomain suggests that **greater** caregiver confidence at baseline (i.e., in patient symptom recognition) was significantly associated with their poorer physical health at the 6-month follow-up (TP2).

Table 22 shows there was a statistically significant *partner effect* for baseline self-care management (β = 0.360, *t* = 2.351, ***p* = 0.021**), which suggests that the patient's greater self-care management at baseline (TP1) predicted the caregiver's **better** physical health at the 6-month follow-up (TP2). Table 22 also shows a statistically significant *partner effect* for caregivers' contribution to self-care management (β = 0.383, *t* = 2.495, ***p* = 0.014**), which indicates that caregivers' greater contribution to patient self-care management at TP1 was associated with patients' better physical health at the 6-months follow-up (TP2).

6.3 Effects of self-care (management, maintenance and confidence on mental health (SF-12) outcomes

6.3.1 Mental Health (SF-12 MCS)

Table 22 indicates one statistically significant *actor effect* of baseline self-care confidence (β = 0.552, *t* = 2.646, ***p* = 0.010**) on their mental health (SF-12) outcomes at the 6-month follow-up (TP2). This indicates that patients' **greater** self-care confidence significantly predicted their better mental health (SF-12) outcomes at 6 months (TP2). In addition, Table 22 indicates two statistically significant *actor effects* for caregivers' baseline self-care maintenance (β = 0.402, *t* = 2.686, ***p* = 0.009**) and self-care confidence (β = 0.501, *t* = 2.401, ***p* = 0.018**) on the mental health (SF-12) outcomes at 6 months (TP2). These results suggest that caregivers' **greater** contribution to self-care maintenance at baseline, resulted in their **better** mental quality of life (SF-12) outcomes at the 6-month follow-up (TP2). Similarly, **greater** caregiver self-care confidence (i.e., in patient symptom recognition) at baseline was associated with their better mental quality of life (SF-12) outcomes at the 6-month follow-up (TP2).

There were no statistically significant *partner* effects of patients' baseline self-care maintenance or self-care confidence on the mental health (SF-12) outcomes of caregivers at the 6-month follow-up (TP2). However, there were two significant *partner effects* for caregivers' baseline self-care management (β = -0.504, *t* = -2.167, ***p* = 0.033**) and self-care maintenance (β = -0.712, *t* = -4.521, ***p* < 0.001**). This suggests that a caregiver's **greater** contribution to the patient's self-care management at baseline (TP1) predicted the patient's **poorer** mental health outcomes at the 6-month follow-up (TP2). For the maintenance domain, the results suggest the caregiver's **greater** contribution to patient self-care maintenance at baseline was associated with the patient's **poorer** mental health (SF-12) outcomes at the 6-month follow-up (TP2) (Table 22).

Table 22: Self-care as predictors of physical health (PCS) and mental health (MCS) outcomes (APIM)

Questionnaire SF-12 PCS T2 (Outcome)	**Patients**			**Caregivers**			**Questionnaire SF-12 MCS T2 (Outcome)**	**Patients**			**Caregivers**		
	Beta	***t***	***p***	**Beta**	***t***	***p***		**Beta**	***t***	***p***	**Beta**	***t***	***p***
Self-care Management							**Self-care Management**						
Actor effect (SCM, TP1)	-0.032	-0.209	0.835	-0.158	-1.023	0.309	*Actor effect (SCM, TP1)*	-0.273	-1.169	0.246	-0.058	-0.252	0.802
Partner effect (SCM, TP1)	0.360	2.351	**0.021***	0.383	2.495	**0.014***	*Partner effect (SCM, TP1)*	-0.190	-0.820	0.414	-0.504	-2.167	**0.033***
Actor effect (PCS, TP1)	0.258	2.082	**0.040***	0.183	1.477	0.143	*Actor effect (MCS, TP1)*	0.198	1.646	0.103	0.022	0.188	0.851
Partner effect (PCS, TP1)	0.118	0.951	0.344	0.407	3.262	**0.002****	*Partner effect (MCS, TP1)*	-0.078	-0.575	0.567	0.424	3.126	**0.002****
Self-care Maintenance							**Self-care Maintenance**						
Actor effect (SCMain,TP1)	0.090	0.810	0.420	-0.358	-3.194	**0.002***	*Actor effect (SCMain, TP1)*	0.173	1.156	0.251	0.402	2.686	**0.009****
Partner effect SCMain, TP1)	0.184	1.637	0.105	-0.008	-0.077	0.938	*Partner effect (SCMain, TP1)*	-0.138	-0.881	0.381	-0.712	-4.521	**0.001*****
Actor effect (PCS, TP1)	0.284	2.335	**0.022***	0.247	2.031	**0.045***	*Actor effect* (MCS, TP1)	0.106	0.992	0.324	-0.000	-0.004	0.997
Partner effect (PCS, TP1)	0.065	0.521	0.604	0.462	3.668	**0.001*****	*Partner effect* (MCS, TP1)	-0.144	-1.154	0.252	0.423*	3.390	**0.001****
Self-care Confidence							**Self-care Confidence**						
Actor effect (SCC, TP1)	-0.010	-0.065	0.948	-0.410	-2.641	**0.010***	*Actor effect (SCC, TP1)*	0.552	2.646	**0.010***	0.501	2.401	**0.018***
Partner effect (SCC, TP1)	0.252	1.585	0.116	0.060	0.378	0.706	*Partner effect (SCC, TP1)*	0.026	0.121	0.904	-0.272	-1.239	0.219
Actor effect (PCS, TP1)	0.292	2.303	**0.024***	0.295	2.328	**0.022***	*Actor effect* (MCS, TP1)	0.154	1.337	0.158	-0.025	-0.223	0.824
Partner effect (PCS, TP1)	0.068	0.499	0.619	0.403	2.933	**0.004****	*Partner effect* (MCS, TP1)	-0.024	-0.186	0.853	0.445	3.379	**0.001****

PCS, physical component score; T2 time-point two (6months); SCM self-care management; SCMain self-care maintenance; SCC, self-care confidence; TP1, time-point one (baseline) MCS, mental component score; SF-12 – SF-12 – Short Form Health Survey; $p < 0.05$*; $p < 0.01$**; $p < 0.001$***

6.4 Effects of self-care (management, maintenance and confidence on health-related quality-of-life outcomes

6.4.1 MLwHFQ total score

Table 23 indicates two statistically significant *actor effect* of patients' self-care maintenance (β = -0.982, *t* = -2.135, ***p* = *0.036***) and self-care confidence (β = -2.227, *t* = -3.730, ***p* < 0.001**). This suggests that **greater** patient contribution to self-care maintenance and self-care confidence at baseline was associated with lower MLwHFQ total scores, i.e., **better** quality of life at the 6-month follow-up (TP2). Two statistically significant *actor effects* were found for caregivers' contribution to self-care maintenance (β = -1.192, *t* = -2.591, ***p* = 0.012**) and self-care confidence (β = - 1.647, *t* = -2.758, ***p* = 0.007**). This suggests that **greater** caregiver contribution to self-care maintenance and self-care confidence at baseline was associated with **better** quality of life (MLwHFQ total score) at the 6-month follow-up (TP2).

There were no statistically significant *partner effects* of patient's baseline self-care management, self-care maintenance and self-care confidence on caregiver's quality of life (MLwHFQ total score) at the 6-month follow-up (TP2). However, one statistically significant *partner effect* was found for caregiver's baseline contribution to self-care maintenance (β = 1.606, *t* = 3.040, ***p* = 0.003**) on patient's MLwHFQ total score at the 6-month follow-up (TP2). This suggests the caregiver's **greater** contribution to self-care maintenance at baseline was significantly associated with the patient's **higher** scores for MLwHFQ (total score) i.e., **poorer** quality of life at the 6-month follow-up (TP2) (Table 23).

Table 23: Self-care as predictors of MLwHFQ (total score) outcome (APIM)

Questionnaire MLwHFQ (total score) T2 (outcome)	**Patients**			**Caregivers**		
	Beta	***t***	***p***	**Beta**	***t***	***p***
Self-care Management						
Actor effect (SCM, TP1)	-1.338	-1.743	0.086	-1.084	-1.412	0.162
Partner (SCM, TP1)	0.754	1.120	0.267	0.355	0.528	0.599
Actor effect (MLwHFQ, TP1)	0.928	6.027	**0.001*****	0.154	1.000	0.321
Partner effect (MLwHFQ, TP1)	0.559	3.371	**0.001****	0.658	3.969	**0.001*****
Self-care Maintenance						
Actor effect (SCMain, TP1)	-0.982	-2.135	**0.036***	-1.192	-2.591	**0.012***
Partner effect (SCMain, TP1)	0.583	1.105	0.273	1.606	3.040	**0.003****
Actor effect (MLwHFQ, TP1)	0.735	5.153	**0.001*****	0.045	0.318	0.752
Partner effect (MLwHFQ, TP1)	0.262	1.690	0.095	0.498	3.204	**0.002****
Self-care Confidence						
Actor effect (SCC, TP1)	-2.227	-3.730	**0.001*****	-1.647	-2.758	**0.007****
Partner effect (SCC, TP1)	0.602	-0.883	0.380	0.182	0.267	0.790
Actor effect (MLwHFQ, TP1)	0.732	4.926	**0.001*****	-0.043	-0.291	0.772
Partner effect (MLwHFQ, TP1)	0.407	2.727	**0.008****	0.510	3.419	**0.001****

MLwHFQ, Minnesota Living with Heart Failure Questionnaire; T2 time-point two (6months); SCM self-care management; SCMain, self-care maintenance; SCC, self-care confidence; TP1, time-point one (baseline) $p < 0.05$*; $p < 0.01$**; $p < 0.001$***

6.5 Effects of self-care (management, maintenance and confidence on physical health (PCS) outcomes (MLwHFQ)

6.5.1 Physical Health MLwHFQ

Table 24 shows one statistically significant actor *effect* of patients' self-care confidence (β = - 0.802, *t* = -3.015, ***p* = 0.003**) on their physical health (MLwHFQ PCS), which suggests their **greater** self-care confidence was associated with their better physical health (i.e., lower MLwHFQ PCS scores indicate better quality of life) at the 6-month follow-up (TP2).

Table 24 shows no statistically significant *partner effects* of patient's baseline self-care on the caregiver's physical health (MLwHFQ PCS) at the 6-month follow-up (TP2). However, one statistically significant *partner effect* was seen for caregiver's baseline self-care maintenance (β = 0.488, *t* = 2.051, ***p* = 0.043**) on the patient’s physical health (MLwHFQ PCS) at the 6-month follow-up (TP2). This suggests that **greater** caregiver contribution to patient self-care maintenance at baseline was associated with poorer physical health at the 6-month follow-up (TP2) (Table 24).

Table 24: Self-care as predictors of physical health (PCS) and emotional health (ECS) (MLwHFQ) outcomes (APIM)

Questionnaire MLwHFQ PCS (T2 outcome)	Patients			Caregivers			**Questionnaire MLwHFQ ECS (T2 outcome)**	Patients			Caregivers		
	Beta	***t***	***p***	**Beta**	***t***	***p***		**Beta**	***t***	***p***	**Beta**	***t***	***p***
Self-care Management							**Self-care Management**						
Actor effect (SCM, TP1)	-0.118	-0.352	0.726	-0.400	-1.191	0.237	*Actor effect (SCM, TP1)*	-0.530	-2.213	**0.031***	-0.255	-1.067	0.290
Partner effect (SCM, TP1)	0.120	0.408	0.684	-0.288	-0.977	0.332	*Partner effect (SCM, TP1)*	0.289	1.382	0.172	0.294	1.408	0.164
Actor effect (PCS, TP1)	0.354	5.240	**0.001*****	0.675	1.000	0.320	*Actor effect (ECS, TP1)*	0.739	4.669	**0.001*****	0.114	0.723	0.473
Partner effect t (PCS, TP1)	0.204	2.817	**0.006****	0.247	3.407	**0.001****	*Partner effect (ECS, TP1)*	0.263	1.748	0.086	0.741	4.926	**0.001*****
Self-care Maintenance							**Self-care Maintenance**						
Actor effect (SCMain, TP1)	-0.127	-0.596	0.553	-0.281	-1.316	0.192	*Actor effect (SCMain, TP1)*	-0.531	-4.144	**0.001*****	-0.442	-3.446	**0.001****
Partner effect (SCMain, TP1)	0.234	0.986	0.327	0.488	2.051	**0.043***	*Partner effect (SCMain, TP1)*	0.341	2.431	**0.018***	0.438	3.125	**0.003****
Actor effect (PCS, TP1)	0.651	4.390	**0.001*****	-0.005	-0.036	0.971	*Actor effect (ECS, TP1)*	0.556	4.454	**0.001*****	0.019	0.160	0.873
Partner effect t (PCS, TP1)	0.394	2.330	**0.022***	0.495	2.932	**0.004****	*Partner effect (ECS, TP1)*	0.070	0.548	0.585	0.623	4.839	**0.001*****
Self-care Confidence							**Self-care Confidence**						
Actor effect (SCC, TP1)	-0.802	-3.015	**0.003****	-0.483	-1.817	0.073	*Actor effect (SCC, TP1)*	-0.683	-3.816	**0.001*****	-0.570	-3.186	**0.002****
Partner effect (SCC, TP1)	-0.275	-0.892	0.375	0.087	0.283	0.778	*Partner effect (SCC, TP1)*	-0.185	-0.968	0.337	-0.233	-1.217	0.228
Actor effect (PCS, TP1)	0.607	4.021	**0.001*****	-0.062	-0.416	0.679	*Actor effect (ECS, TP1)*	0.422	3.173	**0.002****	-0.949	-0.712	0.479
Partner effect (PCS, TP1)	0.508	3.159	**0.002****	0.502	3.123	**0.002****	*Partner effect (ECS, TP1)*	0.112	0.823	0.413	0.653	4.800	**0.001*****

MLwHFQ, Minnesota Living with Heart Failure Questionnaire; PCS, physical component score; ECS, emotional component score; T2 time-point two (6months); SCM self-care management; SCMain self-care maintenance; SCC, self-care confidence; TP1, time-point one (baseline) $p < 0.05$*; $p < 0.01$**; $p < 0.001$***

6.6 Effects of self-care (management, maintenance and confidence on emotional health (ECS) outcomes (MLwHFQ)

6.6.1 Emotional Health (MLwHFQ)

Table 24 shows three statistically significant *actor effects* of patients' baseline self-care management (β = -0.530, *t* = -2.219, ***p* = 0.031**), self-care maintenance (β = -0.531, *t* = - 4.144, ***p* < 0.001**), and self-care confidence (β = -0.683, *t* = - 3.816, ***p* < 0.001**) on their emotional health (MLwHFQ ECS) at the 6-month follow-up (TP2). In the management sub-domain, an **increase** in patient self-care management at baseline significantly predicted their **better** emotional health (MLwHFQ), i.e., lower ECS indicate better quality of life at the 6-month follow-up (TP2). In the maintenance sub-domain, an **increase** in patient self-care maintenance at baseline predicted **better** emotional health (MLwHFQ ECS) at the 6-month follow-up (TP2). Similarly, an **increase** in patient self-care confidence at baseline predicted **better** emotional health (MLwHFQ ECS) at the 6-month follow-up (TP2). Table 24 also shows two statistically significant *actor effects* on caregivers' baseline self-care maintenance (β = -0.422, *t* = -3.466, ***p* = 0.001**) and self-care confidence (β = -0.570, *t* = -3.186, ***p* = 0.002**). In the maintenance sub-domain, an **increase** in caregivers' contribution to self-care maintenance significantly predicted the caregivers' **better** emotional health (MLwHFQ ECS) at the 6-month follow-up (TP2). Similarly, an **increase** in caregivers' self-care confidence was significantly associated with caregivers' **lower** scores, i.e., **better** emotional health (MLwHFQ ECS) at the 6-month follow-up (TP2).

Table 24 also shows a statistically significant *partner effect* of patient's baseline self-care maintenance (β = 0.341, *t* = 2.431, ***p* = 0.018**) on the caregiver's emotional health (MLwHFQ ECS) at the 6-month follow-up (TP2). These results suggest an **increase** in patient self-care maintenance was associated with the caregiver's **higher** scores, i.e., **poorer** emotional health (MLwHFQ ECS) at the 6-month follow-up (TP2). In addition, Table 24 demonstrates a statistically significant *partner effect* of caregiver's baseline contribution to self-care maintenance (β = 0.438, *t* = 3.125, ***p* = 0.003**) on patient's emotional health (MLwHFQ ECS) at the 6-month follow-up (TP2). The results indicate an **increase** in the caregiver's contribution to patient self-care maintenance was associated with the patient's **poorer** emotional health (MLwHFQ ECS) at 6-month follow-up (TP2).

Figure 6 (see page 127) shows both the *actor* and *partner effects* of baseline self-care maintenance on the emotional health (MLwHFQ ECS) of both members of the dyad at the 6-month follow-up (TP2). This represents a mutual dyadic effect, i.e., within the dyad; the patient and caregiver baseline self-care maintenance influenced their own and their partner's emotional heath (MLwHFQ ECS) at the 6-month follow-up (TP2). Additional information on the *actor* and *partner effects* of self-care on quality-of-life outcomes (SF-12 and MLwHFQ) is presented in Tables 22 to 24.

6.7 Effects of baseline physical and mental health on quality of life of the dyad at time-point two

6.7.1 Baseline physical health (SF-12 PCS)

Table 22 shows three statistically significant *actor effects* of patients' baseline physical health (SF-12 PCS) (β = 0.258, *t* = 2.082, ***p* = 0.040**; β = 0.284, *t* = 2.355, ***p* = 0.022**; β = 0.292, *t* = 2.303, ***p* = 0.024**) on their physical health-related quality of life at 6 months (TP2) in the models for self-care management, self-care maintenance and self-care confidence. These results suggest that **better** physical health at baseline (i.e., increased scores in SF-12 denote better health) was significantly associated with **better** physical health (outcome) at the 6-month follow-up (TP2). Table 22 also shows two statistically significant *actor effects of* caregivers' baseline physical health (SF-12 PCS) (β = 0.247, *t = 2.*031, ***p* = 0.045**; β = 0.295, *t* = 2.328, ***p* = 0.022**), indicating that their physical health at baseline was significantly associated with their **better** physical health at the 6-month follow-up (TP2).

There were no statistically significant *partner effects* of the patient's baseline physical (SF-12 PCS) on the caregiver's physical health-related quality of life at the 6-month follow-up (Table 22). This indicates that the patient's baseline physical health status had no impact on the physical health status of the caregiver at the 6-month follow-up (TP2). However, there were three statistically significant *partner effects* for baseline physical health (SF-12 PCS) (β = 0.407, *t* = 3.262, ***p* = 0.002**; β = 0.462, *t* = 3.668, ***p* < 0.001**; β = 0.403, *t* = 2.933, ***p* = 0.004**) on the patient's physical health (outcome) at the 6-month follow-up (TP2). This indicates that the caregiver's **better** physical health status at baseline was significantly associated with the patient's **better** physical health status at the 6-month follow-up (TP2).

6.7.2 Baseline mental health (SF-12 MCS)

There were no statistically significant *actor effects* of the patients' or the caregivers' baseline mental health (SF-12 MCS) on their own mental health at the 6-month follow-up (TP2) (Table 22).

There were no statistically significant *partner effects* of patient's baseline mental health (SF-12 MCS) on their partner's mental health (outcome) at the 6-month follow-up (TP2). However, there were three statistically significant *partner effects* of caregivers' baseline mental health (SF-12 MCS) (β =0.424, *t* = 3.126, ***p* = 0.002**; β = 0.423, *t* = 3.390, ***p* = 0.001**; β = 0.445, *t* = 3.379, ***p* = 0.001**) on the patient's mental health (outcome) at 6 months. These findings suggest that caregiver's **better** baseline mental health was significantly associated with **better** patient's mental health (outcome) at the 6-month follow-up (TP2). Table 22 presents additional information on the *actor* and *partner effects* of baseline physical health (PCS) and mental health (MCS) on quality-of-life outcomes (SF-12) at the 6-month follow-up (TP2).

6.8 Effects of baseline MLwHFQ total score, physical and emotional health on quality of life of the dyad at time-point two

6.8.1 Baseline MLwHFQ total score

Table 23 demonstrates three statistically significant *actor effects* for patients' baseline MLwHFQ (total scores) (β = 0.928, *t* = 6.027, ***p* < 0.001**; β = 0.735, *t* = 5.153, ***p* < 0.001**; β = 0.732, *t* = 4.926, ***p* < 0.001**) on their overall quality of life at the 6-month follow-up (TP2) in the models for self-care management, self-care maintenance and self-care confidence. These findings suggest that higher baseline scores for MLwHFQ (total score), i.e., poor quality of life at baseline, is significantly associated with worse quality of life at the 6-month follow-up (TP2).

There were two statistically significant *partner effects* of patient's baseline MLwHFQ (total score) (β = 0.559, *t* = 3.371, ***p* = 0.001**; β = 0.407, *t* = 2.727, ***p* = 0.008**) on the caregiver's overall quality of life at the 6-month follow-up (TP2). These findings suggest that patient's higher baseline scores (i.e., worse quality of life) for MLwHFQ (total score) was significantly associated with the caregiver's **worse** quality of life at the 6-month follow-up (TP2). In addition, three statistically significant *partner effects* were found for caregiver's baseline MLwHFQ (total scores) (β = 0.658, *t* = 3.969, ***p* < 0.001**; β = 0.498, *t* = 3.204, ***p* = 0.002**; β = 0.510, *t* = 3.419, ***p* = 0.001**). This suggests that caregiver's higher baseline MLwHFQ scores (i.e., worse quality of life) was significantly associated with the patient's worse quality of life at the 6-month follow-up (TP2).

6.8.2 Baseline physical component score (MLwHFQ PCS)

Table 24 shows three statistically significant *actor effects* of patients' baseline physical health (MLwHFQ PCS) (β = 0.354, *t* = 5.240, ***p* < 0.001**; β = 0.651, *t* = 4.390, ***p* < 0.001**; β = 0.607, *t* = 4.021, ***p* < 0.001**) on their physical health-related quality of life (MLwHFQ PCS) at the 6-month follow-up (TP2) for the models of self-care management, self-care maintenance, and self-care confidence. This suggests that higher baseline PCS scores, i.e., worse quality of life, are significantly associated with the patients' MLwHFQ PCS (outcome) at the 6-month follow-up (TP2).

Table 24 shows three statistically significant *partner effects* of patient's baseline physical health (MLwHFQ PCS) (β = 0.204, *t* = 2.817, ***p* = 0.006**; β = 0.394, *t* = 2.330, ***p* = 0.022**; β = 0.508, *t* = 3.159, ***p* = 0.002**) on the caregiver's physical health-related quality of life (MLwHFQ PCS) at 6 months (TP2). These findings suggest that higher baseline scores (i.e., worse quality of life for patient's MLwHFQ PCS) is significantly associated with the caregiver's MLwHFQ (PCS) outcome at the 6-month follow-up (TP2). Similarly, there were three statistically significant *partner effects* of caregiver's baseline physical health (MLwHFQ PCS) (β = 0.247, *t* = 3.407, ***p* = 0.001**; β = 0.495, *t* = 2.932, ***p* = 0.004**; β = 0.502, *t* = 3.123, ***p* = 0.002**) on the patient's physical health (MLwHFQ PCS) (outcome) at the 6-month follow-up (TP2). These suggest that higher scores (i.e., poorer quality of life) for MLwHFQ (PCS) at baseline are significantly associated with patient's poorer physical health-related quality of life (MLwHFQ PCS) at the 6-month follow-up (TP2).

6.8.3 Baseline mental health: emotional component score (MLwHFQ ECS)

Table 24 also shows three statistically significant *actor effects* of patients' baseline emotional health (MLwHFQ ECS) (β = 0.739, *t* = 4.669, ***p* < 0.001**; β = 0.556, *t* = 4.454, ***p* < 0.001**; β = 0.422, *t* = 3.173, ***p* = 0.002**) on their emotional health (MLwHFQ ECS) (outcome) at the 6-month follow-up (TP2). These findings suggest that higher baseline scores (i.e., worse quality of life) for MLwHFQ ECS is significantly associated with poorer emotional health (MLwHFQ ECS) at the 6-month follow-up (TP2).

There were three significant *partner effects* of baseline emotional health (β = 0.741, *t* = 4.926, ***p* < 0.001**; β = 0.623, *t* = 4.839, ***p* < 0.001**; β = 0.653, *t* = 4.800, ***p* < 0.001**) on the patient's emotional health (outcome) at the 6-month follow-up (TP2) (Table 24). These findings suggest that caregiver's higher scores, i.e., poorer quality of life, for baseline MLwHFQ (ECS) were significantly associated with the patient's poorer emotional health (MLwHFQ ECS) at the 6-month follow-up (TP2). Table 24 presents additional information on the *actor* and *partner effects* of the baseline MLwHFQ scores on the quality-of-life outcomes (MLwHFQ) at the 6-month follow-up (TP2).

Chapter 6.0 has addressed research question 3: What are the effects of patient self-care and family caregiver contributions to self-care at baseline (TP1) on their own and their partner's quality of life at 6 months (TP2)? Several *actor* and *partner effects* were found for patients' and caregivers' physical and mental health-related quality of life.

Greater caregiver contribution to patient self-care maintenance and self-care confidence predicted their poorer physical health (SF-12 PCS) at 6 months (TP2) (*actor effects*). Patient's greater contribution to self-care management predicted the caregiver's better physical health at 6 months (TP2) (*partner effect*) and greater caregiver's contribution to self-care management predicted the patient's better physical health at 6 months (TP2) (*partner effect*).

Greater patient self-care confidence at baseline significantly predicted their better mental health (SF-12 MCS) at 6 months (TP2) (*actor effect*). Greater caregiver self-care maintenance and self-care confidence at baseline predicted their better mental health at 6 months (TP2) (*actor effect*). Caregivers' greater contribution to patient self-care management and maintenance at baseline predicted patients' poorer mental health at 6 months (TP2) (*partner effect*).

Greater patient self-care maintenance and confidence at baseline predicted better quality of life (MLwHFQ total score) at 6 months (TP2) (*actor effect*). Greater caregivers' contribution to patient self-care maintenance and confidence at baseline predicted better quality of life at 6 months (TP2) (*actor effects*). Greater caregivers' contribution to self-care maintenance at baseline significantly predicted poorer patient quality of life at 6 months (TP2) (*partner effect*).

Greater patient self-care confidence at baseline predicted better physical quality of life (MLwHFQ PCS) at 6 months (TP2) (*actor effect*). Caregivers' greater baseline contribution to patient self-care maintenance predicted poorer patients' physical health at 6 months (TP2) (*partner effects*).

Greater patient self-care management, self-care maintenance and self-care confidence at baseline predicted better emotional health (MLwHFQ ECS) at 6 months (TP2) (*actor effects*). Greater caregivers' contribution to patient self-care maintenance and self-care confidence at baseline predicted better emotional health at 6 months (TP2) (*actor effects*). Patients' greater self-care maintenance at baseline predicted caregivers' poorer emotional health at 6 months (TP2) (*partner effect*). Caregivers' greater contribution to self-care maintenance at baseline predicted patients' poorer emotional health at 6 months (TP2) (*partner effect*).

Patients' greater baseline physical health (SF-12 PCS) predicted better physical health at 6 months (TP2) (*actor effect).* Caregivers' greater baseline physical health predicted better physical health at 6 months (TP2) (*actor effect*). Caregivers' baseline physical health predicted better patients' physical health at 6 months (TP2) (*partner effect*).

Caregivers' better baseline mental health (SF-12-MCS) predicted patients' better mental health at 6 months (TP2) (*partner effect*).

Increased patients' baseline scores (MLwHFQ total) predicted worse quality of life at 6 months (TP2) (*actor effect*). Increased patients' baseline MLwHFQ (total score) predicted caregivers' worse quality of life at 6 months (TP2) (*partner effect*). Increased caregivers' baseline MLwHFQ (total score) predicted patients' worse quality of life at 6 months (TP2) (*partner effect*).

Increased patients' baseline physical health (MLwHFQ PCS) predicted worse physical quality of life at 6 months (TP2) (*actor effect*). Increased patients' baseline (MLwHFQ PCS) predicted worse caregivers' physical health at 6 months (TP2) (*partner effect*). Increased caregivers' baseline (MLwHFQ PCS) predicted worse patients' physical health at 6 months (TP2) (*partner effect*).

Increased patients' baseline emotional health (MLwHFQ ECS) predicted worse emotional health at 6 months (TP2) (*actor effect).* Increased caregivers' baseline emotional health predicted poorer patients' emotional health at 6 months (TP2) (*partner effect*).

Table 25 provides an overall summary of the key finding from each of the results chapters. The following chapter will discuss the salient findings from each of the chapter summaries and will be discussed in relation to the literature review and any recent empirical research.

Table 25: Summary of the main results from Chapters 4, 5 and 6 of the thesis

Chapters	Research Question	Findings
Chapter 4	Are there differences between patients' and family caregivers' self-care and quality of life at TP1 (after diagnosis) and TP2 (6 months later)?	• There were statistically significant differences between the patients' and caregivers' self-care maintenance at TP1, but not at TP2. There were also statistically significant differences between patients' and caregivers' physical health (SF-12 PCS), quality of life (MLwHFQ total score), physical health (MLwHFQ PCS) and emotional health (MLwHFQ ECS) at TP1 and TP2. These differences were accounted for by the patients' poorer physical and emotional health at both TP1 and TP2.
Chapter 5	What patient and family caregiver characteristics and self-care at TP1 (baseline) correlated with caregiver burden at 6 months (TP2)?	**Patient Correlations:** • There were statistically significant negative correlations between patients' baseline self-care confidence and caregiver burden at TP2, indicating that patients' increased confidence was associated with a reduction in caregiver burden at TP2. • There were statistically significant negative correlations between patients' baseline mental health (SF-12 MCS) and caregiver burden at TP2, indicating that patients' better mental health was associated with a reduction in caregiver burden at TP2. • There were statistically significant positive correlations between patients' baseline quality of life (MLwHFQ total score), patients' baseline emotional health (MLwHFQ ECS) and patients' baseline physical

		inactivity levels and caregiver burden at TP2, indicating that increased caregiver burden was associated with worse patient QoL, emotional health and patients increased physical inactivity levels. **Caregiver Correlations:** • There were statistically significant positive correlations between baseline caregiver burden, baseline self-care maintenance, baseline physical health (MLwHFQ PCS) and emotional health (MLwHFQ ECS) on caregiver burden at TP2, indicating that increased caregiver burden at TP2 was associated with increased baseline contribution to self-care maintenance and increased baseline caregiver burden and poorer baseline physical and emotional health. • There were statistically significant negative correlations between caregivers' baseline self-care confidence and caregiver burden at TP2, indicating that caregiver burden at TP2 was reduced by caregivers' increased baseline self-care confidence.
Chapter 5	What patient and family caregiver baseline characteristics and self-care predicted caregiver burden at 6 months (TP2)?	**Predictors of caregiver burden (outcome):** • The patients' baseline physical activity level significantly predicted caregiver burden at TP2, indicating that increased caregiver burden at TP2 was associated with patients' increased physical inactivity at baseline. • The caregivers' baseline caregiver burden and emotional health (MLwHFQ ECS) significantly predicted caregiver burden at TP2, indicating that

		increased caregiver burden at TP2 was associated with caregivers' increased baseline burden and poorer emotional health.
Chapter 6	What are the effects of patient self-care and family caregiver contributions to self-care (at TP1) on their own and their partner's quality of life at 6 months (TP2)?	**Patients' baseline self-care as predictors of their quality of life (*actor effects*).** • The patients' baseline self-care confidence significantly predicted their own mental health (SF-12 MCS) at TP2, indicating that greater self-care confidence (i.e., following treatment advice/evaluating effectiveness of remedies) significantly predicted their better mental health (SF-12 MCS) at TP2. • The patients' baseline self-care maintenance and self-care confidence predicted their own quality of life (MLwHFQ total score) at TP2, indicating that greater self-care maintenance (i.e., symptom monitoring) and self-care confidence (i.e., following treatment advice/evaluating effectiveness of remedies) significantly predicted their better quality of life (MLwHFQ total score) at TP2. • The patients' baseline self-care confidence significantly predicted their own physical quality of life (MLwHFQ PCS) at TP2, indicating that greater self-care confidence (i.e., following treatment advice/evaluating effectiveness of remedies) significantly predicted their better physical helth (MLwHFQ PCS) at TP2. • The patients' baseline self-care management, maintenance and self-care confidence significantly predicted their own emotional quality of life (MLwHFQ

		ECS) at TP2, indicating that greater self-care management (i.e., treatment implementation), self-care maintenance (i.e., symptom monitoring) and self-care confidence (i.e., following treatment advice/evaluating effectiveness of remedies) significantly predicted their better emotional health (MLwHFQ ECS) at TP2. ***Total number of patient *actor effects* = 7**
Chapter 6	What are the effects of patient self-care and family caregiver contributions to self-care (at TP1) on their own and their partner's quality of life at 6 months (TP2)?	**Caregivers' baseline self-care as predictors of their quality of life (*actor effects*)** • The caregivers' baseline contribution to self-care maintenance/self-care confidence significantly predicted their own physical (SF-12 PCS) and mental health (SF-12 MCS) at TP2, indicating that greater contribution to self-care maintenance (i.e., symptom monitoring) and self-care confidence (i.e., following treatment advice/evaluating effectiveness of remedies) significantly predicted their poorer physical health (SF-12 PCS), but significantly predicted their better mental health (SF-12 MCS) at TP2. • The caregivers' baseline contribution to self-care maintenance/self-care confidence significantly predicted their quality of life (MLwHFQ total score) and their emotional quality of life (MLwHFQ ECS) at TP2, indicating that greater contribution to self-care maintenance (i.e., symptom monitoring) and self-care confidence (i.e., following treatment advice/evaluating effectiveness of remedies) significantly predicted their

		better quality of life (MLwHFQ total score) and emotional health (MLwHFQ ECS) TP2. ***Total number of caregiver *actor effects* = 8**
Chapter 6	What are the effects of patient self-care and family caregiver contributions to self-care (at TP1) on their own and their partner's quality of life at 6 months (TP2)?	**Patient's baseline self-care as predictors of caregiver's quality of life at TP2 (*partner effects*)** • The patient's baseline self-care management significantly predicted the caregiver's physical health (SF-12 PCS) at T2, indicating that patient's greater contribution to self-care management (i.e., treatment implementation) significantly predicted the caregiver's better physical health (MLwHFQ PCS) at TP2. • The patient's baseline self-care maintenance significantly predicted the caregiver's emotional health (MLwHFQ ECS) at TP2, indicating that patient's greater contribution to self-care maintenance (i.e., symptom monitoring) significantly predicted the caregiver's poorer emotional health (MLwHFQ ECS) at TP2. ***Total number of patient *partner effects* = 2**
Chapter 6	What are the effects of patient self-care and family caregiver contributions to self-care (at TP1) on their own and their partner's quality of life at 6 months (TP2)?	**Caregiver's baseline contribution to self-care as predictors of patient's quality of life at TP2 (*partner effects*):** • The caregiver's baseline self-care management significantly predicted the patient's physical health (SF-12 PCS) at TP2, indicating that the caregiver's

		greater contribution to self-care management (i.e., treatment implementation) significantly predicted the patient’s better physical health (SF-12 PCS) at TP2. • The caregiver’s baseline self-care management and self-care maintenance significantly predicted the patient’s mental health (SF-12 MCS) at TP2, indicating that the caregiver’s greater contribution to self-care management (i.e., treatment implementation) and maintenance (i.e., symptom monitoring) significantly predicted the patient’s poorer mental health at TP2. • The caregiver’s baseline self-care maintenance significantly predicted the patient’s overall quality of life (MLwHFQ total score), physical health (MLwHFQ PCS) and emotional health (MLwHFQ ECS) at TP2, indicating that caregiver’s greater contribution to self-care maintenance (i.e., symptom monitoring) significantly predicted the patient’s poorer quality of life (MLwHFQ total score), physical health (MLwHFQ PCS) and emotional health (MLwHFQ ECS) at TP2. ***Total number of caregiver *partner effects* = 6**

CHAPTER 7

DISCUSSION

7.1 Introduction

This chapter discusses the sample characteristics and their representativeness to the wider HF population and published literature. It will progress by discussing the salient findings as they relate to the overall aim of the study and the three research questions. The first section will discuss differences between patients' and family caregivers' self-care and quality of life at baseline (TP1) and 6 months (TP2) (research question 1). The next section will discuss the patients' and family caregivers' baseline characteristics, including features of self-care that predict caregiver burden at 6 months (TP2) (research question 2). Section three will discuss the impact of patients' baseline self-care and family caregivers' contributions to self-care on their own, and their partner's quality of life at TP2 (research question 3). These findings will be discussed and compared to previous research in the field of HF self-care, quality of life and caregiver burden. The study strengths, limitations, overall conclusion, implications for clinical practice and recommendations for future research are also discussed.

7.2 The study sample

7.2.1 Sociodemographic characteristics

The final sample size of 46 patients and caregivers was adequate for dyadic research and is in line with Chung et al.'s (2009) HF study that used the APIM. From an original sample of 52, six patient–caregiver dyads were lost to the 6-months follow-up (TP2); five patients died, and one patient–caregiver dyad failed to return the follow-up questionnaires. The patient and family caregiver who failed to return the questionnaires were in NYHA class IV, and this is consistent with previous research (Aldred et al., 2005; Quinn et al., 2010) that recognises the challenges associated with HF dyadic research and the burden associated with questionnaire completion. Despite the ten percent attrition rate that is reported in dyad research (Quinn et al., 2010), and noted in the current study, the final sample size of *n*=46 ensured that significant predictors of outcome could be demonstrated.

A greater number of male than female patients were found in this study, which is representative of the sex ratio in Scotland (Campbell et al., 2018; Thomson et al., 2020a and Lee et al., 2021). Furthermore, from a local perspective, NHS Ayrshire & Arran currently have 3126 patients on their CHD database; 1917 patients are male, and 1209 patients are female, which reflects the sex ratio in other Scottish health boards. However, this differs from Conrad et al.'s (2018) UK population-based study, where an almost equal percentage of males to females were found (49%/51%), which is most likely due to the larger and more diverse geographical areas included in the study. The family caregivers in this study were predominantly female, which is consistent with previous HF dyadic studies in Italy, the USA and Scotland (Vellone et al., 2014; Chung et al., 2009; Thomson et al., 2020a).

7.2.2 Clinical characteristics

Given the clinical findings in the current study, the sample is considered to be representative of HF patients and caregivers in Scotland. The patients were on a combination of HF medications, as outlined by the ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure (Ponikowski, 2016), suggesting that they are representative of the wider patient sample. For example, more than half (61.5%) of the participants were on either an angiotensin converting enzyme inhibitor/angiotensin receptor blocker or angiotensin receptor neprilysin inhibitor. However, only 26.9% of the patients were on a combination of three drugs (ACEi/ARB/ARNI; beta-blocker and MRA). Similarly, O'Hara et al.'s (2020) Scottish Heart Failure Optimisation project found that less than 50% of patients were on three HF medications. The optimisation of these drugs is pivotal in improving patients' quality of life and decreasing mortality. The current study findings regarding the optimisation of HF medication are therefore representative of other NHS sites and the National Heart Failure Audit (National Institute for Cardiovascular Outcomes Research (NICOR), 2017).

More than half of the study patients (54.3%) were in NYHA class III, which suggests marked limitation of physical activity, with 4.3% in class IV, which suggested an inability to carry out any physical activity without discomfort. These findings are consistent with Campbell et al.'s (2015) RCT of HF patients in Glasgow and Thomson et al.'s (2020a) cross-sectional dyadic study in Scotland, again highlighting representativeness that the current sample to the HF patients in Scotland. Further, the NYHA classification in this study is also consistent with the wider HF population, with NYHA class III being frequently observed in dyadic HF studies within the USA, Italy and Sweden (Vellone et al., 2014; Agren et al., 2011; Chung et al., 2009; Durante et al., 2019) that examined aspects of self-care, caregiver burden and quality of life. Consistent with the results of Thomson et al.'s (2020a) and Chung et al.'s (2009) studies, most of the patients (84.8%) in this study had an ejection fraction of < 40% (HFrEF category), which occurs when the left ventricular ejection fraction (LVEF) is 40% or less, and as result, there is progressive dilatation of the left ventricle and adverse remodelling (Ponikowski, 2016). Unlike other studies (Lyons et al., 2015; Cameron et al., 2017; Agren et al., 2011), this study usefully identified different categories (%) of EFs, which assist in describing the sample characteristic, with only 2.2% not being recorded. Further, more than half of the study patients had a new diagnosis of HF, which contrasts with Vellone et al.'s (2014) and Lyons et al.'s (2015) dyadic studies, where the patients had been living with HF for three and five years, respectively. This may have enabled a greater opportunity for them to adjust psychologically and emotionally to the diagnosis.

Twenty-five per cent of the caregivers in this study reported more than one medical condition, which was consistent with previous research (Pihl et al., 2011; Hooley et al., 2005; Bradley, 2003; Hughes et al., 1999). Unlike this study, Agren et al.'s included caregivers with a diagnosis of cardiovascular disease in their research. Caregivers with a similar diagnosis were excluded from this research, as it was thought that this would potentially impact on their perceptions of caregiver burden and their potential to contribute to patient self-care.

7.3 Differences between patients' and family caregivers' self-care and quality of life at TP1 and TP2

Section one of the chapter discusses the results relating to differences between the patients' and family caregivers' self-care and quality of life at baseline (TP1) and at the 6-month follow-up (TP2) (research question 1).

7.3.1 Differences between patients' self-care and caregivers' contribution to self-care at TP1 and TP2

To the best of my knowledge, no other studies have looked at both patients' and caregivers' contribution to self-care over time using the SCHFI and CCSCHFI. Overall, the patients' self-care and caregivers' contribution to self-care scores in the current study were below the recommended threshold of 70 at both TP1 and TP2. This is consistent with previous cross-sectional studies in the UK and elsewhere (Koirala et al., 2020; Chen et al., 2017; Bidwell et al., 2015; Vellone et al., 2015, 2014, 2013; Cochierri et al., 2015; Jaarsma et al., 2013; Moser et al., 2012; Britz & Dunn, 2010; Riegel et al., 2009).

Further, statistically significant differences were found between the patients' and caregivers' **self-care maintenance** (i.e., symptom monitoring and treatment adherence) at TP1, but not at TP2. The patients were contributing more to self-care maintenance than their caregivers were assisting them with, which is consistent with the findings of Bidwell et al. (2015). It may be that the caregivers only contribute to aspects of self-care maintenance (i.e., observing for ankle oedema and encouraging a low salt diet) when there was a noticeable decline or deterioration in the patients' health status. There were no statistically significant changes in the patients' self-care scores from TP1 to TP2, and similarly for the caregivers. This contrasts with Vellone et al.'s (2020a) randomised controlled trial on motivational interviewing, which identified an increase in patients' self-care maintenance scores from baseline to 1 year (TP4). This change is likely to be associated with the goal-directed and patient-centred counselling method that was used to assist patients to change their behaviours regarding self-care.

When the individual questions in the SCHFI and CCSCHFI were examined within the **self-care maintenance** domain, the study patients gave greater priority to seeing their doctor or nurse and checking their ankles for oedema at both TP1 and TP2. Least priority was given to adhering to a low salt diet when eating out and exercising for 30 minutes at both TP1 and TP2. The low level of exercise is likely to be attributed to the increased number of physically inactive patients in the current study, as well as possible exacerbations in symptoms. This is consistent with the findings of Riegel et al. (2013), as well as the cultural differences in da Conceição et al.'s (2015), Cocchieri et al.'s (2015) and Vellone et al.'s (2020b) cross-sectional studies.

Similarly, the caregivers in my study gave greater priority to prompting patients to see their doctor or nurse, checking their ankles for oedema, and trying to avoid them becoming sick at both TP1 and TP2. Caregivers gave least priority to reminding patients to ask for low salt items when eating out, encouraging exercise, and reminding patients to weigh themselves at TP1 and TP2. These findings contrast with those of Vellone et al. (2015), but the differences between my study and the cross-sectional studies (da Conceição et al., 2015; Cocchieri et al., 2015; Vellone et al., 2020b) may be explained by the cultural variation between the UK and Italy; in the UK salt restriction is a dietary choice, whilst salt restriction is prescribed in Italy.

In the **self-care management** domain (dealing with symptoms) there were no statistically significant differences between the patients' and caregivers' self-care management at TP1 and TP2, which suggests their priorities were similar when responding to HF symptoms. These findings also suggest that self-care management is more complex than self-care maintenance, and for it to be effective, it requires input from others – a finding also reported by Riegel et al. (2016) in their situation-specific theory of heart failure self-care. When the individual questions in the SCHFI and CCSCHFI were examined within the **self-care management** domain, patients gave greater priority to calling their doctor or nurse for guidance and reducing their fluid intake at TP1 and TP2. Calling the doctor or nurse for guidance was also a priority identified in da Conceição et al.'s (2015) study and Vellone et al.'s (2020b) study. Least priority was given by patients to evaluating the effectiveness of remedies, recognising HF-related symptoms, and taking an additional diuretic, which contrasts with Vellone et al.'s (2020b) results. This may be explained by the fact that most patients in the current study had a new diagnosis of HF and would not have been comfortable in exercising such autonomy with “as required” medications. Furthermore, self-care management requires an understanding of the disease, and being able to respond to changes in health status, as well as make appropriate decisions. A possible explanation for the poor response to symptom recognition may be associated with cognitive impairment, which has clinical significance in the HF population (Currie et al., 2014), and is a variable that should be considered in future HF self-care research.

Similarly, the caregivers gave greater priority to calling their loved one’s doctor or nurse and reducing salt intake at both TP1 and TP2, which contrasts with Srisuk et al.’s (2021) cross-sectional study, where caregivers had a major role in symptom monitoring and treatment adherence. Greater caregiver input in Srisuk et al.’s (2021) study was because of limited access to HF services – a problem that patients and caregivers in the current study did not report. Least priority was given to assessing the efficacy of remedies, as well as relating changes in symptoms to a possible episode of HF decompensation – a finding also reported in Vellone et al.’s (2015) study, where more than half of the caregivers were unable to identify signs and symptoms of worsening HF.

In the **self-care confidence** domain, there were no statistically significant differences between the patients and caregivers at TP1 and TP2, which suggests that they identified similar priorities. When the individual questions in the SCHFI and CCSCHFI were examined within the **self-care confidence** domain, the patients’ and caregivers’ priorities were the same at TP1 and TP2. The study patients gave greater priority to following treatment advice, which is consistent with the findings for patients in Brazilian and Italian studies (da Conceição et al., 2015; Vellone et al., 2020b). A further priority was given to the importance of recognising changes in health status, which supports the findings of previous research (da Conceição et al., 2015; Vellone et al., 2020b). Being able to recognise changes in health status is integral to effective self-care, but equally important is being able to relate such changes to a possible episode of decompensation; an area that was given least priority in the self-care management domain in the current study. Within the self-care confidence domain, patients gave least priority to being able to remain free of HF symptoms and having confidence in the effectiveness of remedies. Remaining free of HF symptoms was also given least priority in da Conceição et al.'s (2015) study. It is not surprising that patients lacked confidence in being free of HF symptoms, given that the symptom burden of HF is worse than many disseminated cancers (Brunner-La Rocca et al., 2012).

Similarly, the study caregivers' **self-care confidence** was, by and large, similar to the patients' ratings in the **self-care confidence** domain. They gave greater priority to following treatment advice, which extends the findings of Srisuk et al.'s (2021) cross-sectional study. A further priority was given to being confident in recognising changes in their loved one's health status, but, like the patients, there is a need to be able to relate these changes to a possible episode of HF decompensation. Caregivers in the current study gave least priority at TP1 and TP2 to confidently preventing HF symptoms, as well as confidently evaluating the effectiveness of HF remedies – findings also reported in previous cross-sectional caregiver studies (Vellone et al., 2015; Srisuk et al., 2021). A possible explanation regarding the caregivers' lack of confidence in preventing and helping HF symptoms may be associated with a lack of knowledge and understanding of the HF trajectory. Previous studies in other caregiving populations found that knowledge of the disease is associated with greater caregiver confidence, as well as more meaningful contributions to patient self-care (Terpstra et al., 2012; Huang et al., 2013).

Whilst there are no known longitudinal studies with which direct comparisons might be made, the results of the current study have contributed significantly to the HF self-care literature. This study was unique in that it examined longitudinally the differences between the patients' and caregivers' self-care domains at baseline and 6 months, as well as individual items in each of the self-care domains. The results suggest that the self-care maintenance domain was the most influential, with patients contributing more (i.e., keeping doctor or nurse appointments and checking ankles for oedema) than their caregivers. Interestingly, an increase in scores was observed for these two areas of self-care maintenance at TP2, which suggests that, as the disease progresses, these areas of self-care may become even more important. In addition, the results highlight that the patients and caregivers in the current study are better at responding to health-professional-directed treatment advice, compared to self-directed self-care activities, such as adhering to a low salt diet and engaging in physical activity. Furthermore, it has highlighted the need for caregivers to have an equal understanding and involvement in the monitoring and interpretation of HF symptoms.

7.3.2 Differences between patients' and caregivers' quality of life (SF-12) at TP1 and TP2

To the best of my knowledge, this is the first HF study that has used both a generic (SF-12) and disease-specific questionnaire (MLwHFQ total, PCS and MCS) in both patients and caregivers to investigate health-related quality of life longitudinally. As anticipated, the physical health of the patients in this study was statistically significantly poorer than their caregivers at both TP1 and TP2. This is consistent with the findings of Trivedi et al. (2016) and Vellone et al. (2014), but contrary to Luttick et al. (2009), who reported poorer overall quality of life in caregivers, irrespective of their partner's diagnosis. Like this study, Trivedi et al. (2016) and Vellone et al. (2014) also found that the SF-12 PCS scores remained below the population average for both patients and caregivers. This suggests that patients diagnosed with HF in Scotland and their caregivers have poor physical health-related quality of life which is consistent with the findings from other countries. There were no statistically significant changes in the patients' and caregivers' physical quality of life (SF-12 PCS) from TP1 to TP2. For the study caregivers, this is in contrast to the caregivers' SF-12 PCS reported by Trivedi et al. (2016) at follow-up, which identified a deterioration in their physical health (SF-12 PCS). This may be attributed to the findings in Rausch et al.'s (2007) and Hooley et al.'s (2005) studies, which suggest that caregiving can also be associated with poor outcomes and increased burden. However, further studies are needed that use longer follow-up periods to assess the quality of life of the dyad, which would assist in comparisons being made with the patients and caregivers in this study.

No statistically significant differences were found between the patients' and caregivers' mental health at TP1 and TP2, as measured by the SF-12 MCS. These findings are consistent with other HF studies (Pihl et al., 2005; Chung et al., 2009, Auld et al., 2018; Agren et al., 2011), which suggest that patients and caregivers experience similar levels of perceived mental health. The study patients' MCS scores were higher than those reported in Vellone et al.'s (2014) cross-sectional study of dyads, suggesting that the patients' perceived mental health at baseline was better in the current study. Such differences between these studies' findings and the current study may be associated with culture differences between the UK and Italian populations, and the level of support being offered. Further, the management of HF in Italy is variable; it is reported that just over a quarter of cases are managed by a cardiologist, with limited provision for psychological support (Maggioni et al., 2016). In relation to the caregivers in this study, a comparable SF-12 MCS result was noted with the caregivers in Vellone et al.'s (2014) study.

Whilst there were no statistically significant changes in the patients' and caregivers' mental health (SF-12 MCS) from TP1 to TP2, there was a trend for lower scores at follow-up, which is consistent with Trivedi et al.'s (2016) study. The SF-12 MCS scores remain below the population average of 50. This suggests that patients diagnosed with HF in Scotland and their caregivers have poor mental health-related quality of life, which is consistent with the findings from other countries.

7.3.3 Differences between patients' and caregivers' quality of life (MLwHFQ) at TP1 and TP2

Statistically significant differences were found between the patients' and caregivers' overall quality of life (MLwHFQ total score) at both TP1 and TP2, using the disease-specific questionnaire. These findings confirm that HF patients' quality of life is much poorer than that of their caregivers and are consistent with the findings of previous studies (Trivedi et al., 2016; Chen et al., 2010; Tang et al., 2010; McCallum & Hughes, 2009). From a dyadic perspective, the current study findings are comparable with those of Thomson et al.'s (2020a), as the caregivers' MLwHFQ total scores were similar, suggesting that their quality of life was moderately impaired (Rector, 2004). This finding may be associated with the fact that just over 32% of the caregivers had one health-related issue and almost 24% reported having more than one. Indeed, these caregiver health-related issues could have impacted on their quality of life, even prior to considering the physical, emotional and social demands of caregiving that Pressler et al. (2013) highlighted. No longitudinal studies were found with which to compare differences between the patients' and caregivers' MLwHFQ total scores in this study.

Unlike the current study, Thomson et al. (2020a) reported that patients' quality of life was moderate. These differences may be explained by a greater number of patients in the current study having an ejection fraction < 40% and a greater number of patients being in NYHA III. The only other known dyadic HF study that used the MLwHFQ total score was Chung et al.'s (2009) cross-sectional study, in which the patients' quality of life was considered moderate, and the caregivers' quality of life was considered good. Such differences may be associated with the cultural differences between the USA and UK, as well as differences in NYHA classification. There were no statistically significant changes in the patients' and caregivers MLwHFQ total score from TP1 to TP2, which contrasts with the patients in Trivedi et al.'s (2016) study.

Statistically significant differences were found between the patients' and caregivers' MLwHFQ PCS at TP1 and TP2, which indicated the patients' physical quality of life remained poorer than their caregivers at follow-up. This is consistent with the poor patient quality of life reported in previous HF and HF dyadic cross-sectional studies (Chen et al., 2010; Tang et al., 2010; McCallum & Hughes, 2009; Chung et al., 2009; Vellone et al., 2014, Thomson et al., 2020a). This is the first known longitudinal study to use both a generic and disease-specific questionnaire in patient–caregiver dyads, which confirmed that the caregivers' physical quality of life is statistically significantly better than the patients at baseline (TP1) and the 6-month follow-up (TP2). There were no significant changes between the patients' and caregivers' MLwHFQ PCS from TP1 to TP2, and no studies were identified with which direct comparisons with the MLwHFQ sub-domain results could be made.

Statistically significant differences were also identified between the patients and caregivers' MLwHFQ ECS at TP1 and TP2. These differences in emotional health are consistent with the study conducted by Evangelista et al. (2002), who found that patients' emotional health was poorer than the caregivers, but inconsistent with Årestedt et al.'s (2012) results. This variation between the studies' findings may be explained by cultural differences, and with the patients in Årestedt et al.'s (2012) study having been diagnosed with HF for longer, perhaps giving them more time to deal with the additional emotional symptoms (i.e., somatisation, obsession-compulsion, hostility and psychoticism), as reported by Thomson et al. (2020a).

No published cross-sectional or longitudinal studies were found that have used the MLwHFQ ECS for caregivers. The findings for caregivers' emotional health in this study are, however, broadly consistent with Lang et al.'s (2018) home-based HF rehabilitation intervention for patients and caregivers, and Pressler et al.'s (2013) family caregivers study, which examined caregiver burden and physical and emotional health-related quality of life over time. These similarities in the studies' findings may be reflective of the positive emotions associated with providing care that was reported in Evangelista et al.'s (2002) and Fried et al.'s (2005) studies, which used the SF-12 MCS to assess the mental health and well-being of the caregivers. The findings of the current study suggest that caregivers have better emotional health than their loved ones at follow-up, which may be further explained by the theory of emotional contagion; emotions are easily transferred from one individual to another, particularly those who are engaged in an intimate interpersonal relationship (Gump & Kulik, 1997). In addition, no statistically significant changes were noted in the patients' and caregivers' MLwHFQ ECS from TP1 to TP2. Although statistically non-significant, the trend for patients of an increased ECS at TP2 indicated poorer emotional health. This highlights the need for early interventions to avoid deterioration in patients' emotional health-related quality of life.

In summary, the quality-of-life scores reported in this section confirm the hypothesis; there were statistically significant differences between the patients' and family caregivers' quality of life at TP1 (after diagnosis) and TP2 (6 months later), except for MCS (SF-12) (research question 1). The study has also highlighted the need to use both a generic and a disease-specific quality-of-life tool. Using the disease-specific quality-of-life tool (MLwHFQ) helped ensure greater sensitivity in directing clinically important decisions relating to changes over time, i.e., the MLwHFQ PCS captures HF specific symptoms, such as breathlessness and fatigue, that are not examined within the SF-12 generic quality-of-life tool (Rector, 2004). Furthermore, this is the only known study that has used all the MLwHFQ sub-domains in the caregiver population. Future dyadic studies should use this questionnaire to strengthen the findings of the current study and extend the body of knowledge on both patients' and caregivers' quality of life over time.

7.4 Patient and family caregiver characteristics, self-care and quality of life at TP1 that are associated with caregiver burden at TP2

This second section of the chapter will discuss changes in the caregiver burden scores (as measured by the Zarit Burden Interview scale, Hooley et al., 2005) from baseline (TP1) to the 6-month follow-up (TP2). It will discuss the patients' and caregivers' baseline (TP1) characteristics (including self-care, caregiver contribution to self-care, caregiver burden, physical activity and quality of life) that significantly correlated with caregiver burden at the 6-month follow-up (TP2). The statistically significant correlations entered into the multiple linear regression models as predictors of caregiver burden (research question 2) will also be discussed, as will their relationship with the published literature, to conclude the section.

7.4.1 Changes in caregiver burden from TP1 to TP2

The caregiver burden (total scores) did not change statistically significantly from baseline (TP1) to the 6-month follow-up (TP2); instead, trends in scores indicate greater perceived caregiver burden. These findings are consistent with those of Gilotra et al.'s (2021) longitudinal study of patients and caregivers enrolled in an ambulatory HF programme, but differ from other research (Lyons et al., 2009; Garlo et al., 2010; Pressler et al., 2013), that reported a reduction in the level of caregiver burden at follow-up. A potential explanation for the non-significant increase in caregiver burden scores in the current study may be that over fifty per cent of the patients were in NYHA classification III at enrolment, so would already have significant limitations on their functional status. These differences between these studies' findings may also be accounted for by the different caregiver burden tools used and the duration of the follow-up periods. The trends in scores in the current study suggest the importance of early caregiver assessment, to negate deterioration in an already vulnerable group.

7.4.2 Correlations and regression models

Table 16 shows five statistically significant correlations between the patients' baseline variables and caregiver burden at TP2, i.e., self-care confidence; mental health (SF-12 MCS); MLwHFQ (total score); emotional health (MLwHFQ ECS); and physical activity. In the multiple regression (Model 1) analysis, only patients' baseline mental health (SF-12 MCS) and physical activity significantly predicted caregiver burden at the 6-month follow-up (TP2). The association between patients' baseline mental health and caregiver burden is consistent with Hooley et al. (2005); Chung et al. (2016); Hwang et al. (2011); Lum et al. (2014) and Albert et al. (2018). Previous studies have also recognised the association between patients' physical activity levels and caregiver burden (Luttick et al., 2007; Pressler et al., 2009; Agren et al., 2010; Pressler et al., 2013; Dionne-Odom et al., 2017).

Table 19 shows six statistically significant correlations between the caregivers' baseline variables and caregiver burden at TP2, i.e., caregivers' contribution to self-care maintenance, self-care confidence, MLwHFQ (total score), physical health (MLwHFQ PCS), emotional health (MLwHFQ ECS), and baseline (T1) caregiver burden. In the multiple regression (Model 2), only caregivers' baseline emotional health and baseline (TP1) caregiver burden significantly predicted caregiver burden at TP2. Other caregiving studies (Chung et al., 2010; Hooley et al., 2005; Luttick et al., 2007a; Garlo et al., 2010) also found associations between emotional health and increased caregiver burden. However, the association between increased baseline caregiver burden and increased caregiver burden at follow-up contrasted with Garlo et al.'s (2010) study, who found no association between time and the level of caregiver burden.

Model 3 of the multiple regression analysis included the significant (patient and caregiver) predictors from Model 1 and Model 2. Only the patients' baseline physical activity level, caregivers' baseline burden and caregivers' baseline emotional health (MLwHFQ ECS) significantly predicted caregiver burden at the 6-month follow-up (TP2), suggesting that they were the strongest overall predictors of caregiver burden (outcome). It is not entirely surprising that the study patients' physical activity levels were the strongest predictor of caregiver burden at TP2, given the fact that almost 60% were physically inactive.

The hypothesis has been confirmed that there are patient and caregiver factors at baseline (TP1) that contribute to caregiver burden at the 6-month follow-up (TP2) (research question 2). Surprisingly, in the multiple regression, the patients' baseline self-care and caregivers' contribution to self-care did not significantly predict caregiver burden at TP2. Similar to Durante et al. (2019), caregivers' contribution to self-care did not predict caregiver burden at TP2 when added to the regression model. However, Durante et al. (2019) only used the self-care maintenance and management domains in cross-sectional analysis, and caregiver burden (outcome) was measured using the Caregiver Burden Inventory. A greater number of patients in the current study were within NYHA class III, compared to Durante et al. (2019). This suggests that the study patients had greater physical limitations because of HF symptoms, which may have increased the demands placed on the caregivers and the level of burden that they experienced.

7.5 Self-care as predictors of quality of life (outcomes) in patient–caregiver dyads

This third section of the chapter discusses the effects of patient self-care and family caregivers' contribution to self-care at baseline (TP1) on their own and their partner's quality of life at the 6-month follow-up (TP2) (research question 3). The statistically significant *actor* and *partner effects* of baseline self-care on quality-of-life outcomes are discussed and comparisons are made to previous dyadic HF studies. The *actor effect* refers to the impact of an individual's characteristics, i.e., the patient's self-care (or caregivers' contribution to self-care) on their own quality of life at 6 months, whilst controlling for the individual's quality of life at baseline. The *partner effect* refers to the impact of an individual's characteristics, i.e., the patient's baseline self-care (or caregiver's contribution to self-care) on his or her partner's quality of life at 6 months, while controlling for quality of life at baseline.

7.5.1 Patients' actor effects: self-care on quality-of-life outcomes (SF-12 and MLwHFQ)

This is the first known longitudinal study that has examined self-care and quality of life outcomes using the APIM model. Patients' increased self-care confidence (greater engagement in symptom monitoring, implementing and evaluating treatment) significantly predicted their improved mental health (SF-12 MCS) at the 6-month follow-up (*actor effect*). This a new finding in the HF literature that has used the APIM model. Previously, the association between patients' greater self-efficacy and improved mental health was identified by Lee et al. (2011), although Trivedi et al. (2016) found a deterioration in mental health at follow-up.

Surprisingly, self-care management, self-care maintenance and self-care confidence did not significantly predict the patients' physical health (SF-12 PCS) at TP2. This suggests that patients' engagement in self-care at baseline (TP1) had no significant impact on their physical quality of life at TP2. This finding contrasts with Vellone et al.'s (2014) cross-sectional study using the APIM, which found that greater patient engagement in self-care maintenance and management was associated with poorer physical health. These differences in results may be due to the different study designs and use of a generic quality-of-life tool by Vellone et al. (2014), which does not capture the specific symptoms associated with HF.

Using the MLwHFQ, patients' greater self-care maintenance (symptom monitoring) and self-care confidence (greater engagement in symptom monitoring, implementing and evaluating treatment) at TP1 significantly predicted their better quality of life (MLwHFQ total score) at TP2 (*actor effects*). Whilst no known longitudinal studies were found that used the APIM for comparison, the findings are consistent with the wider HF literature that promotes self-care as a method of improving quality of life (Lyons et al., 2015; Buck et al., 2015; Sebern & Riegel., 2009).

Similarly, patients' greater self-care confidence (greater engagement in symptom monitoring, implementing and evaluating treatment) at TP1 was statistically significantly associated with better physical health (MLwHFQ PCS) at TP2 (*actor effect*). Also, patients' greater self-care management (treatment implementation), self-care maintenance (symptom monitoring) and self-care confidence (greater engagement in symptom monitoring, implementing and evaluating treatment) significantly predicted their better emotional health (MLwHFQ ECS) at TP2 (*actor effects*). The association between patients' greater self-care confidence and better physical health in the current study is, overall, consistent with that found by Kessing et al. (2017). However, direct comparisons cannot be made, as the APIM was not used, and the European Self-Care Behaviour scale was used to measure self-care. Also, prior research by Seto et al. (2011) found that greater self-care maintenance and self-care confidence were associated with patients' better emotional quality of life, although the APIM and the MLwHFQ were not used.

7.5.2 Caregivers' actor effects: self-care on quality-of-life outcomes (SF-12 and MLwHFQ)

This study found that increased caregivers' contribution to self-care maintenance (symptom monitoring) and self-care confidence (greater engagement in symptom monitoring, implementing and evaluating treatment) at baseline was significantly associated with their poorer physical health at TP2 (*actor effects*). The association between caregivers' contribution to self-care maintenance and poorer physical health is consistent with the findings of Vellone et al.'s (2014) cross-sectional APIM study. It is not surprising that increased contribution to self-care is associated with caregivers' poorer physical health. It can be explained by the physical demands of the caregiving role, which has been recognised in prior caregiver studies (Rausch et al., 2007; Pressler et al., 2013). Greater caregivers' contribution to self-care maintenance (symptom monitoring) and self-care confidence (greater engagement in symptom monitoring, implementing and evaluating treatment) at baseline was significantly associated with their better mental health (SF-12 MCS) at TP2 (*actor effects*). These are new findings in the HF dyadic literature, for, although Vellone et al. (2014) identified an association between increased caregivers' self-care confidence and improved mental health, theirs was a cross-sectional study.

Using the MLwHFQ, caregivers' greater contribution to self-care maintenance (symptom monitoring) and self-care confidence (greater engagement in symptom monitoring, implementing, and evaluating treatment) was significantly associated with their better quality of life (MLwHFQ total score) and emotional health (MLwHFQ ECS) at TP2 (*actor effects*). Hooker et al. (2018) found similar associations between self-care maintenance and self-care confidence and quality-of-life outcomes in dyads, which were thought to be a result of greater mutuality between the patient and their caregiver. It may be that the caregivers found many positive aspects associated with providing care to their loved one (Pressler et al., 2009; Ruasch et al., 2007). Interestingly, the study caregivers' contribution to self-care management, self-care maintenance and self-care confidence did not demonstrate any statistically significant *actor effects* on their own physical health (MLwHFQ PCS) at TP2. No known studies have used all three domains of the MLwHFQ with caregivers, which limits comparisons being made with the current study findings.

7.5.3 Patients' partner effects: self-care on quality-of-life outcomes (SF-12 and MLwHFQ)

Patients' greater baseline self-care management (i.e., symptom evaluation) was significantly associated with the caregiver's better physical health (SF-12 PCS) at TP2 (*partner effect*)*.* This study finding contributes to the body of literature on dyadic research. No *partner effect* of the patient's greater self-care management being associated with better physical health in the caregiver has been identified in APIM studies. However, Dion-Odem et al. (2019) found that offering greater support to patients who were non-adherent to self-care practices resulted in caregivers being physically exhausted. It is therefore logical to assume that, in patients who are independently managing their self-care, the physical exhaustion and poor physical health experienced by caregivers would lessen.

Perhaps the most significant study finding was that a mutual dyadic effect was found for baseline self-care maintenance and emotional health (outcome). The patient's greater baseline self-care maintenance was significantly associated with the caregiver's poorer emotional health (MLwHFQ ECS) at the 6-month follow-up (TP2) and vice versa, the caregivers' baseline self-care maintenance was significantly associated with the patient's poorer emotional health (MLwHFQ ECS) at TP2 (*mutual dyadic effect*). This usefully demonstrates the inter-partner relationship and influence that one member of the dyad has on the other. In non-APIM studies (i.e., studies comparing patients and caregivers as groups instead of patient–caregiver pairs), a mutual dyadic effect such as this could be missed. No known dyadic studies are available that used the APIM to explore self-care and emotional health (MLwHFQ ECS) longitudinally with which the study findings might be compared.

7.5.4 Caregivers' partner effects: self-care on quality-of-life outcomes (SF-12 and MLwHFQ)

Caregivers' greater contribution to self-care management was significantly associated with the patient's better physical health (SF-12 PCS) at TP2 (*partner effect*). This finding contrasts with that of Vellone et al. (2014), who found no *partner effect*, but is consistent with previous studies that recognised the benefits of caregivers' contribution to patient care and improved outcomes (Trivedi et al., 2012; Schwarz & Elman, 2003; Clark et al., 2009). Moreover, the caregiver's greater contribution to self-care management and self-care maintenance were significantly associated with the patient's poorer mental health (SF-12 MCS) at TP2 (*partner effects*). No prior APIM studies of self-care and mental health (SF-12 MCS) could be found to support the study findings. However, a number of other studies exist that recognise the impact of caregivers' influence on patients' psychological well-being (Buck et al., 2013; Evangelista et al., 2002; Kitko et al., 2015). Further, Rosalind et al. (2010) identified that caregivers' "nagging" regarding treatment compliance negatively impacted on the patients' mental health.

Using the MLwHFQ, the caregiver's contribution to self-care maintenance was significantly associated with the patient's poorer quality of life (MLwHFQ total score) and physical health (MLwHFQ PCS) at TP2 (*partner effects*). No known dyadic APIM studies were found to compare the current study findings. It may be that the caregiver only contributed to the patient’s self-care when a noticeable deterioration had occurred in their condition.

7.5.5 The actor and partner effects of baseline quality of life on quality of life at TP2

This study identified that patients’ better baseline physical health (increased scores in the SF-12 PCS) was significantly associated with their better physical health at TP2 (*actor effects*), which contrasts with Trivedi et al. (2016), where a deterioration was noted in the physical health (SF-12 PCS) at follow-up. Furthermore, the patients’ poorer baseline overall quality of life (MLwHFQ total), physical health (MLwHFQ PCS) and emotional health (MLwHFQ ECS) were significantly associated with their poorer overall quality of life, and physical and emotional health at TP2 (*actor effects*). The caregivers’ better baseline physical health (increased scores in the SF-12 PCS) was significantly associated with their better physical health at TP2 (*actor effect*).

In terms of *partner effects*, the patient’s poorer baseline physical health (MLwHFQ PCS) was significantly associated with the caregiver’s poorer physical health at TP2 (*partner effect*). It is not surprising that patients’ poorer physical health was associated with the caregiver’s poorer physical health at TP2, as most patients in the current study were in NYHA class III, and almost 60% reported being physically inactive. The caregiver’s better baseline physical (SF-12 PCS) and mental (SF-12 MCS) health were significantly associated with the patient’s better physical and mental health at TP2 (*partner effects*). The association with caregivers’ mental health impacting on patients’ mental health was also reported by Trivedi et al. (2012). Similarly, the caregiver’s poorer baseline overall quality of life (MLwHFQ total score), physical health (MLwHFQ PCS) and emotional health (MLwHFQ ECS) were significantly associated with the patient’s poorer overall quality of life, physical health and emotional health at TP2 (*partner effects*). The association between caregivers’ emotional health and patients’ emotional health was also reported in Evangelista et al.’s (2002) study. The only known APIM longitudinal study that considered the impact of baseline quality of life on quality-of-life outcomes was in cardiac rehabilitation patient–caregiver dyads (Thomson et al., 2020b). This study found that baseline mental health (as measured by the SF-12 MCS) predicted the mental health of the dyad at follow-up.

In summary, overall, the hypothesis that patients' self-care and caregivers' contribution to self-care would impact their own and their partner's quality of life at 6 months (TP2) (research question 3) has been confirmed. It was an interesting finding that not all of the self-care domains significantly predicted the patients and caregivers' quality-of-life outcomes. Patients' baseline self-care confidence most frequently predicted their quality-of-life outcomes, followed by self-care maintenance (*actor effects*). The caregivers' baseline self-care confidence and self-care maintenance were both important predictors of their quality of life at 6 months (*actor effects*). It was a novel finding that both the patients' and caregivers' baseline self-care maintenance impacted on their own and their partner's emotional health at 6 months (TP2) (mutual dyadic effect). No longitudinal studies were found for direct comparison of this result. The patients' quality-of-life outcomes (SF-12 MCS, MLwHFQ total score, PCS and ECS) were more frequently influenced by the caregivers' contribution to self-care maintenance (*partner effects*).

7.6 Strengths of the study

This study has a number of strengths that should be highlighted. The ESC HF diagnostic criteria (Ponikowski et al., 2016) were taken into account during the screening process adopted in this study, therefore ensuring that the patients who were recruited had a diagnosis of heart failure confirmed. The use of the self-care and caregiver contribution to self-care questionnaire domains (self-care maintenance, management and confidence), as well as the individual items on the questionnaire, were assessed longitudinally. The analysis of the responses to this questionnaire highlighted areas where the patients and caregivers require support, i.e., on the importance of daily weights and being able to relate changes in symptoms to a possible episode of decompensation.

Another strength of the study is that it assessed both patient and caregiver predictors of caregiver burden, which extends knowledge and understanding of factors that influence caregiver burden over time. Further, both patient and caregiver outcome measures (PROMs) were assessed, as was the impact of self-care, caregiver burden and quality of life over time. Although previous studies have adopted these measures, no other studies have used all of them (i.e., CCSCHFI, SCHFI, SF-12, MLwHFQ and the Zarit Burden) in combination in longitudinal research.

A significant strength of this study lies in its use of an analytical method, i.e., the APIM, which yielded statistically significant *actor* and *partner effects.* Whilst other dyadic studies have used the APIM, this is the first study in the UK and elsewhere to assess the impact of patient and family caregiver contribution to self-care on their own, and their partner's, quality of life longitudinally. The findings from this research (as per clinical doctorate guidelines) have made a major contribution to the advancement of research methods, a result of using the APIM analytical method longitudinally in HF dyads. By using this novel method, the body of knowledge regarding inter-partner relationships has been extended, which further highlights the need to assess both patients and their caregivers in HF. A further strength of the study lies in its recruitment of patient and caregiver pairs, which is a recognised challenge in HF research (Quinn et al., 2010), but it enabled the identification of the *actor* and *partner effects* highlighted within the study.

Appendix 34 presents a research article prepared for publication, which reports some of the findings of this doctoral thesis.

7.7 Study limitations

There are some recognised limitations to this clinical doctorate study. A convenience sampling method was used to recruit a relatively small sample of patients and their caregivers. Whilst the sample size was small, and limitations of convenience sampling have been highlighted previously, it is a commonly used method in both nursing and health care research when resources and time are limited (McKenzie, 2013). Whilst convenience sampling can affect the representativeness of a sample, it is believed that the sample included in this study is representative, as discussed earlier.

Whilst the data collection involved the recruitment of a multi-centre cohort of HF patients and caregivers, the generalisability of the results may be limited to the UK population alone. There was no information on the response rate as such, because the initial recruitment was carried out by the cardiac nurse specialists. This could have been helped by the use of a screening log to ascertain how many patients were approached and how many were not interested in participating. In hindsight, the use of an initial screening log could have been used, as it would have enabled an assessment of non-responders' reasons for refusing the invitation.

It is acknowledged that women are often under-represented in HF research (Tomasoni et al., 2021), and this is evident from the findings of this study, with a greater number of male patients (80.4% vs 19.6%). A recent systematic review of randomised controlled trials, which included *n*= 183,097 patients with HFrEF substantiated this claim; women were under-enrolled in most of the included studies, which represented only 25.5% of the patients. Clinically, Taylor et al.'s (2021) analysis of UK national health registries of HF patients from the years 2000-2017 explained that females were older than men at point of diagnosis – almost five years older (76.9 vs 74.8 years) - and had a better prognosis after adjusting for age. Whilst comorbid cardiovascular disease was common between men and women, hypertension was more prevalent in women and ischaemic heart disease, previous MI, smoking and diabetes had a greater prevalence in males. So given that women with HF are different clinically from men, the fact that they are underrepresented in this research, is a potential limitation. The findings could therefore have been different had there been a representative proportion of women in the sample.

Also, self-care and quality of life was assessed by self-report, which again, is typical of most HF studies. Nonetheless, disadvantages include poor recall of symptoms and whether the reported self-care is reflective of reality. Further, the patients and caregivers were asked to complete their questionnaires separate from each other at two time-points, i.e., on the patient's discharge from hospital and 6 months later, but there was no way of ensuring that this was adhered to. Despite this limitation, the data were longitudinal, which meant that the direction of causality of association could be determined. This has not been possible in previous dyadic studies using the APIM, which have mostly employed a cross-sectional design.

The lack of data on confounding variables was acknowledged as a recognised limitation. Whist the study did not look to examine the impact of confounding variables, such as hospital readmission rates, life stressors, social support, and new diagnoses, studying their impact on self-care and quality of life would have been illuminating. Indeed, Skelly et al. (2012) recognise the importance of demographic and clinical factors as potential confounders, and that failure to consider such confounders can bias the results and conclusions. Therefore, the omission of possible study confounders should be taken into consideration when interpreting the results and will inform the basis of further research.

A further limitation of the study was that a number of statistical tests were conducted, e.g., for differences between the patients' and the caregivers' self-care and quality of life at TP1 and TP2, increasing the risk of Type 1 errors. However, adjustments were made for this using the Bonferroni correction method (Appendix 33).

7.8 Conclusions

In conclusion, several important findings have been identified as a result of conducting this longitudinal research. The aims and research questions, I believe, have been answered. A summary of the research findings from each question are presented below.

Question 1: Are there differences between patients' and family caregivers' self-care and quality of life at TP1 (after diagnosis) and TP2 (6 months later)?

- There were statistically significant differences between the patients' and caregivers' self-care maintenance at TP1, which indicated that patients were contributing more to their own self-care (i.e., monitoring their own symptoms and adhering to treatment).

- The research also identified patient and caregiver areas of self-care that were given least priority at TP1 and TP2. In the **self-care maintenance** domain, patients gave least priority to adhering to a low salt diet when eating out and exercising for 30 minutes at TP1 and TP2. Caregivers gave least priority to reminding patients to ask for low salt items when eating out, reminding them to perform daily weights and using a reminder system for medication at TP1 and TP2.
- In the **self-care management** domain (i.e., symptom evaluation), patients gave least priority to trying a remedy to help their symptoms and being able to recognise changes in symptoms as being related to their HF at TP1 and TP2. These issues were also identified for caregivers at TP1 and TP2.
- In the **self-care confidence** domain (i.e., greater engagement in symptom monitoring, implementing, and evaluating treatment), patients were least confident in being able to remain free of HF symptoms and being able to evaluate remedies used to relieve symptoms at TP1 and TP2. These issues were also identified for caregivers at TP1 and TP2.
- Consistent with previous research, self-care and caregiver contribution to self-care is below the recommended threshold of 70. This research has extended these findings, as it is also poor at follow-up.
- There were statistically significant differences between the patients' and caregivers' physical quality of life at both TP1 and TP2; the patients' physical health was poorer than the caregivers.
- There were statistically significant differences between the patients' and caregivers' emotional health at TP1 and TP2; the patients' emotional health was poorer than that of the caregivers.
- Consistent with previous research, the mental health of the patients and caregivers were similar.

Question 2: What patient and family caregiver characteristics and self-care at TP1 (baseline) predict caregiver burden at 6 months (TP2)?

- Only patients' baseline physical activity level significantly predicted caregiver burden at TP2. This was not surprising, as almost 60% of the patients in the study were physically inactive.

- Caregivers’ poorer emotional health at baseline significantly predicted increased caregiver burden at TP2.
- Caregivers’ greater caregiver burden at baseline significantly predicted increased caregiver burden at TP2.
- Unlike Durante et al.’s (2019), this study is longitudinal and confirms that caregiver contribution to self-care maintenance, management and confidence, when added to the final multiple regression model, does not predict caregiver burden.

Question 3: What are the effects of patient self-care and family caregiver contribution to self-care (at TP1) on their own and their partner’s quality of life at 6 months (TP2)?

The study findings were unique, in that no known longitudinal studies have explored patients’ self-care and caregivers’ contribution to self-care as a predictor of quality-of-life outcomes using the APIM. A number of important *actor* and *partner* effects were identified:

- Patients’ self-care influenced their own quality-of-life outcomes at TP2; greater self-care confidence significantly predicted their better mental health (SF-12 MCS); greater self-care maintenance and confidence significantly predicted their better overall quality of life (MLwHFQ total score) at TP2; greater self-care confidence significantly predicted their better physical quality of life (MLwHFQ PCS) at TP2; greater self-care management, maintenance and confidence significantly predicted their emotional health (MLwHFQ ECS) at TP2 (*actor effects*).
- Caregivers’ contribution to patients’ self-care influenced their own quality-of-life outcomes at TP2; greater self-care maintenance and confidence significantly predicted their poorer physical health (SF-12 PCS), but significantly predicted their better mental health (SF-12 MCS); greater self-care maintenance and self-care confidence significantly predicted their better quality of life (MLwHFQ total score) and emotional health (MLwHFQ ECS) at TP2 (*actor effects*).
- Patient’s self-care influenced their partner’s quality of life at TP2; greater self-care management significantly predicted the caregiver’s better

physical health (MLwHFQ PCS) at TP2; greater contribution to self-care maintenance significantly predicted the caregiver's poorer emotional health (MLwHFQ ECS) at TP2 (*partner effects*).

- With the exception of caregiver's contribution to self-care management on the patient's physical health at TP2, the caregiver's contribution to self-care maintenance and self-care management significantly predicted the patient's poorer mental health (SF-12 MCS) and greater self-care maintenance significantly predicted the patient's poorer quality of life (MLwHFQ total score); physical health (MLwHFQ PCS) and emotional health (MLwHFQ ECS) at TP2 (*partner effects*).
- The most significant study finding was that caregivers' greater baseline self-care maintenance was associated with the patient's poorer emotional health and vice versa, i.e., the patient's baseline self-care maintenance predicted the caregiver's poorer emotional health at TP2 *(mutual dyadic effect*).
- Patients' better baseline physical health (SF-12 PCS) significantly predicted their better physical health at TP2 (*actor effect*); poorer baseline quality of life (MLwHFQ total score), physical health (MLwHFQ PCS) and emotional health (MLwHFQ ECS) were significantly associated with their poorer overall quality of life, physical and emotional health at TP2 (*actor effects*).
- Caregivers' better baseline physical health (SF-12 PCS) was significantly associated with their better physical health at TP2 (*actor effects*).
- Patients' poorer baseline physical health (MLwHFQ PCS) was significantly associated with the caregiver's poorer physical health at TP2 (*partner effect*).
- The caregiver's better baseline physical health (SF-12 PCS) and mental health (SF-12 MCS) were significantly associated with the patient's better physical and mental health at TP2. The caregiver's poorer baseline quality of life (MLwHFQ total score), physical health (MLwHFQ PCS) and emotional health (MLwHFQ ECS) were significantly associated with the patient's poorer overall quality of life, physical and emotional health at TP2 (*partner effects*).

- The caregivers' baseline variables influenced patients' outcomes more than patients' baseline variables influenced caregivers' outcomes.

7.9 Implications for practice and future research

The findings identified through the completion of this doctoral thesis have highlighted several implications for clinical practice. Patients' level of self-care and caregiver contribution to self-care were poor at both baseline and follow-up. The fact that the patients and caregivers were unable to relate dyspnoea and ankle oedema to a possible episode of HF decompensation is a cause for concern. Indeed, the use of an instrument to measure patient and caregiver contribution to self-care has identified specific areas of self-care to which patients and caregivers give least priority. Whilst it widely acknowledged that HF nurses empower patients to manage their HF symptoms through education, this study provides a clear focus for them to target their education on the specific areas that have been shown to be problematic and continued to be problematic at the follow-up period. Given the fact that the same areas of self-care remained problematic at follow-up suggests the need for assessment of patients' and caregivers' comprehension at baseline and regularly throughout the trajectory. Indeed, following a recent discussion with one of the HF Consultants, it is proposed that, following the first clinic review, patients and their caregivers will be invited to attend a drop-in session on self-care practice. This will focus on the areas that were given least priority (diet, fluid intake, daily weights and recognising key symptoms that are suggestive of an episode of decompensation) by patients and their family caregivers in the current study. This will form the basis of a future RCT that assesses changes in both patients' self-care and caregivers' contribution to self-care maintenance, management and confidence over time, following attendance at an education session versus normal care.

The low activity levels reported by the patients in this study require a multi-disciplinary assessment to avoid the hazards associated with inactivity and periods of immobility. The health-care team could educate the patients and their caregivers regarding the importance of participating in passive/gentle exercises prior to discharge, which could then be reinforced by the HFLNs in the community. Further, the patients' poorer emotional health at the follow-up period highlights the need for clinicians to explore further their exact concerns regarding their HF and its ongoing management. More specifically, it may be more appropriate to refer the patient and their caregiver to the clinical psychology team.

A number of issues relating to caregiver burden need to be considered. Whilst the changes in caregiver burden from baseline to the 6-month follow-up (TP2) were not statistically significant, a trend in increased scores was observed. This highlights the need for practitioners to identify early the caregivers who are at risk of increased burden, as well as gaining consensus on the tool used to measure its outcome. Further, it provides the opportunity to offer ongoing and emotional and practical support as appropriate.

It was a notable finding in this study that the caregivers' contribution to self-care at baseline did not increase caregiver burden at TP2. This gives confidence that clinicians can utilise the help of caregivers with self-care without directly increasing their level of burden. Future research studies are needed to assess the impact of patient and caregiver contribution to self-care maintenance, management and confidence on the level of caregiver burden at periods of greater than 6 months.

Finally, the mutual dyadic effect (i.e., *actor* and *partner effects*) for increased self-care maintenance and caregiver contribution to self-care maintenance on emotional quality of life highlights the importance of targeted interventions by clinicians to support the emotional health of both members of the dyad. Further longitudinal research is required to replicate the study findings, specifically in relation to which aspects of self-care exert more influence on the individual and the patient–caregiver dyad over time, and to target these appropriately.

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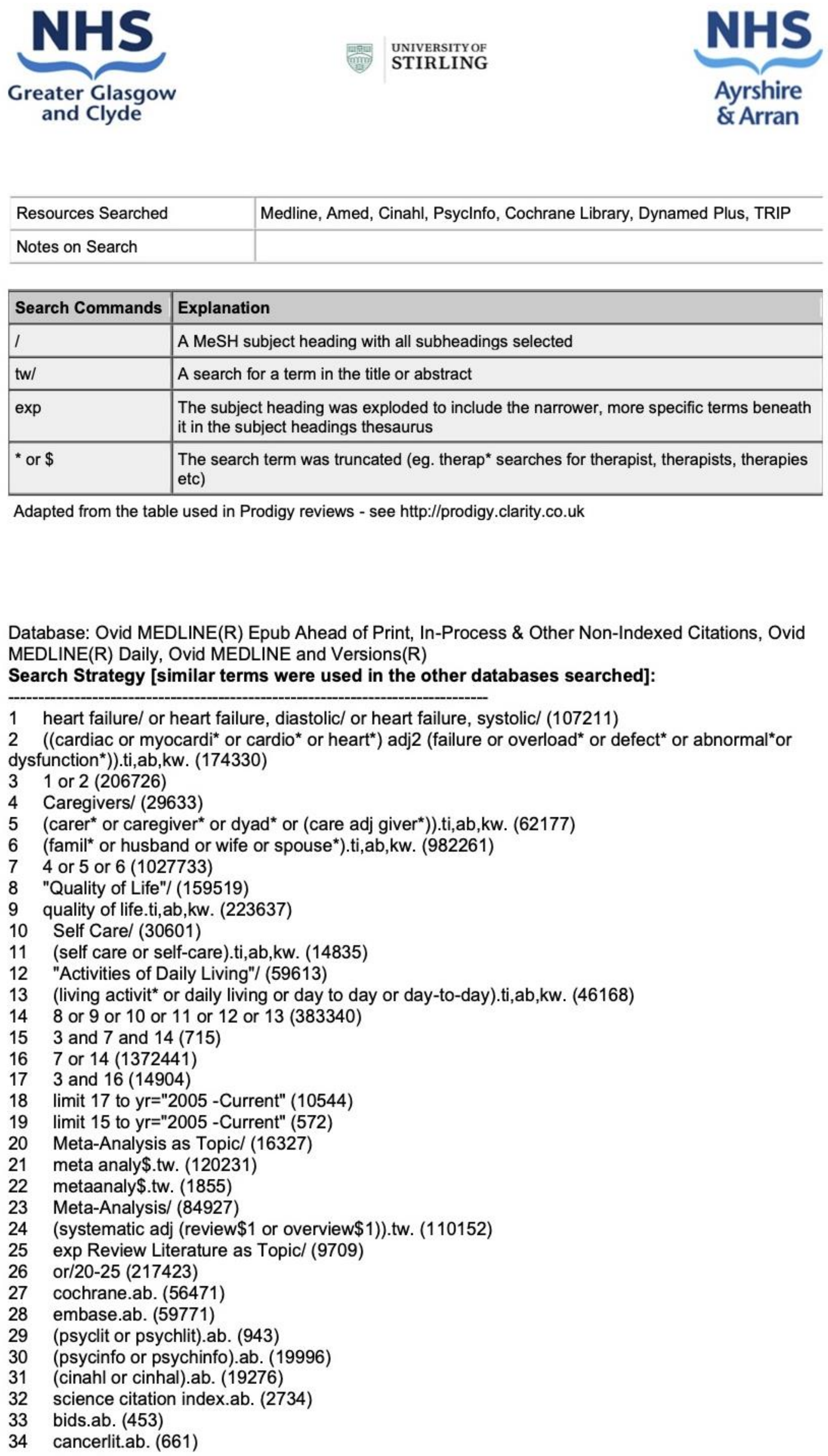
Appendices

Appendix 1: Literature Search Strategy



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Resources Searched	Medline, Amed, Cinahl, PsycInfo, Cochrane Library, Dynamed Plus, TRIP
Notes on Search	

Search Commands	Explanation
/	A MeSH subject heading with all subheadings selected
tw/	A search for a term in the title or abstract
exp	The subject heading was exploded to include the narrower, more specific terms beneath it in the subject headings thesaurus
* or $	The search term was truncated (eg. therap* searches for therapist, therapists, therapies etc)

Adapted from the table used in Prodigy reviews - see http://prodigy.clarity.co.uk

Database: Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily, Ovid MEDLINE and Versions(R)

Search Strategy [similar terms were used in the other databases searched]:

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1 heart failure/ or heart failure, diastolic/ or heart failure, systolic/ (107211)
2 ((cardiac or myocardi* or cardio* or heart*) adj2 (failure or overload* or defect* or abnormal*or dysfunction*)).ti,ab,kw. (174330)
3 1 or 2 (206726)
4 Caregivers/ (29633)
5 (carer* or caregiver* or dyad* or (care adj giver*)).ti,ab,kw. (62177)
6 (famil* or husband or wife or spouse*).ti,ab,kw. (982261)
7 4 or 5 or 6 (1027733)
8 "Quality of Life"/ (159519)
9 quality of life.ti,ab,kw. (223637)
10 Self Care/ (30601)
11 (self care or self-care).ti,ab,kw. (14835)
12 "Activities of Daily Living"/ (59613)
13 (living activit* or daily living or day to day or day-to-day).ti,ab,kw. (46168)
14 8 or 9 or 10 or 11 or 12 or 13 (383340)
15 3 and 7 and 14 (715)
16 7 or 14 (1372441)
17 3 and 16 (14904)
18 limit 17 to yr="2005 -Current" (10544)
19 limit 15 to yr="2005 -Current" (572)
20 Meta-Analysis as Topic/ (16327)
21 meta analy$.tw. (120231)
22 metaanaly$.tw. (1855)
23 Meta-Analysis/ (84927)
24 (systematic adj (review$1 or overview$1)).tw. (110152)
25 exp Review Literature as Topic/ (9709)
26 or/20-25 (217423)
27 cochrane.ab. (56471)
28 embase.ab. (59771)
29 (psyclit or psychlit).ab. (943)
30 (psycinfo or psychinfo).ab. (19996)
31 (cinahl or cinhal).ab. (19276)
32 science citation index.ab. (2734)
33 bids.ab. (453)
34 cancerlit.ab. (661)

35 or/27-34 (97164)
36 reference list$.ab. (14780)
37 bibliograph$.ab. (15519)
38 hand-search$.ab. (5709)
39 relevant journals.ab. (1035)
40 manual search$.ab. (3598)
41 or/36-40 (36415)
42 selection criteria.ab. (26654)
43 data extraction.ab. (15734)
44 42 or 43 (40322)
45 Review/ (2354719)
46 44 and 45 (26894)
47 Comment/ (701317)
48 letter/ (985607)
49 Editorial/ (448770)
50 animal/ (6286651)
51 human/ (17222766)
52 50 not (50 and 51) (4493686)
53 or/47-49,52 (6043992)
54 26 or 35 or 41 or 46 (261758)
55 54 not 53 (248159)
56 18 and 55 (582)
57 Cross-Sectional Studies/ (256470)
58 (cross-sectional or cross sectional or prevalence).mp. (880993)
59 57 or 58 (880993)
60 18 and 59 (1341)
61 Longitudinal Studies/ (113644)
62 longitudinal.mp. (252017)
63 61 or 62 (252017)
64 18 and 63 (313)
65 Randomized Controlled Trials as Topic/ (116228)
66 randomized controlled trial/ (475935)
67 Random Allocation/ (95175)
68 Double Blind Method/ (150971)
69 Single Blind Method/ (25395)
70 clinical trial/ (529635)
71 clinical trial, phase i.pt. (19309)
72 clinical trial, phase ii.pt. (31076)
73 clinical trial, phase iii.pt. (14497)
74 clinical trial, phase iv.pt. (1546)
75 controlled clinical trial.pt. (96101)
76 randomized controlled trial.pt. (475935)
77 multicenter study.pt. (235875)
78 clinical trial.pt. (529635)
79 exp Clinical Trials as topic/ (319585)
80 or/65-79 (1261037)
81 (clinical adj trial$).tw. (308811)
82 ((singl$ or doubl$ or treb$ or tripl$) adj (blind$3 or mask$3)).tw. (161328)
83 PLACEBOS/ (35433)
84 placebo$.tw. (200726)
85 randomly allocated.tw. (24003)
86 (allocated adj2 random$).tw. (27068)
87 or/81-86 (560807)
88 80 or 87 (1479786)
89 case report.tw. (267283)
90 letter/ (985607)
91 historical article/ (350250)
92 or/89-91 (1589024)
93 88 not 92 (1446202)
94 18 and 93 (2453)

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95    56 or 60 or 64 or 94 (4052)
96    19 and 95 (245)
97    18 and 95 (4052)
98    97 not 96 (3807)
***************************
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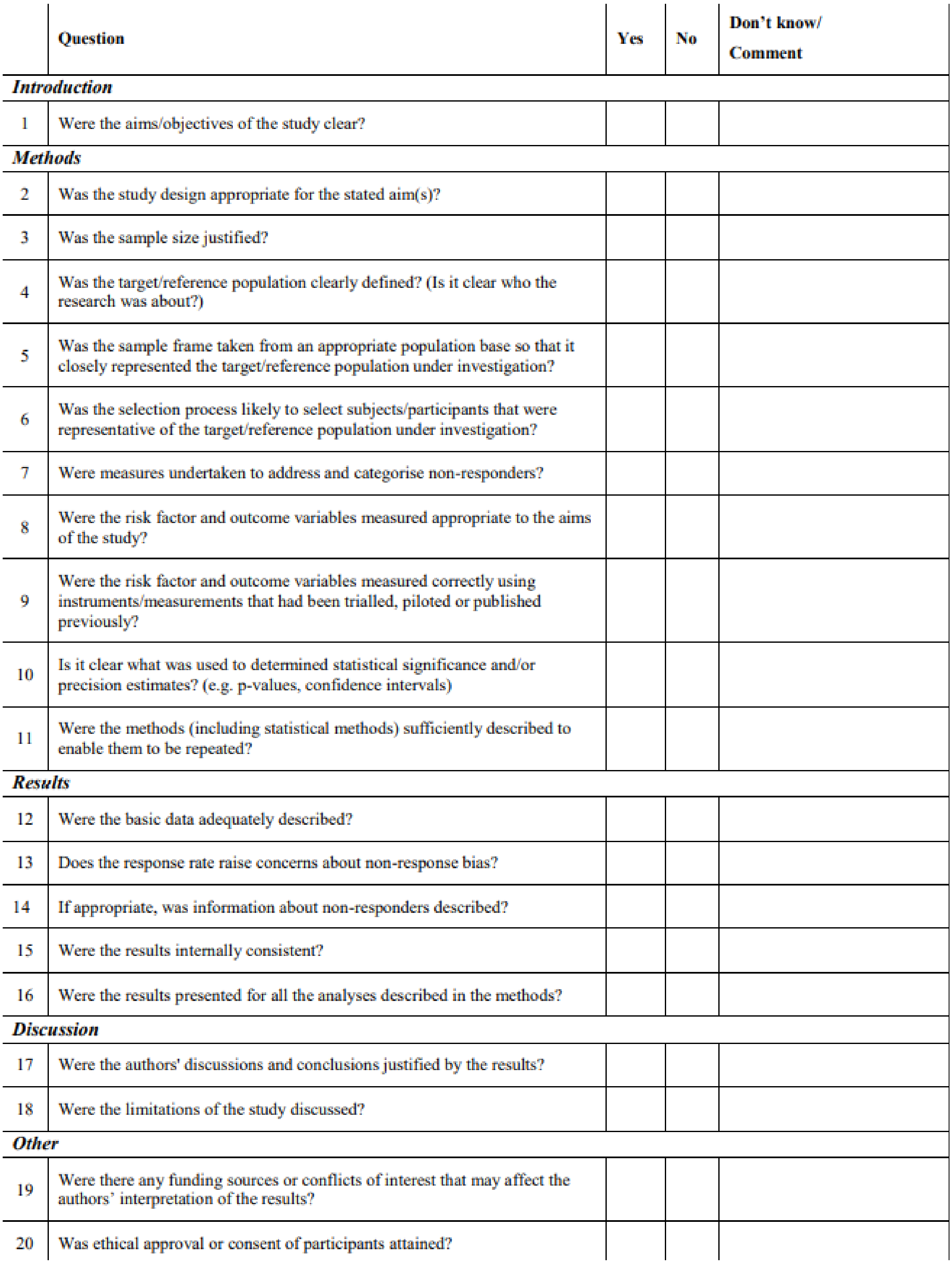
SIGN, 2017. **Cardiac rehabilitation. SIGN 150.**
(see page 7)
http://www.sign.ac.uk/assets/sign150.pdf

NICE, 2010. **Chronic heart failure in adults: management. CG108.**
https://www.nice.org.uk/guidance/cg108

NICE, 2011. **Chronic heart failure in adults. QS9.**
https://www.nice.org.uk/guidance/qs9

Appendix 2: AXIS Tool for Cross-sectional Studies



	Question	Yes	No	Don't know/ Comment
Introduction				
1	Were the aims/objectives of the study clear?			
Methods				
2	Was the study design appropriate for the stated aim(s)?			
3	Was the sample size justified?			
4	Was the target/reference population clearly defined? (Is it clear who the research was about?)			
5	Was the sample frame taken from an appropriate population base so that it closely represented the target/reference population under investigation?			
6	Was the selection process likely to select subjects/participants that were representative of the target/reference population under investigation?			
7	Were measures undertaken to address and categorise non-responders?			
8	Were the risk factor and outcome variables measured appropriate to the aims of the study?			
9	Were the risk factor and outcome variables measured correctly using instruments/measurements that had been trialled, piloted or published previously?			
10	Is it clear what was used to determined statistical significance and/or precision estimates? (e.g. p-values, confidence intervals)			
11	Were the methods (including statistical methods) sufficiently described to enable them to be repeated?			
Results				
12	Were the basic data adequately described?			
13	Does the response rate raise concerns about non-response bias?			
14	If appropriate, was information about non-responders described?			
15	Were the results internally consistent?			
16	Were the results presented for all the analyses described in the methods?			
Discussion				
17	Were the authors' discussions and conclusions justified by the results?			
18	Were the limitations of the study discussed?			
Other				
19	Were there any funding sources or conflicts of interest that may affect the authors' interpretation of the results?			
20	Was ethical approval or consent of participants attained?			

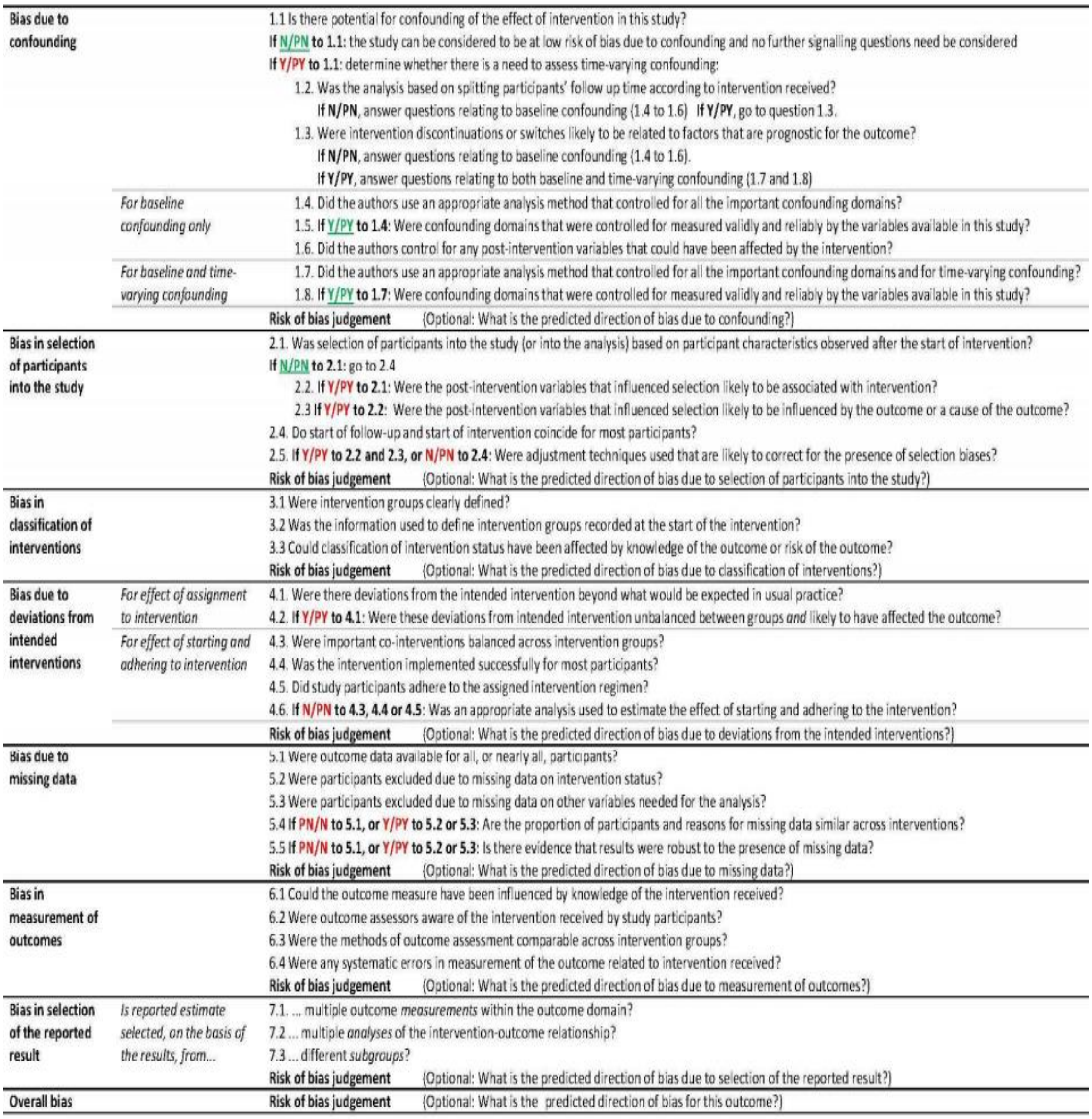
Axis Citations

Citation	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20
Luttick et al. 2007	y	y	N	Y	N	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	?
Hooley et al. 2005	Y	Y	N	Y	N	N	N	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	N	Y
Chung et al. 2016	Y	Y	N	N	N	N	N	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	N	Y
Durante et al. 2019	Y	Y	N	Y	Y	N	N	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	N	Y
Agren et al. 2010	Y	Y	Y	Y	N	N	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	N	Y
Hooker et al. 2018	Y	Y	Y	Y	N	N	N	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	N	?
Gallagher et al. 2011	Y	Y	N	Y	Y	N	N	Y	Y	Y	Y	Y	Y	N	Y	Y	N	Y	N	Y
Cocchieri et al. 2015	Y	Y	N	Y	Y	N	N	Y	Y	Y	Y	Y	N	N	Y	Y	Y	Y	N	Y
Seto et al. 2011	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Buck et al. 2015	Y	Y	Y	Y	N	N	N	Y	Y	Y	Y	Y	N	N	Y	Y	Y	Y	N	Y
Riegel et al. 2009	N	Y	N	Y	N	N	N	Y	Y	Y	Y	Y	N	N	Y	Y	Y	Y	?	Y
Jaarsma et al. 2013	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	N	N	Y	Y	N	Y	N	?

Citation	**Q1**	**Q2**	**Q3**	**Q4**	**Q5**	**Q6**	**Q7**	**Q8**	**Q9**	**Q10**	**Q11**	**Q12**	**Q13**	**Q14**	**Q15**	**Q16**	**Q17**	**Q18**	**Q19**	**Q20**
Hadjuk et al. 2013	Y	Y	N	Y	N	N	N	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	N	Y
Sayers et al. 2008	Y	Y	N	Y	N	N	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	N	Y	N	Y
Chung et al. 2006	Y	Y	N	Y	Y	N	N	Y	Y	Y	Y	Y	N	N	Y	Y	N	Y	N	Y
Seid et al. 2019	Y	Y	N	Y	Y	Y	N	Y	Y	Y	Y	Y	N	N	Y	Y	Y	Y	N	Y
Chuang et al. 2019	Y	Y	N	Y	N	N	N	Y	Y	Y	Y	Y	N	N	Y	Y	Y	Y	N	Y
Heo et al. 2008	Y	Y	N	Y	N	N	N	Y	Y	Y	Y	Y	N	N	Y	Y	Y	Y	N	Y
Heo et al. 2014	Y	Y	N	Y	N	N	N	Y	Y	Y	Y	Y	N	N	Y	Y	N	Y	N	Y
Arestedt et al. 2013	Y	Y	N	Y	N	N	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	N	Y	N	Y
Audi et al. 2017	N	Y	N	Y	N	N	N	Y	Y	Y	Y	Y	N	N	Y	Y	N	Y	N	Y
Gallagher et al. 2019	Y	Y	N	Y	N	N	N	Y	Y	Y	N	Y	Y	N	Y	Y	N	Y	Y	Y
Saunders et al. 2009	Y	Y	N	Y	N	N	N	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	?	Y
Hu et al. 2016	Y	Y	N	Y	N	N	N	Y	Y	Y	Y	Y	Y	N	Y	Y	N	Y	Y	Y
Chung et al. 2013	Y	Y	N	Y	N	N	N	Y	Y	Y	Y	Y	N	Y	Y	N	N	Y	Y	Y

Citation	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20
Hwang et al. 2014	Y	Y	N	Y	N	N	N	Y	Y	Y	N	Y	N	N	Y	Y	N	Y	N	Y
Agren et al. 2011	Y	Y	N	Y	N	N	Y	Y	Y	Y	Y	Y	N	N	Y	Y	N	Y	Y	Y
Chung et al. 2009	Y	Y	Y	Y	N	N	N	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y
Cameron et al. 2017	Y	Y	N	N	N	N	N	Y	Y	Y	Y	Y	Y	N	Y	Y	N	Y	N	Y
Vellone et al. 2014	Y	Y	N	Y	Y	N	N	Y	Y	Y	Y	N	N	N	Y	Y	Y	Y	N	Y
Vellone et al. 2015	Y	Y	N	Y	N	N	N	Y	Y	Y	Y	Y	N	N	Y	Y	Y	Y	N	Y
Lyons et al. 2015	Y	Y	N	Y	N	N	N	Y	Y	Y	Y	Y	Y	N	Y	Y	N	Y	Y	Y
Lum et al. 2014	Y	Y	Y	Y	N	N	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y
Bidwell et al. 2015	Y	Y	N	Y	N	N	N	Y	Y	Y	Y	Y	Y	N	Y	Y	N	Y	Y	Y
Vellone et al. 2018	Y	Y	N	Y	N	N	N	Y	Y	Y	Y	Y	Y	N	Y	Y	N	Y	Y	Y
Sebern & Riegel 2009	Y	Y	Y	Y	N	N	N	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	N	Y
Lee et al. 2015	Y	Y	N	N	N	N	N	Y	Y	Y	Y	Y	Y	N	Y	Y	N	Y	Y	Y

Appendix 3: Cochrane Risk of Bias Tool



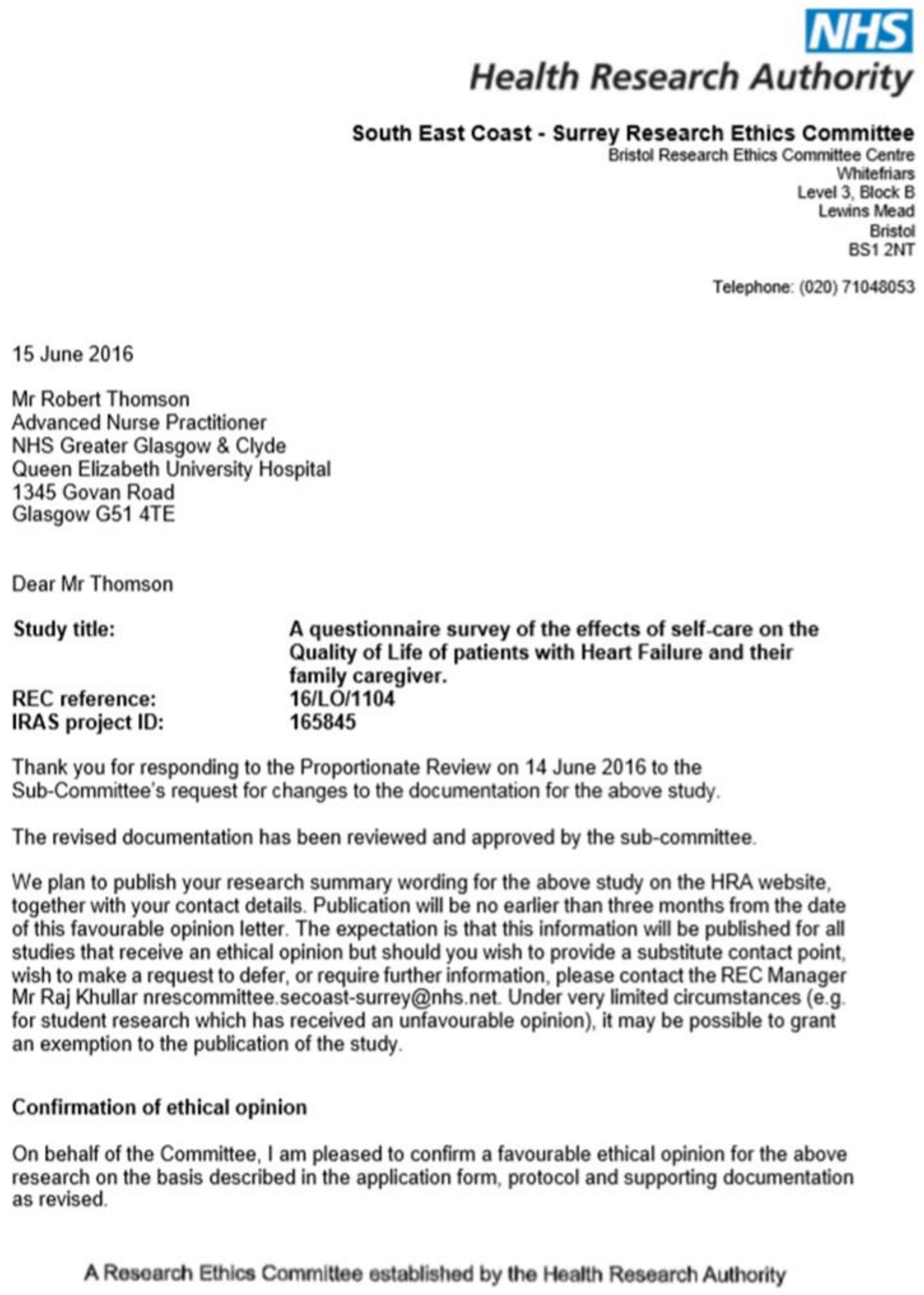
Bias due to confounding		1.1 Is there potential for confounding of the effect of intervention in this study? If **N/PN to 1.1:** the study can be considered to be at low risk of bias due to confounding and no further signalling questions need be considered If **Y/PY to 1.1**: determine whether there is a need to assess time-varying confounding: 1.2. Was the analysis based on splitting participants' follow up time according to intervention received? If **N/PN**, answer questions relating to baseline confounding (1.4 to 1.6) If **Y/PY**, go to question 1.3. 1.3. Were intervention discontinuations or switches likely to be related to factors that are prognostic for the outcome? If **N/PN**, answer questions relating to baseline confounding (1.4 to 1.6). If **Y/PY**, answer questions relating to both baseline and time-varying confounding (1.7 and 1.8)
	For baseline confounding only	1.4. Did the authors use an appropriate analysis method that controlled for all the important confounding domains? 1.5. If **Y/PY to 1.4**: Were confounding domains that were controlled for measured validly and reliably by the variables available in this study? 1.6. Did the authors control for any post-intervention variables that could have been affected by the intervention?
	For baseline and time-varying confounding	1.7. Did the authors use an appropriate analysis method that controlled for all the important confounding domains and for time-varying confounding? 1.8. If **Y/PY to 1.7**: Were confounding domains that were controlled for measured validly and reliably by the variables available in this study?
		Risk of bias judgement (Optional: What is the predicted direction of bias due to confounding?)
Bias in selection of participants into the study		2.1. Was selection of participants into the study (or into the analysis) based on participant characteristics observed after the start of intervention? If **N/PN to 2.1:** go to 2.4 2.2. If **Y/PY to 2.1**: Were the post-intervention variables that influenced selection likely to be associated with intervention? 2.3 If **Y/PY to 2.2**: Were the post-intervention variables that influenced selection likely to be influenced by the outcome or a cause of the outcome? 2.4. Do start of follow-up and start of intervention coincide for most participants? 2.5. If **Y/PY to 2.2 and 2.3, or N/PN to 2.4**: Were adjustment techniques used that are likely to correct for the presence of selection biases? **Risk of bias judgement** (Optional: What is the predicted direction of bias due to selection of participants into the study?)
Bias in classification of interventions		3.1 Were intervention groups clearly defined? 3.2 Was the information used to define intervention groups recorded at the start of the intervention? 3.3 Could classification of intervention status have been affected by knowledge of the outcome or risk of the outcome? **Risk of bias judgement** (Optional: What is the predicted direction of bias due to classification of interventions?)
Bias due to deviations from intended interventions	*For effect of assignment to intervention*	4.1. Were there deviations from the intended intervention beyond what would be expected in usual practice? 4.2. If **Y/PY to 4.1**: Were these deviations from intended intervention unbalanced between groups *and* likely to have affected the outcome?
	For effect of starting and adhering to intervention	4.3. Were important co-interventions balanced across intervention groups? 4.4. Was the intervention implemented successfully for most participants? 4.5. Did study participants adhere to the assigned intervention regimen? 4.6. If **N/PN to 4.3, 4.4 or 4.5**: Was an appropriate analysis used to estimate the effect of starting and adhering to the intervention?
		Risk of bias judgement (Optional: What is the predicted direction of bias due to deviations from the intended interventions?)
Bias due to missing data		5.1 Were outcome data available for all, or nearly all, participants? 5.2 Were participants excluded due to missing data on intervention status? 5.3 Were participants excluded due to missing data on other variables needed for the analysis? 5.4 If **PN/N to 5.1, or Y/PY to 5.2 or 5.3**: Are the proportion of participants and reasons for missing data similar across interventions? 5.5 If **PN/N to 5.1, or Y/PY to 5.2 or 5.3**: Is there evidence that results were robust to the presence of missing data? **Risk of bias judgement** (Optional: What is the predicted direction of bias due to missing data?)
Bias in measurement of outcomes		6.1 Could the outcome measure have been influenced by knowledge of the intervention received? 6.2 Were outcome assessors aware of the intervention received by study participants? 6.3 Were the methods of outcome assessment comparable across intervention groups? 6.4 Were any systematic errors in measurement of the outcome related to intervention received? **Risk of bias judgement** (Optional: What is the predicted direction of bias due to measurement of outcomes?)
Bias in selection of the reported result	*Is reported estimate selected, on the basis of the results, from...*	7.1. ... multiple outcome *measurements* within the outcome domain? 7.2 ... multiple *analyses* of the intervention-outcome relationship? 7.3 ... different *subgroups*? **Risk of bias judgement** (Optional: What is the predicted direction of bias due to selection of the reported result?)
Overall bias		**Risk of bias judgement** (Optional: What is the predicted direction of bias for this outcome?)

Citations – Longitudinal Studies

Citation	Bias due to confounding	Bias in selection of participants	Bias in classification of interventions	Bias due to missing data	Bias in measurement of the outcomes	Bias in selection of the reported results
Albert et al. (2018)	Y	Y	N	N	N	N
Pressler et al. (2013).	Y	Y	N	N	N	N
Kessing et al. (2017)	N	y	N	N	N	Y
Shahriari et al. (2013)	Y	Y	N	N	N	N
Nesbitt et al. (2014)	N	Y	N	Y	N	N
Lee et al. (2015)	y	y	N	N	N	N
Wu et al. (2013)	y	Y	N	Y	N	N
Hoekstra et al. (2013)	N	Y	N	Y	N	N
Grigorovich et al. (2017)	N	Y	N	Y	Y	N
Goodman et al. (2013)	Y	Y	N	N	N	N
Iqbal et al. (2010)	N	Y	N	Y	N	N

Citation	Bias due to confounding	Bias in selection of participants	Bias in classification of interventions	Bias due to missing data	Bias in measurement of the outcomes	Bias in selection of the reported results
Holland et al. (2010)	N	y	N	Y	N	Y
Trivedi et al. (2016)	N	N	N	N	N	N
Tsai et al. (2014)	N	Y	N	Y	N	N
Rohrabugh et al. (2006)	N	Y	N	N	N	Y
Pressler et al. (2009)	N	Y	N	Y	N	N
Bidwell et al. (2017b)	N	N	N	N	N	N

Appendix 4: NHS Ethics Approval



NHS
Health Research Authority

South East Coast - Surrey Research Ethics Committee
Bristol Research Ethics Committee Centre
Whitefriars
Level 3, Block B
Lewins Mead
Bristol
BS1 2NT

Telephone: (020) 71048053

15 June 2016

Mr Robert Thomson
Advanced Nurse Practitioner
NHS Greater Glasgow & Clyde
Queen Elizabeth University Hospital
1345 Govan Road
Glasgow G51 4TE

Dear Mr Thomson

Study title: **A questionnaire survey of the effects of self-care on the Quality of Life of patients with Heart Failure and their family caregiver.**
REC reference: **16/LO/1104**
IRAS project ID: **165845**

Thank you for responding to the Proportionate Review on 14 June 2016 to the Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

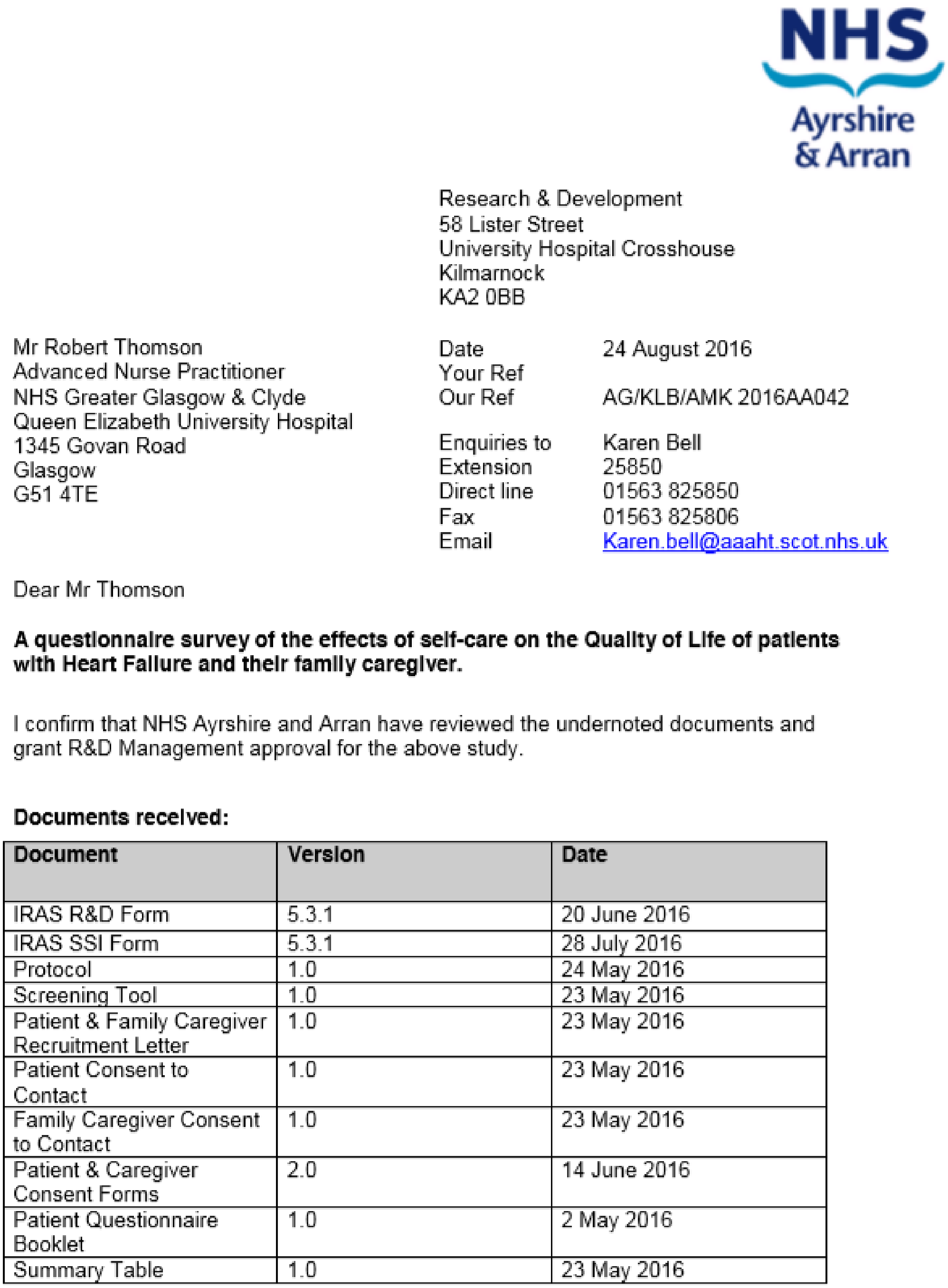
We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Mr Raj Khullar nrescommittee.secoast-surrey@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

A Research Ethics Committee established by the Health Research Authority

Appendix 5: Research & Development approval from NHS Ayrshire & Arran



NHS
Ayrshire
& Arran

Research & Development
58 Lister Street
University Hospital Crosshouse
Kilmarnock
KA2 0BB

Mr Robert Thomson
Advanced Nurse Practitioner
NHS Greater Glasgow & Clyde
Queen Elizabeth University Hospital
1345 Govan Road
Glasgow
G51 4TE

Date	24 August 2016
Your Ref	
Our Ref	AG/KLB/AMK 2016AA042
Enquiries to	Karen Bell
Extension	25850
Direct line	01563 825850
Fax	01563 825806
Email	Karen.bell@aaaht.scot.nhs.uk

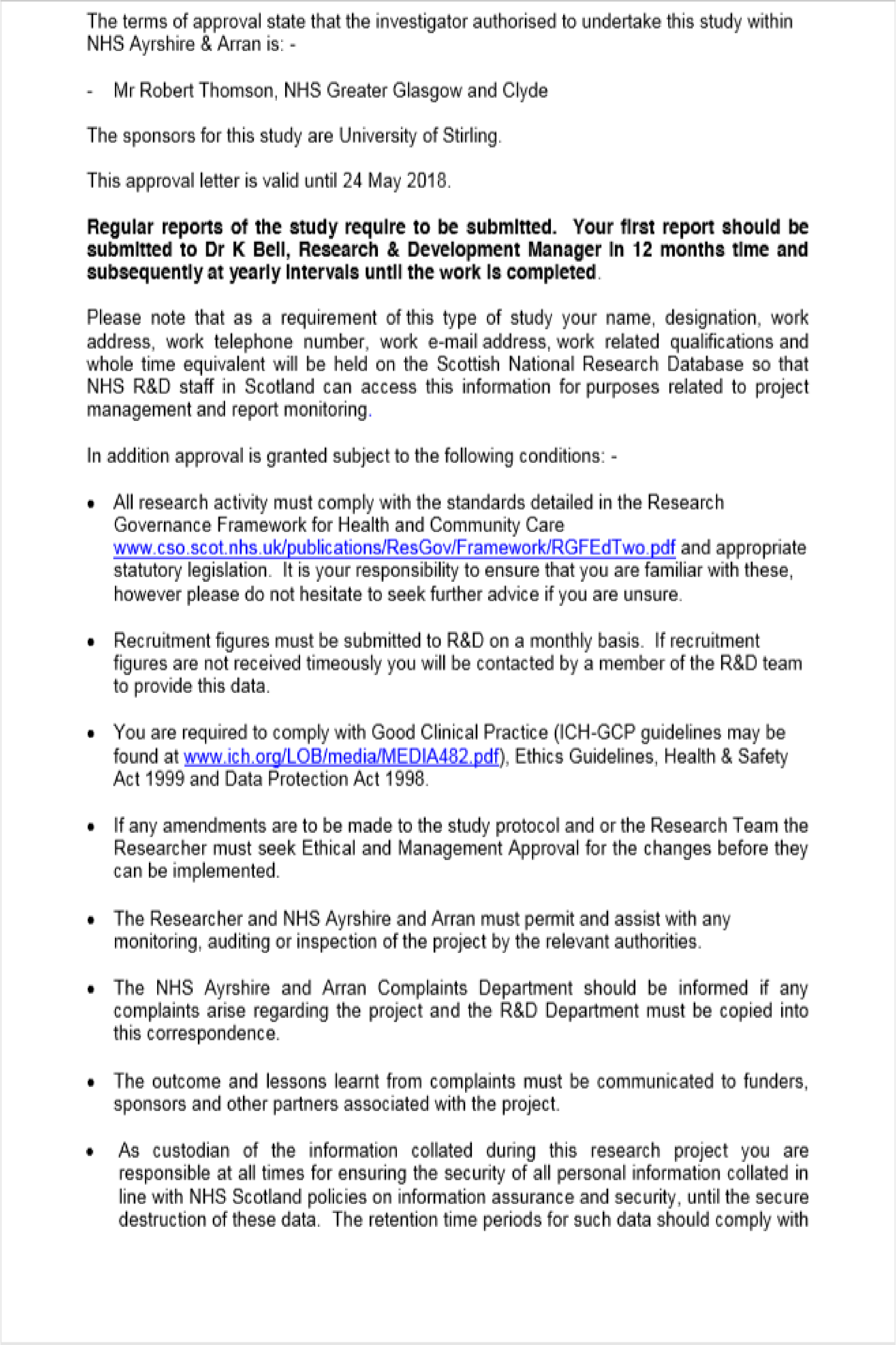
Dear Mr Thomson

A questionnaire survey of the effects of self-care on the Quality of Life of patients with Heart Failure and their family caregiver.

I confirm that NHS Ayrshire and Arran have reviewed the undernoted documents and grant R&D Management approval for the above study.

Documents received:

Document	Version	Date
IRAS R&D Form	5.3.1	20 June 2016
IRAS SSI Form	5.3.1	28 July 2016
Protocol	1.0	24 May 2016
Screening Tool	1.0	23 May 2016
Patient & Family Caregiver Recruitment Letter	1.0	23 May 2016
Patient Consent to Contact	1.0	23 May 2016
Family Caregiver Consent to Contact	1.0	23 May 2016
Patient & Caregiver Consent Forms	2.0	14 June 2016
Patient Questionnaire Booklet	1.0	2 May 2016
Summary Table	1.0	23 May 2016



The terms of approval state that the investigator authorised to undertake this study within NHS Ayrshire & Arran is: -

- Mr Robert Thomson, NHS Greater Glasgow and Clyde

The sponsors for this study are University of Stirling.

This approval letter is valid until 24 May 2018.

Regular reports of the study require to be submitted. Your first report should be submitted to Dr K Bell, Research & Development Manager in 12 months time and subsequently at yearly intervals until the work is completed.

Please note that as a requirement of this type of study your name, designation, work address, work telephone number, work e-mail address, work related qualifications and whole time equivalent will be held on the Scottish National Research Database so that NHS R&D staff in Scotland can access this information for purposes related to project management and report monitoring.

In addition approval is granted subject to the following conditions: -

- All research activity must comply with the standards detailed in the Research Governance Framework for Health and Community Care www.cso.scot.nhs.uk/publications/ResGov/Framework/RGFEdTwo.pdf and appropriate statutory legislation. It is your responsibility to ensure that you are familiar with these, however please do not hesitate to seek further advice if you are unsure.

- Recruitment figures must be submitted to R&D on a monthly basis. If recruitment figures are not received timeously you will be contacted by a member of the R&D team to provide this data.

- You are required to comply with Good Clinical Practice (ICH-GCP guidelines may be found at www.ich.org/LOB/media/MEDIA482.pdf), Ethics Guidelines, Health & Safety Act 1999 and Data Protection Act 1998.

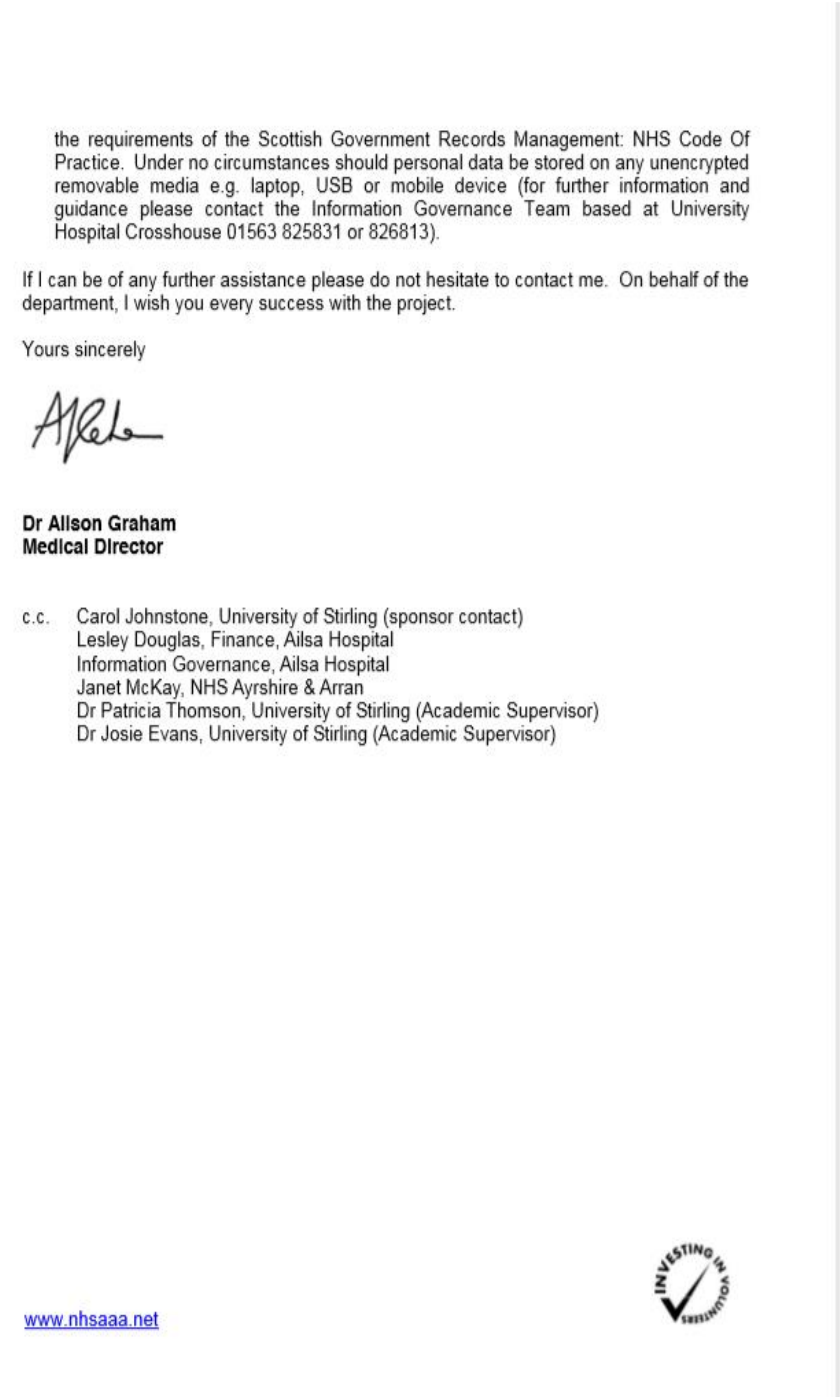
- If any amendments are to be made to the study protocol and or the Research Team the Researcher must seek Ethical and Management Approval for the changes before they can be implemented.

- The Researcher and NHS Ayrshire and Arran must permit and assist with any monitoring, auditing or inspection of the project by the relevant authorities.

- The NHS Ayrshire and Arran Complaints Department should be informed if any complaints arise regarding the project and the R&D Department must be copied into this correspondence.

- The outcome and lessons learnt from complaints must be communicated to funders, sponsors and other partners associated with the project.

- As custodian of the information collated during this research project you are responsible at all times for ensuring the security of all personal information collated in line with NHS Scotland policies on information assurance and security, until the secure destruction of these data. The retention time periods for such data should comply with



the requirements of the Scottish Government Records Management: NHS Code Of Practice. Under no circumstances should personal data be stored on any unencrypted removable media e.g. laptop, USB or mobile device (for further information and guidance please contact the Information Governance Team based at University Hospital Crosshouse 01563 825831 or 826813).

If I can be of any further assistance please do not hesitate to contact me. On behalf of the department, I wish you every success with the project.

Yours sincerely

Dr Alison Graham
Medical Director

c.c. Carol Johnstone, University of Stirling (sponsor contact)
Lesley Douglas, Finance, Ailsa Hospital
Information Governance, Ailsa Hospital
Janet McKay, NHS Ayrshire & Arran
Dr Patricia Thomson, University of Stirling (Academic Supervisor)
Dr Josie Evans, University of Stirling (Academic Supervisor)

www.nhsaaa.net

Appendix 6: NHS Ayrshire & Arran Heart Failure Referral Criteria

NHS
Ayrshire
& Arran

Thank you for your referral regarding the above patient. Unfortunately, he/she does not fulfil the criteria to the service at this time. We would, however, be happy to review him/her should they go on to fulfil the criteria set out below:

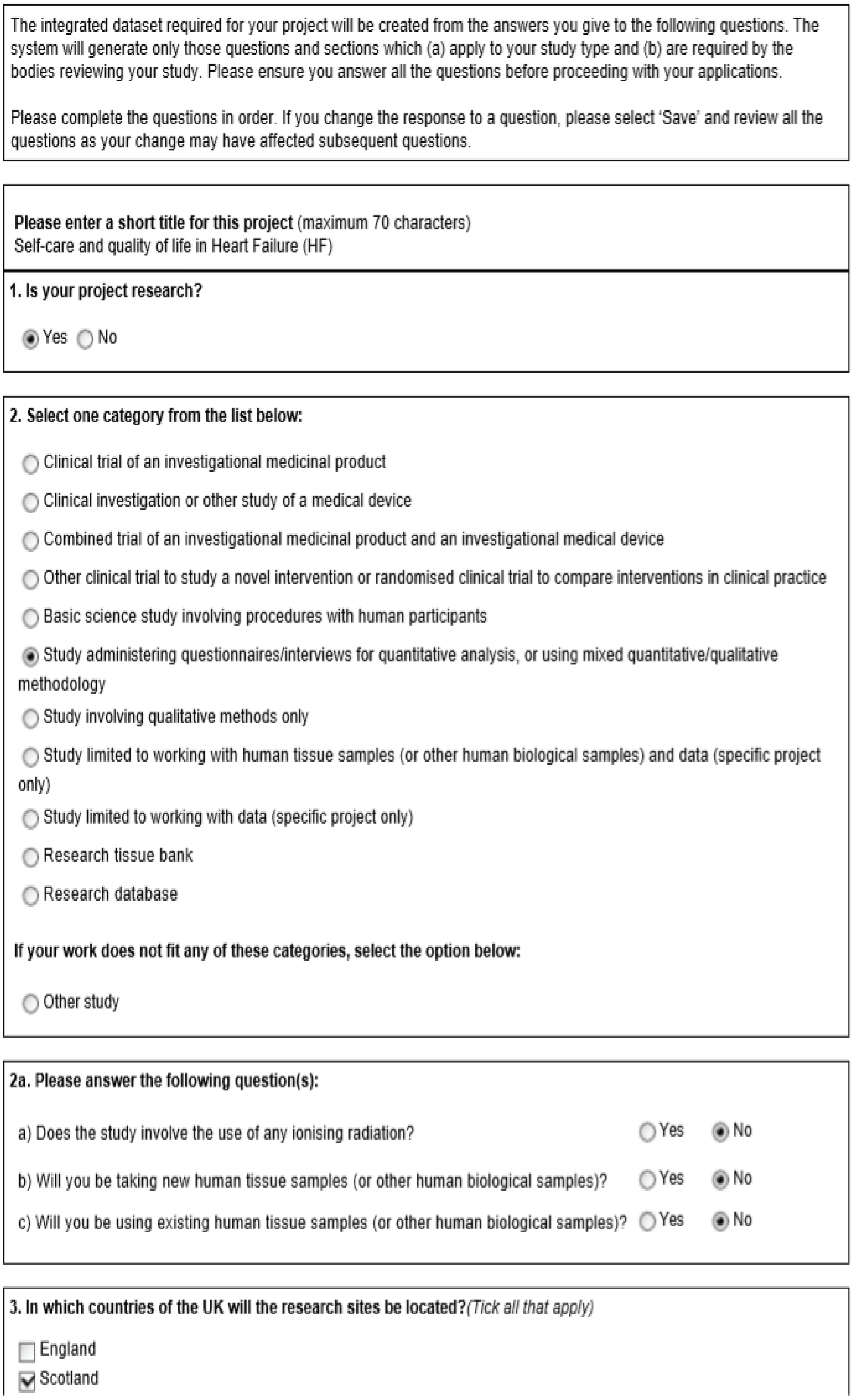
- Echocardiographic evidence of LVSD
- Deteriorating heart failure symptoms such as:
  - New/worsening peripheral oedema
  - New/worsening breathlessness
  - Decompensated event within the last 6 months

Please do not hesitate to contact me if I can be of further assistance.

Advanced Cardiac Specialist Nurse

Heart Failure Nursing Service.

Appendix 7: Substantial Amendment Form



The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
Self-care and quality of life in Heart Failure (HF)

1. Is your project research?

● Yes ○ No

2. Select one category from the list below:

○ Clinical trial of an investigational medicinal product

○ Clinical investigation or other study of a medical device

○ Combined trial of an investigational medicinal product and an investigational medical device

○ Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

○ Basic science study involving procedures with human participants

● Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology

○ Study involving qualitative methods only

○ Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)

○ Study limited to working with data (specific project only)

○ Research tissue bank

○ Research database

If your work does not fit any of these categories, select the option below:

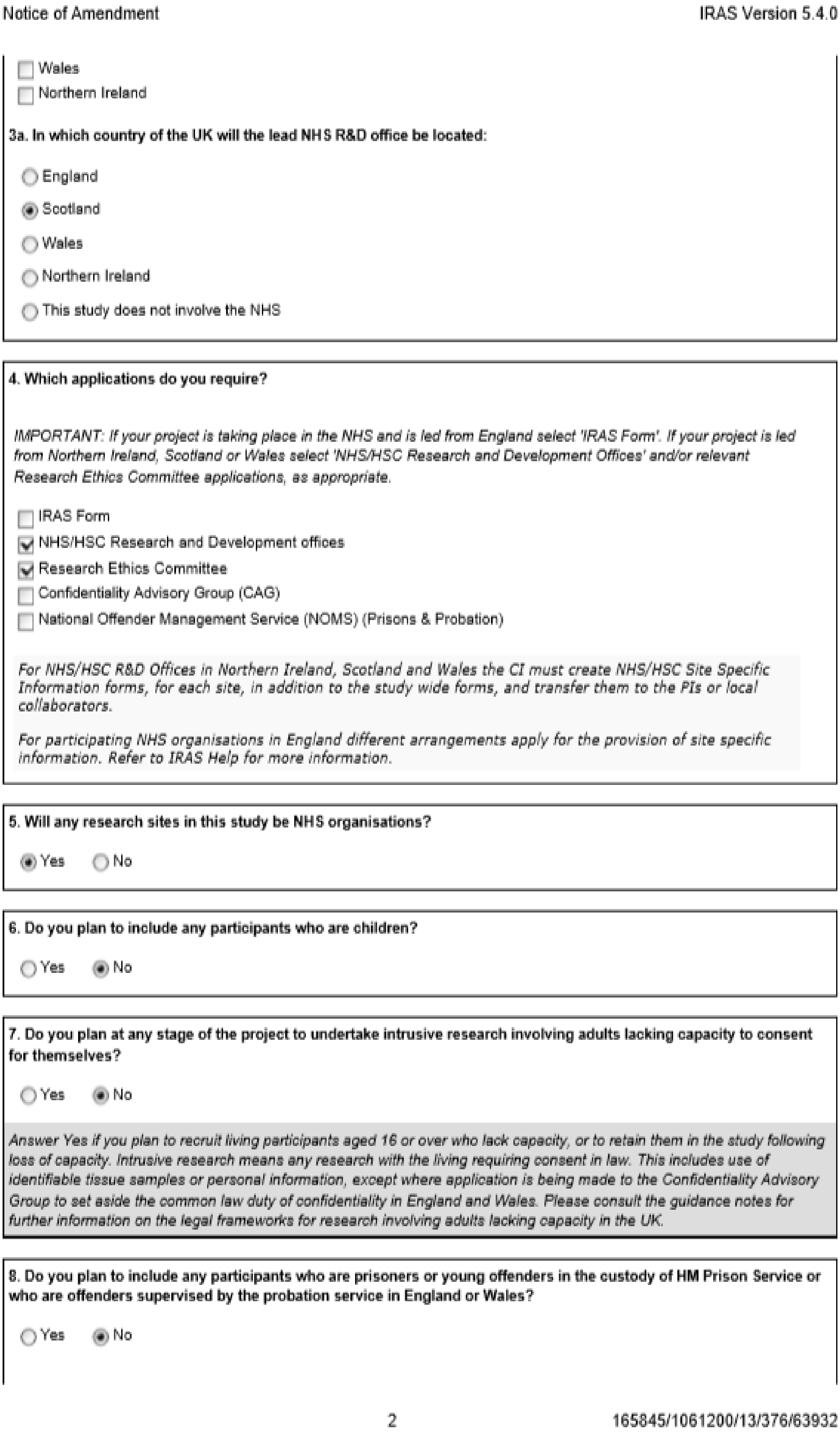
○ Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation?	○ Yes	● No
b) Will you be taking new human tissue samples (or other human biological samples)?	○ Yes	● No
c) Will you be using existing human tissue samples (or other human biological samples)?	○ Yes	● No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

☐ England
☑ Scotland



Notice of Amendment IRAS Version 5.4.0

☐ Wales
☐ Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

○ England
● Scotland
○ Wales
○ Northern Ireland
○ This study does not involve the NHS

4. Which applications do you require?

IMPORTANT: If your project is taking place in the NHS and is led from England select 'IRAS Form'. If your project is led from Northern Ireland, Scotland or Wales select 'NHS/HSC Research and Development Offices' and/or relevant Research Ethics Committee applications, as appropriate.

☐ IRAS Form
☑ NHS/HSC Research and Development offices
☑ Research Ethics Committee
☐ Confidentiality Advisory Group (CAG)
☐ National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D Offices in Northern Ireland, Scotland and Wales the CI must create NHS/HSC Site Specific Information forms, for each site, in addition to the study wide forms, and transfer them to the PIs or local collaborators.

For participating NHS organisations in England different arrangements apply for the provision of site specific information. Refer to IRAS Help for more information.

5. Will any research sites in this study be NHS organisations?

● Yes ○ No

6. Do you plan to include any participants who are children?

○ Yes ● No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

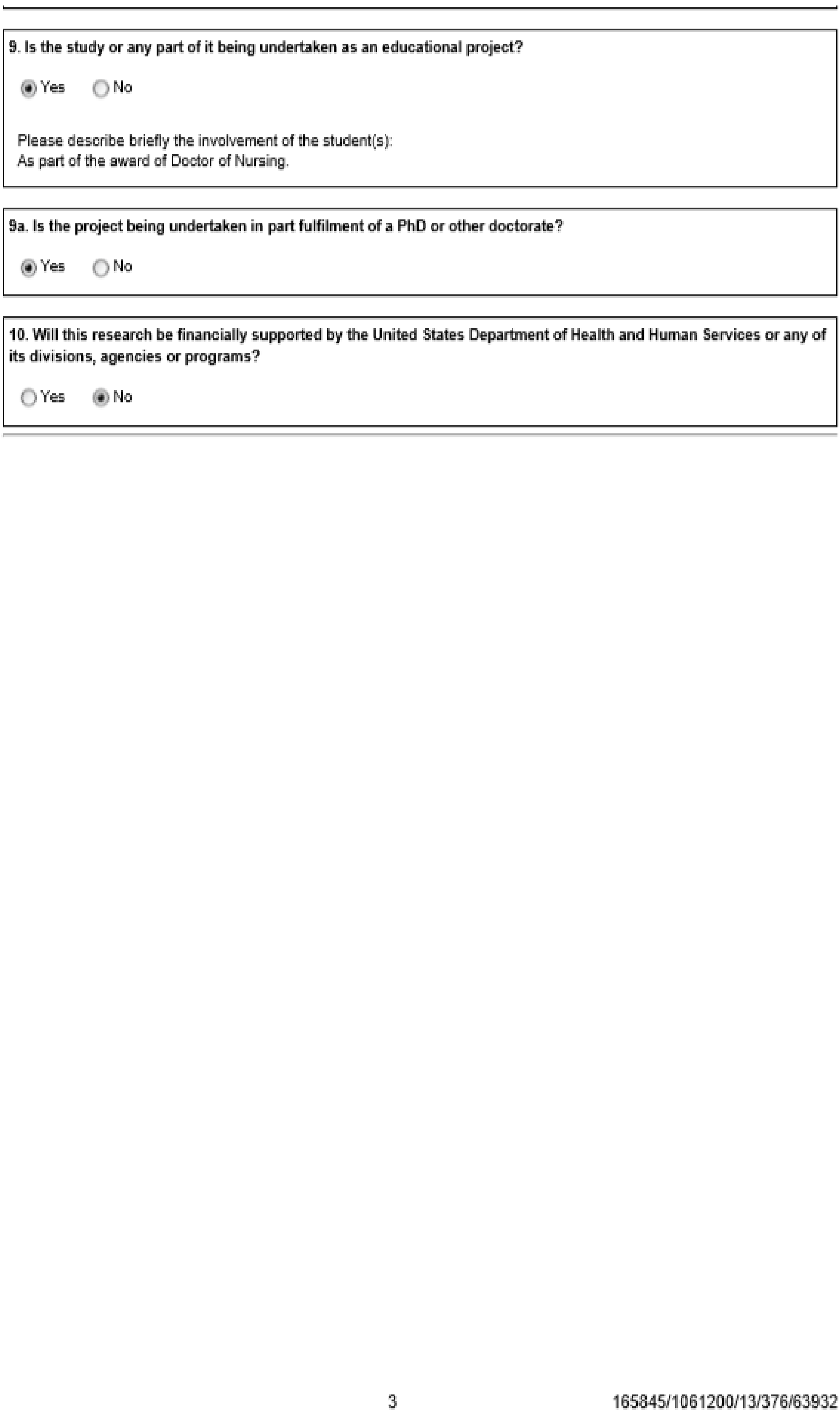
○ Yes ● No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ● No

2 165845/1061200/13/376/63932



9. Is the study or any part of it being undertaken as an educational project?

● Yes ○ No

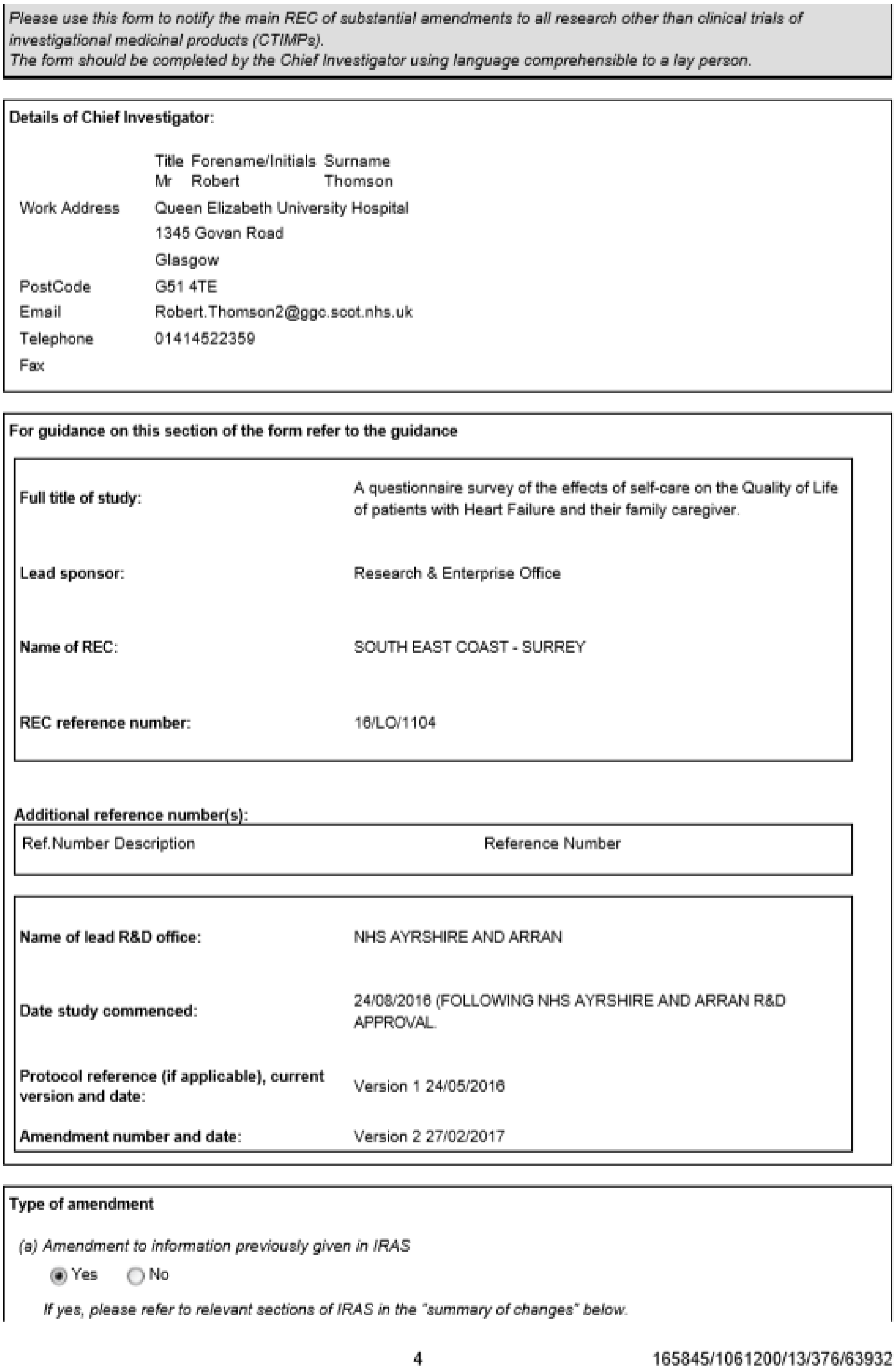
Please describe briefly the involvement of the student(s):
As part of the award of Doctor of Nursing.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

● Yes ○ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ● No



Please use this form to notify the main REC of substantial amendments to all research other than clinical trials of investigational medicinal products (CTIMPs).
The form should be completed by the Chief Investigator using language comprehensible to a lay person.

Details of Chief Investigator:

	Title	Forename/Initials	Surname
	Mr	Robert	Thomson

Work Address	Queen Elizabeth University Hospital 1345 Govan Road Glasgow
PostCode	G51 4TE
Email	Robert.Thomson2@ggc.scot.nhs.uk
Telephone	01414522359
Fax	

For guidance on this section of the form refer to the guidance

Full title of study:	A questionnaire survey of the effects of self-care on the Quality of Life of patients with Heart Failure and their family caregiver.
Lead sponsor:	Research & Enterprise Office
Name of REC:	SOUTH EAST COAST - SURREY
REC reference number:	16/LO/1104

Additional reference number(s):

Ref.Number Description	Reference Number

Name of lead R&D office:	NHS AYRSHIRE AND ARRAN
Date study commenced:	24/08/2016 (FOLLOWING NHS AYRSHIRE AND ARRAN R&D APPROVAL.
Protocol reference (if applicable), current version and date:	Version 1 24/05/2016
Amendment number and date:	Version 2 27/02/2017

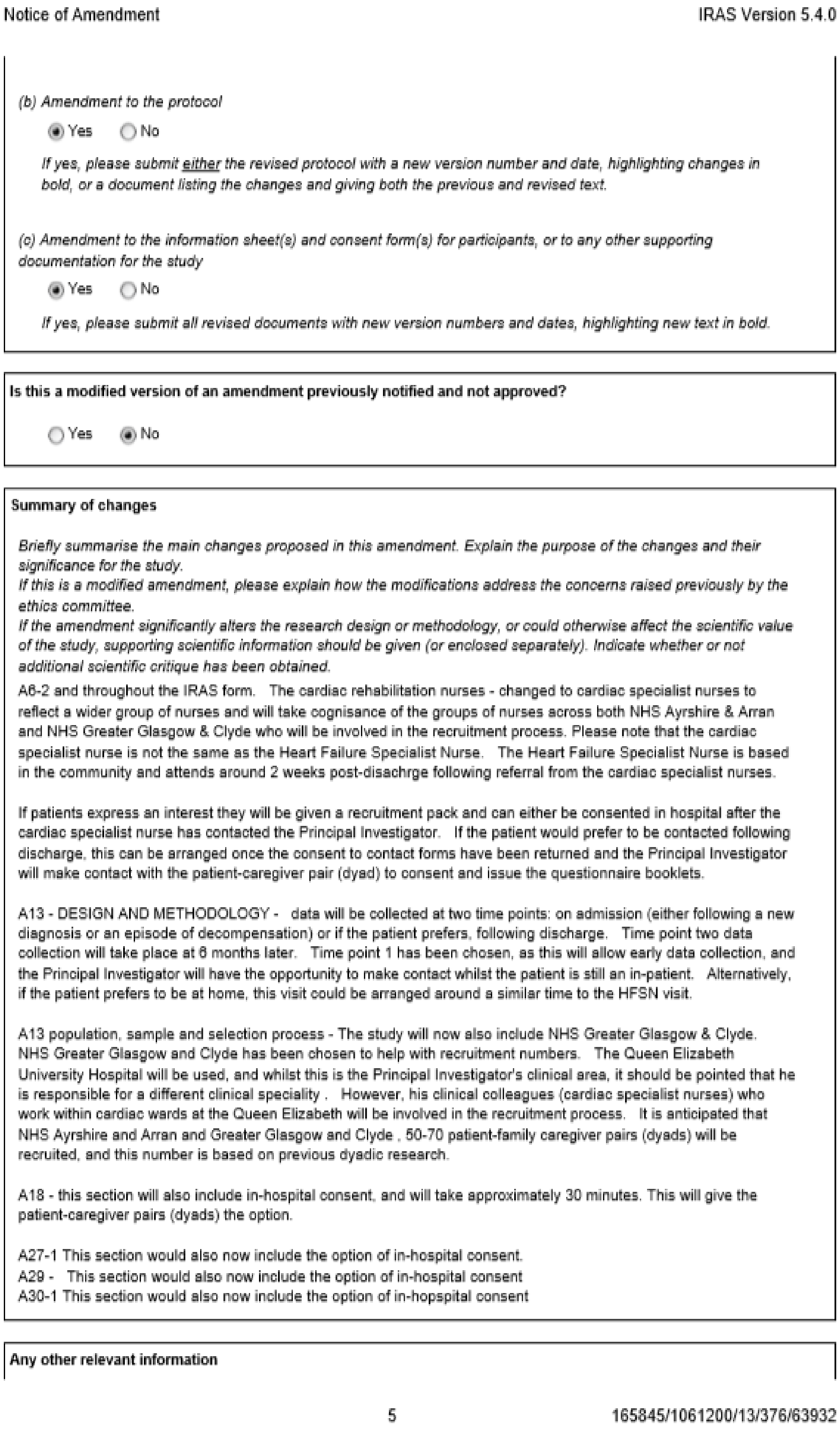
Type of amendment

(a) Amendment to information previously given in IRAS

● Yes ○ No

If yes, please refer to relevant sections of IRAS in the "summary of changes" below.

4 165845/1061200/13/376/63932



(b) Amendment to the protocol

● Yes ○ No

If yes, please submit either the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.

(c) Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study

● Yes ○ No

If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.

Is this a modified version of an amendment previously notified and not approved?

○ Yes ● No

Summary of changes

Briefly summarise the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study.
If this is a modified amendment, please explain how the modifications address the concerns raised previously by the ethics committee.
If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.

A6-2 and throughout the IRAS form. The cardiac rehabilitation nurses - changed to cardiac specialist nurses to reflect a wider group of nurses and will take cognisance of the groups of nurses across both NHS Ayrshire & Arran and NHS Greater Glasgow & Clyde who will be involved in the recruitment process. Please note that the cardiac specialist nurse is not the same as the Heart Failure Specialist Nurse. The Heart Failure Specialist Nurse is based in the community and attends around 2 weeks post-disachrge following referral from the cardiac specialist nurses.

If patients express an interest they will be given a recruitment pack and can either be consented in hospital after the cardiac specialist nurse has contacted the Principal Investigator. If the patient would prefer to be contacted following discharge, this can be arranged once the consent to contact forms have been returned and the Principal Investigator will make contact with the patient-caregiver pair (dyad) to consent and issue the questionnaire booklets.

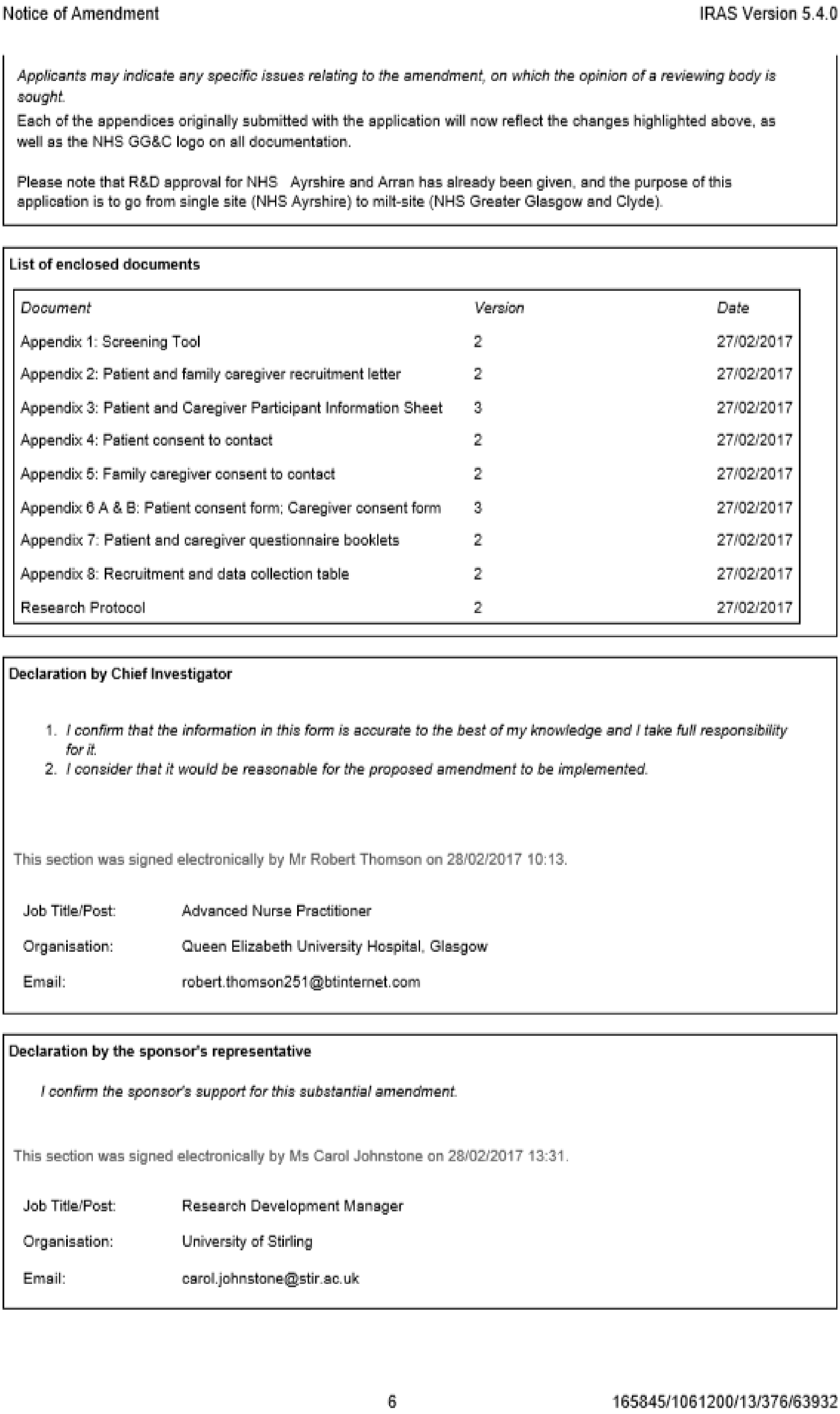
A13 - DESIGN AND METHODOLOGY - data will be collected at two time points: on admission (either following a new diagnosis or an episode of decompensation) or if the patient prefers, following discharge. Time point two data collection will take place at 6 months later. Time point 1 has been chosen, as this will allow early data collection, and the Principal Investigator will have the opportunity to make contact whilst the patient is still an in-patient. Alternatively, if the patient prefers to be at home, this visit could be arranged around a similar time to the HFSN visit.

A13 population, sample and selection process - The study will now also include NHS Greater Glasgow & Clyde. NHS Greater Glasgow and Clyde has been chosen to help with recruitment numbers. The Queen Elizabeth University Hospital will be used, and whilst this is the Principal Investigator's clinical area, it should be pointed that he is responsible for a different clinical speciality . However, his clinical colleagues (cardiac specialist nurses) who work within cardiac wards at the Queen Elizabeth will be involved in the recruitment process. It is anticipated that NHS Ayrshire and Arran and Greater Glasgow and Clyde , 50-70 patient-family caregiver pairs (dyads) will be recruited, and this number is based on previous dyadic research.

A18 - this section will also include in-hospital consent, and will take approximately 30 minutes. This will give the patient-caregiver pairs (dyads) the option.

A27-1 This section would also now include the option of in-hospital consent.
A29 - This section would also now include the option of in-hospital consent
A30-1 This section would also now include the option of in-hopspital consent

Any other relevant information



Applicants may indicate any specific issues relating to the amendment, on which the opinion of a reviewing body is sought.

Each of the appendices originally submitted with the application will now reflect the changes highlighted above, as well as the NHS GG&C logo on all documentation.

Please note that R&D approval for NHS Ayrshire and Arran has already been given, and the purpose of this application is to go from single site (NHS Ayrshire) to milt-site (NHS Greater Glasgow and Clyde).

List of enclosed documents

Document	*Version*	*Date*
Appendix 1: Screening Tool	2	27/02/2017
Appendix 2: Patient and family caregiver recruitment letter	2	27/02/2017
Appendix 3: Patient and Caregiver Participant Information Sheet	3	27/02/2017
Appendix 4: Patient consent to contact	2	27/02/2017
Appendix 5: Family caregiver consent to contact	2	27/02/2017
Appendix 6 A & B: Patient consent form; Caregiver consent form	3	27/02/2017
Appendix 7: Patient and caregiver questionnaire booklets	2	27/02/2017
Appendix 8: Recruitment and data collection table	2	27/02/2017
Research Protocol	2	27/02/2017

Declaration by Chief Investigator

1. *I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.*
2. *I consider that it would be reasonable for the proposed amendment to be implemented.*

This section was signed electronically by Mr Robert Thomson on 28/02/2017 10:13.

Job Title/Post: Advanced Nurse Practitioner

Organisation: Queen Elizabeth University Hospital, Glasgow

Email: robert.thomson251@btinternet.com

Declaration by the sponsor's representative

I confirm the sponsor's support for this substantial amendment.

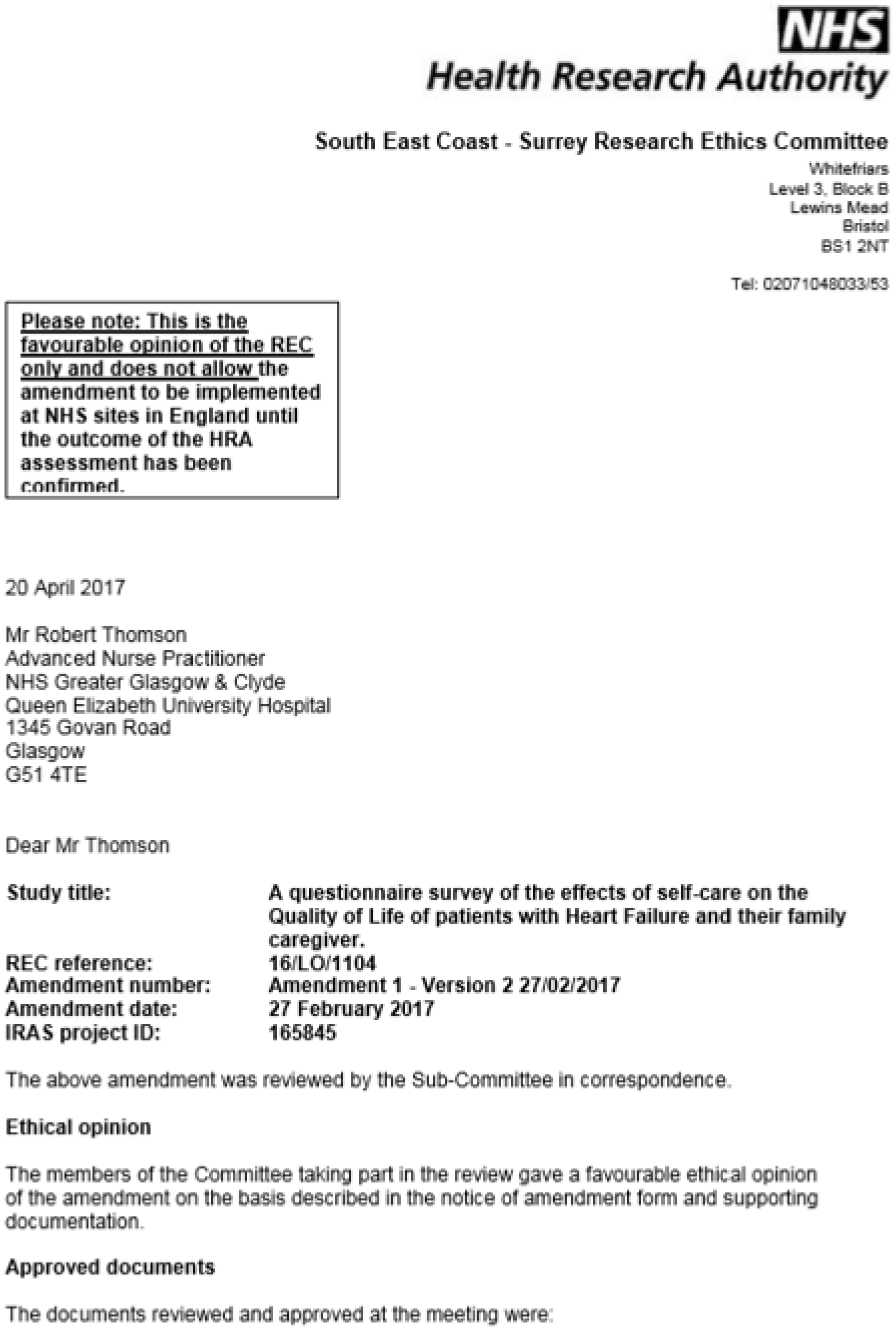
This section was signed electronically by Ms Carol Johnstone on 28/02/2017 13:31.

Job Title/Post: Research Development Manager

Organisation: University of Stirling

Email: carol.johnstone@stir.ac.uk

Appendix 8: NHS Ethical Approval (Substantial Amendment)



NHS
Health Research Authority

South East Coast - Surrey Research Ethics Committee
Whitefriars
Level 3, Block B
Lewins Mead
Bristol
BS1 2NT

Tel: 02071048033/53

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

20 April 2017

Mr Robert Thomson
Advanced Nurse Practitioner
NHS Greater Glasgow & Clyde
Queen Elizabeth University Hospital
1345 Govan Road
Glasgow
G51 4TE

Dear Mr Thomson

Study title:	**A questionnaire survey of the effects of self-care on the Quality of Life of patients with Heart Failure and their family caregiver.**
REC reference:	**16/LO/1104**
Amendment number:	**Amendment 1 - Version 2 27/02/2017**
Amendment date:	**27 February 2017**
IRAS project ID:	**165845**

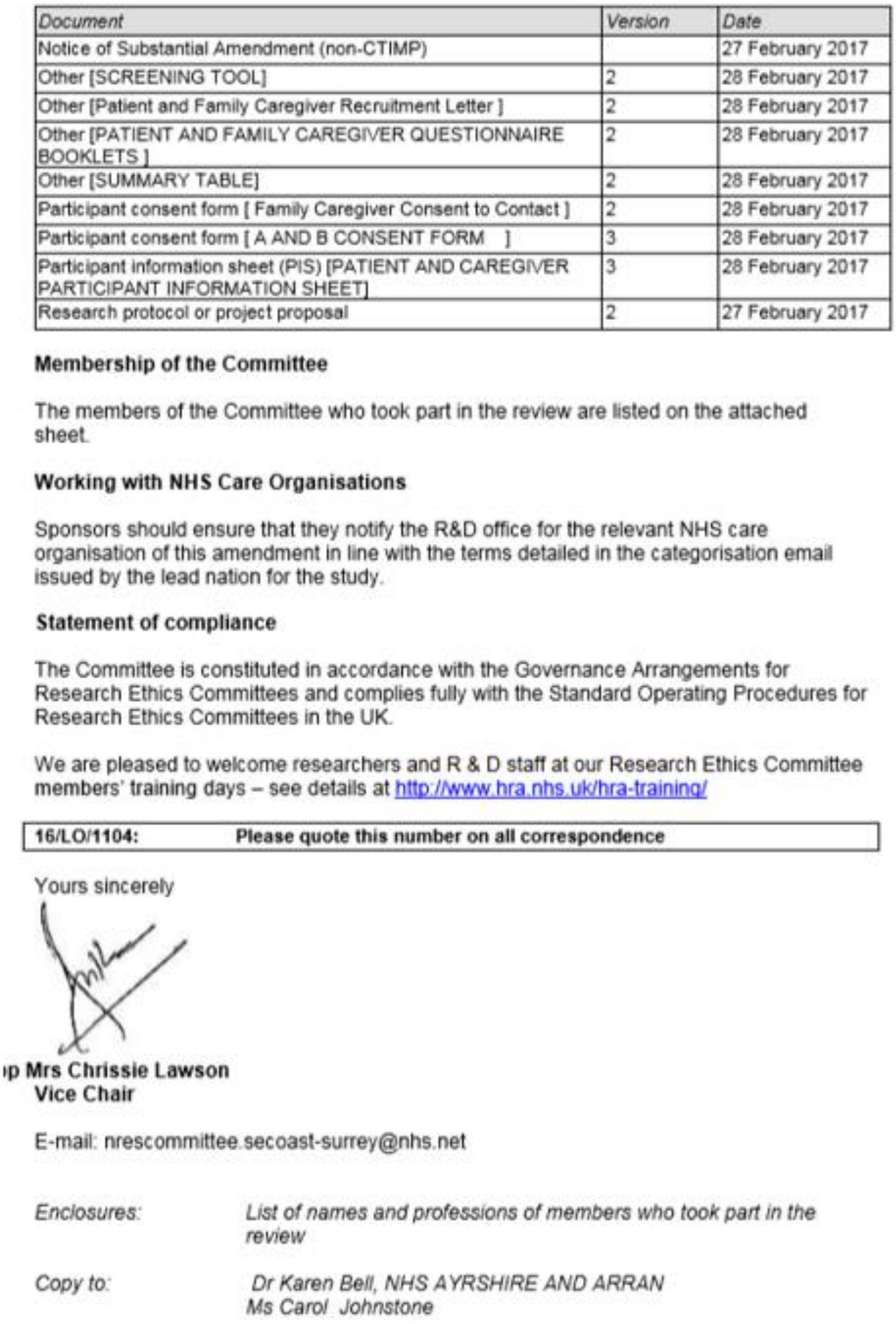
The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:



Document	Version	Date
Notice of Substantial Amendment (non-CTIMP)		27 February 2017
Other [SCREENING TOOL]	2	28 February 2017
Other [Patient and Family Caregiver Recruitment Letter]	2	28 February 2017
Other [PATIENT AND FAMILY CAREGIVER QUESTIONNAIRE BOOKLETS]	2	28 February 2017
Other [SUMMARY TABLE]	2	28 February 2017
Participant consent form [Family Caregiver Consent to Contact]	2	28 February 2017
Participant consent form [A AND B CONSENT FORM]	3	28 February 2017
Participant information sheet (PIS) [PATIENT AND CAREGIVER PARTICIPANT INFORMATION SHEET]	3	28 February 2017
Research protocol or project proposal	2	27 February 2017

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

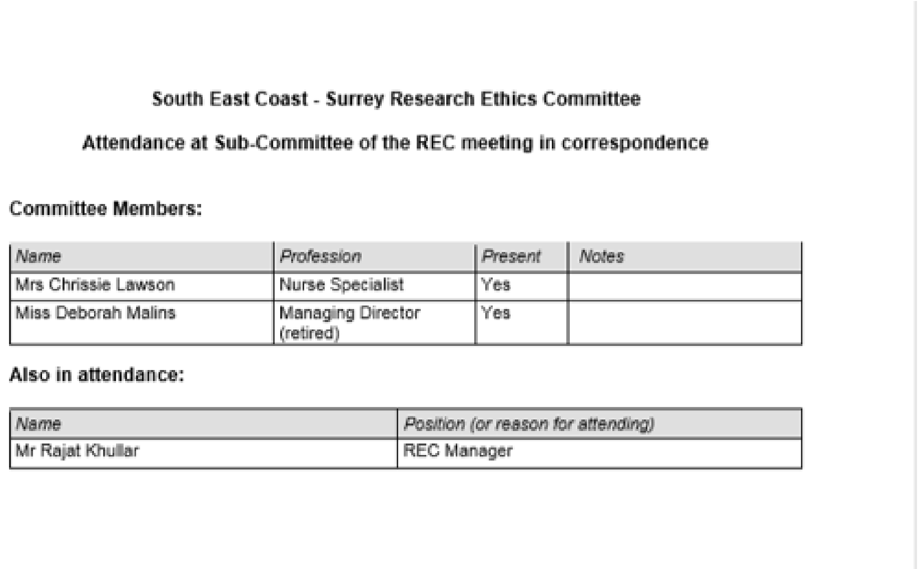
16/LO/1104:	Please quote this number on all correspondence

Yours sincerely

p Mrs Chrissie Lawson
Vice Chair

E-mail: nrescommittee.secoast-surrey@nhs.net

Enclosures:	*List of names and professions of members who took part in the review*
Copy to:	*Dr Karen Bell, NHS AYRSHIRE AND ARRAN* *Ms Carol Johnstone*



South East Coast - Surrey Research Ethics Committee

Attendance at Sub-Committee of the REC meeting in correspondence

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mrs Chrissie Lawson	Nurse Specialist	Yes	
Miss Deborah Malins	Managing Director (retired)	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mr Rajat Khullar	REC Manager

Appendix 9: NHS Ayrshire & Arran Research & Development Approval

NHS
Ayrshire
& Arran

Research & Development Office
58 Lister Street
University Hospital Crosshouse
Kilmarnock
KA2 0BB

Mr Robert Thomson
Advanced Nurse Practitioner
NHS Greater Glasgow & Clyde
Queen Elizabeth University Hospital
1345 Govan Road
Glasgow, G51 4TE

Date	17 May 2017
Our Ref	AG/KLB/NM R&D 2016AA042
Enquiries to	Karen Bell
Extension	25850
Direct line	01563 825850
Fax	01563 825806
Email	Karen.bell@aaaht.scot.nhs.uk

Dear Mr Thomson

A questionnaire survey of the effects of self-care on the Quality of Life of patients with Heart Failure and their family caregiver (Amendment 01)

I have received the undernoted documentation, relating to proposed changes to the above study:

- REC Favourable opinion 20/04/17
- Notice of Amendment Form 28/02/17
- Appendix 1 Screening Tool v2.0 February 2017
- Appendix 2 Patient and Family Caregiver Recruitment Letter v2.0 February 2017
- Appendix 3 Patient And Caregiver Participant Information Sheet v3.0 March 2017
- Appendix 4 Patient Consent to Contact v2.0 February 2017
- Appendix 5 Family Caregiver Consent to Contact v2.0 February 2017
- Appendix 6 A and B Consent Form v3.0 February 2017
- Appendix 7 Patient and Family Caregiver Questionnaire Booklets v2.0 February 2017
- Appendix 8 Summary Table v2.0 February 2017
- Protocol v2.0 27/02/17

I can confirm that the above amendment has been approved.

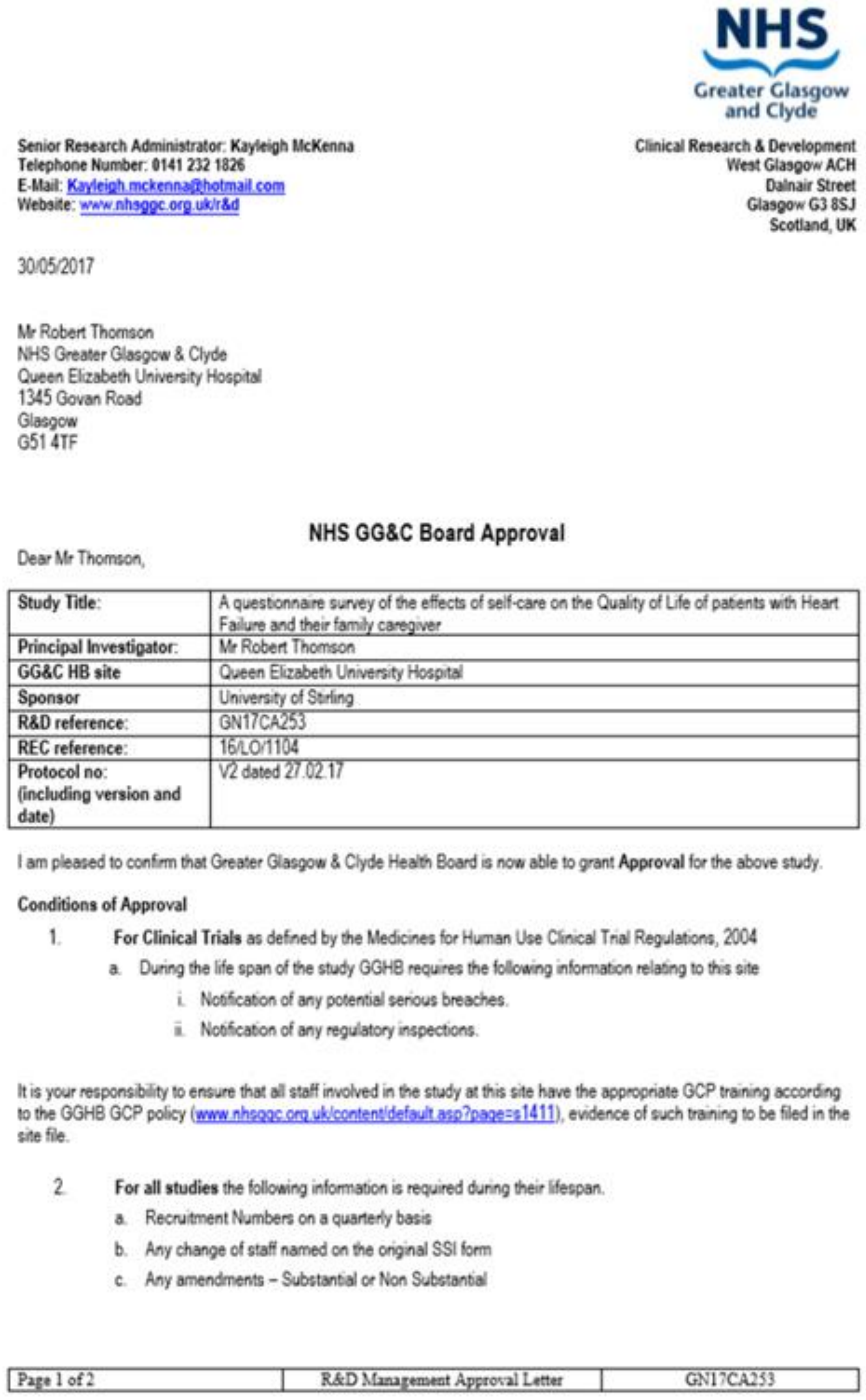
Please contact the R&D Office if you have any queries. On behalf of the department, I wish you every success with the project.

Yours sincerely

Dr Alison Graham
Medical Director

www.nhsaaa.net

Appendix 10: NHS Greater Glasgow & Clyde Research & Development Approval



Senior Research Administrator: Kayleigh McKenna
Telephone Number: 0141 232 1826
E-Mail: Kayleigh.mckenna@hotmail.com
Website: www.nhsggc.org.uk/r&d

Clinical Research & Development
West Glasgow ACH
Dalnair Street
Glasgow G3 8SJ
Scotland, UK

30/05/2017

Mr Robert Thomson
NHS Greater Glasgow & Clyde
Queen Elizabeth University Hospital
1345 Govan Road
Glasgow
G51 4TF

NHS GG&C Board Approval

Dear Mr Thomson,

Study Title:	A questionnaire survey of the effects of self-care on the Quality of Life of patients with Heart Failure and their family caregiver
Principal Investigator:	Mr Robert Thomson
GG&C HB site	Queen Elizabeth University Hospital
Sponsor	University of Stirling
R&D reference:	GN17CA253
REC reference:	16/LO/1104
Protocol no: (including version and date)	V2 dated 27.02.17

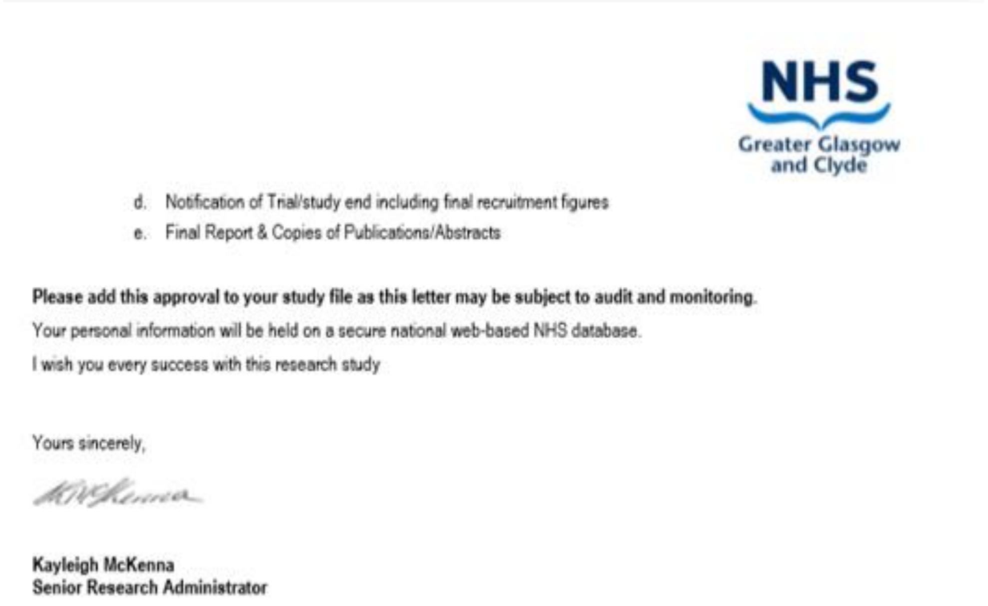
I am pleased to confirm that Greater Glasgow & Clyde Health Board is now able to grant **Approval** for the above study.

Conditions of Approval

1. **For Clinical Trials** as defined by the Medicines for Human Use Clinical Trial Regulations, 2004
    a. During the life span of the study GGHB requires the following information relating to this site
        i. Notification of any potential serious breaches.
        ii. Notification of any regulatory inspections.

It is your responsibility to ensure that all staff involved in the study at this site have the appropriate GCP training according to the GGHB GCP policy (www.nhsggc.org.uk/content/default.asp?page=s1411), evidence of such training to be filed in the site file.

2. **For all studies** the following information is required during their lifespan.
    a. Recruitment Numbers on a quarterly basis
    b. Any change of staff named on the original SSI form
    c. Any amendments – Substantial or Non Substantial



d. Notification of Trial/study end including final recruitment figures
e. Final Report & Copies of Publications/Abstracts

Please add this approval to your study file as this letter may be subject to audit and monitoring.

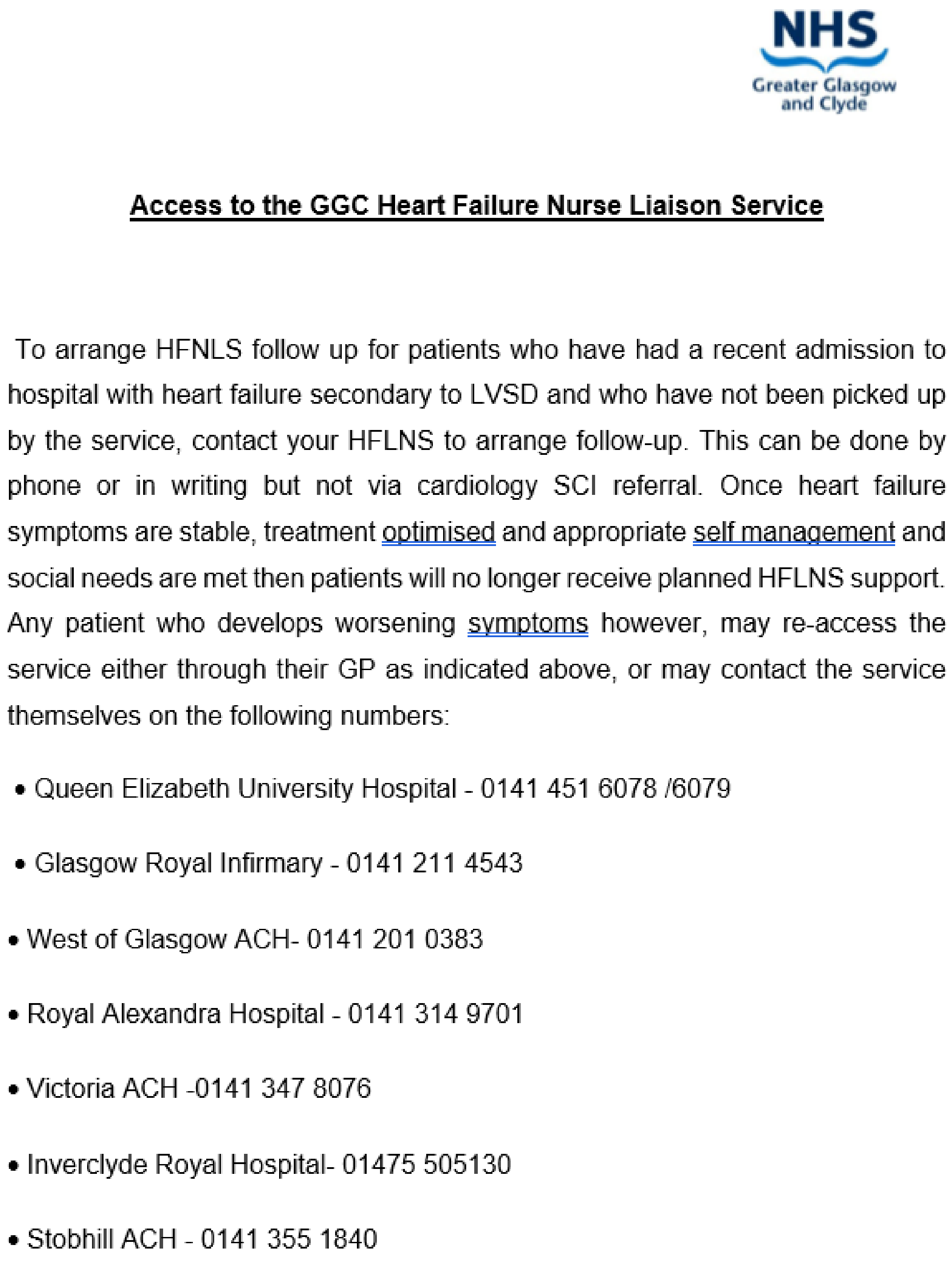
Your personal information will be held on a secure national web-based NHS database.

I wish you every success with this research study

Yours sincerely,

Kayleigh McKenna
Senior Research Administrator

Appendix 11: NHS Greater Glasgow & Clyde HF Pathway

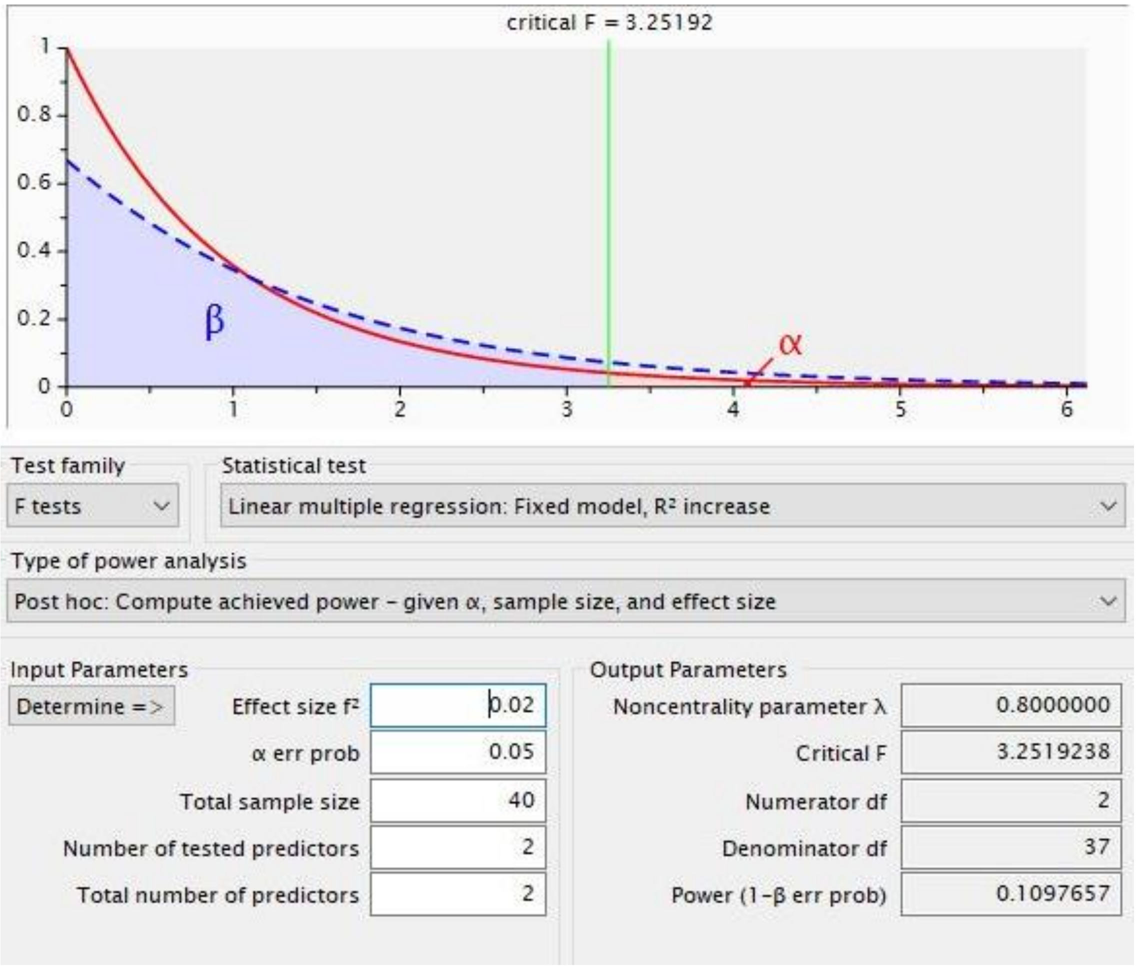


Access to the GGC Heart Failure Nurse Liaison Service

To arrange HFNLS follow up for patients who have had a recent admission to hospital with heart failure secondary to LVSD and who have not been picked up by the service, contact your HFLNS to arrange follow-up. This can be done by phone or in writing but not via cardiology SCI referral. Once heart failure symptoms are stable, treatment optimised and appropriate self management and social needs are met then patients will no longer receive planned HFLNS support. Any patient who develops worsening symptoms however, may re-access the service either through their GP as indicated above, or may contact the service themselves on the following numbers:

- Queen Elizabeth University Hospital - 0141 451 6078 /6079
- Glasgow Royal Infirmary - 0141 211 4543
- West of Glasgow ACH- 0141 201 0383
- Royal Alexandra Hospital - 0141 314 9701
- Victoria ACH -0141 347 8076
- Inverclyde Royal Hospital- 01475 505130
- Stobhill ACH - 0141 355 1840

Appendix 12: Small effect size



Test family: F tests

Statistical test: Linear multiple regression: Fixed model, R² increase

Type of power analysis: Post hoc: Compute achieved power – given α, sample size, and effect size

Input Parameters

Effect size f²: 0.02

α err prob: 0.05

Total sample size: 40

Number of tested predictors: 2

Total number of predictors: 2

Output Parameters

Noncentrality parameter λ: 0.8000000

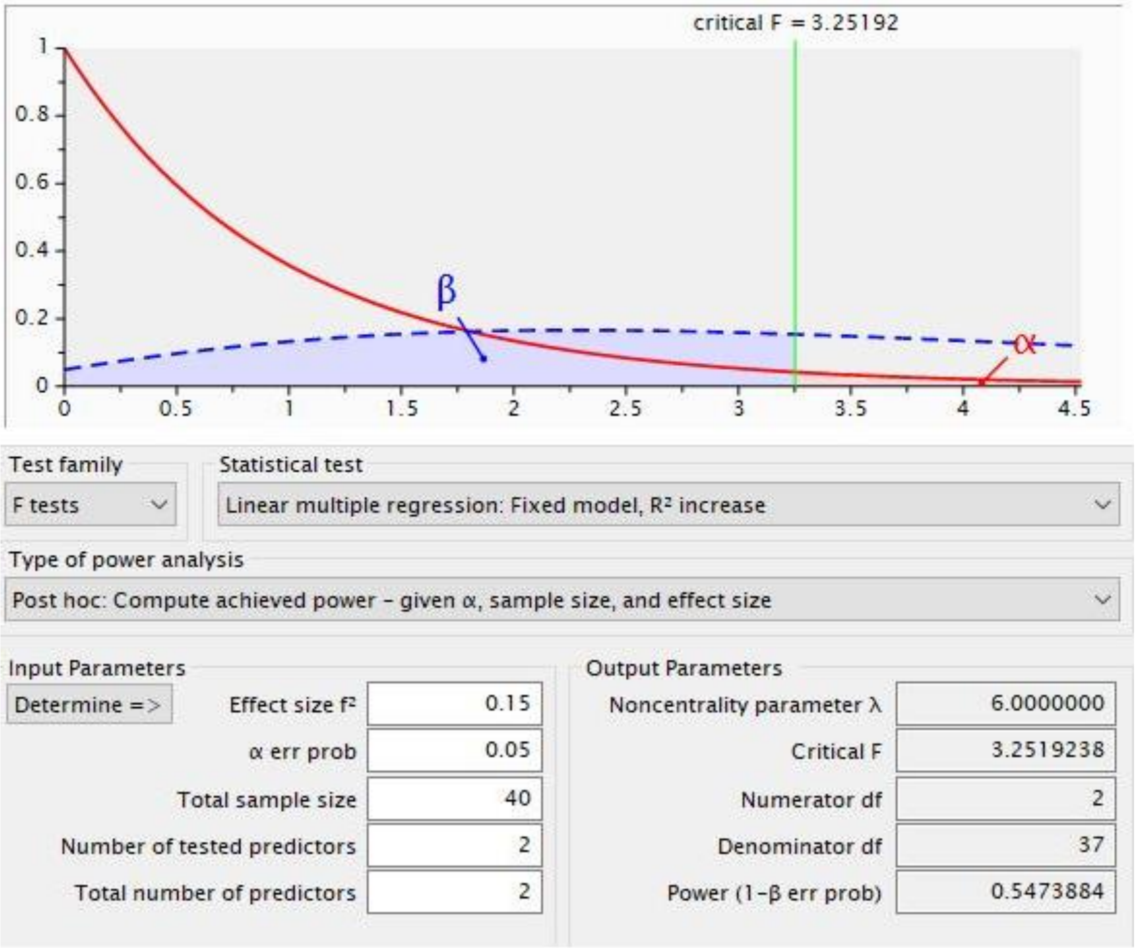
Critical F: 3.2519238

Numerator df: 2

Denominator df: 37

Power (1–β err prob): 0.1097657

Appendix 13: Medium effect size



Test family: F tests

Statistical test: Linear multiple regression: Fixed model, R² increase

Type of power analysis: Post hoc: Compute achieved power – given α, sample size, and effect size

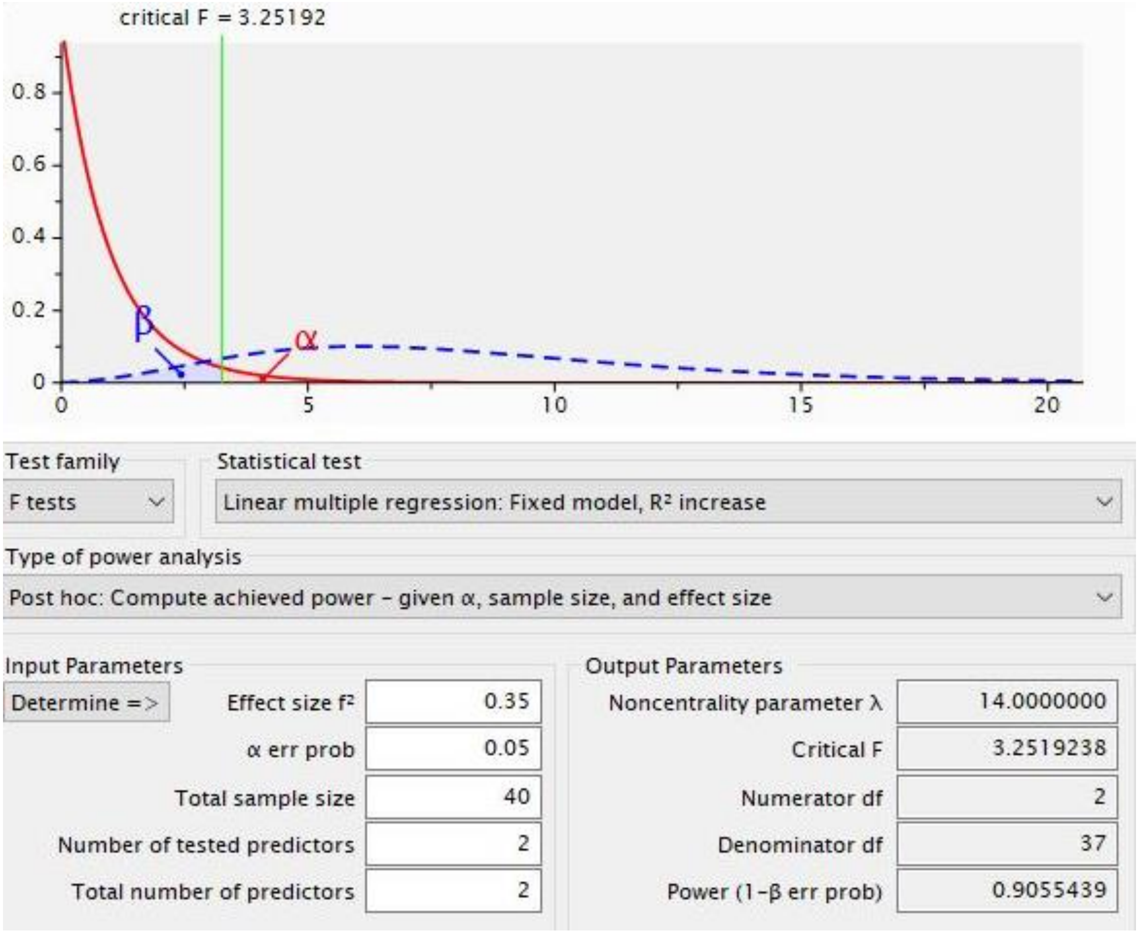
Input Parameters

Effect size f²: 0.15
α err prob: 0.05
Total sample size: 40
Number of tested predictors: 2
Total number of predictors: 2

Output Parameters

Noncentrality parameter λ: 6.0000000
Critical F: 3.2519238
Numerator df: 2
Denominator df: 37
Power (1-β err prob): 0.5473884

Appendix 14: Large effect size



Test family

F tests

Statistical test

Linear multiple regression: Fixed model, R^2 increase

Type of power analysis

Post hoc: Compute achieved power – given α, sample size, and effect size

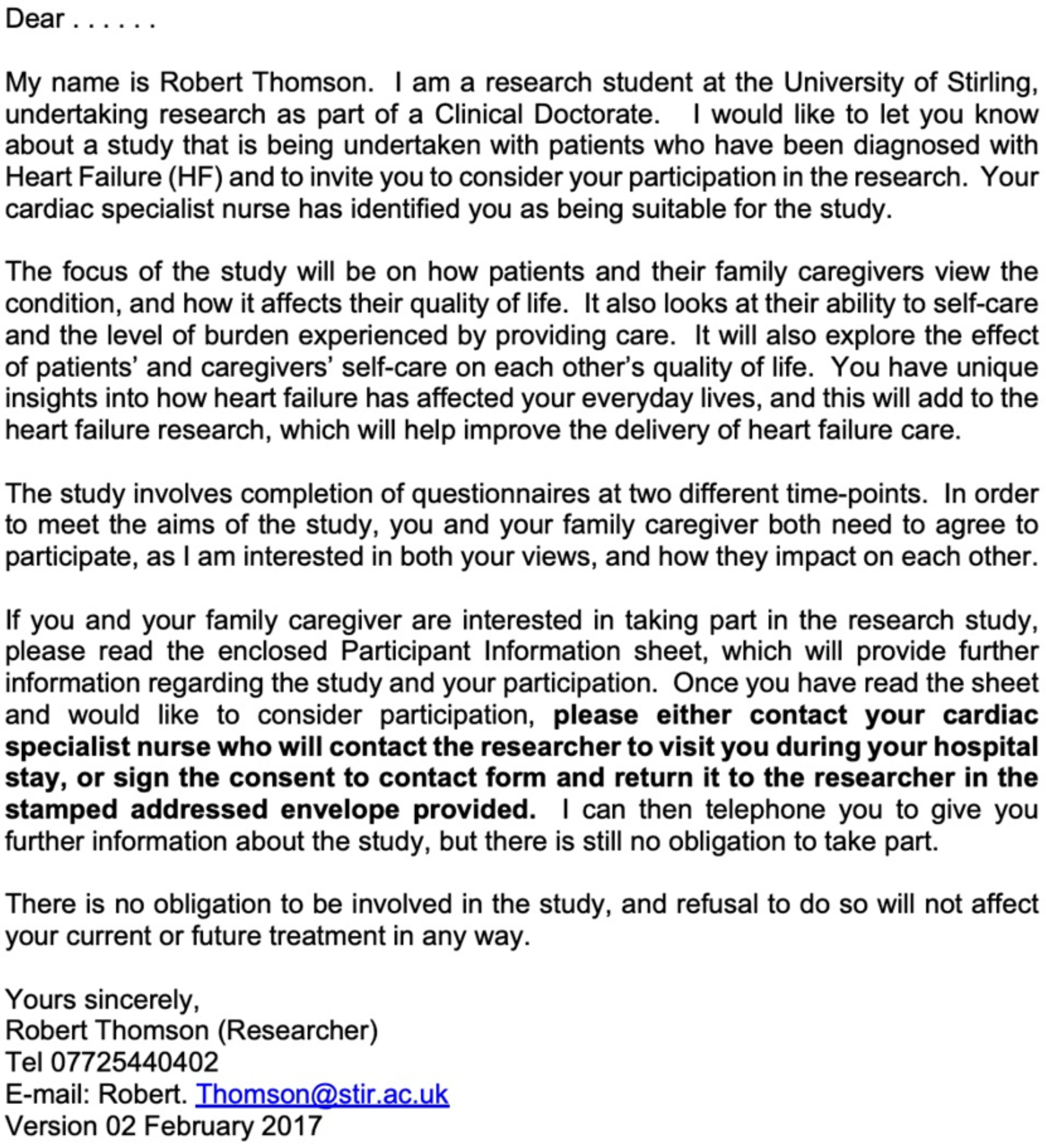
Input Parameters

Effect size f^2	0.35
α err prob	0.05
Total sample size	40
Number of tested predictors	2
Total number of predictors	2

Output Parameters

Noncentrality parameter λ	14.0000000
Critical F	3.2519238
Numerator df	2
Denominator df	37
Power (1−β err prob)	0.9055439

Appendix 15: Patient and Family Caregiver Recruitment Letter



Dear . . . . . .

My name is Robert Thomson. I am a research student at the University of Stirling, undertaking research as part of a Clinical Doctorate. I would like to let you know about a study that is being undertaken with patients who have been diagnosed with Heart Failure (HF) and to invite you to consider your participation in the research. Your cardiac specialist nurse has identified you as being suitable for the study.

The focus of the study will be on how patients and their family caregivers view the condition, and how it affects their quality of life. It also looks at their ability to self-care and the level of burden experienced by providing care. It will also explore the effect of patients' and caregivers' self-care on each other's quality of life. You have unique insights into how heart failure has affected your everyday lives, and this will add to the heart failure research, which will help improve the delivery of heart failure care.

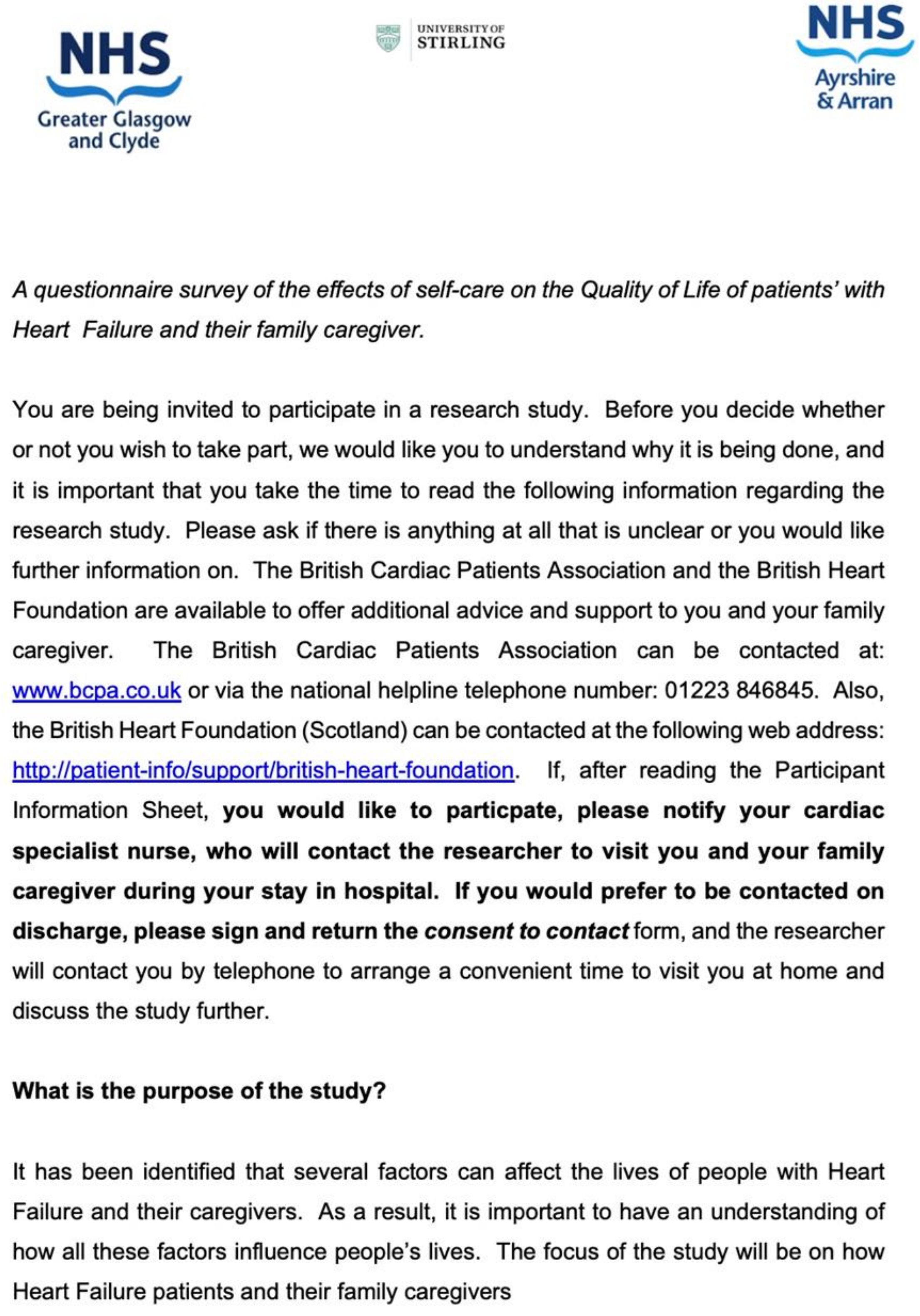
The study involves completion of questionnaires at two different time-points. In order to meet the aims of the study, you and your family caregiver both need to agree to participate, as I am interested in both your views, and how they impact on each other.

If you and your family caregiver are interested in taking part in the research study, please read the enclosed Participant Information sheet, which will provide further information regarding the study and your participation. Once you have read the sheet and would like to consider participation, **please either contact your cardiac specialist nurse who will contact the researcher to visit you during your hospital stay, or sign the consent to contact form and return it to the researcher in the stamped addressed envelope provided.** I can then telephone you to give you further information about the study, but there is still no obligation to take part.

There is no obligation to be involved in the study, and refusal to do so will not affect your current or future treatment in any way.

Yours sincerely,
Robert Thomson (Researcher)
Tel 07725440402
E-mail: Robert. Thomson@stir.ac.uk
Version 02 February 2017

Appendix 16: Patient and Caregiver Participant Information Sheet



NHS Greater Glasgow and Clyde

University of Stirling

NHS Ayrshire & Arran

A questionnaire survey of the effects of self-care on the Quality of Life of patients' with Heart Failure and their family caregiver.

You are being invited to participate in a research study. Before you decide whether or not you wish to take part, we would like you to understand why it is being done, and it is important that you take the time to read the following information regarding the research study. Please ask if there is anything at all that is unclear or you would like further information on. The British Cardiac Patients Association and the British Heart Foundation are available to offer additional advice and support to you and your family caregiver. The British Cardiac Patients Association can be contacted at: www.bcpa.co.uk or via the national helpline telephone number: 01223 846845. Also, the British Heart Foundation (Scotland) can be contacted at the following web address: http://patient-info/support/british-heart-foundation. If, after reading the Participant Information Sheet, **you would like to particpate, please notify your cardiac specialist nurse, who will contact the researcher to visit you and your family caregiver during your stay in hospital. If you would prefer to be contacted on discharge, please sign and return the *consent to contact*** form, and the researcher will contact you by telephone to arrange a convenient time to visit you at home and discuss the study further.

What is the purpose of the study?

It has been identified that several factors can affect the lives of people with Heart Failure and their caregivers. As a result, it is important to have an understanding of how all these factors influence people's lives. The focus of the study will be on how Heart Failure patients and their family caregivers view the condition, and how it affects their quality of life, their ability to manage their own care and the level of burden experienced by providing care. In addition, it will explore the effect of patients' and family caregivers' ability to care for each other, and how this will affect their quality of life.

In order to improve the services offered to patients and to better understand the effects on you both, we would like to hear of your experiences.

Why have I been chosen?

As you have been diagnosed with Heart Failure, you have been identified as being suitable for the research study by the cardiac specialist nurses involved in your care. Other patients have also been identified as being suitable and will also be contacted. The study is also looking at the views of family caregivers, and we are also inviting your family caregiver to take part. By family caregiver, we are referring to a marital or cohabiting relationship (spouse or partner) living in the same household who provides personal care and support. I am very interested in both of your experiences and views, and through completion of the questionnaires, I will gain some useful information. You and your family caregiver will receive separate questionnaires, which should be completed independently.

Do I have to take part in the study?

No, completion of the questionnaires is entirely voluntary, and it is therefore up to you and your family caregiver whether you wish to take part or not. However, this study is specifically interested in recruiting pairs i.e. patient-caregiver pairs.

Once you have read the information and agree to participate, there are separate consent forms for you and your family caregiver to sign. If you decide not to take part in the study, then you do not have to do anything further.

What will happen to me if I agree to take part?

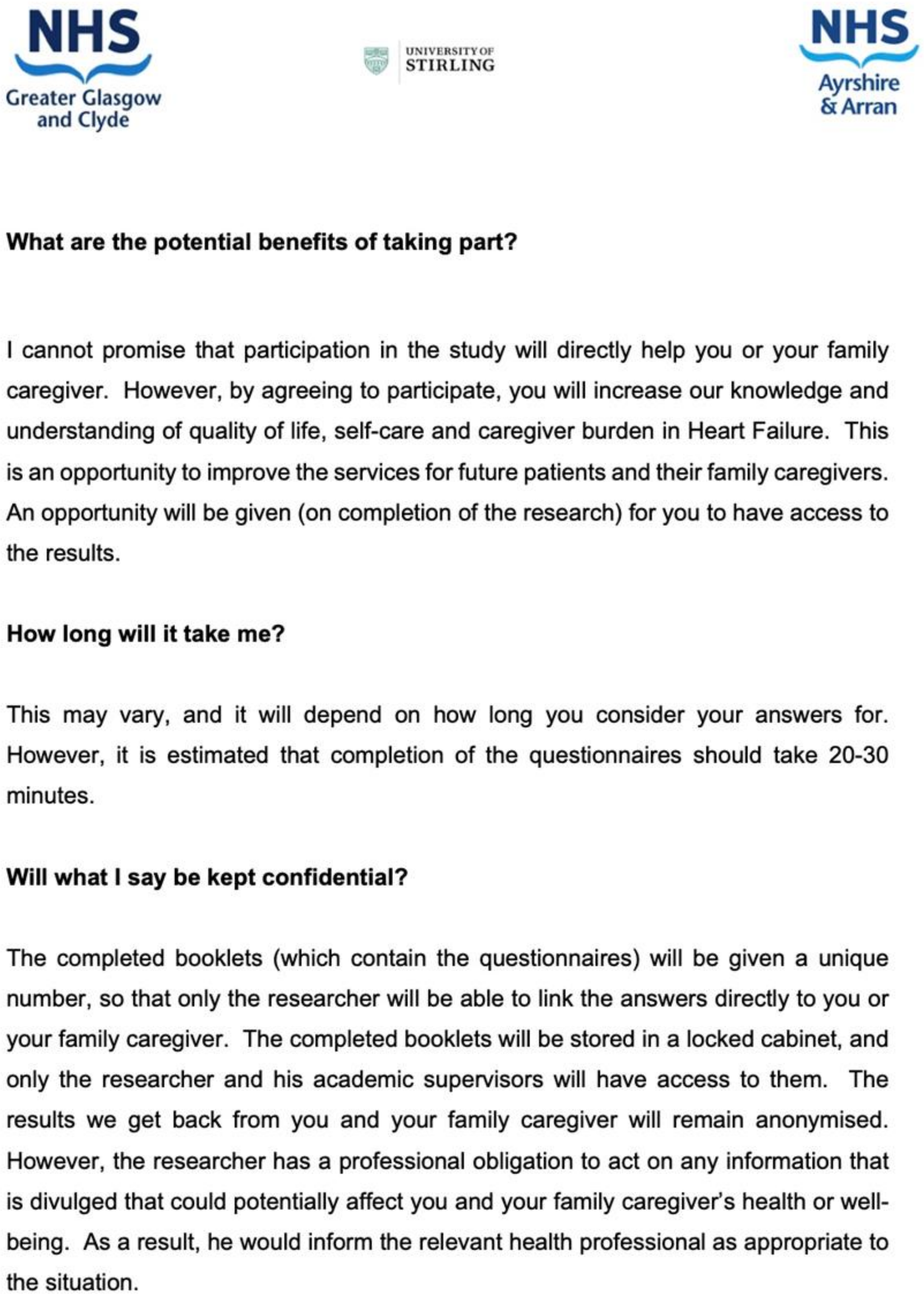
If you and your family caregiver agree to be contacted, please let your cardiac specialist nurse know and he/she will contact the researcher who will come and chat with you during your hospital stay. If at the end of this meeting, you and your family caregiver feel you would like to participate in the study, you will be asked to sign a consent form, indicating agreement to completion of questionniares, and to be followed up again at 6 months. The researcher will issue you both with a questionnaire, which should be completed seperately and returned to your cardiac specialist nurse who will contact the researcher when the form can be collected fom the ward. Two weeks prior to the 6 month follow-up, the reseearcher will contact you to check for continued participation and the questionnaires will be posted seperately. Once complete, they should be returned in the separate stamped addressed envelopes to the cardiac specialist nurse secretaries.

If you would prefer not to be contacted whilst in hospital, the researcher can visit you on discharge and this would require you to sign and return the separate consent to contact forms, which will be included within the recruitment pack issued by the cardiac specialist nurse. Once the researcher receives both signed **consent to contact** forms, he will contact you by telephone to arrange a convenient time to visit you at your home to discuss the study further and answer any specific questions regarding participation. If at the end of this meeting, you and your family caregiver feel you would like to particiapte in the followed up study, you will be asked to sign a further consent form, indicating agreement to completion of questionnaires, and to be again at 6 months. If you and your family caregiver sign the additional consent form, the researcher will issue you and your family caregiver separate questionnaire booklets. The questionnaire will ask specific questions regarding your health. It is recommended that you and your caregiver complete the questionnaires separately to avoid influencing each other's answers.

Once completed, the questionnaires should be returned in the stamped addressed envelope provided to the cardiac specialist nurse secretaries. If the postal questionnaires are not returned after 2 weeks, a reminder telephone call will be made. If they are not returned after the reminder telephone call, it will be assumed that you no longer wish to participate in the study, and no further contact will be made. If the questionnaires are returned, you will be asked to complete the questionnaires again at 6 months, and conact will be made with you 2 weeks prior to this. The questionniares will be posted separately to you and your family caregiver at home, and once complete, should be returned in the stamped addressed envelope to the cardiac specialist nurse secretaries. Like the first questionnaire booklets, a reminder telephone call will be made if they are not returned after a period of 2 weeks. If you agree to participate, your General Practitioner (GP) will be notified.

What are the disadvantages of taking part?

The only thing that is required of you is a short period of your time to complete the questionnaires. This will allow you to share your thoughts and experiences, and the reseracher would be grateful to hear from as many patient/family caregiver pairs as possible. If you decide not to participate, your future care <u>will not</u> be affected.



NHS Greater Glasgow and Clyde

UNIVERSITY OF STIRLING

NHS Ayrshire & Arran

What are the potential benefits of taking part?

I cannot promise that participation in the study will directly help you or your family caregiver. However, by agreeing to participate, you will increase our knowledge and understanding of quality of life, self-care and caregiver burden in Heart Failure. This is an opportunity to improve the services for future patients and their family caregivers. An opportunity will be given (on completion of the research) for you to have access to the results.

How long will it take me?

This may vary, and it will depend on how long you consider your answers for. However, it is estimated that completion of the questionnaires should take 20-30 minutes.

Will what I say be kept confidential?

The completed booklets (which contain the questionnaires) will be given a unique number, so that only the researcher will be able to link the answers directly to you or your family caregiver. The completed booklets will be stored in a locked cabinet, and only the researcher and his academic supervisors will have access to them. The results we get back from you and your family caregiver will remain anonymised. However, the researcher has a professional obligation to act on any information that is divulged that could potentially affect you and your family caregiver's health or well-being. As a result, he would inform the relevant health professional as appropriate to the situation.

Who is organising and funding the research?

This research is being undertaken as part of a Clinical Doctorate in Nursing at the University of Stirling. The research is being part-funded by NHS Greater Glasgow & Clyde.

Who has reviewed this study?

To promote your safety, rights and well-being, the research will be monitored by the Research & Ethics Commiittee at the University of Stirling, as well as the West of Scotland Research & Ethics Committee.

How will the findings of the study be used?

When the booklets are returned to the researcher, analysis of the quetionnaires will take place on University premises. On completion of the doctorate, the results will be published in an academic journal and the results presented at relevant nursing conferences. This will allow us to improve the services offered to future patients and their family caregivers.

What if there is a problem?

If you are unhappy with how you have been approached regarding this research, or at at any stage throughout the reseasrch process, please use the contact details below:

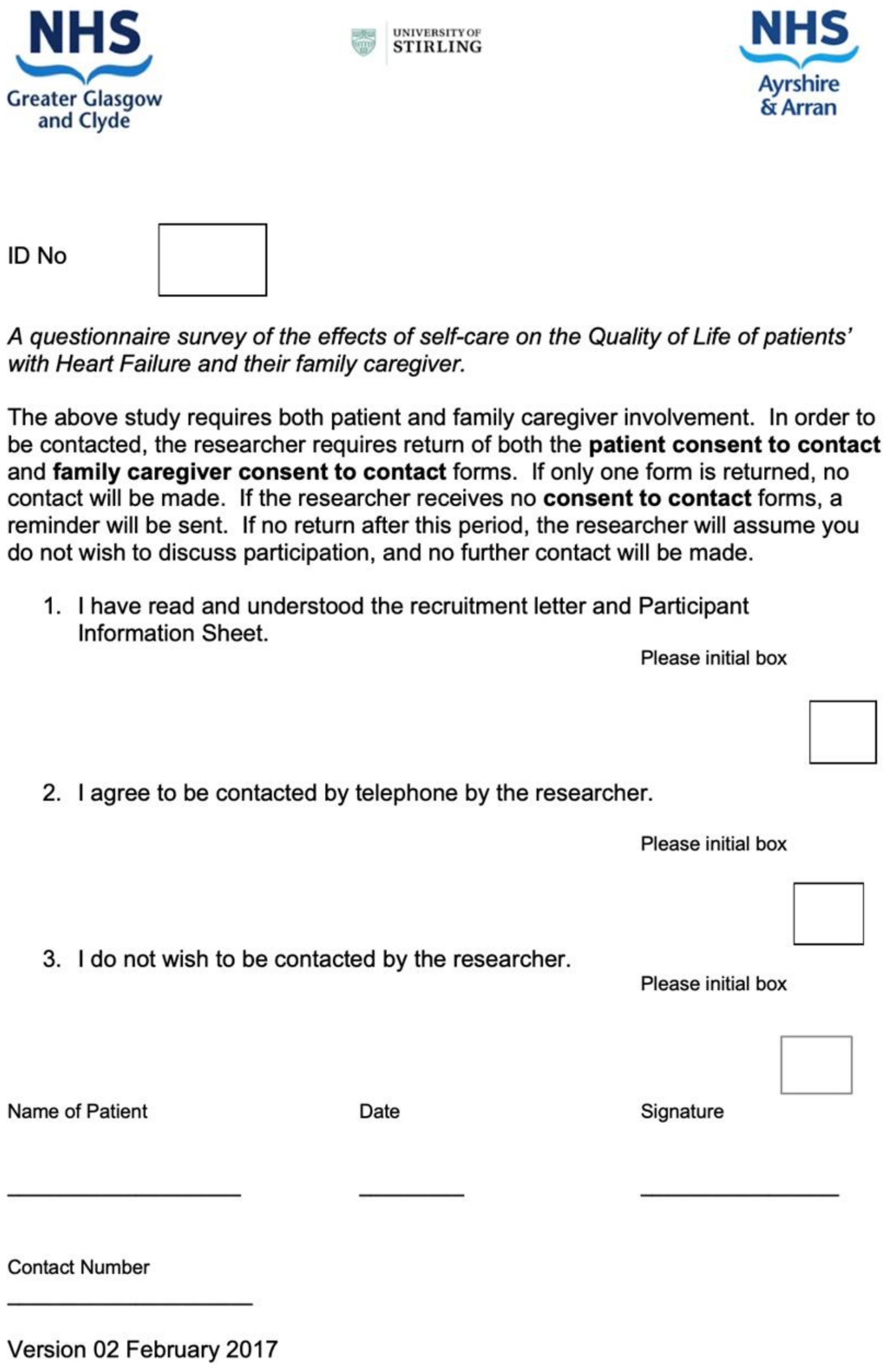
Mr Robert Thomson (Researcher)
Tel: 07725440402
E-mail: Robert.Thomson@stir.ac.uk

Dr Patricia Thomson (Academic Supervisor)
Tel: 01786466396
E-mail: patricia.thomson@stir.ac.uk

Professor Jayne Donaldson (Independent Contact)
Tel: 01786473171
E-mail: jayne.donaldson@stir.ac.uk

Version 3 February 2017

Appendix 17: Patient Consent to Contact Form



NHS Greater Glasgow and Clyde

UNIVERSITY OF STIRLING

NHS Ayrshire & Arran

ID No ☐

A questionnaire survey of the effects of self-care on the Quality of Life of patients' with Heart Failure and their family caregiver.

The above study requires both patient and family caregiver involvement. In order to be contacted, the researcher requires return of both the **patient consent to contact** and **family caregiver consent to contact** forms. If only one form is returned, no contact will be made. If the researcher receives no **consent to contact** forms, a reminder will be sent. If no return after this period, the researcher will assume you do not wish to discuss participation, and no further contact will be made.

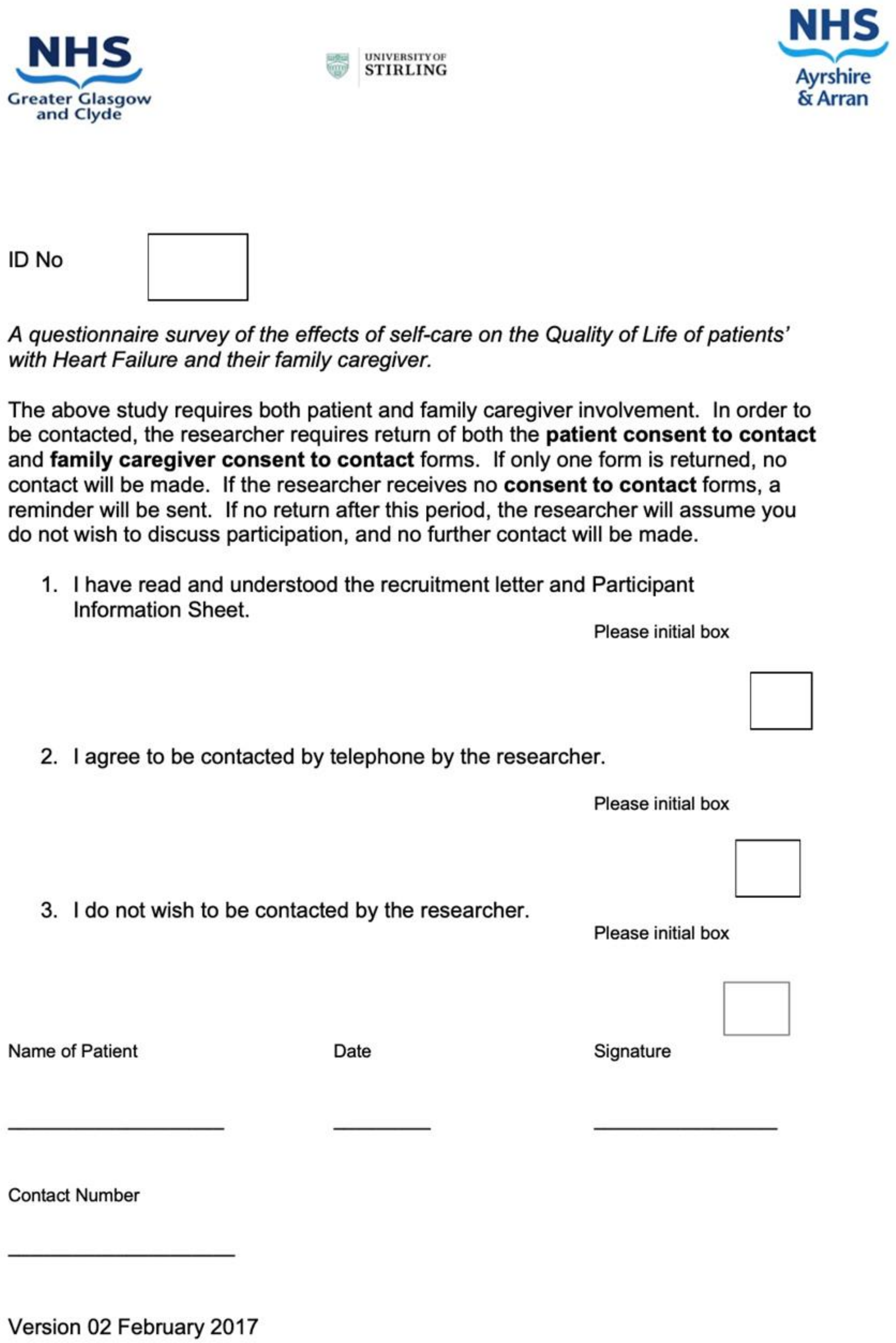
1. I have read and understood the recruitment letter and Participant Information Sheet.
   Please initial box ☐
2. I agree to be contacted by telephone by the researcher.
   Please initial box ☐
3. I do not wish to be contacted by the researcher.
   Please initial box ☐

Name of Patient	Date	Signature
____________________	_________	_________________

Contact Number
____

Version 02 February 2017

Appendix 18: Caregiver Consent to Contact Form



NHS Greater Glasgow and Clyde

University of Stirling

NHS Ayrshire & Arran

ID No ☐

A questionnaire survey of the effects of self-care on the Quality of Life of patients' with Heart Failure and their family caregiver.

The above study requires both patient and family caregiver involvement. In order to be contacted, the researcher requires return of both the **patient consent to contact** and **family caregiver consent to contact** forms. If only one form is returned, no contact will be made. If the researcher receives no **consent to contact** forms, a reminder will be sent. If no return after this period, the researcher will assume you do not wish to discuss participation, and no further contact will be made.

1. I have read and understood the recruitment letter and Participant Information Sheet.

   Please initial box ☐

2. I agree to be contacted by telephone by the researcher.

   Please initial box ☐

3. I do not wish to be contacted by the researcher.

   Please initial box ☐

Name of Patient ____________________

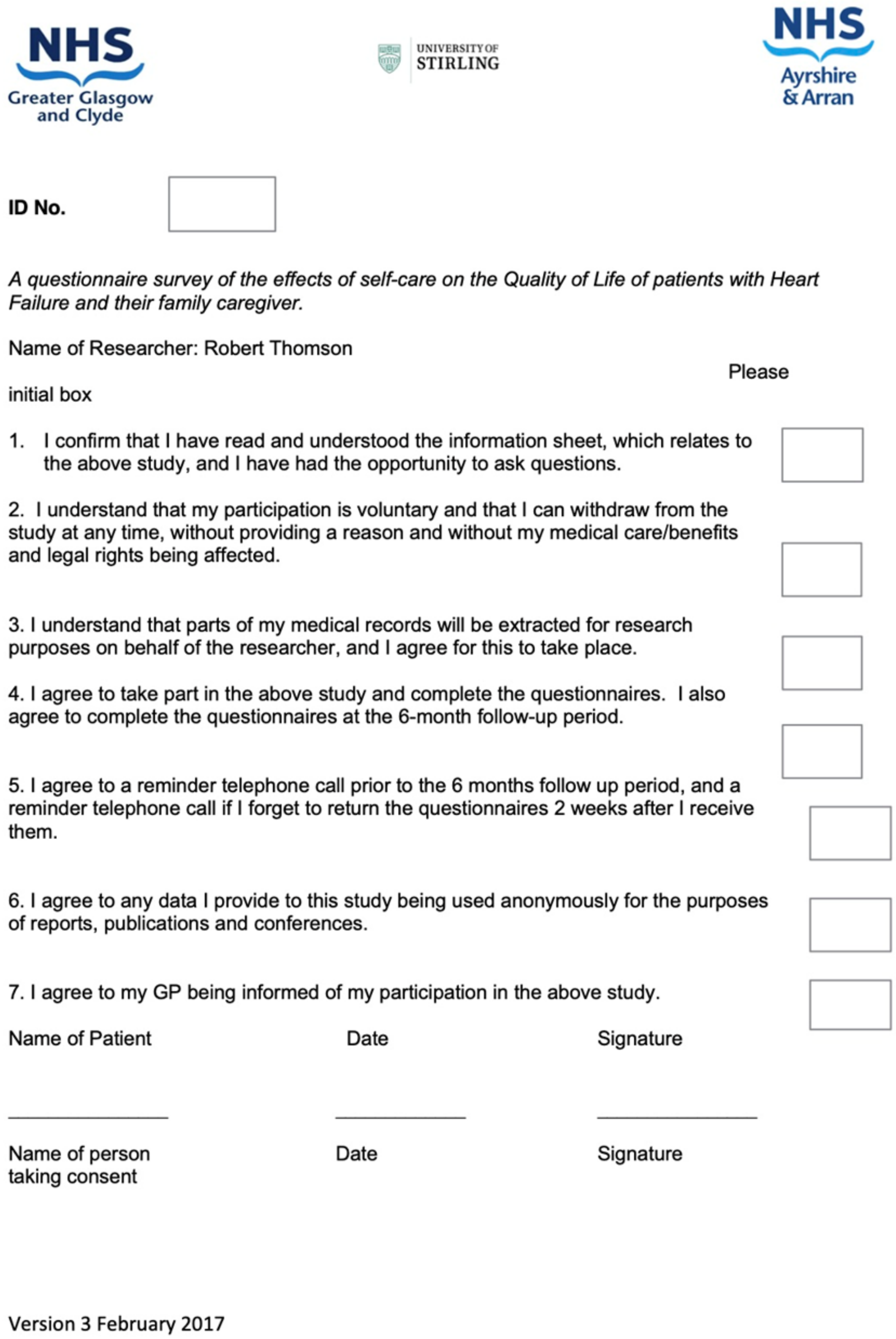
Date __________

Signature _________________

Contact Number ____________________

Version 02 February 2017

Appendix 19a: Consent Form A: Patient



NHS
Greater Glasgow
and Clyde

UNIVERSITY OF
STIRLING

NHS
Ayrshire
& Arran

ID No. ☐

A questionnaire survey of the effects of self-care on the Quality of Life of patients with Heart Failure and their family caregiver.

Name of Researcher: Robert Thomson

Please initial box

1. I confirm that I have read and understood the information sheet, which relates to the above study, and I have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I can withdraw from the study at any time, without providing a reason and without my medical care/benefits and legal rights being affected. ☐

3. I understand that parts of my medical records will be extracted for research purposes on behalf of the researcher, and I agree for this to take place. ☐

4. I agree to take part in the above study and complete the questionnaires. I also agree to complete the questionnaires at the 6-month follow-up period. ☐

5. I agree to a reminder telephone call prior to the 6 months follow up period, and a reminder telephone call if I forget to return the questionnaires 2 weeks after I receive them. ☐

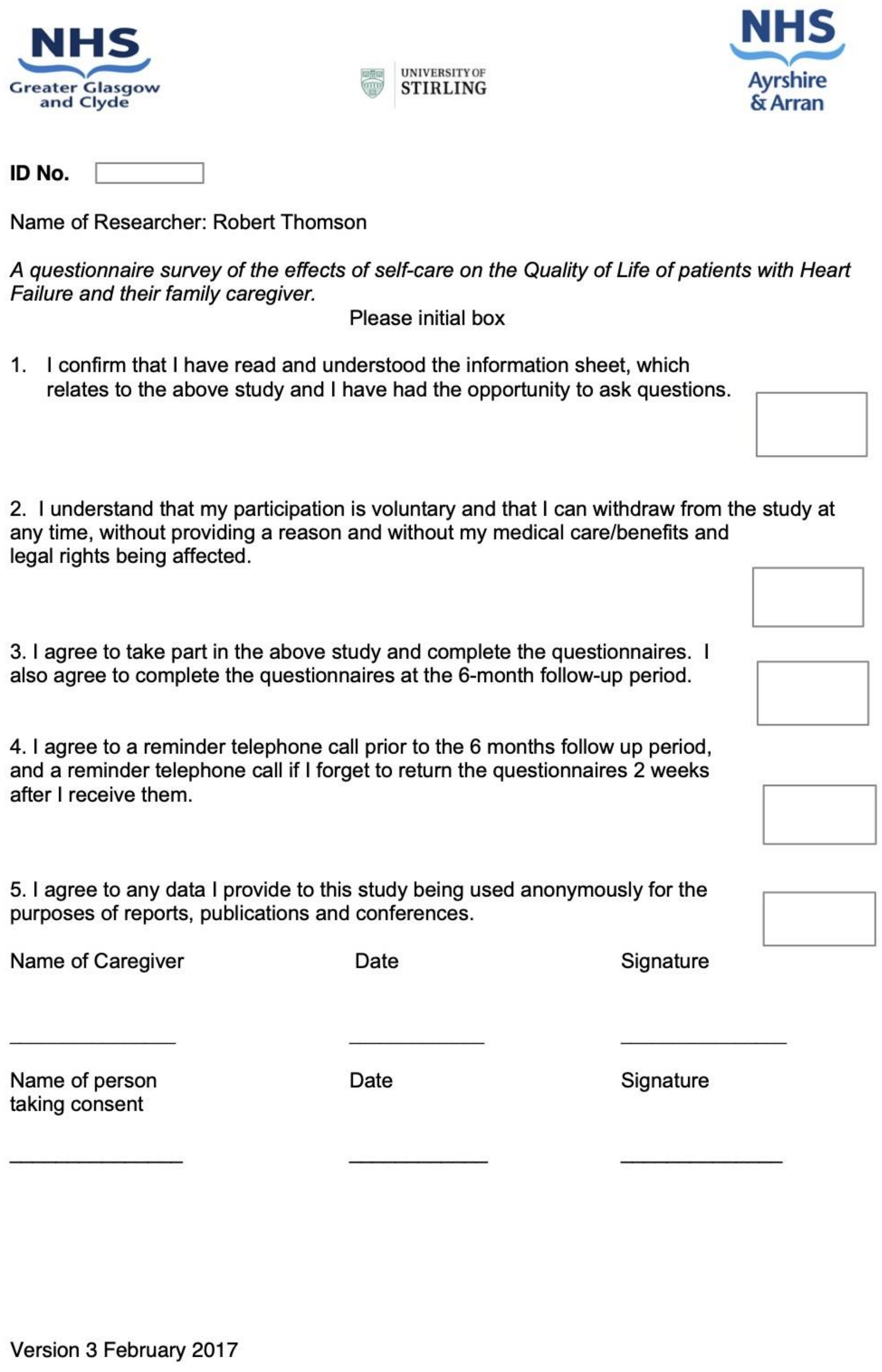
6. I agree to any data I provide to this study being used anonymously for the purposes of reports, publications and conferences. ☐

7. I agree to my GP being informed of my participation in the above study. ☐

Name of Patient	Date	Signature
________________	____________	________________
Name of person taking consent	Date	Signature

Version 3 February 2017

Appendix 19b: Consent Form B: Carer



NHS Greater Glasgow and Clyde

University of Stirling

NHS Ayrshire & Arran

ID No. ☐

Name of Researcher: Robert Thomson

A questionnaire survey of the effects of self-care on the Quality of Life of patients with Heart Failure and their family caregiver.

Please initial box

1. I confirm that I have read and understood the information sheet, which relates to the above study and I have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I can withdraw from the study at any time, without providing a reason and without my medical care/benefits and legal rights being affected. ☐

3. I agree to take part in the above study and complete the questionnaires. I also agree to complete the questionnaires at the 6-month follow-up period. ☐

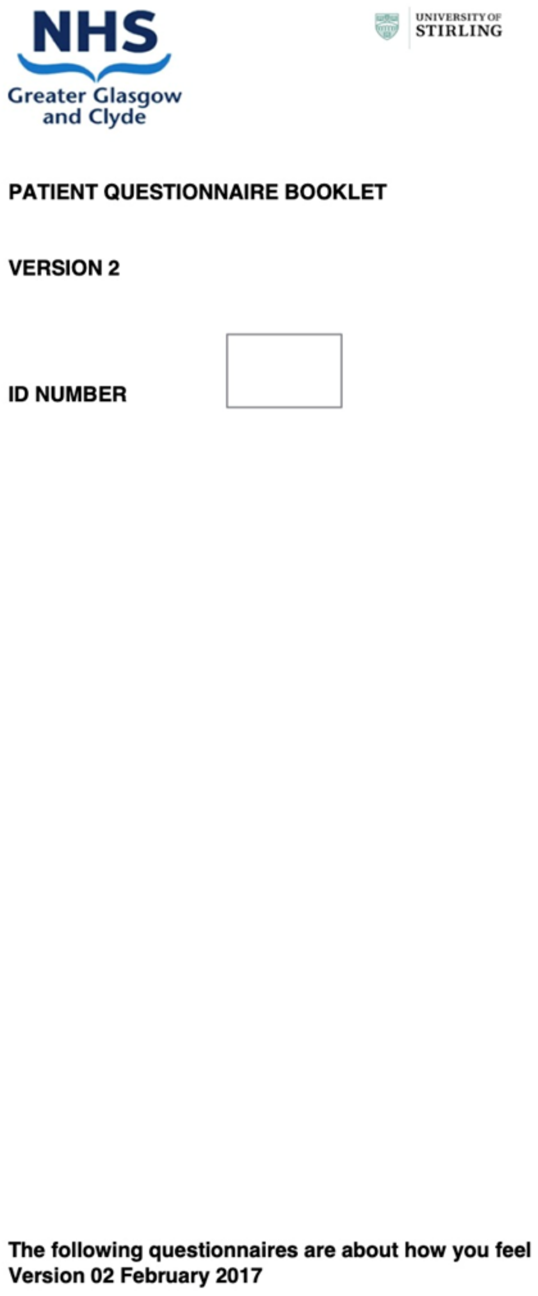
4. I agree to a reminder telephone call prior to the 6 months follow up period, and a reminder telephone call if I forget to return the questionnaires 2 weeks after I receive them. ☐

5. I agree to any data I provide to this study being used anonymously for the purposes of reports, publications and conferences. ☐

Name of Caregiver	Date	Signature
________________	_____________	________________
Name of person taking consent	Date	Signature
________________	_____________	________________

Version 3 February 2017

Appendix 20a: Patient Questionnaire Booklet



NHS Greater Glasgow and Clyde

UNIVERSITY OF STIRLING

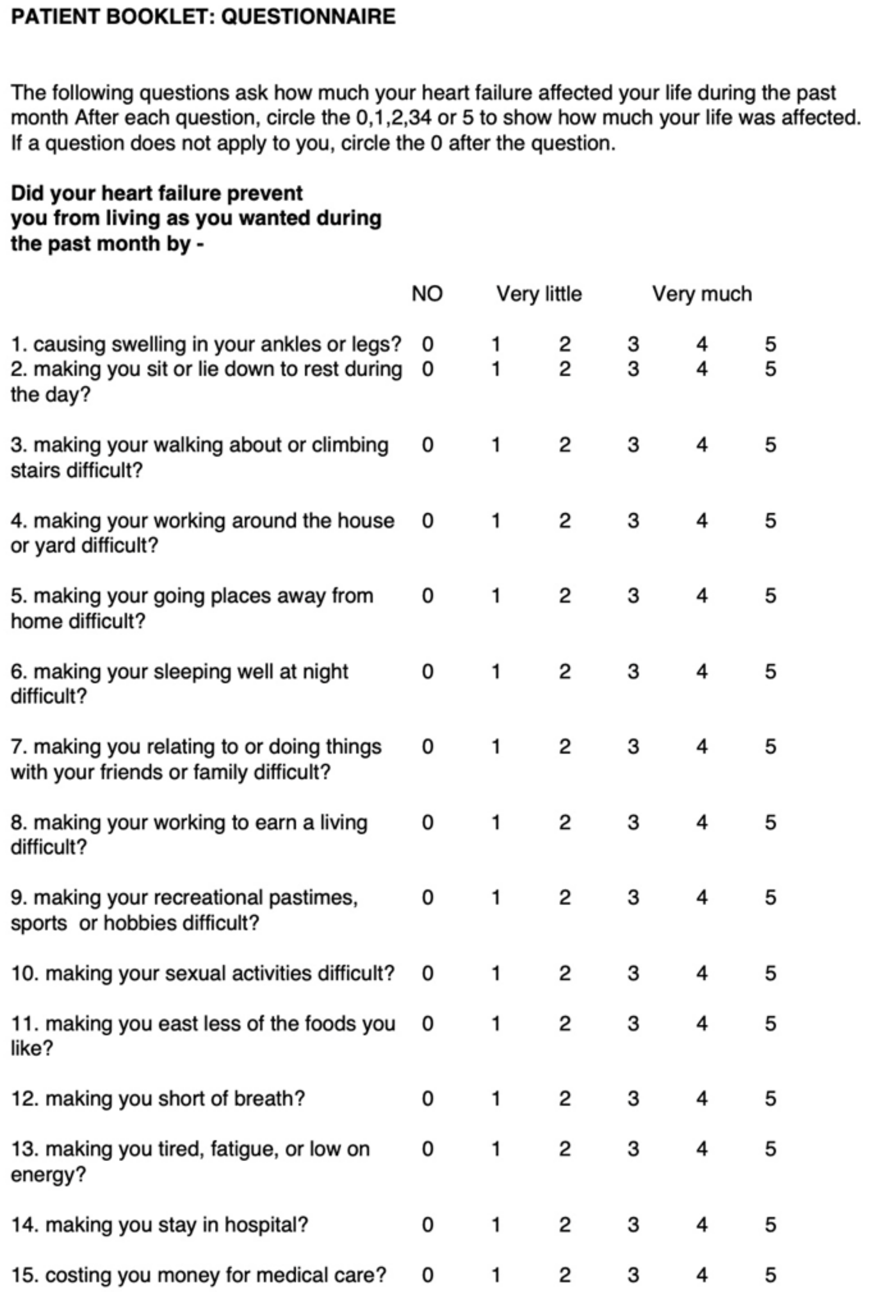
NHS Ayrshire & Arran

PATIENT QUESTIONNAIRE BOOKLET

VERSION 2

ID NUMBER

The following questionnaires are about how you feel
Version 02 February 2017



PATIENT BOOKLET: QUESTIONNAIRE

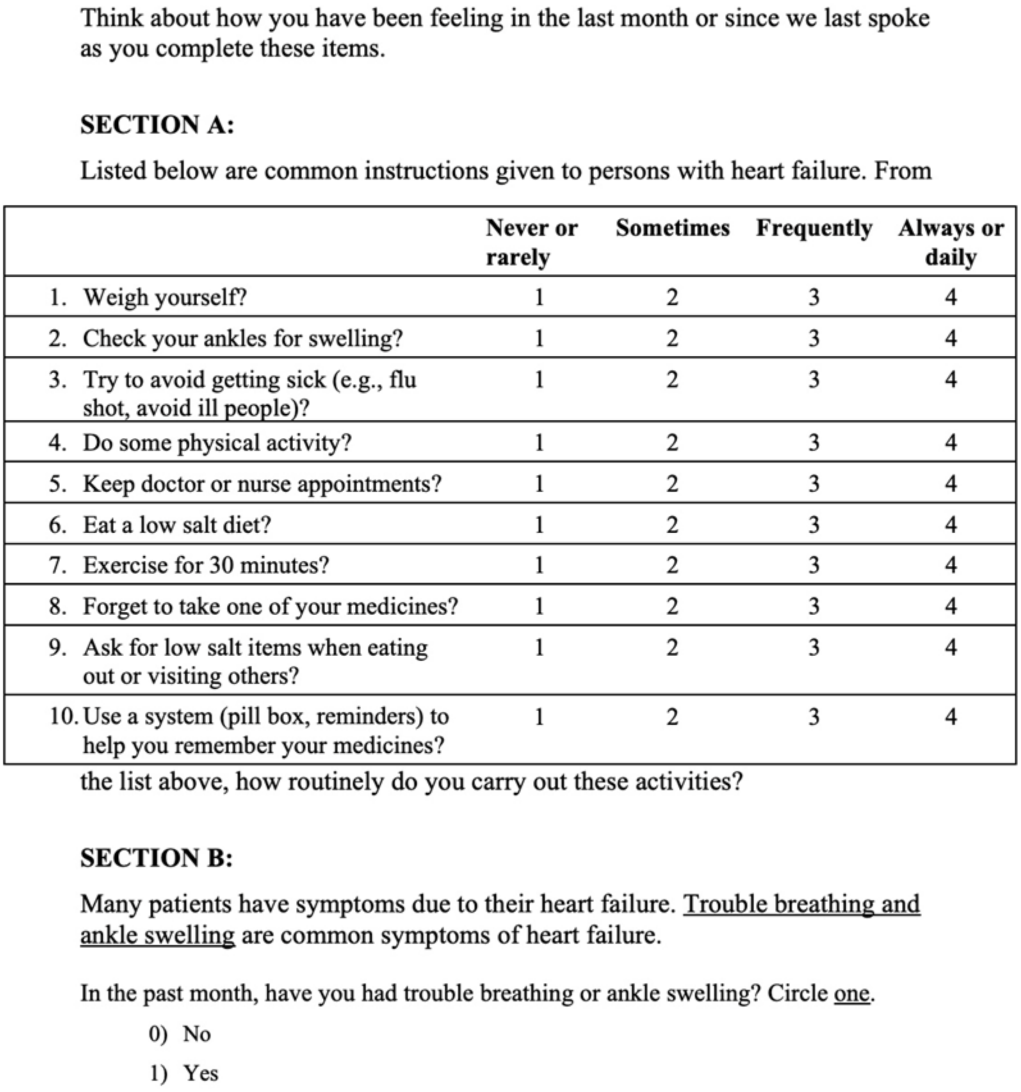
The following questions ask how much your heart failure affected your life during the past month After each question, circle the 0,1,2,34 or 5 to show how much your life was affected. If a question does not apply to you, circle the 0 after the question.

Did your heart failure prevent you from living as you wanted during the past month by -

	NO	Very little			Very much	
1. causing swelling in your ankles or legs?	0	1	2	3	4	5
2. making you sit or lie down to rest during the day?	0	1	2	3	4	5
3. making your walking about or climbing stairs difficult?	0	1	2	3	4	5
4. making your working around the house or yard difficult?	0	1	2	3	4	5
5. making your going places away from home difficult?	0	1	2	3	4	5
6. making your sleeping well at night difficult?	0	1	2	3	4	5
7. making you relating to or doing things with your friends or family difficult?	0	1	2	3	4	5
8. making your working to earn a living difficult?	0	1	2	3	4	5
9. making your recreational pastimes, sports or hobbies difficult?	0	1	2	3	4	5
10. making your sexual activities difficult?	0	1	2	3	4	5
11. making you east less of the foods you like?	0	1	2	3	4	5
12. making you short of breath?	0	1	2	3	4	5
13. making you tired, fatigue, or low on energy?	0	1	2	3	4	5
14. making you stay in hospital?	0	1	2	3	4	5
15. costing you money for medical care?	0	1	2	3	4	5

16. giving you side-effects from treatments?	0	1	2	3	4	5
17. making you feel you are a burden to your family or friends?	0	1	2	3	4	5
18. making you feel a loss of self-control in your life?	0	1	2	3	4	5
19. making you worry?	0	1	2	3	4	5
20. making it difficult for you to concentrate or remember things?	0	1	2	3	4	5
21. making you feel depressed?	0	1	2	3	4	5

PATIENT BOOKLET: QUESTIONNAIRE



Think about how you have been feeling in the last month or since we last spoke as you complete these items.

SECTION A:

Listed below are common instructions given to persons with heart failure. From the list above, how routinely do you carry out these activities?

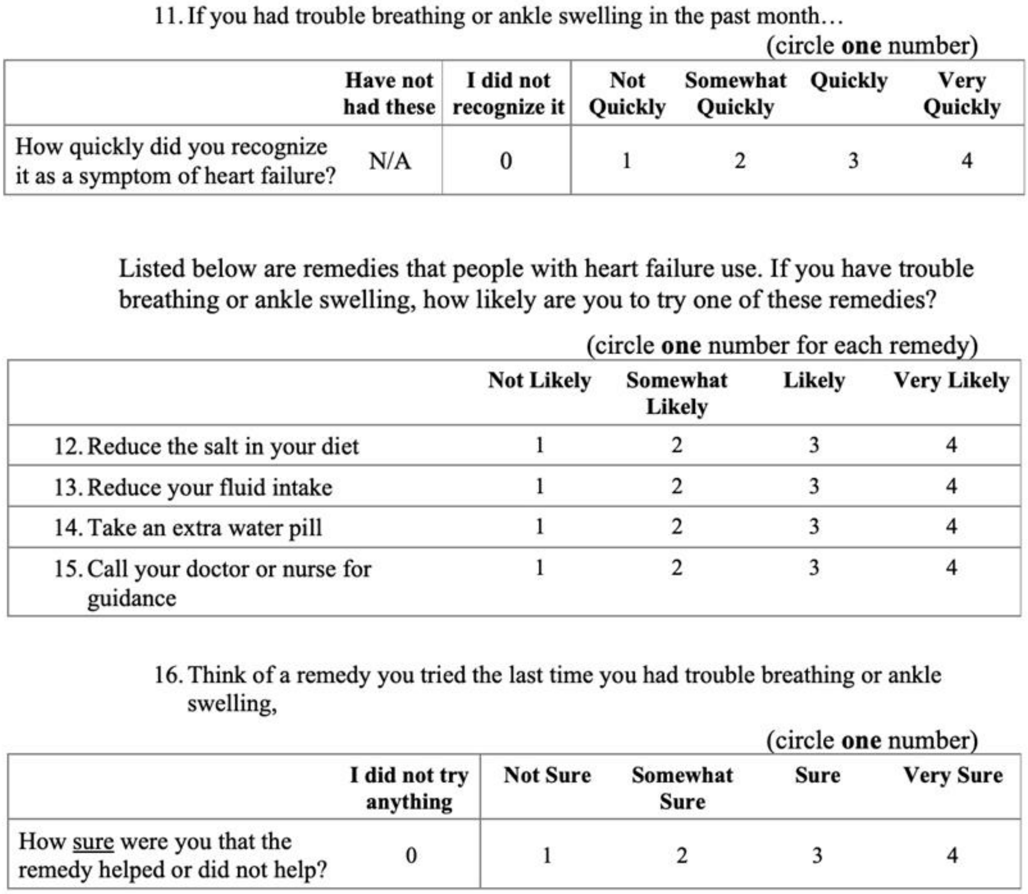
	Never or rarely	Sometimes	Frequently	Always or daily
1. Weigh yourself?	1	2	3	4
2. Check your ankles for swelling?	1	2	3	4
3. Try to avoid getting sick (e.g., flu shot, avoid ill people)?	1	2	3	4
4. Do some physical activity?	1	2	3	4
5. Keep doctor or nurse appointments?	1	2	3	4
6. Eat a low salt diet?	1	2	3	4
7. Exercise for 30 minutes?	1	2	3	4
8. Forget to take one of your medicines?	1	2	3	4
9. Ask for low salt items when eating out or visiting others?	1	2	3	4
10. Use a system (pill box, reminders) to help you remember your medicines?	1	2	3	4

SECTION B:

Many patients have symptoms due to their heart failure. Trouble breathing and ankle swelling are common symptoms of heart failure.

In the past month, have you had trouble breathing or ankle swelling? Circle one.

0) No
1) Yes



11. If you had trouble breathing or ankle swelling in the past month…

(circle **one** number)

	Have not had these	**I did not recognize it**	**Not Quickly**	**Somewhat Quickly**	**Quickly**	**Very Quickly**
How quickly did you recognize it as a symptom of heart failure?	N/A	0	1	2	3	4

Listed below are remedies that people with heart failure use. If you have trouble breathing or ankle swelling, how likely are you to try one of these remedies?

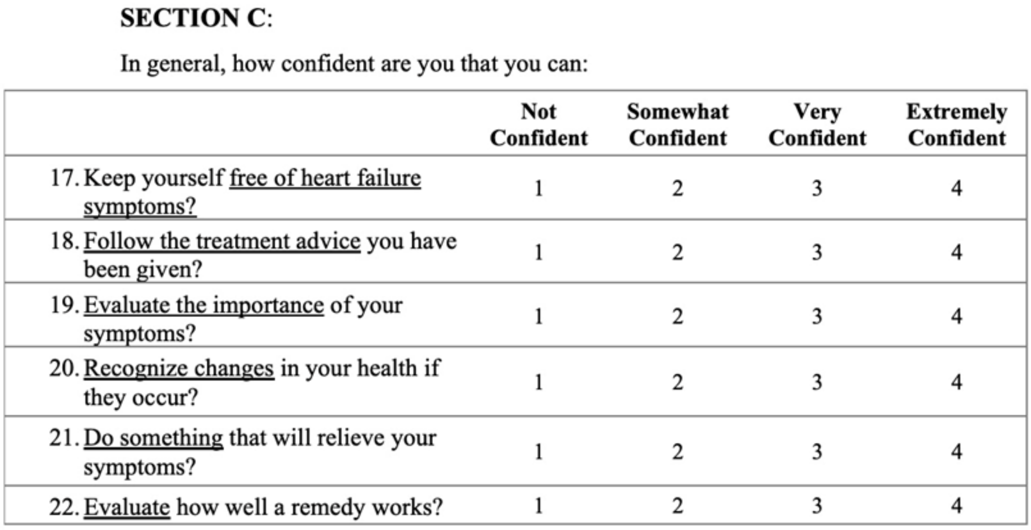
(circle **one** number for each remedy)

	Not Likely	**Somewhat Likely**	**Likely**	**Very Likely**
12. Reduce the salt in your diet	1	2	3	4
13. Reduce your fluid intake	1	2	3	4
14. Take an extra water pill	1	2	3	4
15. Call your doctor or nurse for guidance	1	2	3	4

16. Think of a remedy you tried the last time you had trouble breathing or ankle swelling,

(circle **one** number)

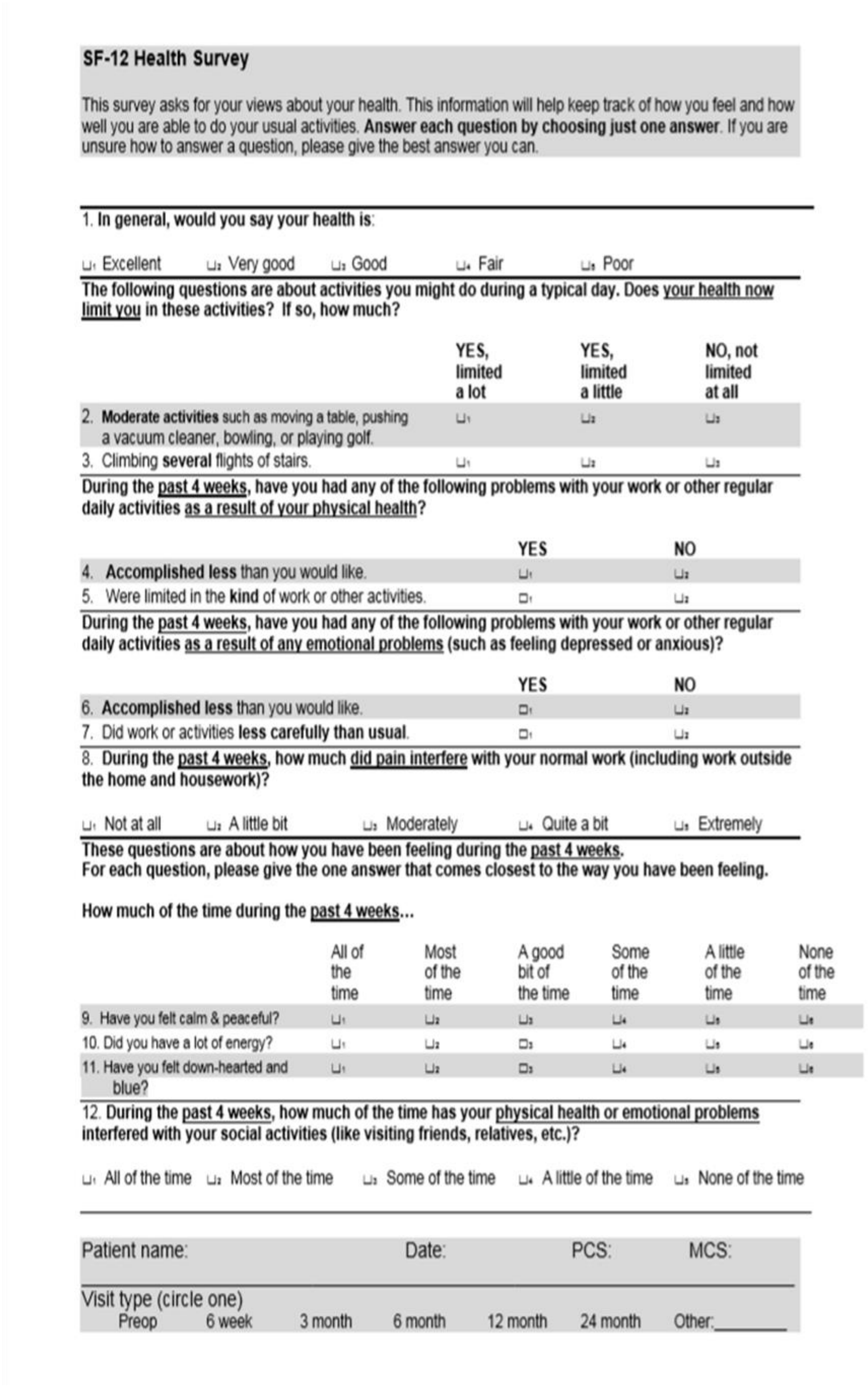
	I did not try anything	**Not Sure**	**Somewhat Sure**	**Sure**	**Very Sure**
How sure were you that the remedy helped or did not help?	0	1	2	3	4



SECTION C:

In general, how confident are you that you can:

	Not Confident	Somewhat Confident	Very Confident	Extremely Confident
17. Keep yourself free of heart failure symptoms?	1	2	3	4
18. Follow the treatment advice you have been given?	1	2	3	4
19. Evaluate the importance of your symptoms?	1	2	3	4
20. Recognize changes in your health if they occur?	1	2	3	4
21. Do something that will relieve your symptoms?	1	2	3	4
22. Evaluate how well a remedy works?	1	2	3	4



SF-12 Health Survey

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. **Answer each question by choosing just one answer**. If you are unsure how to answer a question, please give the best answer you can.

---

1. **In general, would you say your health is**:

☐1 Excellent ☐2 Very good ☐3 Good ☐4 Fair ☐5 Poor

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	YES, limited a lot	**YES, limited a little**	**NO, not limited at all**
2. **Moderate activities** such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.	☐1	☐2	☐3
3. Climbing **several** flights of stairs.	☐1	☐2	☐3

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	YES	**NO**
4. **Accomplished less** than you would like.	☐1	☐2
5. Were limited in the **kind** of work or other activities.	☐1	☐2

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	YES	**NO**
6. **Accomplished less** than you would like.	☐1	☐2
7. Did work or activities **less carefully than usual**.	☐1	☐2

8. **During the past 4 weeks, how much did pain interfere with your normal work (including work outside the home and housework)?**

☐1 Not at all ☐2 A little bit ☐3 Moderately ☐4 Quite a bit ☐5 Extremely

These questions are about how you have been feeling during the past 4 weeks.
For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks…

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
9. Have you felt calm & peaceful?	☐1	☐2	☐3	☐4	☐5	☐6
10. Did you have a lot of energy?	☐1	☐2	☐3	☐4	☐5	☐6
11. Have you felt down-hearted and blue?	☐1	☐2	☐3	☐4	☐5	☐6

12. **During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?**

☐1 All of the time ☐2 Most of the time ☐3 Some of the time ☐4 A little of the time ☐5 None of the time

---

Patient name: Date: PCS: MCS:

Visit type (circle one)
Preop 6 week 3 month 6 month 12 month 24 month Other:________

Appendix 20b: Caregiver Questionnaire Booklet

NHS Greater Glasgow and Clyde

UNIVERSITY OF STIRLING

NHS Ayrshire & Arran

CAREGIVER QUESTIONNAIRE BOOKLET

ID NUMBER

FAMILY CAREGIVER BOOKLET:

We kindly ask you to think about the care you have given to the person with Heart Failure in the past month. There are no right or wrong answers.

How often do you recommend to the person you care for the following things? (Or, how often do you do these activities because the person you care for is not able to do them).

SECTION A:

	Never or rarely	**Sometimes**	**Frequently**	**Always or daily**
To check the weight ?	1	2	3	4
To check the ankles for swelling?	1	2	3	4
To try to avoid getting sick (e.g., flu shot, avoid ill people)?	1	2	3	4
To do some physical activity?	1	2	3	4
To keep doctor or nurse appointments?	1	2	3	4
To eat a low salt diet?	1	2	3	4
To exercise for 30 minutes?	1	2	3	4
To not forget to take medicines?	1	2	3	4
To ask for low salt items when eating out or visiting others?	1	2	3	4
To use a system (pill box, reminders) to help you remember your medicines?	1	2	3	4

SECTION B:

Many patients have symptoms due to their heart failure. Trouble breathing and ankle swelling are common symptoms of heart failure.

In the past month, did **the person you care for** have trouble breathing or ankle swelling? Circle one.

0) No
1) Yes

If **the person you care for** had trouble breathing or ankle swelling in the past month…

(circle **one** number)

	Has not had these	**I did not recognize it**	**Not Quickly**	**Somewhat Quickly**	**Quickly**	**Very Quickly**
How quickly did **you** recognize it as a symptom of heart failure?	N/A	0	1	2	3	4

If the **person you care for** has trouble breathing or ankle swelling, how likely are **you** to recommend (or do) one of these remedies?

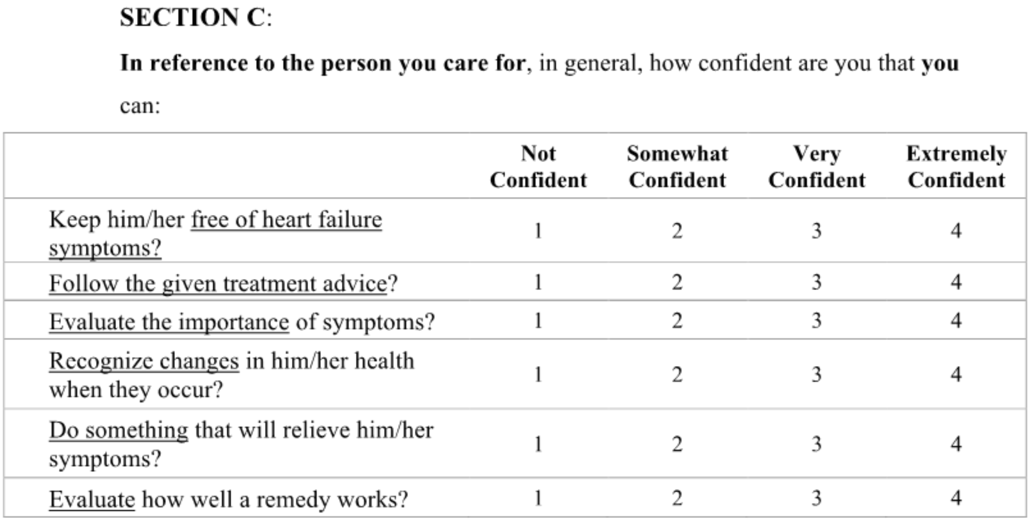
(circle **one** number for each remedy)

	Not Likely	**Somewhat Likely**	**Likely**	**Very Likely**
To reduce the salt in the diet	1	2	3	4
To reduce fluid intake	1	2	3	4
To take an extra water pill	1	2	3	4
To call the doctor or nurse for guidance	1	2	3	4

Think of a remedy **you** tried the last time **the person you care for** had trouble breathing or ankle swelling,

(circle **one** number)

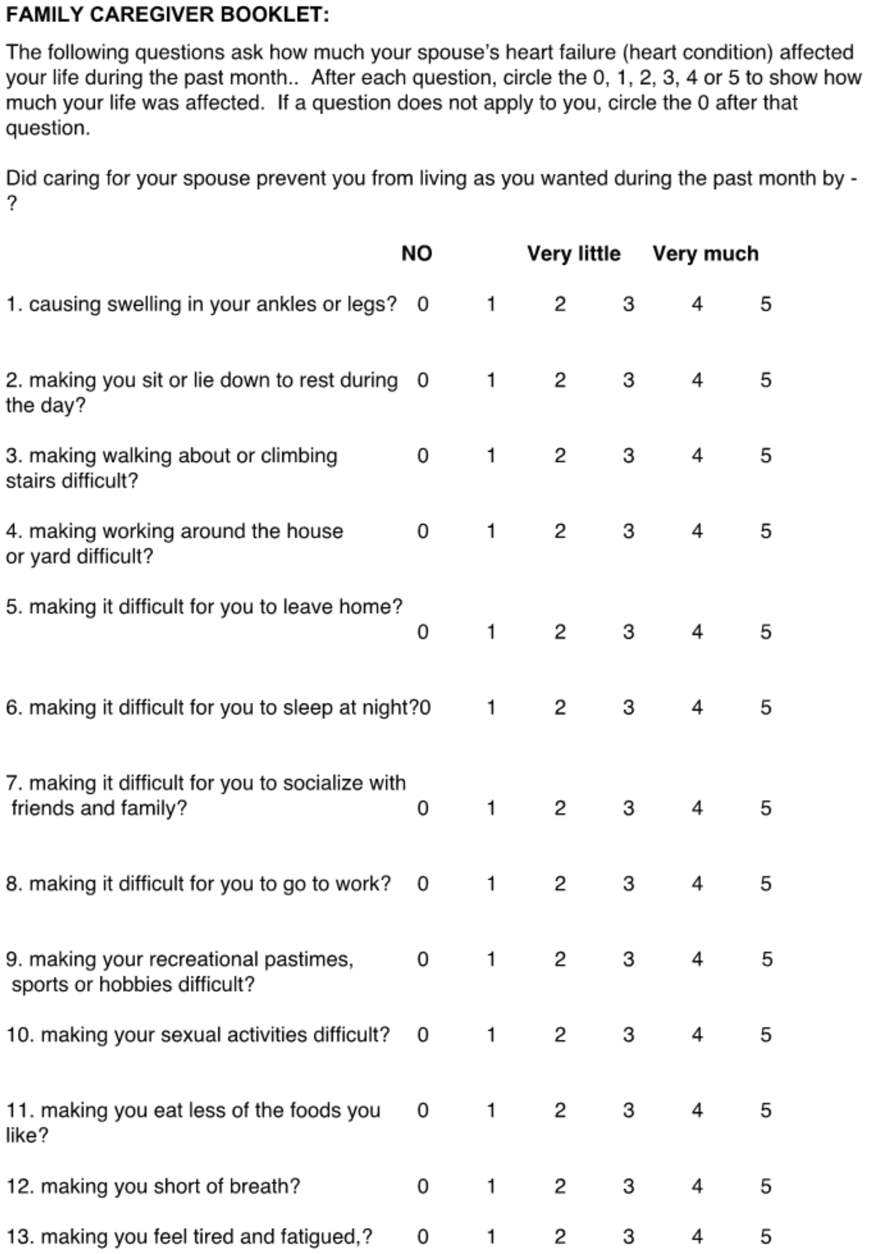
	I did not try anything	**Not Sure**	**Somewhat Sure**	**Sure**	**Very Sure**
How sure were you that the remedy helped or did not help?	0	1	2	3	4



SECTION C:

In reference to the person you care for, in general, how confident are you that **you** can:

	Not Confident	**Somewhat Confident**	**Very Confident**	**Extremely Confident**
Keep him/her free of heart failure symptoms?	1	2	3	4
Follow the given treatment advice?	1	2	3	4
Evaluate the importance of symptoms?	1	2	3	4
Recognize changes in him/her health when they occur?	1	2	3	4
Do something that will relieve him/her symptoms?	1	2	3	4
Evaluate how well a remedy works?	1	2	3	4

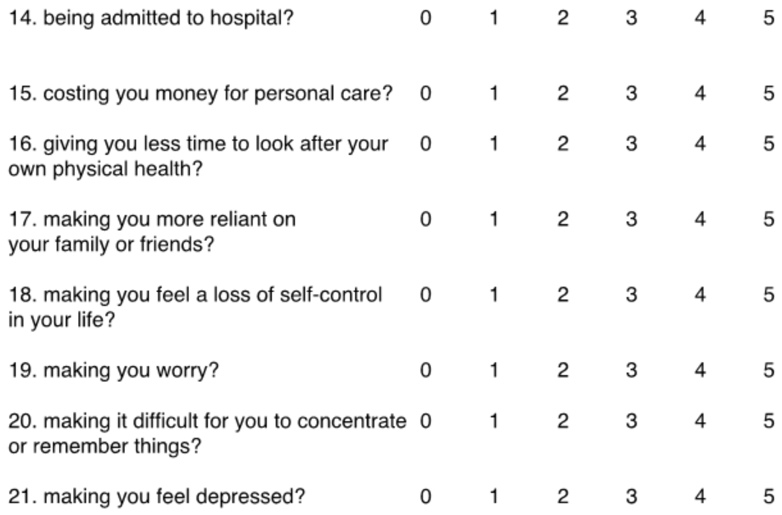


FAMILY CAREGIVER BOOKLET:

The following questions ask how much your spouse's heart failure (heart condition) affected your life during the past month.. After each question, circle the 0, 1, 2, 3, 4 or 5 to show how much your life was affected. If a question does not apply to you, circle the 0 after that question.

Did caring for your spouse prevent you from living as you wanted during the past month by -?

	NO		**Very little**		**Very much**	
1. causing swelling in your ankles or legs?	0	1	2	3	4	5
2. making you sit or lie down to rest during the day?	0	1	2	3	4	5
3. making walking about or climbing stairs difficult?	0	1	2	3	4	5
4. making working around the house or yard difficult?	0	1	2	3	4	5
5. making it difficult for you to leave home?	0	1	2	3	4	5
6. making it difficult for you to sleep at night?	0	1	2	3	4	5
7. making it difficult for you to socialize with friends and family?	0	1	2	3	4	5
8. making it difficult for you to go to work?	0	1	2	3	4	5
9. making your recreational pastimes, sports or hobbies difficult?	0	1	2	3	4	5
10. making your sexual activities difficult?	0	1	2	3	4	5
11. making you eat less of the foods you like?	0	1	2	3	4	5
12. making you short of breath?	0	1	2	3	4	5
13. making you feel tired and fatigued,?	0	1	2	3	4	5



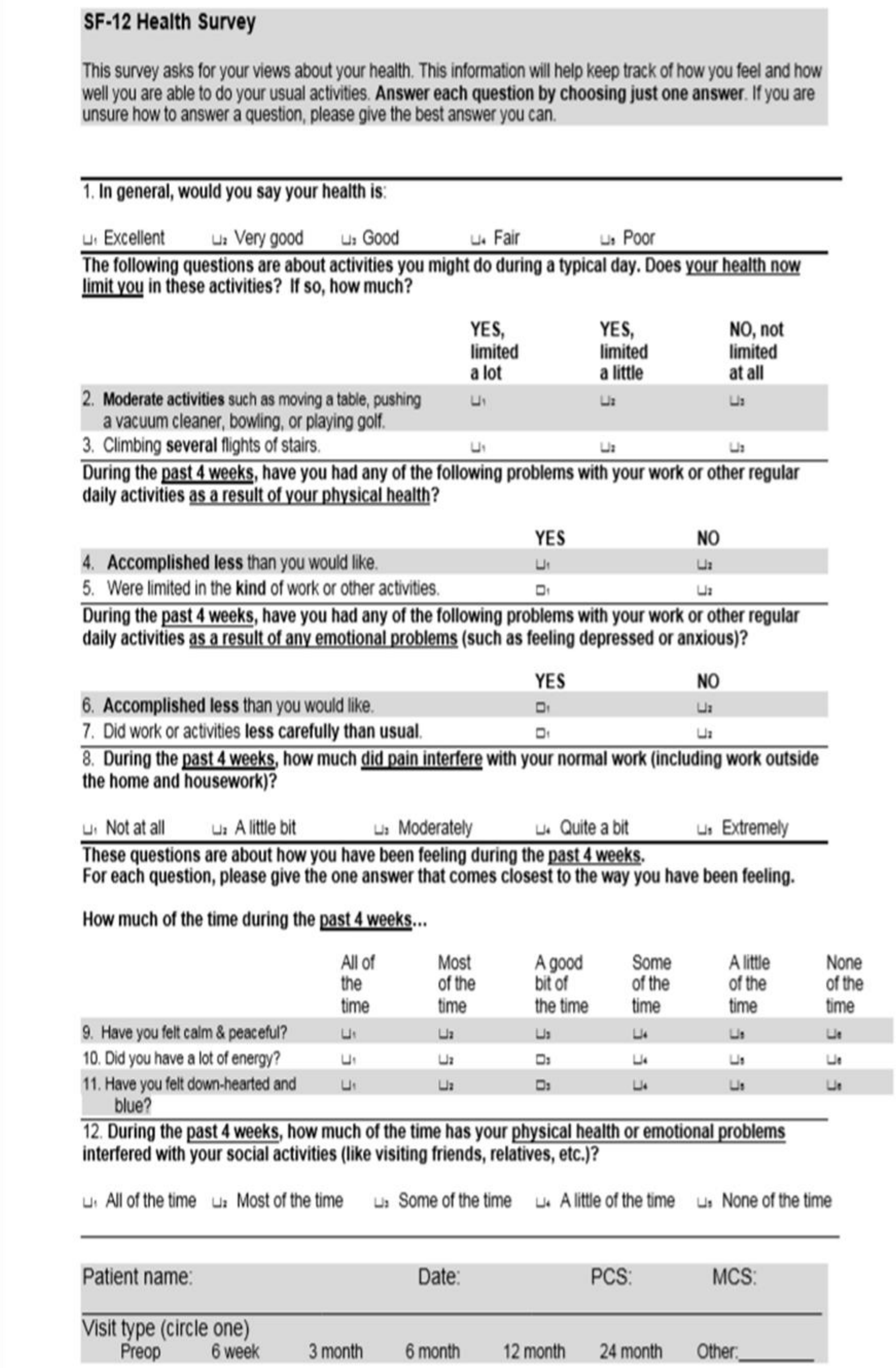
14. being admitted to hospital?	0	1	2	3	4	5
15. costing you money for personal care?	0	1	2	3	4	5
16. giving you less time to look after your own physical health?	0	1	2	3	4	5
17. making you more reliant on your family or friends?	0	1	2	3	4	5
18. making you feel a loss of self-control in your life?	0	1	2	3	4	5
19. making you worry?	0	1	2	3	4	5
20. making it difficult for you to concentrate or remember things?	0	1	2	3	4	5
21. making you feel depressed?	0	1	2	3	4	5

Circle the response that best describes how you feel.

	Never	*Rarely*	*Sometimes*	*Quite frequently*	*Nearly always*
1. Do you feel that your relative asks for more help than he/she needs?	0	1	2	3	4
2. Do you feel that because of the time you spend with your relative that you don't have enough time for yourself?	0	1	2	3	4
3. Do you feel stressed between caring for your relative and trying to meet other responsibilities for your family or work?	0	1	2	3	4
4. Do you feel embarrassed over your relative's behavior?	0	1	2	3	4
5. Do you feel angry when you are around your relative?	0	1	2	3	4
6. Do you feel that your relative currently affects your relationships with other family members or friends in a negative way?	0	1	2	3	4
7. Are you afraid what the future holds for your relative?	0	1	2	3	4
8. Do you feel your relative is dependent on you?	0	1	2	3	4
9. Do you feel strained when you are around your relative?	0	1	2	3	4
10. Do you feel your health has suffered because of your involvement with your relative?	0	1	2	3	4
11. Do you feel that you don't have as much privacy as you would like because of your relative?	0	1	2	3	4
12. Do you feel that your social life has suffered because you are caring for your relative?	0	1	2	3	4
13. Do you feel uncomfortable about having friends over because of your relative?	0	1	2	3	4
14. Do you feel that your relative seems to expect you to take care of him/her as if you were the only one he/she could depend on?	0	1	2	3	4
15. Do you feel that you don't have enough money to take care of your relative in addition to the rest of your expenses?	0	1	2	3	4
16. Do you feel that you will be unable to take care of your relative much longer?	0	1	2	3	4
17. Do you feel you have lost control of your life since your relative's illness?	0	1	2	3	4
18. Do you wish you could leave the care of your relative to someone else?	0	1	2	3	4
19. Do you feel uncertain about what to do about your relative?	0	1	2	3	4
20. Do you feel you should be doing more for your relative?	0	1	2	3	4
21. Do you feel you could do a better job in caring for your relative?	0	1	2	3	4
22. Overall, how burdened do you feel in caring for your relative?	0	1	2	3	4

Instructions for caregiver: The questions above reflect how persons sometimes feel when they are taking care of another person. After each statement, circle the word that best describes how often you feel that way. There are no right or wrong answers.

Scoring instructions: Add the scores for the 22 questions. The total score ranges from 0 to 88. A high score correlates with higher level of burden.



SF-12 Health Survey

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. **Answer each question by choosing just one answer**. If you are unsure how to answer a question, please give the best answer you can.

1. **In general, would you say your health is**:

☐1 Excellent ☐2 Very good ☐3 Good ☐4 Fair ☐5 Poor

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	YES, limited a lot	**YES, limited a little**	**NO, not limited at all**
2. **Moderate activities** such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.	☐1	☐2	☐3
3. Climbing **several** flights of stairs.	☐1	☐2	☐3

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	YES	**NO**
4. **Accomplished less** than you would like.	☐1	☐2
5. Were limited in the **kind** of work or other activities.	☐1	☐2

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	YES	**NO**
6. **Accomplished less** than you would like.	☐1	☐2
7. Did work or activities **less carefully than usual**.	☐1	☐2

8. **During the past 4 weeks, how much did pain interfere with your normal work (including work outside the home and housework)?**

☐1 Not at all ☐2 A little bit ☐3 Moderately ☐4 Quite a bit ☐5 Extremely

These questions are about how you have been feeling during the past 4 weeks.
For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks…

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
9. Have you felt calm & peaceful?	☐1	☐2	☐3	☐4	☐5	☐6
10. Did you have a lot of energy?	☐1	☐2	☐3	☐4	☐5	☐6
11. Have you felt down-hearted and blue?	☐1	☐2	☐3	☐4	☐5	☐6

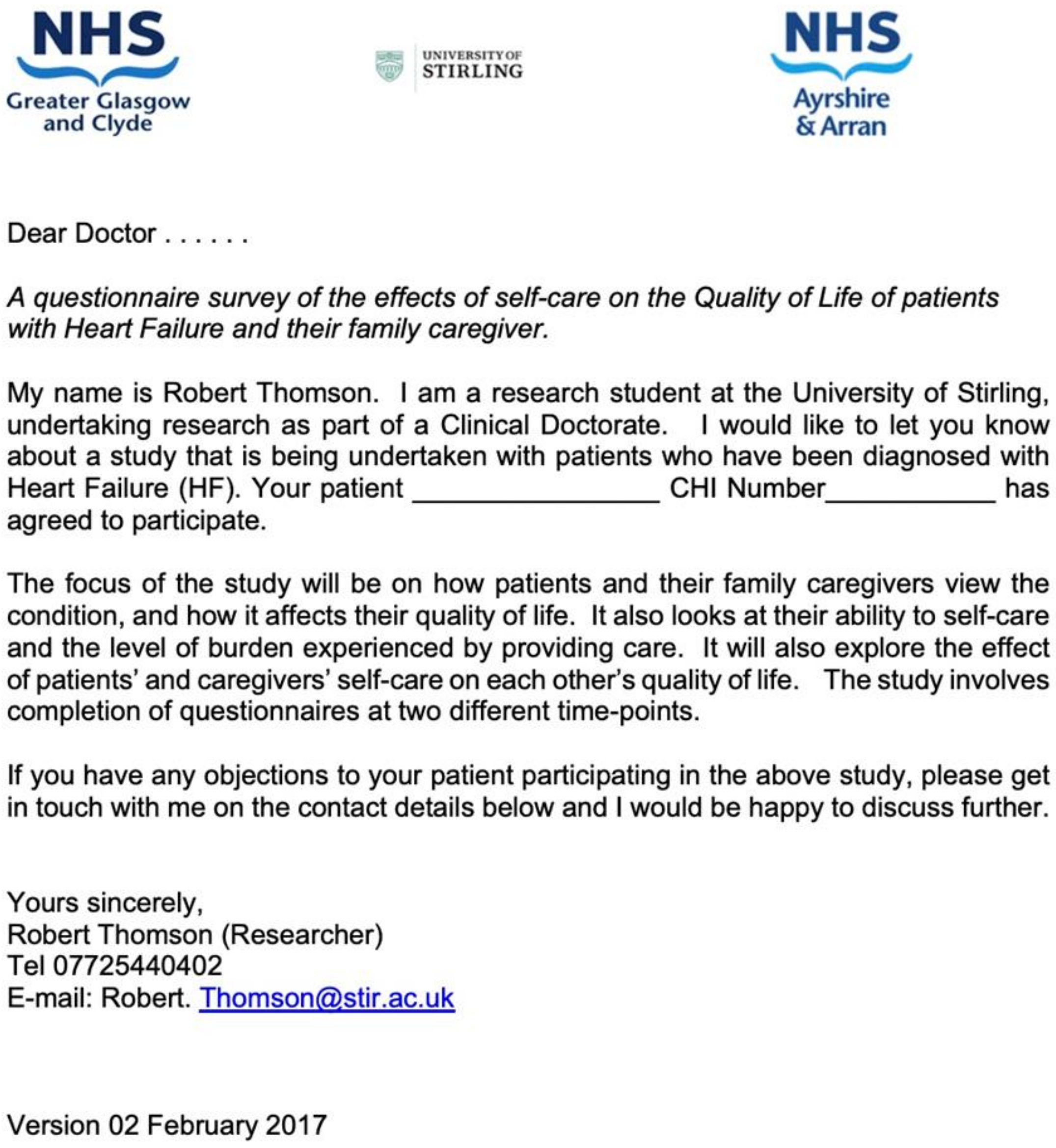
12. **During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?**

☐1 All of the time ☐2 Most of the time ☐3 Some of the time ☐4 A little of the time ☐5 None of the time

Patient name: Date: PCS: MCS:

Visit type (circle one)
Preop 6 week 3 month 6 month 12 month 24 month Other:________

Appendix 21: GP Letter



NHS Greater Glasgow and Clyde

University of Stirling

NHS Ayrshire & Arran

Dear Doctor . . . . . .

A questionnaire survey of the effects of self-care on the Quality of Life of patients with Heart Failure and their family caregiver.

My name is Robert Thomson. I am a research student at the University of Stirling, undertaking research as part of a Clinical Doctorate. I would like to let you know about a study that is being undertaken with patients who have been diagnosed with Heart Failure (HF). Your patient _________________ CHI Number____________ has agreed to participate.

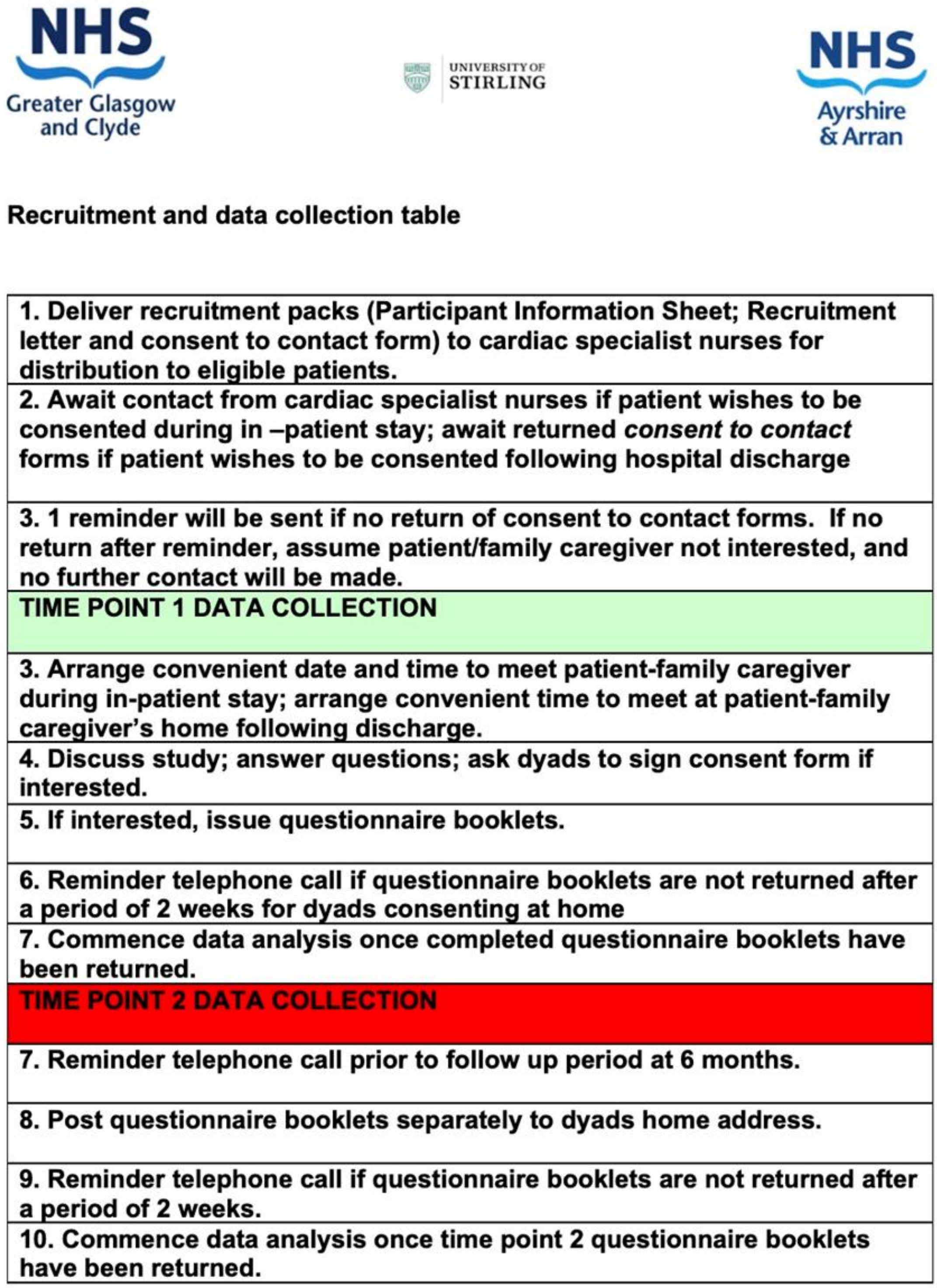
The focus of the study will be on how patients and their family caregivers view the condition, and how it affects their quality of life. It also looks at their ability to self-care and the level of burden experienced by providing care. It will also explore the effect of patients' and caregivers' self-care on each other's quality of life. The study involves completion of questionnaires at two different time-points.

If you have any objections to your patient participating in the above study, please get in touch with me on the contact details below and I would be happy to discuss further.

Yours sincerely,
Robert Thomson (Researcher)
Tel 07725440402
E-mail: Robert. Thomson@stir.ac.uk

Version 02 February 2017

Appendix 22: Recruitment and data collection table



NHS Greater Glasgow and Clyde

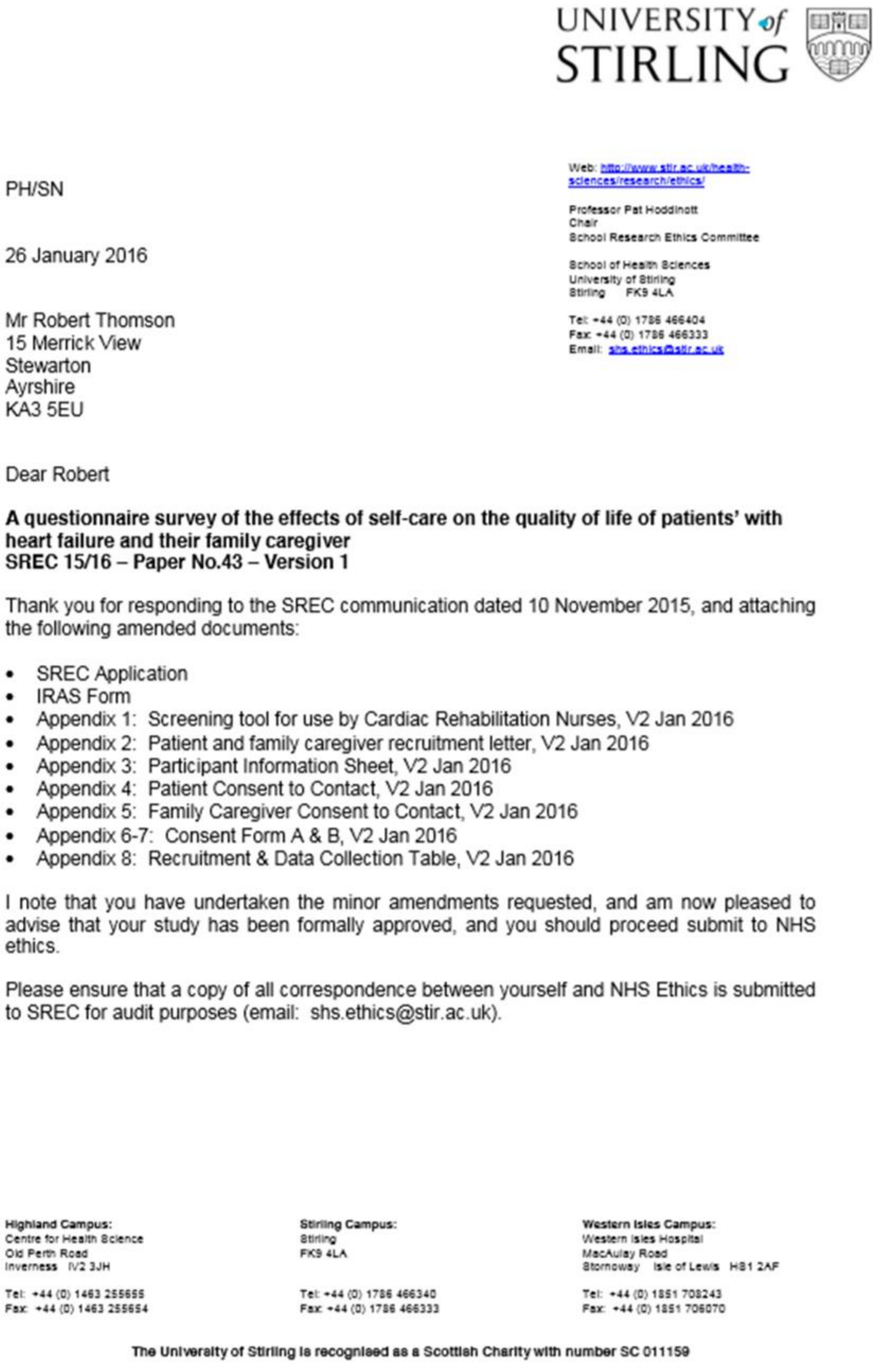
University of Stirling

NHS Ayrshire & Arran

Recruitment and data collection table

1. Deliver recruitment packs (Participant Information Sheet; Recruitment letter and consent to contact form) to cardiac specialist nurses for distribution to eligible patients.
2. Await contact from cardiac specialist nurses if patient wishes to be consented during in –patient stay; await returned *consent to contact* forms if patient wishes to be consented following hospital discharge
3. 1 reminder will be sent if no return of consent to contact forms. If no return after reminder, assume patient/family caregiver not interested, and no further contact will be made.
TIME POINT 1 DATA COLLECTION
3. Arrange convenient date and time to meet patient-family caregiver during in-patient stay; arrange convenient time to meet at patient-family caregiver's home following discharge.
4. Discuss study; answer questions; ask dyads to sign consent form if interested.
5. If interested, issue questionnaire booklets.
6. Reminder telephone call if questionnaire booklets are not returned after a period of 2 weeks for dyads consenting at home
7. Commence data analysis once completed questionnaire booklets have been returned.
TIME POINT 2 DATA COLLECTION
7. Reminder telephone call prior to follow up period at 6 months.
8. Post questionnaire booklets separately to dyads home address.
9. Reminder telephone call if questionnaire booklets are not returned after a period of 2 weeks.
10. Commence data analysis once time point 2 questionnaire booklets have been returned.

Appendix 23: SREC Approval Letter



UNIVERSITY of STIRLING

Web: http://www.stir.ac.uk/health-sciences/research/ethics/

Professor Pat Hoddinott
Chair
School Research Ethics Committee

School of Health Sciences
University of Stirling
Stirling FK9 4LA

Tel: +44 (0) 1786 466404
Fax: +44 (0) 1786 466333
Email: shs.ethics@stir.ac.uk

PH/SN

26 January 2016

Mr Robert Thomson
15 Merrick View
Stewarton
Ayrshire
KA3 5EU

Dear Robert

A questionnaire survey of the effects of self-care on the quality of life of patients' with heart failure and their family caregiver
SREC 15/16 – Paper No.43 – Version 1

Thank you for responding to the SREC communication dated 10 November 2015, and attaching the following amended documents:

- SREC Application
- IRAS Form
- Appendix 1: Screening tool for use by Cardiac Rehabilitation Nurses, V2 Jan 2016
- Appendix 2: Patient and family caregiver recruitment letter, V2 Jan 2016
- Appendix 3: Participant Information Sheet, V2 Jan 2016
- Appendix 4: Patient Consent to Contact, V2 Jan 2016
- Appendix 5: Family Caregiver Consent to Contact, V2 Jan 2016
- Appendix 6-7: Consent Form A & B, V2 Jan 2016
- Appendix 8: Recruitment & Data Collection Table, V2 Jan 2016

I note that you have undertaken the minor amendments requested, and am now pleased to advise that your study has been formally approved, and you should proceed submit to NHS ethics.

Please ensure that a copy of all correspondence between yourself and NHS Ethics is submitted to SREC for audit purposes (email: shs.ethics@stir.ac.uk).

Highland Campus:
Centre for Health Science
Old Perth Road
Inverness IV2 3JH

Tel: +44 (0) 1463 255655
Fax: +44 (0) 1463 255654

Stirling Campus:
Stirling
FK9 4LA

Tel: +44 (0) 1786 466340
Fax: +44 (0) 1786 466333

Western Isles Campus:
Western Isles Hospital
MacAulay Road
Stornoway Isle of Lewis HS1 2AF

Tel: +44 (0) 1851 708243
Fax: +44 (0) 1851 706070

May I remind you of the need to inform SREC prior to making any amendments to this protocol, of any changes to the duration of the project and provide notification of study completion. A site file of all documents related to the research should be maintained throughout the life of the project, and kept up to date at all times. The site file template can be found on the SREC page of the School's website.
http://www.stir.ac.uk/health-sciences/research/ethics/

Please bear in mind that your study could be audited for adherence to research governance and research ethics protocols.

Ref: SREC 15/16 – Paper No.43 – Version 1
Please quote this number on all correspondence

Yours sincerely

Pat Hoddinott

PROF. PAT HODDINOTT
(Chair)
School of Health Sciences Research Ethics Committee

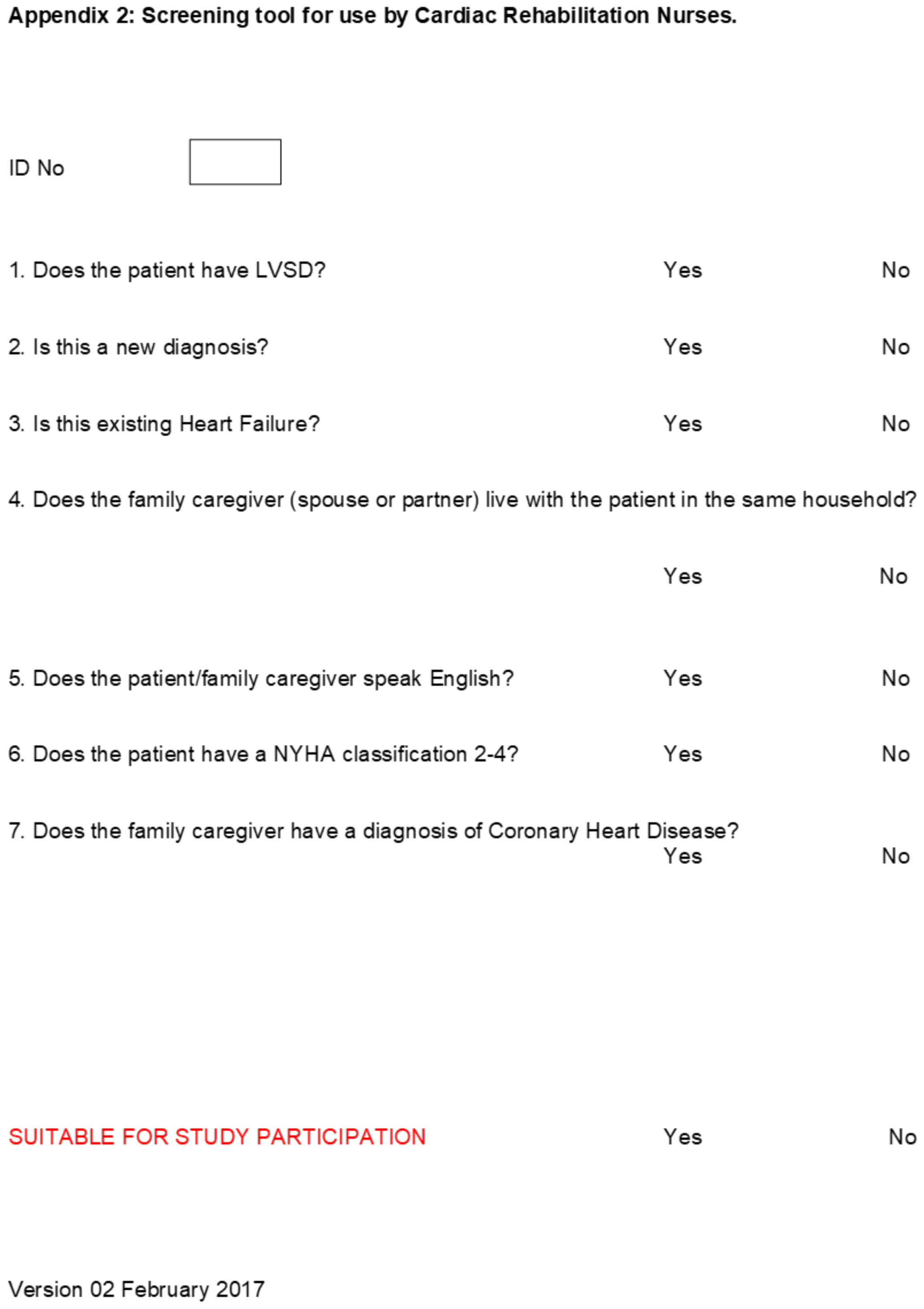
Cc Dr Pat Thomson, Supervisor
Dr Josie Evans, Supervisor

Appendix 24: Screening Tool for use by Cardiac Rehab Nurses

NHS
Greater Glasgow and Clyde

UNIVERSITY OF STIRLING

NHS
Ayrshire & Arran



Appendix 2: Screening tool for use by Cardiac Rehabilitation Nurses.

ID No ☐

1. Does the patient have LVSD? Yes No

2. Is this a new diagnosis? Yes No

3. Is this existing Heart Failure? Yes No

4. Does the family caregiver (spouse or partner) live with the patient in the same household?

Yes No

5. Does the patient/family caregiver speak English? Yes No

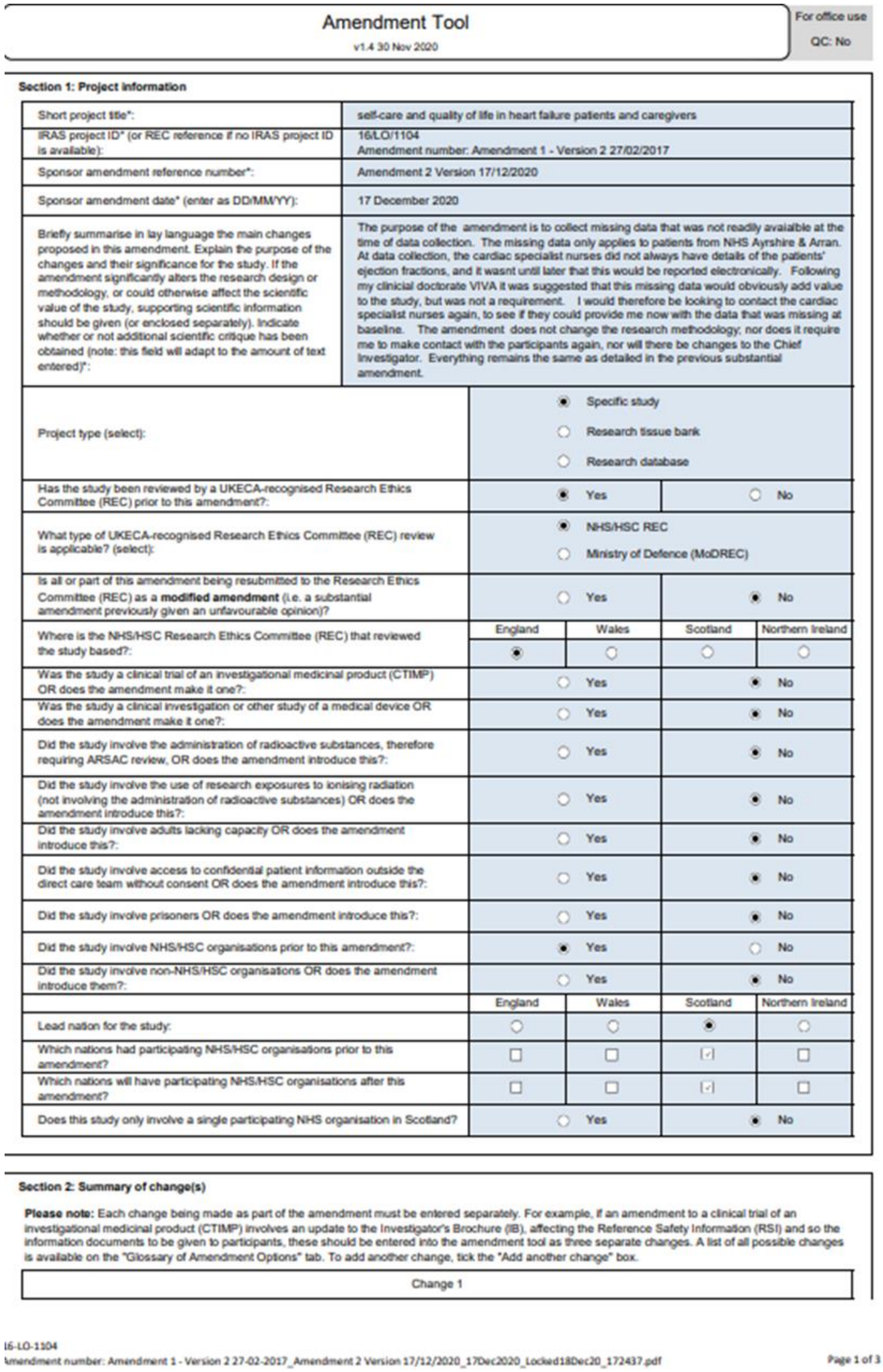
6. Does the patient have a NYHA classification 2-4? Yes No

7. Does the family caregiver have a diagnosis of Coronary Heart Disease?
Yes No

SUITABLE FOR STUDY PARTICIPATION Yes No

Version 02 February 2017

Appendix 25: Amendment Tool v1.4 30 November 2020 NHS/HSC REC



Amendment Tool
v1.4 30 Nov 2020

For office use
QC: No

Section 1: Project information

Short project title*:	self-care and quality of life in heart failure patients and caregivers
IRAS project ID* (or REC reference if no IRAS project ID is available):	16/LO/1104 Amendment number: Amendment 1 - Version 2 27/02/2017
Sponsor amendment reference number*:	Amendment 2 Version 17/12/2020
Sponsor amendment date* (enter as DD/MM/YY):	17 December 2020
Briefly summarise in lay language the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study. If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained (note: this field will adapt to the amount of text entered)*:	The purpose of the amendment is to collect missing data that was not readily avaialble at the time of data collection. The missing data only applies to patients from NHS Ayrshire & Arran. At data collection, the cardiac specialist nurses did not always have details of the patients' ejection fractions, and it wasnt until later that this would be reported electronically. Following my clinicial doctorate VIVA it was suggested that this missing data would obviously add value to the study, but was not a requirement. I would therefore be looking to contact the cardiac specialist nurses again, to see if they could provide me now with the data that was missing at baseline. The amendment does not change the research methodology; nor does it require me to make contact with the participants again, nor will there be changes to the Chief Investigator. Everything remains the same as detailed in the previous substantial amendment.

Project type (select):	● Specific study ○ Research tissue bank ○ Research database			
Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	● Yes		○ No	
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select):	● NHS/HSC REC ○ Ministry of Defence (MoDREC)			
Is all or part of this amendment being resubmitted to the Research Ethics Committee (REC) as a **modified amendment** (i.e. a substantial amendment previously given an unfavourable opinion)?	○ Yes		● No	
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	England	Wales	Scotland	Northern Ireland
	●	○	○	○
Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	○ Yes		● No	
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	○ Yes		● No	
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	○ Yes		● No	
Did the study involve the use of research exposures to ionising radiation (not involving the administration of radioactive substances) OR does the amendment introduce this?:	○ Yes		● No	
Did the study involve adults lacking capacity OR does the amendment introduce this?:	○ Yes		● No	
Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:	○ Yes		● No	
Did the study involve prisoners OR does the amendment introduce this?:	○ Yes		● No	
Did the study involve NHS/HSC organisations prior to this amendment?:	● Yes		○ No	
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	○ Yes		● No	
	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	○	○	●	○
Which nations had participating NHS/HSC organisations prior to this amendment?	☐	☐	☑	☐
Which nations will have participating NHS/HSC organisations after this amendment?	☐	☐	☑	☐
Does this study only involve a single participating NHS organisation in Scotland?	○ Yes		● No	

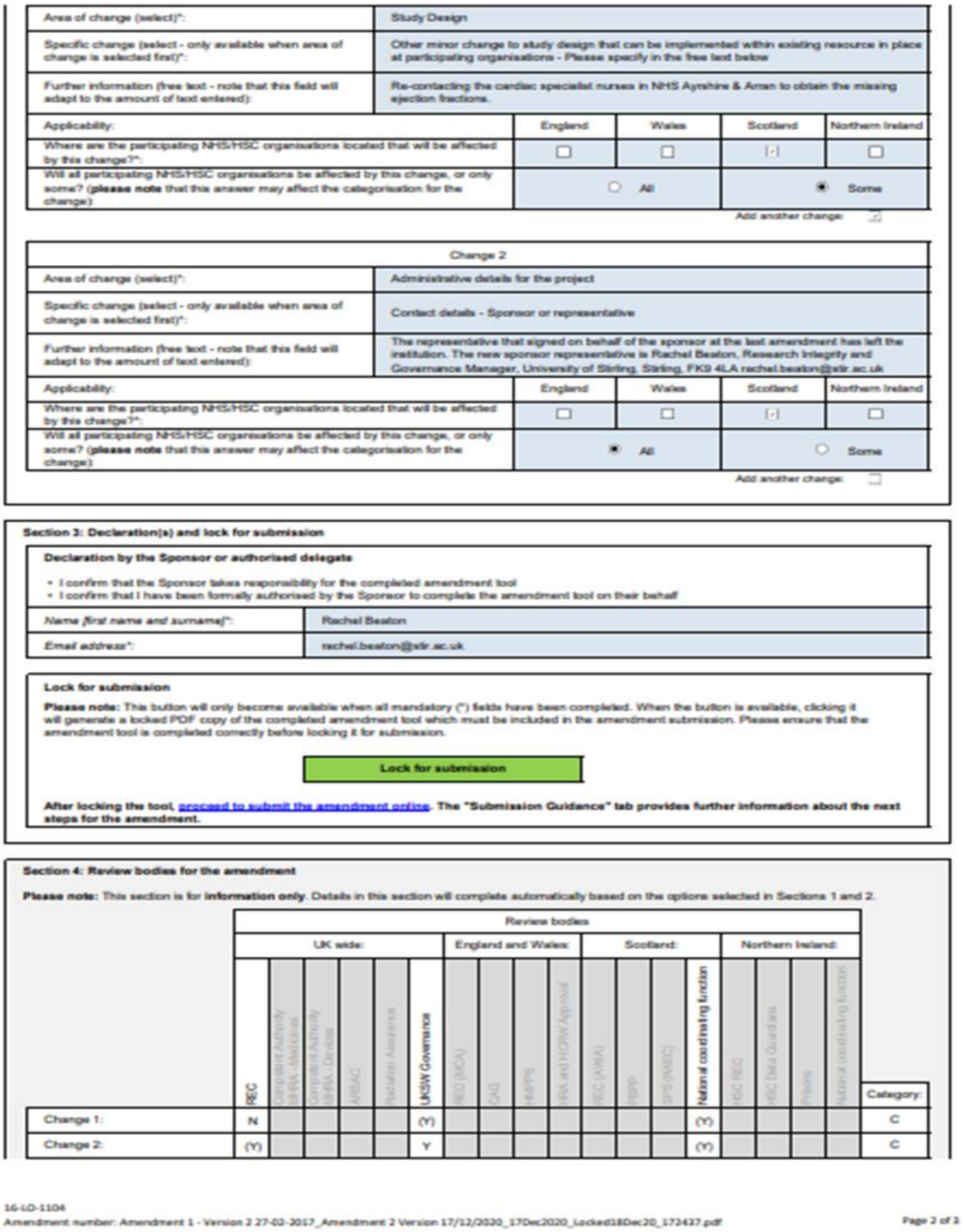
Section 2: Summary of change(s)

Please note: Each change being made as part of the amendment must be entered separately. For example, if an amendment to a clinical trial of an investigational medicinal product (CTIMP) involves an update to the Investigator's Brochure (IB), affecting the Reference Safety Information (RSI) and so the information documents to be given to participants, these should be entered into the amendment tool as three separate changes. A list of all possible changes is available on the "Glossary of Amendment Options" tab. To add another change, tick the "Add another change" box.

Change 1

16-LO-1104
mendment number: Amendment 1 - Version 2 27-02-2017_Amendment 2 Version 17/12/2020_17Dec2020_Locked18Dec20_172437.pdf

Page 1 of 3



Area of change (select)*:	Study Design
Specific change (select - only available when area of change is selected first)*:	Other minor change to study design that can be implemented within existing resource in place at participating organisations - Please specify in the free text below
Further information (free text - note that this field will adapt to the amount of text entered):	Re-contacting the cardiac specialist nurses in NHS Ayrshire & Arran to obtain the missing ejection fractions.

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☐	☐	☑	☐
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	○ All		● Some	

Add another change: ☑

Change 2	
Area of change (select)*:	Administrative details for the project
Specific change (select - only available when area of change is selected first)*:	Contact details - Sponsor or representative
Further information (free text - note that this field will adapt to the amount of text entered):	The representative that signed on behalf of the sponsor at the last amendment has left the institution. The new sponsor representative is Rachel Beaton, Research Integrity and Governance Manager, University of Stirling, Stirling, FK9 4LA rachel.beaton@stir.ac.uk

Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	☐	☐	☑	☐
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	● All		○ Some	

Add another change: ☐

Section 3: Declaration(s) and lock for submission

Declaration by the Sponsor or authorised delegate

- I confirm that the Sponsor takes responsibility for the completed amendment tool
- I confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf

Name (first name and surname):	Rachel Beaton
Email address:	rachel.beaton@stir.ac.uk

Lock for submission

Please note: This button will only become available when all mandatory (*) fields have been completed. When the button is available, clicking it will generate a locked PDF copy of the completed amendment tool which must be included in the amendment submission. Please ensure that the amendment tool is completed correctly before locking it for submission.

Lock for submission

After locking the tool, proceed to submit the amendment online. The "Submission Guidance" tab provides further information about the next steps for the amendment.

Section 4: Review bodies for the amendment

Please note: This section is for **information only**. Details in this section will complete automatically based on the options selected in Sections 1 and 2.

	Review bodies																		
	UK wide:						England and Wales:				Scotland:				Northern Ireland:				
	REC	Competent Authority MHRA - Medicines	Competent Authority MHRA - Devices	ARSAC	Radiation Assurance	UKSW Governance	REC (MCA)	CAG	HMPPS	HRA and HCRW Approval	REC (AWA)	PBPP	SPS (RAEC)	National coordinating function	HSC REC	HSC Data Guardians	Prisons	National coordinating function	Category:
Change 1:	N					(Y)								(Y)					C
Change 2:	(Y)					Y								(Y)					C

16-LO-1104
Amendment number: Amendment 1 - Version 2 27-02-2017_Amendment 2 Version 17/12/2020_17Dec2020_Locked18Dec20_172437.pdf

Page 2 of 3

Appendix 26: Sponsorship Letter

UNIVERSITY of STIRLING

Rachel Beaton
Research Integrity and Governance Manager

Research and Innovation Services
University of Stirling
Stirling FK9 4LA
Scotland UK

T : +44 (0) 1786 466196
E : rachel.beaton@stir.ac.uk
W : www.stir.ac.uk

18 December 2020

To Whom It May Concern

Research Study: A questionnaire survey of the effects of self-care on the Quality of Life of patients with Heart Failure and their family caregiver

I am pleased to confirm that the University of Stirling will undertake the role of sponsor as outlined in the UK Policy Framework on Health and Social Care Research for the project entitled "A questionnaire survey of the effects of self-care on the Quality of Life of patients with Heart Failure and their family caregiver" Chief Investigator Robert Thomson, Faculty of Health Sciences and Sport, University of Stirling.

Yours sincerely

R Beaton

Rachel Beaton
Research Integrity and Governance Manager

The University of Stirling is a charity registered in Scotland, number SC 011159.

BE THE DIFFERENCE

Appendix 27: IRAS approval notification of amendment

IRAS 165845 - notification of an amendment

GRAM Nrspcc <gram.nrspcc@nhs.scot>
Thu 14/01/2021 08:13

To: rachel.beaton@stir.ac.uk <rachel.beaton@stir.ac.uk>; RandDProjectTeam@aapct.scot.nhs.uk <RandDProjectTeam@aapct.scot.nhs.uk>; Karen Bell (Karen.Bell2@aapct.scot.nhs.uk) <Karen.Bell2@aapct.scot.nhs.uk>

Good morning,

IRAS Project ID:	165845
Short Study Title:	Self-care and quality of life in Heart Failure (HF)
Amendment No./Sponsor Ref:	Amendment 2 Version 17/12/2020
Amendment Date:	17.12.20
Overall Amendment Type:	Non-Substantial
Amendment category and implementation date for NHS/HSC organisations in Northern Ireland and/or Scotland:	Category C, can be implemented immediately **(providing conditions are met).**

I am pleased to confirm that your amendment documentation is complete and implementation information is above.
If not already provided, please email to us any regulatory approvals (where applicable) once available.
This amendment has been shared with participating R&D departments.

User Feedback
We are continually striving to provide a high-quality service to all applicants and sponsors. You are invited to give your views on the amendment process through the amendment process survey.
Please do not hesitate to contact me if you require further information.

Kind regards,
Kalyar

Kalyar Lwin
Senior Administrator
NRS Permissions Coordinating Centre
Foresterhill House Annexe
Aberdeen
Email: gram.nrspcc@nhs.scot
**** I am currently working remotely with no access to office phone line ****

Appendix 28: SCHFI individual questions scale

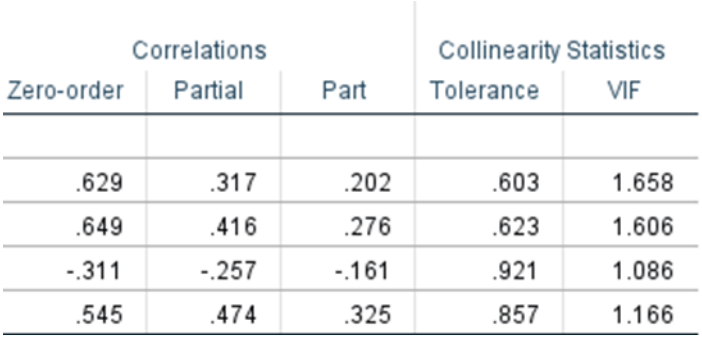
Patient Self-care Maintenance Questions	**Mean TP1**	**(SD)**	**Mean TP2**	**(SD)**
1) Weigh yourself?	2.63	1.20	2.78	0.94
2) Check your ankles for swelling	2.96	1.06	3.21	0.75
3) Try to avoid getting sick?	2.64	0.97	2.79	1.09
4) Do some physical activity?	2.03	1.11	2.02	1.11
5) See your doctor or nurse?	3.65	0.78	3.75	0.67
6) Eat a low salt diet?	2.51	1.19	2.48	1.05
7) Exercise for 30 minutes?	1.71	0.99	1.67	1.03
8) Forget to take one of your medicines?	1.51	0.91	1.30	0.66
9) Ask for low salt items while eating out or visiting others?	1.25	0.55	1.32	0.76
10) Use a system to help you remember to take your pills?	2.42	1.39	2.36	1.41
Patient Self-care Management Questions				
11) How quickly did you recognize it as a symptom of heart failure?	1.76	1.27	1.86	1.19
12) Reduce the salt in your diet	2.09	1.15	2.21	1.17
13) Reduce your fluid intake	2.23	1.11	2.40	1.16
14) Take an extra water pill	1.88	1.11	2.23	1.13
15) Call your doctor or nurse for guidance	3.01	1.17	2.97	1.15
16) How sure were you that the remedy helped or did not help?	1.48	1.26	1.52	1.30
Patient Self-care Confidence Questions				
17) Keep yourself free of heart failure symptoms?	1.76	0.87	1.84	0.89
18) Follow the treatment advice you have been given?	3.00	0.94	3.21	0.78
19) Evaluate the importance of your symptoms?	2.53	0.91	2.68	0.97
20) Recognize changes in your health if they occur?	2.82	0.83	3.00	0.76
21) Do something that will relieve your symptoms?	2.25	0.96	2.39	0.97
22) Evaluate how well a remedy works?	2.19	1.01	2.21	0.94

Appendix 29: CCSCHFI individual questions scale

Caregiver Contribution to Self-care Maintenance Questions	**Mean TP1**	**(SD)**	**Mean TP2**	**(SD)**
How often do you recommend that the person you care for do the following things?				
1) Weigh themselves?	1.78	0.95	2.05	1.16
2) Check their ankles for swelling?	2.19	0.95	2.27	1.06
3) Try to avoid them getting sick?	2.25	1.16	2.37	1.07
4) Do some physical activity?	1.90	0.93	1.97	0.99
5) See their doctor or nurse?	2.76	1.27	2.65	1.33
6) Eat a low salt diet?	1.94	0.99	1.79	0.89
7) Exercise for 30 minutes?	1.65	0.92	1.61	0.87
8) Remember to take medicine	1.92	1.04	2.07	1.20
9) Ask for low salt items while eating out or visiting others?	1.38	0.74	1.45	0.84
10) Use a system to help them remember to take their pills?	1.76	1.14	2.02	1.24
Caregiver Contribution to Self-care Management Questions				
11) If the person you care for had trouble breathing or ankle swelling, how quickly did you recognize it as a symptom of heart failure?	2.05	1.43	1.87	1.24
If the person you care for has trouble breathing or ankle swelling, how likely are you to recommend (or do) one of the following remedies?				
12) Reduce the salt in their diet	2.39	1.15	2.38	1.12
13) Reduce their fluid intake	2.21	1.15	2.36	1.01
14) Give an extra water pill	2.07	1.16	2.22	1.12
15) Call their doctor or nurse for guidance	3.05	1.03	3.26	1.07
16) How sure were you that the remedy helped or did not help?	1.63	1.26	1.63	1.26
Caregiver Contribution to Self-care Confidence Questions				
In reference to the person you care for, how confident are you that you can				
17) Prevent heart failure symptoms?	1.57	0.84	1.60	0.74
18) Follow the treatment advice?	2.98	0.87	3.17	1.64
19) Evaluate the importance of HF symptoms?	2.63	0.97	2.65	0.89
20) Recognize health changes in the person you care for?	2.82	0.75	2.90	0.81
21) Do something that will relieve HF symptoms?	2.30	1.00	2.22	0.99
22) Evaluate how well a remedy works?	2.19	0.97	2.20	0.97

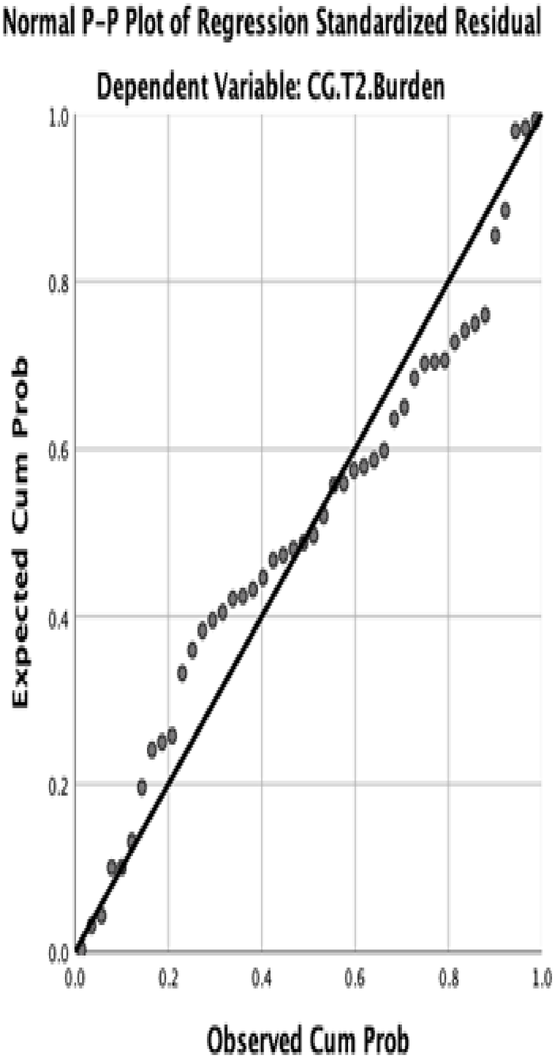
Appendix 30: Tests of Multi-collinearity

Final Regression Model 3

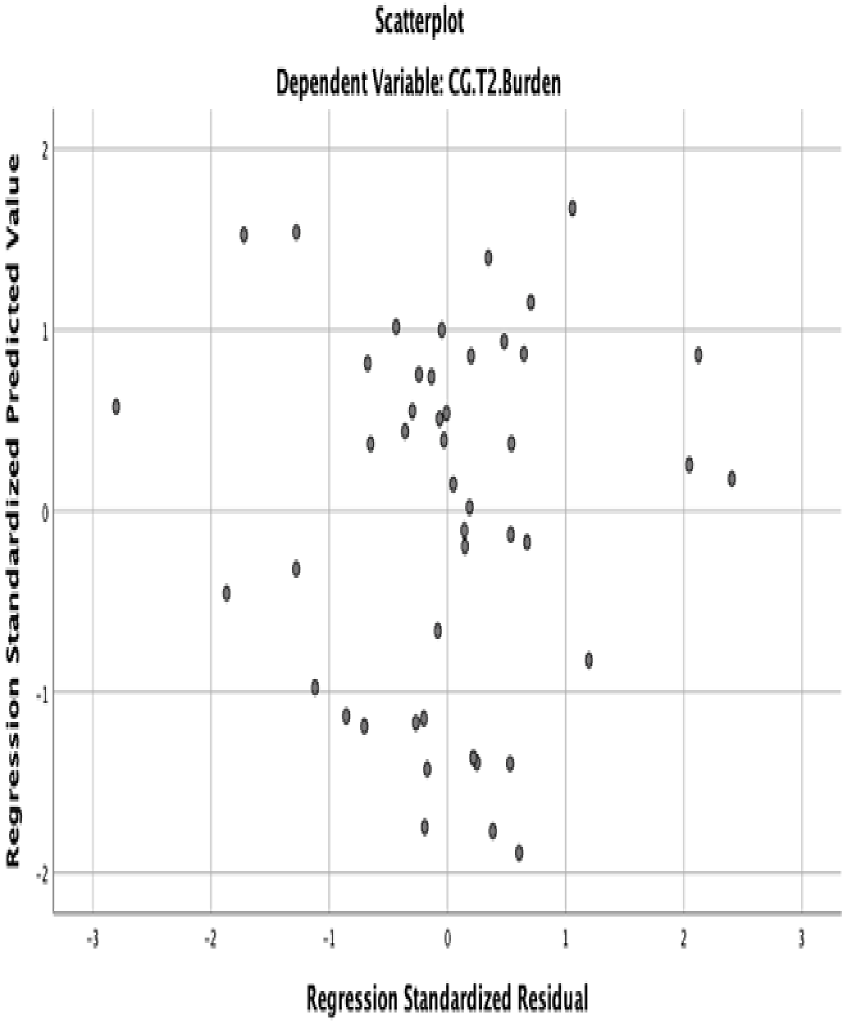


Correlations			Collinearity Statistics	
Zero-order	Partial	Part	Tolerance	VIF
.629	.317	.202	.603	1.658
.649	.416	.276	.623	1.606
-.311	-.257	-.161	.921	1.086
.545	.474	.325	.857	1.166

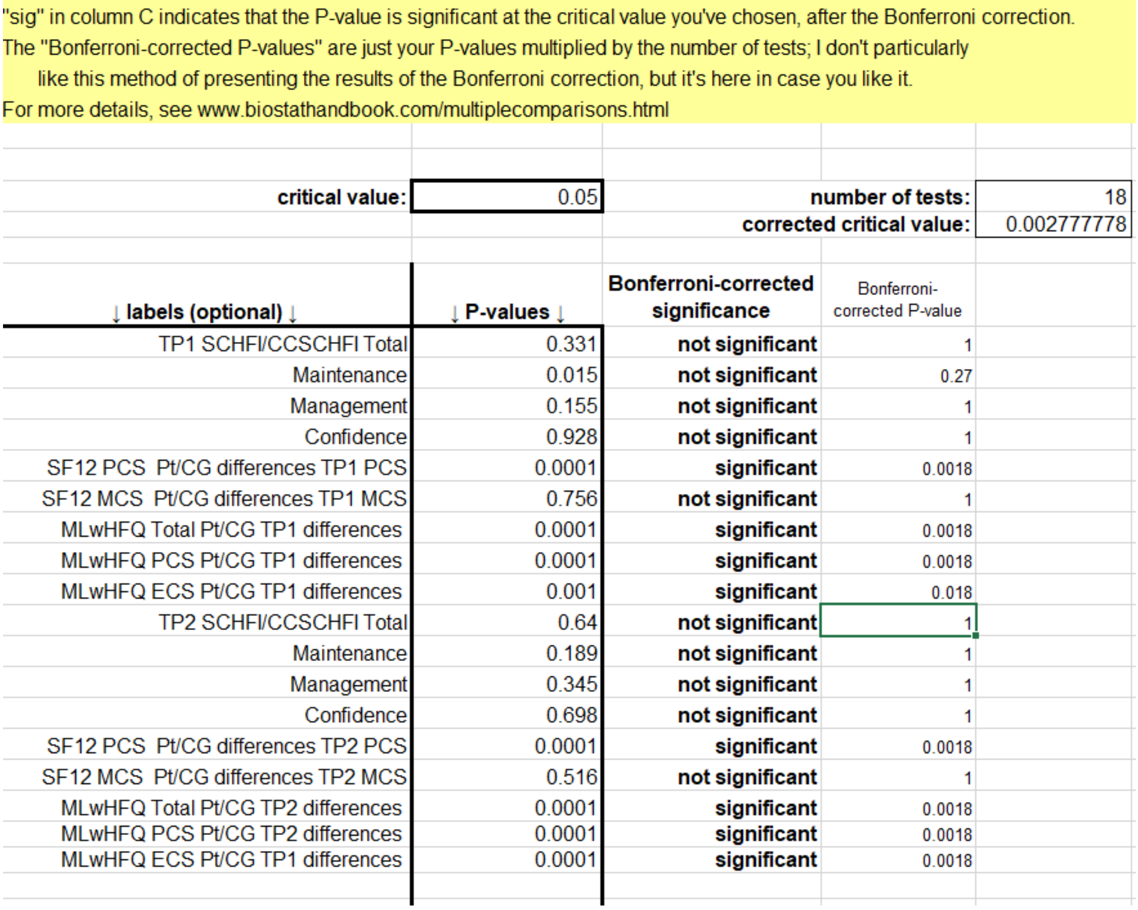
Appendix 31: P-P Plot Caregiver Burden (TP2)



Appendix 32: Scatterplot Caregiver Burden (TP2)



Appendix 33: Bonferroni adjustment for multiple comparisons



"sig" in column C indicates that the P-value is significant at the critical value you've chosen, after the Bonferroni correction.
The "Bonferroni-corrected P-values" are just your P-values multiplied by the number of tests; I don't particularly
like this method of presenting the results of the Bonferroni correction, but it's here in case you like it.
For more details, see www.biostathandbook.com/multiplecomparisons.html

critical value: 0.05

number of tests: 18

corrected critical value: 0.002777778

↓ labels (optional) ↓	↓ P-values ↓	Bonferroni-corrected significance	Bonferroni-corrected P-value
TP1 SCHFI/CCSCHFI Total	0.331	not significant	1
Maintenance	0.015	not significant	0.27
Management	0.155	not significant	1
Confidence	0.928	not significant	1
SF12 PCS Pt/CG differences TP1 PCS	0.0001	significant	0.0018
SF12 MCS Pt/CG differences TP1 MCS	0.756	not significant	1
MLwHFQ Total Pt/CG TP1 differences	0.0001	significant	0.0018
MLwHFQ PCS Pt/CG TP1 differences	0.0001	significant	0.0018
MLwHFQ ECS Pt/CG TP1 differences	0.001	significant	0.018
TP2 SCHFI/CCSCHFI Total	0.64	not significant	1
Maintenance	0.189	not significant	1
Management	0.345	not significant	1
Confidence	0.698	not significant	1
SF12 PCS Pt/CG differences TP2 PCS	0.0001	significant	0.0018
SF12 MCS Pt/CG differences TP2 MCS	0.516	not significant	1
MLwHFQ Total Pt/CG TP2 differences	0.0001	significant	0.0018
MLwHFQ PCS Pt/CG TP2 differences	0.0001	significant	0.0018
MLwHFQ ECS Pt/CG TP1 differences	0.0001	significant	0.0018

Appendix 34: Draft research article of study findings

“Longitudinal effects of self-care (and baseline quality of life) on quality of life outcomes in patients with heart failure and their family caregivers”.

BMC: HEALTH & QoL OUTCOMES: Research Article

Abstract

Purpose

1) to examine the effects of self-care on quality-of-life outcomes in patients with HF and their family caregivers (dyads) at 6 months.

Method

A multifactorial, exploratory longitudinal study was carried outwith 46 patient–caregiver dyads (80.4% male patients and 80.4% female caregivers) completed the SF-12 UK Health Survey; Minnesota Living with Heart Failure Questionnaire, Self-Care of Heart Failure Index; Caregiver Contribution to Heart Failure Self-Care Index at baseline and 6 months later.

Results

There were statistically significant differences between patients’ and caregivers’ self-care maintenance at TP1, which suggested that patients were contributing more to self-care than their caregivers were assisting them. Statistically significant differences were also found between patients’ and caregivers’ overall quality of life (MLwHFQ total), physical health (SF-12 PCS; MLwHFQ PCS) and emotional health (MLwHFQ ECS) at time-point one and time-point two. This suggested that patients’ quality of life was poorer than their caregivers. However, patients’ and caregivers’ mental health were similarly affected and were both below the general population.

Several statistically significant *actor* and *partner effects* were found. Patients’ and caregivers’ contribution to self-care was associated with their own physical and mental health-related quality of life at the 6-month follow-up (*actor effects*). Further, the patient’s self-care was associated with the caregiver’s physical and mental health-related quality of life at 6 months and vice versa (*partner effects*).

Conclusion

This is the first known study that has measured these outcomes longitudinally using the Actor-Partner-Interdependence Model (APIM), which has further developed our understanding of the interdependence of the spousal/cohabiting patient–caregiver dyadic relationship. The specific self-care domains that predict physical and mental health-related quality of life (*actor* and *partner* effects) in the dyad should be examined fully prior to hospital discharge and the appropriate supportive measures identified.

Introduction

Heart Failure (HF) is a complex, progressive syndrome and is recognised as being disabling and deadly and impacts on the patient's ability to self-care (McDonagh et al., 2011; McMurray et al., 2012). Caregivers are pivotal in supporting this, but often their own health is affected, and the burden associated with caregiving is often influenced by certain patient and caregiver characteristics, as well as patients' engagement and caregivers' contribution to self-care (Luttick et al., 2007; Hooley et al., 2005; Iqbal et al., 2010).

Self-care has been recognised as the cornerstone to effective HF management and has been associated with a reduction in the risk of potential decompensation and the "revolving door" scenario that many HF patients face (Jaarsma et al., 2013). However, despite its association with improved outcomes, it remains suboptimal, and the reasons are inconsistently reported in the HF literature (Jaarsma et al., 2013, Riegel et al., 2009; Moser et al., 2012). Due to the demands placed on HF patients, their physical, social and psychological functioning can be severely compromised, which often results in poor self-care, greater depressive symptoms and impaired quality of life (Chung et al., 2013; Heo et al., 2014; Riegel et al., 2009). The importance of perceived social support has been recognised, and the most influential support is provided by a family member (Dunbar et al., 2008). Indeed, Luttick et al. (2005) and Gallagher et al. (2011) suggests that adequate social support results in greater adherence to the prescribed treatment regime, including medication adherence, fluid intake and essential immunisations. Further, Gallagher et al.'s (2011) cross-sectional study identified a statistically significant association between support provided from a partner and overall improved self-care.

Whilst previous heart failure research has examined relationships between couples for decades, there is a paucity of studies that exist that examine specifically the interdependence of heart failure patient–caregiver dyads (Agren et al., 2011; Chung et al., 2009 & Vellone et al., 2014). Dyadic incongruence was reported in a study by Cameron et al. (2017) who found that patient and caregivers who disagreed on HF related issues were at risk of poor mental health and self-care. Chung et al.'s (2009) cross-sectional study used the APIM to assess the effects of depression and anxiety on quality-of-life outcomes in patient–caregiver dyads. Depressive symptoms influenced each other's quality of life (*actor effects*) and only the caregiver's depressive symptoms influenced the patient's quality of life (*partner effect*). The APIM approach has been used widely in general health research (& Driscoll et al., 2012) and in studies of HF dyads (Chung et al., 2009; Vellone et al., 2014; Thomson et al., 2020). The *actor effect* refers to the impact of an individual's characteristics, i.e., the patient's self-care (or caregiver's contribution to self-care) on their own quality of life. The *partner effect* refers to the impact of an individual's characteristics, i.e., the patient's self-care (or caregiver's contribution to self-care) on his or her partner's quality of life. Vellone et al.'s (2014) was the only known cross-sectional study that assessed the influence of self-care on quality of life domains using the APIM, but was limited due to the cross-sectional design, which prevented causal relationships from being identified.

2. Method

2.1 Study design

This study was a multifactorial, exploratory longitudinal study. Patients with heart failure and their family caregivers were recruited from two geographically different areas in Scotland.

2.2 Setting and participants

Data were collected by using convenience sampling and commenced in 2016 until February, 2018. Patients were deemed eligible if they were between the ages of 45-90 years, diagnosed with HF (new or existing) confirmed by echocardiography NYHA classification II-IV, resided with their family caregiver and were in a marital or cohabiting relationship. Both patients and family caregivers were excluded if they were unable to read or speak English, had diagnosed psychological or neurological conditions and the caregivers had a personal history of cardiovascular disease.

2.3 Ethical considerations

The study was approved by the University of Stirling's Research and Ethics Committee and the National Research and Ethics Committee (NRES), South East Coast, Surrey (Rec Ref 16/LO/1104) (IRAS project ID: 165845).

2.4 Procedure

Patients were first approached by the cardiac specialist nurses to consider their participation in the study, and the patients approached their family caregiver for their participation. To be eligible, both the patient and their caregiver had to consent, and were given to options 1) to be contacted by the Investigator during the patient's in-hospital stay or 2) following their discharge home from hospital. If the preferred approach was on discharge, contact was made with the patient and family caregiver on receipt of two signed Consent to Contact forms. Once consent was gained, both members of the dyad were advised to complete and return the questionnaires. A reminder telephone call was made after two weeks if the questionnaires had not been returned. The same questionnaires were sent to the dyads at the 6-month follow-up and a reminder telephone call was given a few weeks prior to sending the questionnaires, to ensure continued study participation. Both patients and caregivers were advised to complete the questionnaires independently of each other.

2.5 Instruments

The SF12 Health Survey was used to measure both patients' and family caregivers' perceived health status (Ware et al., 1998; Jenkinson & Layte, 1997). The SF12 version 2 is a brief measure of perceived physical and mental health and has been referred to frequently in the general cardiovascular literature and has also been used within HF cross-sectional studies (Vellone et al., 2014). Ware et al. (1998) and Thomson et al. (2011) highlight that the validity and reliability of the SF12 is comparable with the SF36 survey by the use of alpha coefficients. In this study, the alpha co-efficient for PCS was 0.72 and MCS 0.73 . Higher scores in the SF12 were associated with better quality of life.

In order to measure patient specific symptoms and quality of life in HF, the **Minnesota Living with Heart Failure Questionnaire (MLHFQ)** was chosen for use in this study because it was disease-specific (Rector, 2004) and unlike the SF12 survey, it would assess the patients' perceptions of HF and establish how it affects their physical, socioeconomic and psychological needs. The questionnaire has 21 items and uses a six-point Likert scale, which ranges from 0 – 5; 0 suggesting no impact on quality of life and 5 suggesting that quality of life is significantly impacted. Rector (2004) summarisies the questionnaire and indicates that the total score for the 21 items can range from 0-105; a higher score indicates that the HF symptoms impact on a patient's quality of life negatively. The Physical Component Score (PCS) ranges from (0-40) and the Emotional Component Score (ECS) ranges from (0-25), and like the overall score, a higher score indicates poorer quality of life. Good internal validity was reported in several HF studies (Lee et al., 2014; Goodman et al., 2013; Heo et al. 2005) as well as in patient–caregiver pairs (dyads) (Thomson et al., 2020). The alpha co-efficient for the patients in this study was 0.78, which indicates a strong positive correlation. To use on caregivers, the wording had to be changed in some of the questions, to reflect their own situation and not their partner's. The alpha co-efficient for caregivers in this study demonstrated a strong positive correlation of 0.79, which is similar to HF studies from the UK that used patient–caregiver dyads (Thomson et al., 2020).

The Self-Care of Heart Failure Index (SCHFI) was used to measure self-care in HF patients (Riegel et al., 2004; Riegel et al., 2009), and consists of three sub-scales: self-care maintenance, self-care management and self-care confidence scales. Within the self-care maintenance scale, 10 items measure the patients' self-monitoring and treatment compliance. For example, monitoring weight on a daily basis and ensuring compliance with medication and dietary advice. The self-care management scale (six items) which measures patients' ability to respond promptly to deteriorating symptoms. In addition, it measures treatment implemented after identification of symptoms and the evaluation of such treatment. The self-care confidence scale (six items) primarily measures the level of confidence patients have with regards to symptom recognition. The measure has a 4-point self-report scale; 1 = never or rarely and 4 = always or daily to perform the self-care activity (i.e weighing or checking ankles for signs of oedema). Total scores range from 0-100 - with higher scores indicative of better self-care; self-care adequacy in each of the sub-scales was assessed using a cut-off score of >70 (Riegel et al. 2009). Further, the SCHFI has demonstrated adequate psychometric properties in the US population (Riegel et al., 2009) and similarly in the Italian population (Vellone et al., 2013). The alpha co-efficient in this study was 0.81, which indicates a very strong positive correlation. Like the SCHFI for patients, the **Caregiver Contribution to Self-care Heart Failure Index (CCSCHFI)** measures the caregivers' contribution to self-care maintenance, management and confidence. The index has the same 10 items, measuring the frequency in which caregivers remind patients to monitor their symptoms and comply with treatment. The scale also has the same cut-off score as the SCHFI. Yuxia et al. (2017) reports that the CCSCHFI demonstrates very strong internal consistency and test-retest reliability as the co-effecients for both were > 0.80. In this study, the alpha co-efficient was 0.78 for caregivers.

2.6 Statistical analysis

Descriptive and inferential statistics were used to summarise the patients' and caregivers' socio-demographic characteristics. As the data was non-normally distributed, the non-parametric *t* test (Wilcoxon Signed Rank test) was used to assess for differences between patients' and caregivers' self-care and quality of life at TP1 and TP2 (research question 1). Table 3a and 3b present the median and inter-quartile range (IQR) as part of the descriptive statistics. The IQR was used as it provides the best measure of variability, and when used in conjunction with the measure of central tendency (median), it provides useful information relating to the dispersion of the data (McKenzie, 2013). Whilst a formal sample size calculation was not conducted prior to recruitment in this study, a retrospective power calculation using G Power* was conducted based on Chung et al.'s (2009) dyadic research. Chung et al. (2009) used a sample size of 40, assuming the alpha level of 0.05, the power of regression F-test to detect a significant prediction model for quality of life was approximately 82% in the presence of a medium size and greater than 95% for a large effect size. In this study a large effect size was 91%, medium effects size 54% and small effect size of 11%.

In order to identify the effects of patient self-care and family caregiver contribution to self-care at TP1 on their own and their partner's quality of life at the 6-month follow-up, longitudinal multi-level dyadic regression modelling, using the APIM for distinguishable dyads was used (Kenny et al., 2006). Fifteen separate APIM were computed. For example, the physical component score (SF-12) was regressed for each of the three self-care domains (maintenance, management and confidence), controlling for baseline PCS. Similarly, the mental component score (SF-12) was regressed for each of the three self-care domains, controlling for baseline MCS. The MLwHFQ total score, MLwHFQ PCS and the MLwHFQ ECS was regressed for each of the three self-care domainsm controlling for baseline, MLwHFQ total score, MLwHFQ PCS and MLwHFQ ECS. Figure 1 demonstrates the MLwHFQ ECS being regressed on each of the self-care domains.

For the multi-level dyadic analysis, the data was reorganised to form a pairwise dyadic data set. In order to achieve the pairwise dyadic data set, Kenny et al. (2006) advises the creation of grand-mean centred scores, using *z* scores to obtain standardised and unstandardised regression coefficients – a necessary step to ensuring both *actor* and *partner effects.*

3. Results

3.1 Characteristics of the participants

Fifty-two patient caregiver dyads agreed to participate in the study at baseline (TP1). At TP2 (6 months) *n*=46 patient–caregiver dyads remained in the study. Five of the patients died prior to follow-up and *n*=1 patient–caregiver dyad failed to return the questionnaire, despite a reminder telephone call. Table 1.0 presents the patient and caregiver socio-demographics. The majority of patients in the study were male (80.4%) compared to female patients (19.6%), with 52% of the patients over 70 years old. Consistent with previous HF research (Bidwell et al., 2018) the majority (80.8%) of the caregivers were female and the largest number (30.4%) were aged between 61-70 years. Statistically significant differences were noted between the patients' and caregivers' physical activity levels, with a greater number (58.7%) of patients being "not very active-physically inactive". Further, more than half of the patients were within NYHA classification III and nine (84.8%) of patients had an EF of < 40%, indicating HF with reduced ejection fraction (HFrEF) (Table 2.0). Of the caregivers, (43.5%) reported no health-related issues.

Table 1: Socio-Demographic variables and lifestyle factors for patients and caregivers at baseline (TP1)

		n (%)		
Parameter		Patients	Care Givers	*P*-value
Gender				**<0.0001**
	Male	37 (80.4)	9 (19.6)	
	Female	9 (19.6)	37 (80.4)	
Age				**0.044**
	40-50	2 (4.3)	1 (2.2)	
	51-60	7 (15.2)	12 (26.1)	
	61-70	13 (28.3)	14 (30.4)	
	71-80	17 (37.0)	12 (26.1)	
	81-90	7 (15.2)	7 (15.2)	
Employment				0.583
	Employed	11 (23.9)	13 (28.3)	
	Unemployed	1 (2.2)	0 (0%)	
	Retired	34 (73.9)	33 (71.7)	
Education				**0.008**
	Secondary	31 (67.4)	20 (43.5)	
	Further Education	6 (13.0)	13 (28.3)	
	University	9 (19.6)	13 (28.3)	
Occupation				0.095
	Professional to intermediate	11 (23.9)	15 (32.6)	
	Skilled (no manual, manual)	12 (26.1)	19 (41.3)	
	Partly skilled, non-skilled	23 (50.0)	12 (26.1)	
Deprivation				1
	SIMD 1–3	25 (54.3)	25 (54.3)	
	SIMD 4–5	21 (45.7)	21 (45.7)	
Physical activity				**<0.0001**
	Very – fairly active	19 (41.3)	35 (76.1)	
	Not very active – physically inactive	27 (58.7)	11 (23.9)	
Alcohol intake				0.241
	Zero	19 (41.3)	12 (26.1)	
	< 14 units/week	19 (41.3)	26 (56.5)	
	> 14 units/week	8 (17.4)	8 (17.4)	
Smoking				**1**
	Smoker	6 (13.0)	11 (23.9)	
	Ex-smoker	24 (52.2)	14 (30.4)	
	Never	16 (34.8)	21 (45.7)	
Health issues				
	no issues		20 (43.5)	
	1 issue		15 (32.6)	
	> 1		11 (23.9)	
Marital Status (Married)			45 (96.2)	

*SIMD Scottish Index of Multiple Deprivation

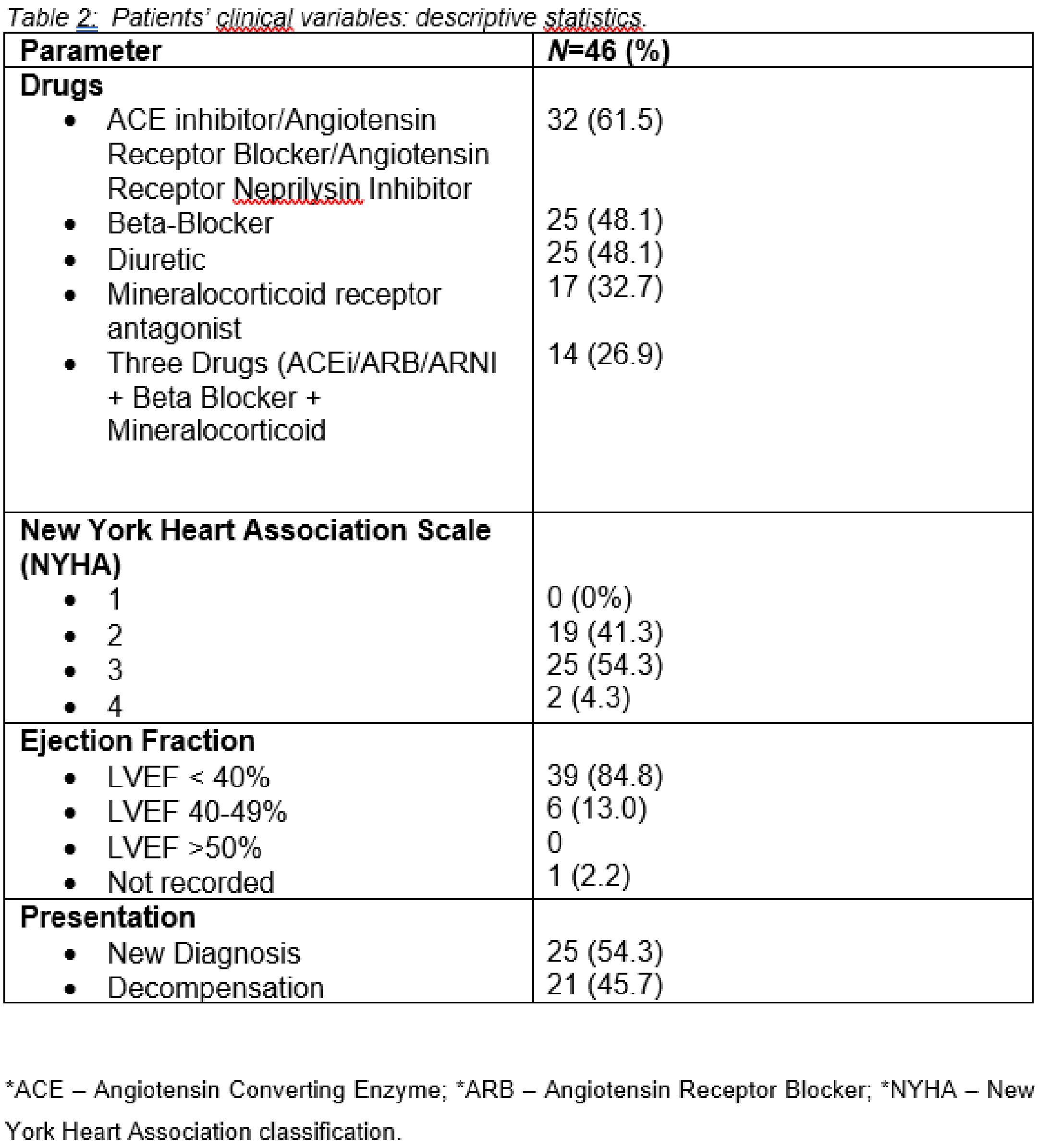


Table 2: Patients' clinical variables: descriptive statistics.

Parameter	***N*=46 (%)**
Drugs	
- ACE inhibitor/Angiotensin Receptor Blocker/Angiotensin Receptor Neprilysin Inhibitor	32 (61.5)
- Beta-Blocker	25 (48.1)
- Diuretic	25 (48.1)
- Mineralocorticoid receptor antagonist	17 (32.7)
- Three Drugs (ACEi/ARB/ARNI + Beta Blocker + Mineralocorticoid	14 (26.9)
New York Heart Association Scale (NYHA)	
- 1	0 (0%)
- 2	19 (41.3)
- 3	25 (54.3)
- 4	2 (4.3)
Ejection Fraction	
- LVEF < 40%	39 (84.8)
- LVEF 40-49%	6 (13.0)
- LVEF >50%	0
- Not recorded	1 (2.2)
Presentation	
- New Diagnosis	25 (54.3)
- Decompensation	21 (45.7)

*ACE – Angiotensin Converting Enzyme; *ARB – Angiotensin Receptor Blocker; *NYHA – New York Heart Association classification.

3.2 Differences between patients' and caregivers' self-care and caregiver contribution to self-care at time-point one and time-point two.

Statistically significant differences were noted for self-care maintenance and caregiver contribution to self-care maintenance (i.e., symptom monitoring and treatment adherence) at time-point one (*p* = 0.001), suggesting that patients were contributing more to their own self-care than their caregivers (Tables 3a and 3b) The scores for both patients and caregivers were both suboptimal and below the recommended threshold of 70 (Cochierri et al., 2015) at both time-points (Tables 3a and 3b). In addition, Tables 4 and 5 highlight the individual items of self-care that patients and caregivers gave least priority to at both time-points, which may explain why the scores are sub-optimal. Within the self-care maintenance domain, patients gave least priority to adhering to dietary recommendations and exercise at both time-points. Least priority was given to evaluating the effectiveness of remedies, recognising HF related symptoms and taking an additional diuretic at both time-points. In the self-care confidence domain, patients were least confident in remaining free of HF symptoms and being confident in the effectiveness of remedies to relieve symptoms at both time-points.

The caregivers gave least priority in the self-care maintenance domain to reminding patients to ask for low salt items when eating out, encouraging exercise and daily weights at both time-points. Least priority was given at both time-points to assessing the effectiveness of remedies and being able to recognise symptoms associated with an episode of decompensation. In the self-care confidence domain, caregivers were least confident in preventing and relieving symptoms, as well as being able to confidently evaluate symptoms.

Table 3a TP1 Differences

Questionnaire	**Patient** **Median**	 **IQR**	**Family Caregiver** **Median**	 **IQR**	***P*-value**
SCHFI/CCSCHFI					
Total score	51.00	(42-57)	48.00	(42-53)	*0.331*
Maintenance	22.00	(19-29)	19.50	(15-23)	***0.015***
Management	13.00	(10-14)	14.00	(11-16)	*0.155*
Confidence	14.50	(10-17)	14.00	(11-17)	*0.928*
SSF-12					
Physical Component Scores	34.96	(31-39)	40.39	(38-46)	**< *0.0001***
Mental Component Scores	46.29	(41-51)	47.42	(42-51)	*0.756*
MLwHFQ					
Total	59.50	(51-75)	29.50	(15-39)	**< *0.0001***
Physical Component Score	29.00	(24-34)	9.50	(5-15)	**< *0.0001***
Emotional Component Score	14.00	(10-19)	10.00	(6-15)	***0.001***

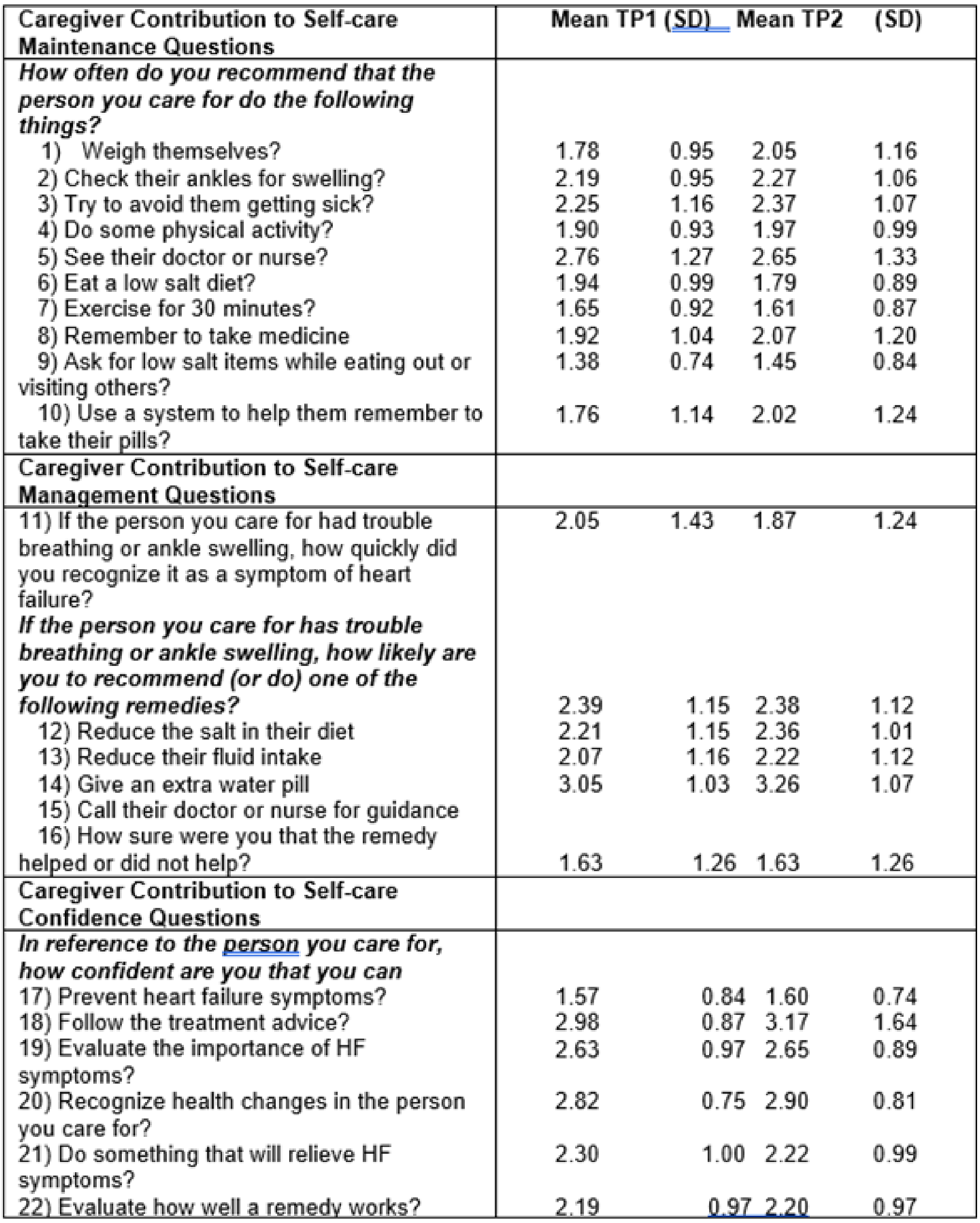
Table 3b TP2 Differences

Questionnaire	**Patient**		**Family Caregiver**		***P*-value**
	Median	**IQR**	**Median**	**IQR**	
SCHFI/CCSCHFI					
Total score	53.00	(47-55)	54.00	(46-57)	*0.640*
Maintenance	22.00	(20-27)	21.00	(16-24)	*0.189*
Management	12.00	(11-17)	13.50	(12-16)	*0.345*
Confidence	15.00	(13-19)	15.00	(12-18)	*0.698*
SF-12					
Physical Component Scores	35.53	(32-39)	40.95	(37-43)	***< 0.0001***
Mental Component Scores	45.09	(40-50)	46.87	(41-51)	*0.516*
MLwHFQ					
Total	66.50	(30-81)	24.00	(5-42)	***< 0.0001***
Physical Component Score	30.50	(20-37)	8.00	(1-17)	***< 0.0001***
Emotional Component Score	17.50	(9-21)	10.00	(2-15)	***< 0.0001***

Table 4 SCHFI individual questions TP1 and TP2

Patient Self-care Maintenance Questions	**Mean TP1**	**(SD)**	**Mean TP2**	**(SD)**
1) Weigh yourself?	2.63	1.20	2.78	0.94
2) Check your ankles for swelling	2.96	1.06	3.21	0.75
3) Try to avoid getting sick?	2.64	0.97	2.79	1.09
4) Do some physical activity?	2.03	1.11	2.02	1.11
5) See your doctor or nurse?	3.65	0.78	3.75	0.67
6) Eat a low salt diet?	2.51	1.19	2.48	1.05
7) Exercise for 30 minutes?	1.71	0.99	1.67	1.03
8) Forget to take one of your medicines?	1.51	0.91	1.30	0.66
9) Ask for low salt items while eating out or visiting others?	1.25	0.55	1.32	0.76
10) Use a system to help you remember to take your pills?	2.42	1.39	2.36	1.41
Patient Self-care Management Questions				
11) How quickly did you recognize it as a symptom of heart failure?	1.76	1.27	1.86	1.19
12) Reduce the salt in your diet	2.09	1.15	2.21	1.17
13) Reduce your fluid intake	2.23	1.11	2.40	1.16
14) Take an extra water pill	1.88	1.11	2.23	1.13
15) Call your doctor or nurse for guidance	3.01	1.17	2.97	1.15
16) How sure were you that the remedy helped or did not help?	1.48	1.26	1.52	1.30
Patient Self-care Confidence Questions				
17) Keep yourself free of heart failure symptoms?	1.76	0.87	1.84	0.89
18) Follow the treatment advice you have been given?	3.00	0.94	3.21	0.78
19) Evaluate the importance of your symptoms?	2.53	0.91	2.68	0.97
20) Recognize changes in your health if they occur?	2.82	0.83	3.00	0.76
21) Do something that will relieve your symptoms?	2.25	0.96	2.39	0.97
22) Evaluate how well a remedy works?	2.19	1.01	2.21	0.94

Table 5 CCSCHFI individual questions TP1 and TP2.



Caregiver Contribution to Self-care Maintenance Questions	**Mean TP1**	**(SD)**	**Mean TP2**	**(SD)**
How often do you recommend that the person you care for do the following things?				
1) Weigh themselves?	1.78	0.95	2.05	1.16
2) Check their ankles for swelling?	2.19	0.95	2.27	1.06
3) Try to avoid them getting sick?	2.25	1.16	2.37	1.07
4) Do some physical activity?	1.90	0.93	1.97	0.99
5) See their doctor or nurse?	2.76	1.27	2.65	1.33
6) Eat a low salt diet?	1.94	0.99	1.79	0.89
7) Exercise for 30 minutes?	1.65	0.92	1.61	0.87
8) Remember to take medicine	1.92	1.04	2.07	1.20
9) Ask for low salt items while eating out or visiting others?	1.38	0.74	1.45	0.84
10) Use a system to help them remember to take their pills?	1.76	1.14	2.02	1.24
Caregiver Contribution to Self-care Management Questions				
11) If the person you care for had trouble breathing or ankle swelling, how quickly did you recognize it as a symptom of heart failure?	2.05	1.43	1.87	1.24
If the person you care for has trouble breathing or ankle swelling, how likely are you to recommend (or do) one of the following remedies?	2.39	1.15	2.38	1.12
12) Reduce the salt in their diet	2.21	1.15	2.36	1.01
13) Reduce their fluid intake	2.07	1.16	2.22	1.12
14) Give an extra water pill	3.05	1.03	3.26	1.07
15) Call their doctor or nurse for guidance				
16) How sure were you that the remedy helped or did not help?	1.63	1.26	1.63	1.26
Caregiver Contribution to Self-care Confidence Questions				
In reference to the person you care for, how confident are you that you can				
17) Prevent heart failure symptoms?	1.57	0.84	1.60	0.74
18) Follow the treatment advice?	2.98	0.87	3.17	1.64
19) Evaluate the importance of HF symptoms?	2.63	0.97	2.65	0.89
20) Recognize health changes in the person you care for?	2.82	0.75	2.90	0.81
21) Do something that will relieve HF symptoms?	2.30	1.00	2.22	0.99
22) Evaluate how well a remedy works?	2.19	0.97	2.20	0.97

3.3 *Patients' and caregivers' actor and partner effects: self-care on quality-of-life outcomes (SF-12 and MLwHFQ)*

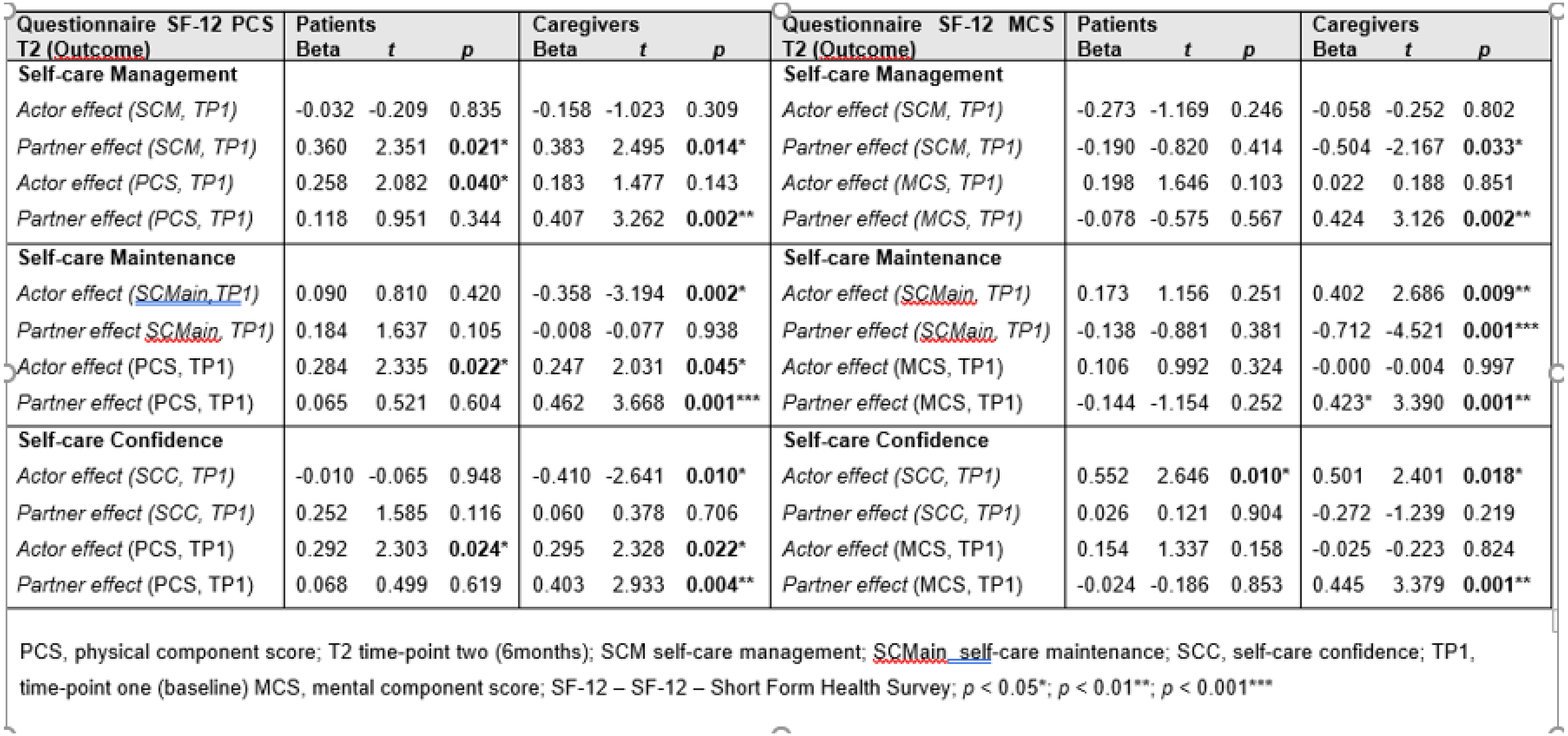
Among the 15 models, a number of statistically significant *actor effects* were identified of patients' self-care on their own quality of life at 6 months. Greater self-care confidence significantly predicted their better mental health (SF-12 MCS) at TP2; greater self-care maintenance and self-care confidence significantly predicted their better quality of life (MLwHFQ total score) at TP2; greater self-care confidence significantly predicted their better physical health (MLwHFQ PCS) at TP2; greater self-care management, self-care maintenance and self-care confidence significantly predicted their better emotional health (MLwHFQ ECS) at TP2 (Tables 6-8)

Similarly, a number of statistically significant *actor effects* were identified of caregivers' contribution to patient self-care on their own quality of life at 6 months. Greater self-care maintenance and self-care confidence significantly predicted their poorer physical (SF-12 PCS) health, but significantly predicted their better mental health (SF-12 MCS) at TP2; greater contribution to self-care maintenance and self-care confidence significantly predicted their better quality of life (MLwHFQ total score) and emotional health (MLwHFQ ECS) at TP2 (Tables 6-8)

Among the 15 models, there were 2 statistically significant *partner effects* of patient's self-care on their partner's quality of life at 6 months. Greater self-care management significantly predicted the caregiver's better physical health (SF-12 PCS) at TP2; greater contribution to self-care maintenance significantly predicted the caregiver's poorer emotional health (MLwHFQ ECS) at TP2 (Tables 6-8).

A greater number of partner effects were identified for caregiver's contribution to self-care on their partner's quality of life at 6 months. Greater contribution to patient self-care management was associated with better physical health (SF-12 PCS) in the patient; greater contribution to patient self-care management and maintenance was associated with poorer mental health (SF-12 MCS) in the patient; greater contribution to patient self-care maintenance was associated with poorer overall quality of life (MLwHFQ total score) in the patient; greater caregiver contribution to patient self-care maintenance was associated with poorer physical health-related quality of life (MLwHFQ PCS); greater caregiver contribution to patient self-care maintenance was associated with poorer emotional health (MLwHFQ ECS) (Tables 6-8).

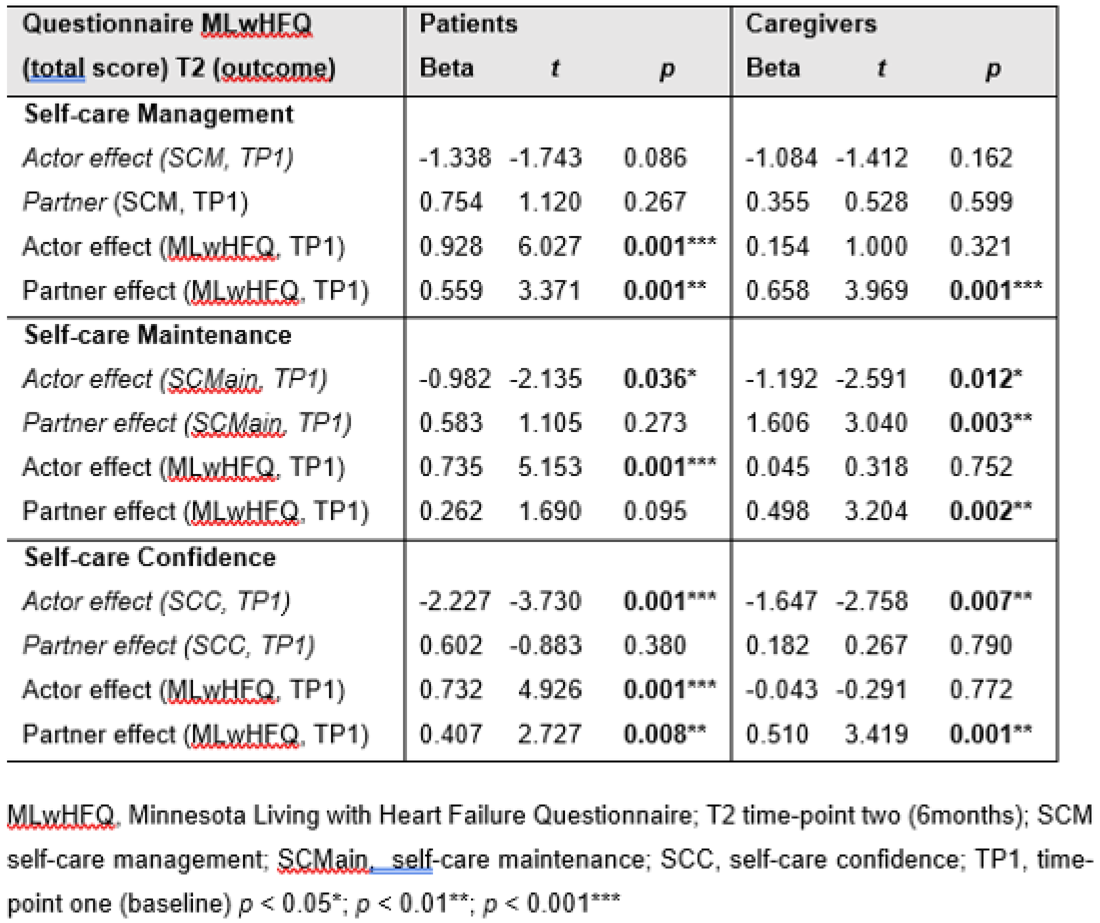
Table 6 Self-care as predictors of physical health (PCS) and mental health (MCS) outcomes (APIM)



Questionnaire SF-12 PCS T2 (Outcome)	Patients			Caregivers			Questionnaire SF-12 MCS T2 (Outcome)	Patients			Caregivers		
	Beta	*t*	*p*	Beta	*t*	*p*		Beta	*t*	*p*	Beta	*t*	*p*
Self-care Management							**Self-care Management**						
Actor effect (SCM, TP1)	-0.032	-0.209	0.835	-0.158	-1.023	0.309	*Actor effect (SCM, TP1)*	-0.273	-1.169	0.246	-0.058	-0.252	0.802
Partner effect (SCM, TP1)	0.360	2.351	**0.021***	0.383	2.495	**0.014***	*Partner effect (SCM, TP1)*	-0.190	-0.820	0.414	-0.504	-2.167	**0.033***
Actor effect (PCS, TP1)	0.258	2.082	**0.040***	0.183	1.477	0.143	*Actor effect (MCS, TP1)*	0.198	1.646	0.103	0.022	0.188	0.851
Partner effect (PCS, TP1)	0.118	0.951	0.344	0.407	3.262	**0.002****	*Partner effect (MCS, TP1)*	-0.078	-0.575	0.567	0.424	3.126	**0.002****
Self-care Maintenance							**Self-care Maintenance**						
Actor effect (SCMain,TP1)	0.090	0.810	0.420	-0.358	-3.194	**0.002***	*Actor effect (SCMain, TP1)*	0.173	1.156	0.251	0.402	2.686	**0.009****
Partner effect SCMain, TP1)	0.184	1.637	0.105	-0.008	-0.077	0.938	*Partner effect (SCMain, TP1)*	-0.138	-0.881	0.381	-0.712	-4.521	**0.001*****
Actor effect (PCS, TP1)	0.284	2.335	**0.022***	0.247	2.031	**0.045***	*Actor effect* (MCS, TP1)	0.106	0.992	0.324	-0.000	-0.004	0.997
Partner effect (PCS, TP1)	0.065	0.521	0.604	0.462	3.668	**0.001*****	*Partner effect* (MCS, TP1)	-0.144	-1.154	0.252	0.423*	3.390	**0.001****
Self-care Confidence							**Self-care Confidence**						
Actor effect (SCC, TP1)	-0.010	-0.065	0.948	-0.410	-2.641	**0.010***	*Actor effect (SCC, TP1)*	0.552	2.646	**0.010***	0.501	2.401	**0.018***
Partner effect (SCC, TP1)	0.252	1.585	0.116	0.060	0.378	0.706	*Partner effect (SCC, TP1)*	0.026	0.121	0.904	-0.272	-1.239	0.219
Actor effect (PCS, TP1)	0.292	2.303	**0.024***	0.295	2.328	**0.022***	*Actor effect* (MCS, TP1)	0.154	1.337	0.158	-0.025	-0.223	0.824
Partner effect (PCS, TP1)	0.068	0.499	0.619	0.403	2.933	**0.004****	*Partner effect* (MCS, TP1)	-0.024	-0.186	0.853	0.445	3.379	**0.001****

PCS, physical component score; T2 time-point two (6months); SCM self-care management; SCMain self-care maintenance; SCC, self-care confidence; TP1, time-point one (baseline) MCS, mental component score; SF-12 – SF-12 – Short Form Health Survey; $p < 0.05$*; $p < 0.01$**; $p < 0.001$***

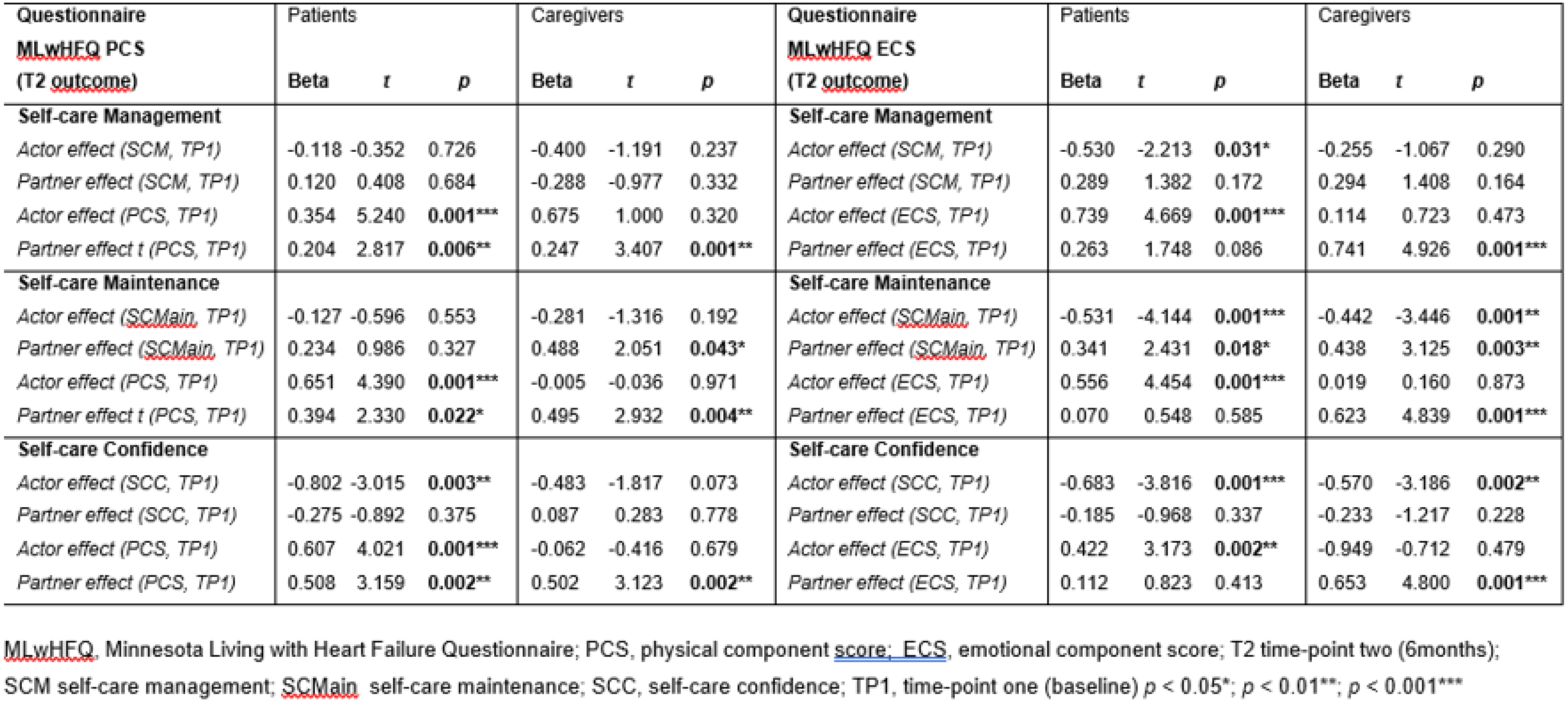
Table 7 Self-Care as predictors MLwHFQ (total score) outcome APIM



Questionnaire MLwHFQ (total score) T2 (outcome)	**Patients**			**Caregivers**		
	Beta	***t***	***p***	**Beta**	***t***	***p***
Self-care Management						
Actor effect (SCM, TP1)	-1.338	-1.743	0.086	-1.084	-1.412	0.162
Partner (SCM, TP1)	0.754	1.120	0.267	0.355	0.528	0.599
Actor effect (MLwHFQ, TP1)	0.928	6.027	**0.001*****	0.154	1.000	0.321
Partner effect (MLwHFQ, TP1)	0.559	3.371	**0.001****	0.658	3.969	**0.001*****
Self-care Maintenance						
Actor effect (SCMain, TP1)	-0.982	-2.135	**0.036***	-1.192	-2.591	**0.012***
Partner effect (SCMain, TP1)	0.583	1.105	0.273	1.606	3.040	**0.003****
Actor effect (MLwHFQ, TP1)	0.735	5.153	**0.001*****	0.045	0.318	0.752
Partner effect (MLwHFQ, TP1)	0.262	1.690	0.095	0.498	3.204	**0.002****
Self-care Confidence						
Actor effect (SCC, TP1)	-2.227	-3.730	**0.001*****	-1.647	-2.758	**0.007****
Partner effect (SCC, TP1)	0.602	-0.883	0.380	0.182	0.267	0.790
Actor effect (MLwHFQ, TP1)	0.732	4.926	**0.001*****	-0.043	-0.291	0.772
Partner effect (MLwHFQ, TP1)	0.407	2.727	**0.008****	0.510	3.419	**0.001****

MLwHFQ, Minnesota Living with Heart Failure Questionnaire; T2 time-point two (6months); SCM self-care management; SCMain, self-care maintenance; SCC, self-care confidence; TP1, time-point one (baseline) $p < 0.05$*; $p < 0.01$**; $p < 0.001$***

Table 8 Self-care as predictors of physical (PCS) and emotional (ECS) MLwHFQ outcome (APIM)



Questionnaire MLwHFQ PCS (T2 outcome)	Patients			Caregivers			**Questionnaire MLwHFQ ECS (T2 outcome)**	Patients			Caregivers		
	Beta	*t*	*p*	**Beta**	*t*	*p*		**Beta**	*t*	*p*	**Beta**	*t*	*p*
Self-care Management							**Self-care Management**						
Actor effect (SCM, TP1)	-0.118	-0.352	0.726	-0.400	-1.191	0.237	*Actor effect (SCM, TP1)*	-0.530	-2.213	**0.031***	-0.255	-1.067	0.290
Partner effect (SCM, TP1)	0.120	0.408	0.684	-0.288	-0.977	0.332	*Partner effect (SCM, TP1)*	0.289	1.382	0.172	0.294	1.408	0.164
Actor effect (PCS, TP1)	0.354	5.240	**0.001*****	0.675	1.000	0.320	*Actor effect (ECS, TP1)*	0.739	4.669	**0.001*****	0.114	0.723	0.473
Partner effect t (PCS, TP1)	0.204	2.817	**0.006****	0.247	3.407	**0.001****	*Partner effect (ECS, TP1)*	0.263	1.748	0.086	0.741	4.926	**0.001*****
Self-care Maintenance							**Self-care Maintenance**						
Actor effect (SCMain, TP1)	-0.127	-0.596	0.553	-0.281	-1.316	0.192	*Actor effect (SCMain, TP1)*	-0.531	-4.144	**0.001*****	-0.442	-3.446	**0.001****
Partner effect (SCMain, TP1)	0.234	0.986	0.327	0.488	2.051	**0.043***	*Partner effect (SCMain, TP1)*	0.341	2.431	**0.018***	0.438	3.125	**0.003****
Actor effect (PCS, TP1)	0.651	4.390	**0.001*****	-0.005	-0.036	0.971	*Actor effect (ECS, TP1)*	0.556	4.454	**0.001*****	0.019	0.160	0.873
Partner effect t (PCS, TP1)	0.394	2.330	**0.022***	0.495	2.932	**0.004****	*Partner effect (ECS, TP1)*	0.070	0.548	0.585	0.623	4.839	**0.001*****
Self-care Confidence							**Self-care Confidence**						
Actor effect (SCC, TP1)	-0.802	-3.015	**0.003****	-0.483	-1.817	0.073	*Actor effect (SCC, TP1)*	-0.683	-3.816	**0.001*****	-0.570	-3.186	**0.002****
Partner effect (SCC, TP1)	-0.275	-0.892	0.375	0.087	0.283	0.778	*Partner effect (SCC, TP1)*	-0.185	-0.968	0.337	-0.233	-1.217	0.228
Actor effect (PCS, TP1)	0.607	4.021	**0.001*****	-0.062	-0.416	0.679	*Actor effect (ECS, TP1)*	0.422	3.173	**0.002****	-0.949	-0.712	0.479
Partner effect (PCS, TP1)	0.508	3.159	**0.002****	0.502	3.123	**0.002****	*Partner effect (ECS, TP1)*	0.112	0.823	0.413	0.653	4.800	**0.001*****

MLwHFQ, Minnesota Living with Heart Failure Questionnaire; PCS, physical component score; ECS, emotional component score; T2 time-point two (6months); SCM self-care management; SCMain self-care maintenance; SCC, self-care confidence; TP1, time-point one (baseline) $p < 0.05$*; $p < 0.01$**; $p < 0.001$***

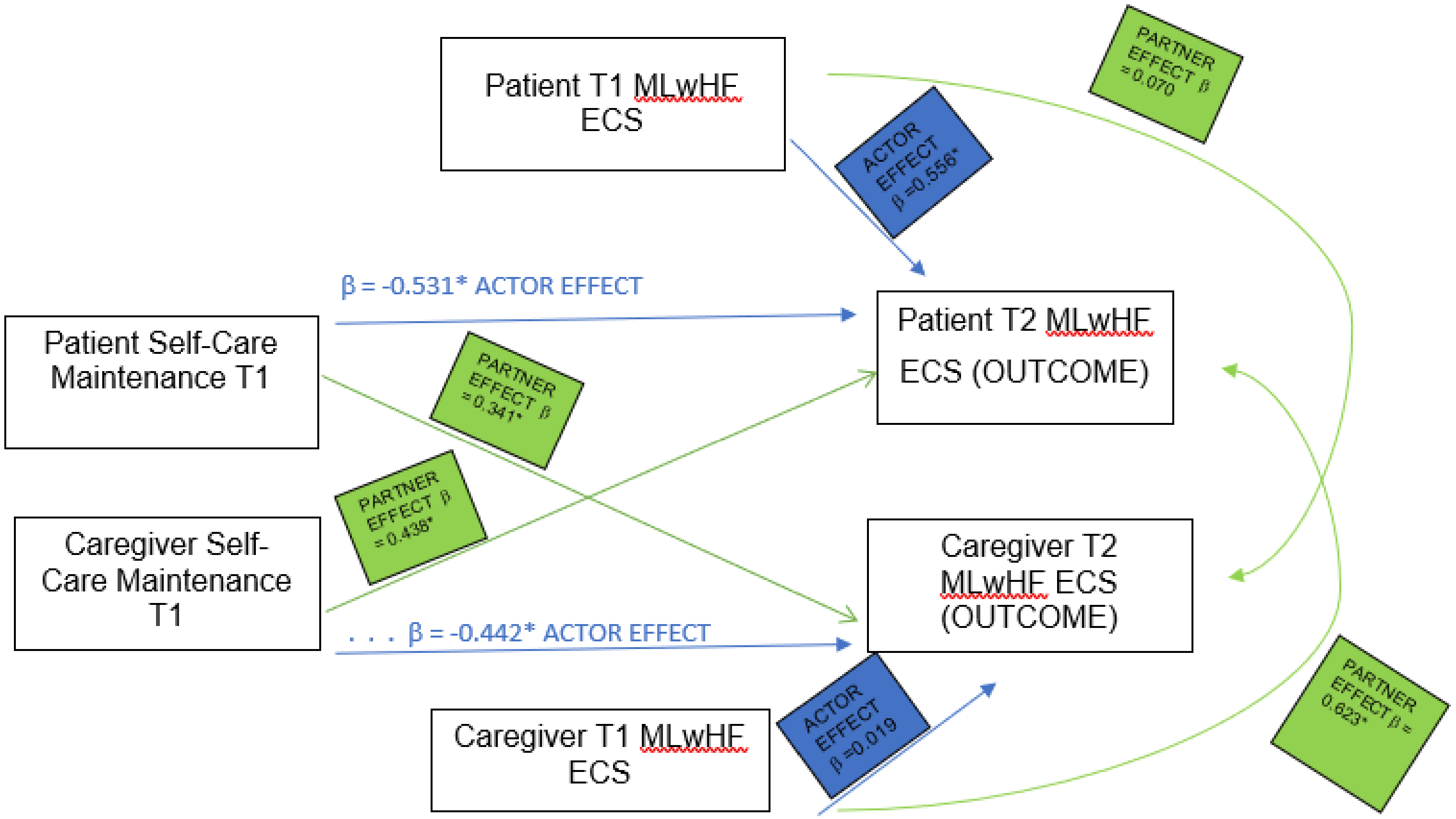


Figure 1: Actor *and* partner *effects of self-care maintenance on time-point two ECS*

4.0 Discussion

This is the first known HF study that has used longitudinal dyadic analysis using the APIM to explore further the unique relationship that exists between spousal/cohabiting couples. Specifically, the study explored the effects of self-care on quality-of-life outcomes in patients with heart failure and their family caregivers at 6 months' follow-up (TP2).

Similar to Jaarsma et al. (2013), Riegel et al. (2009) and Moser et al.'s (2012) studies, patients' and caregivers' contribution to self-care in this study was sub-optimal at both time-points. Statistically significant differences were noted in patients' self-care maintenance and caregivers' contribution to self-care maintenance at TP1 (Table 3), suggesting that patients were contributing more to self-care maintenance (i.e., symptom monitoring and treatment adherence) than their caregivers were assisting them with. Patients contributing more to their self-care maintenance than their caregivers were also identified in Bidwell et al.'s (2015) study.

Consistent with Reigel et al.'s, 2013; Concicao et al.'s, 2015; Cochieri et al.'s (2015) and Vellone et al.'s (202b) cross-sectional studies, in the **self-care maintenance** domain, patients gave least priority to adhering to a low salt diet when eating out and exercising for 30 minutes. In contrast to Vellone et al.'s (2015) study, caregivers in the current study gave least priority to asking for low salt items for the patient when eating out and encouraging them to exercise for 30 minutes. This variation may be explained by the cultural differences between the UK and Italy; in the UK salt restriction is a dietary choice, whilst in Italy, salt restriction is prescribed. Least priority was given in the **self-care management** domain to evaluating remedies, recognising HF-related symptoms and taking an additional diuretic when needed – findings that contrast with Vellone et al.'s (2020b) study. The difference may be explained by the greater number of patients in the current study having a new diagnosis and being much less comfortable exercising autonomy with "as required" medication. Comparable with Vellone et al.'s (2015) and Cochieri et al.'s (2015) study in the self-care management domain, caregivers gave least priority to assessing the effectiveness of remedies and being able to identify changes in symptoms that are associated with worsening HF. In the self-care confidence domain, patients in the current study were least confident in being able to remain free of HF symptoms – a finding also reported in Conceicao et al.'s (2015) study. This is not surprising, given the fact that the symptom burden associated with HF is worse than many disseminated cancers (Brunner- La Rocca et al., 2012). Consistent with other caregiving studies (Vellone et al., 2015; Srisuk et al., 2021) caregivers were least confident in preventing and relieving HF symptoms, which may be explained by a lack of knowledge and understanding of HF. The association between knowledge and greater confidence was reported in other caregiving populations, as well as having a more meaningful relationship with the patient (Terpstra et al., 2012; Huang et al., 2013).

To the best of my knowledge this is the first known study to have used both the generic (SF-12) and disease-specific questionnaire domains (MLwHFQ total, PCS and ECS) for patients and caregivers' quality of life longitudinally. As anticipated, the physical health of the patient was statistically significantly poorer than the caregivers at both TP1 and TP2 (Table 3) and is comparable with previous research (Trivedi et al, 2016; Vellone et al., 2014) but contrary to Luttick et al.'s (2009) study. Both patients and their caregivers experienced similar mental health at TP1 and TP2, which is comparable with other HF studies (Chung et al., 2009; Pihl et al., 2005; Auld et al., 2018; Agren et al., 2011; Thomson et al., 2020a).

Using the disease-specific questionnaire (MLwHFQ), statistically significant differences were found between the patients' and caregivers' quality of life **(MLwHFQ total)** at TP1 and TP2. These findings are consistent with previous studies (Trivedi et al., 2016; Chen et al., 2010; Tang et al., 2010) that reported poorer quality of life in the patient. Statistically significant differences were also found between patients' and caregivers' physical health (**MLwHFQ PCS)** at TP1 and TP2 and is consistent with the poorer patient quality of life reported in previous HF and dyadic HF cross-sectional studies (Chen et al., 2010; Tang et al., 2010; Chung et al., 2009; Vellone et al., 2014; Thomson et al., 2020a). The emotional health **(MLwHFQ ECS)** was also statistically significantly different between patients and caregivers at TP1 and TP2, suggesting that the patients' emotional health was poorer than the caregivers – a finding also reported in Evangelista et al.'s (2002) study, but contrary to Arestedt et al.'s (2012) study. Whilst no cross-sectional or longitudinal studies are available that have used all the MLwHFQ sub-domains for caregivers, the findings relating to quality of life, physical health and emotional health were broadly consistent with previous HF quality of life studies.

In this dyadic analysis, patients' increased self-care confidence significantly predicted their better mental health (SF-12 MCS) at 6 months follow-up (TP2) **(*actor effect*).** This is new finding in the HF literature that has used the APIM model. Nonetheless, the association between greater self-efficacy and improved mental health was identified by Lee et al.'s (2011), although Trivedi et al.'s (2016) found a worsening of mental health at follow-up. Using the MLwHFQ, patients' greater self-care maintenance and self-care confidence at TP1 significantly predicted their better quality of life (MLwHFQ total score) at TP2 **(*actor effects*).** Whilst no known longitudinal studies were found that used the APIM for comparisons, the findings are consistent with the wider HF literature that promotes self-care as a method of improving quality of life (Lyons et al., 2015; Buck et al., 2015; Sebern & Riegel, 2009).

Similarly, patients' greater self-care confidence at TP1 was statistically significantly associated with improved physical health (MLwHFQ PCS) at TP2 **(*actor effect*).** Also, patients' greater self-care management, self-care maintenance and self-care confidence significantly predicted their better emotional health at TP2 **(*actor effects*).** The association between patients' greater self-care confidence and improved physical health in the current study is overall consistent with Kessing et al.'s (2017). However, direct comparisons cannot be made with the current study findings, as the APIM was not used, and the European Self-care Behaviour Scale was used to measure self-care. Also, prior research by Seto et al. (2011) found that greater self-care maintenance and self-care confidence were associated with patients' better emotional quality of life, although the APIM and the MLwHFQ were not used.

The study found that caregivers' greater contribution to self-care maintenance and self-care confidence at TP1 was significantly associated with their poorer physical health (SF-12 PCS) at TP2 **(*actor effects*).** The association between caregivers' greater contribution to self-care maintenance and poorer physical health is consistent with Vellone et al.'s (2014) cross-sectional APIM study. Caregivers' greater contribution to self-care maintenance and self-care confidence at TP1 was significantly associated with their better mental health (SF-12 MCS) at TP2 **(*actor effects*).** These are new findings in the HF dyadic literature for although Vellone et al.'s (2014) identified an association between increased caregivers' self-care confidence and mental health, it was a cross-sectional study. Further no cross-sectional or longitudinal studies were found for comparison of caregivers' contribution to self-care maintenance on their mental health.

Using the MLwHFQ, greater caregivers' contribution to self-care maintenance and self-care confidence was associated with their better quality of life (MLwHFQ total score) and emotional health (MLwHFQ ECS) at TP2 **(*actor effects*).** Hooker et al.'s (2018) study found similar associations between self-care maintenance and self-care confidence on quality-of-life outcomes in dyads, which were thought to be as a result of greater mutuality between the patient and their caregiver. It may be that the caregivers found many positive aspects associated with providing care to their loved one, which have been reported in previous caregiving studies (Pressler et al., 2009; Ruasch et al., 2007). Interestingly, caregivers' contribution to self-care management, self-care maintenance and self-care confidence did not demonstrate any statistically significant actor effects on their own physical health (MLwHFQ PCS) at TP2. Few studies have used the MLwHFQ (and the individual domains) for caregivers, so it difficult to make direct comparisons with the study findings.

The dyadic analysis also demonstrated statically significant ***partner effects.*** Patient's greater self-care management was significantly associated with the caregiver's better physical health (SF-12 PCS) at TP2 **(*partner effect*).** This study finding contributes to the body of literature on dyadic research as no *partner* effect of greater self-care management being associated with better physical health in the caregiver has been identified in APIM studies. However, Odem et al. (2019) found that offering greater support to patients who were non-adherent to self-care practices, resulted in caregivers being physically exhausted. It is therefore logical to assume that patients' who are independently managing their self-care, the physical exhaustion and poor physical health experienced by the caregiver would lessen.

Perhaps the most significant study finding was that a mutual dyadic effect was found for TP1 self-care maintenance and emotional health (outcome). The patient's greater baseline self-care maintenance was significantly associated with the caregiver's poorer emotional health (MLwHFQ ECS) at 6 months follow up (TP2) and vice versa, the caregivers' baseline self-care maintenance was significantly associated with the patient's poorer emotional health (MLwHFQ ECS) at TP2 **(*mutual dyadic effect*).** This is a significant finding that demonstrates inter-partner relationships and influence of one member of the dyad on the other. In non APIM studies (i.e., studies comparing patients and caregivers as groups instead of patient–caregiver pairs) mutual dyadic effects such as these could be missed. No known dyadic studies are available that used the APIM to explore self-care and emotional health (MLwHFQ ECS) longitudinally for comparison with the study findings.

Caregiver's greater contribution to self-care management was significantly associated with the patient's better physical health (SF-12 PCS) at TP2 **(*partner effect*).** This contrasts with Vellone et al.'s (2014) study that found no *partner effect* but is consistent with previous studies the recognised the benefits of caregivers' contribution to patient care and improved outcomes (Trivedi et al., 2012; Schwarz & Elman, 2003; Clark et al., 2009). Moreover, caregiver's greater contribution to self-care management and self-care maintenance were significantly associated with the patient's poorer mental health (SF-12 MCS) at TP2 (*partner effects*). No prior APIM studies of self-care and mental health (SF-12 MCS) could be found to support the study findings. However, a number of other studies exist that recognise the impact of caregivers' influence on patients' psychological well-being (Buck et al., 2013; Evangelista et al., 2002; Kitko et al., 2015). Further, Rosalind et al.'s (2010) identified that caregivers' "nagging" regarding treatment compliance negatively impacted on the patients' mental health.

Using the MLwHFQ, the caregiver's contribution to self-care maintenance was significantly associated with the patient's poorer quality of life (MLwHFQ total score) and physical health (MLwHFQ PCS) at TP2 **(*partner effects*).** No known dyadic APIM studies could be found to compare the current study findings with. It may be that the caregiver only contributed to patient's self-care when a noticeable deterioration has occurred in their condition.

6 Implications for practice

Several practice implications were noted from this study. Firstly, the patients' and caregivers' contribution to self-care were poor at both baseline and follow-up, which further supports existing research. In addition, the study identified specific self-care behaviours that were given least priority by patients and their caregivers, which reinforces the need for clinical staff to target these areas during periods of self-care education. Indeed, competence in these areas (i.e., symptom recognition, sodium restriction and daily weights) could prevent unnecessary episodes of decompensation and increased mortality. From a dyadic perspective, the mutual dyadic effect (i.e., *actor* and *partner effects*) for increased self-care maintenance and caregiver contribution to self-care maintenance on emotional quality of life, highlights the importance of targeted interventions by clinicians to support improved emotional health of both members of the dyad.

7 Conclusions

Unlike other HF self-care studies, this study provides information relating to the differences in self-care between patients and caregivers longitudinally. It demonstrates statistically significant differences in patients and caregivers' contribution to self-care maintenance at TP1, which indicates that patients are contributing more to this area of self-care than their caregivers. It also examines specific patient and caregiver self-care behaviours at both time points, which will assist clinicians in targeting problematic areas of self-care during educational sessions. Most importantly, the study is unique, in that, it is the first known HF study to use the APIM longitudinally. Specifically, it provides additional knowledge and understanding regarding the *actor effects* of self-care on the individual (i.e., patients and caregivers) self-care on their own quality of life at

TP2. It also identifies statistically significant *partner effects*, i.e., the patient's self-care on the caregiver's quality of life at TP2.

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