Development of a theory-based, complex palliative care intervention for patients with heart failure and their family carers

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I declare that this thesis is my own work and has not been submitted for the award of a higher degree elsewhere. I declare that the thesis does not exceed the permitted maximum of 80,000 words.

Abstract

Development of a theory-based, complex palliative care intervention for patients with heart failure and their family carers

Introduction: Patients with heart failure have significant palliative care needs but few receive palliative care. Guidance is lacking on how to integrate palliative care into standard heart failure care. Palliative care interventions often lack an underpinning theory and understanding of their key components and how they interact to achieve an impact. Understanding how and why an intervention works enhances implementation.

Aim: Develop and refine a theory-based, complex palliative care intervention for patients with heart failure and their family carers.

Methods: Intervention development using the Medical Research Council framework for developing complex interventions and Theory of Change approach. A systematic review of palliative care needs-assessment and measurement tools in heart failure was conducted. Next, a preliminary intervention and underpinning theory that explains its causal mechanism were co-designed in Theory of Change workshops with stakeholders from a hospital heart failure multidisciplinary team. Subsequently, patient, family carer, and professional caregiver interviews on integrated palliative care were analysed. Findings from the analysis were discussed with stakeholders to refine the intervention and underlying theory and co-develop a feasibility study protocol.

Results: NAT:PD-HF was identified as the most appropriate palliative care needs-assessment tool in the review and after discussion with stakeholders. At the Theory of Change workshops, the agreed intervention impact was to meet the holistic palliative care needs of patients and families. Three long-term outcomes were identified: reduced unnecessary hospitalisations, symptom burden, and caregiving burden. To achieve these outcomes, many preconditions, contextual conditions, and intervention activities (education, collaboration, and completing NAT:PD-HF) must exist.

Conclusion: The study provided novel insights into complex intervention development and the potential mechanism of integrating palliative care in heart failure. It outlined how the complex intervention works and identified the active ingredients necessary for replication. The developed Theory of Change serves as a model for researchers and policymakers to use. A feasibility study protocol was developed.

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1 Introduction

Heart failure is a life-limiting illness[1,2], and patients have a significant symptom burden and a need for *palliative care* to improve their quality of life[3,4]. Nonetheless, most patients have poor or late access to palliative care[5-9]. Several barriers to providing palliative care to patients with heart failure exist such as the unpredictable illness trajectory and difficulty to identify the palliative care needs of patients[10,11]. Many guidelines and policies call for integrating palliative care into standard heart failure care[12-18], but guidance is lacking on how best to achieve that. This study aims to address this issue through developing a palliative care intervention underpinned by a *programme theory* to explain how and why palliative care integration can work[19].

In this chapter, the study aim and objectives and the motivation behind the research are outlined. Next, a brief introduction to heart failure is provided including its definition, epidemiology, classifications, mortality, and burden on patients and families. Palliative care is then introduced and its importance in heart failure is highlighted. The evidence for, and barriers to, palliative care in heart failure are discussed, and palliative care guidelines and policies are debated. Subsequently, the importance of theory-based and well-described complex interventions is emphasised to understand the mechanism of integrating palliative care into standard heart failure care. The chapter ends with an outline of the thesis.

1.1 Research aim and objectives

1.1.1 Aim

Develop and refine a theory-based, complex palliative care intervention for patients with heart failure and their family carers.

1.1.2 Objectives

1. Identify the most appropriate palliative care needs-assessment and measurement tools for patients with heart failure.

2. Develop and refine a programme theory that underpins the intervention and illustrates the mechanism of integrating palliative into standard heart failure care.
3. Describe the complex intervention and its key components in detail.
4. Describe the systematic development and refinement process of the intervention.
5. Develop a feasibility study protocol to test the acceptability and feasibility of the developed intervention and underpinning theory and inform a full definitive trial.

The research aim and objectives changed with COVID-19 restrictions on research. The original aim was to develop an intervention and test it in a feasibility study. However, after about one year of development work, the UK was hit by COVID-19 and all non-COVID research in the NHS was suspended to minimise social contact and allow time for staff to fight the disease. At that time, I was writing my feasibility study protocol and preparing it for ethics approval. With COVID restrictions on research, the feasibility study was impossible to conduct. This was an opportunity to look back at the developed intervention and further refine it before testing its feasibility. Eventually, the focus of the thesis shifted towards enhancing the development of the complex, palliative care intervention and exploring its mechanism of action.

1.2 Background of the researcher

Since I earned my Master’s degree in Clinical Pharmacy in August 2012, I worked in different organisations to identify and address treatment issues for patients with chronic illnesses. Shortly after graduation, I worked in a hospital with a cancer care centre, where I saw the suffering of patients and family carers and heard healthcare professionals talk about palliative care. Three years after I left this job, I worked as a university academic instructor, where part of my role was to supervise undergraduates in their clinical pharmacy practice across different hospital departments, including the intensive care unit, cardiology, and nephrology departments. There, I saw patients with different chronic illnesses, including heart failure, who were struggling with breathlessness and having similar problems to those with lung cancer. Nonetheless, discussions about palliative care were rare. I started to think about this and wonder why palliative care was not discussed for patients with heart failure despite their evident suffering. I wanted these patients to benefit from palliative care, in a similar way to those with cancer. My desire to further understand this issue was the motivation to pursue my PhD.

1.3 Heart failure

1.3.1 Epidemiology and classifications

Heart failure is a complex, progressive clinical syndrome that results from structural or functional heart abnormalities, which prohibit effective pumping of the blood to the organs[18]. It is a global problem that affects approximately 38 million people worldwide[20], including about one million people in the UK[21]. Its prevalence in the adult population in developed countries is estimated to be 1-2%[21-23], which increases to more than 10% for those aged 60 years or older[24]. The prevalence of heart failure is increasing, with an ageing population and advancements in care[20,21]. A calculation based on the expected rise in the number of people aged 70 years or older demonstrated that the number of patients with heart failure will triple by 2060[25].

Heart failure is typically divided into chronic and acute heart failure. Patients with chronic heart failure have an established heart failure diagnosis or more gradual onset of symptoms[18]. Patients with acute heart failure have a rapid or gradual onset of symptoms that are severe enough for patients to seek urgent medical attention, leading to unplanned hospitalisations or emergency department visits[18]. For this thesis, heart failure will refer to chronic heart failure unless indicated otherwise. Classifications were developed for heart failure to assess symptom severity and disease progression and inform treatment (**Table-1**). Heart failure is commonly described in terms of the measurement of Left Ventricular Ejection Fraction (LVEF), which is the percentage of blood that the left ventricle pumps out with each contraction (normal value ≥50%)[12,18]. Based on the LVEF value, the European Society of Cardiology (ESC) categorised heart failure into three groups: Heart Failure with reduced Ejection Fraction (HFrEF), Heart Failure with mildly reduced Ejection Fraction (HFmrEF), and Heart Failure with preserved

Ejection Fraction (HFpEF)[18]. These categories comprise different underlying aetiologies, comorbidities, and treatment responses[26,27].

Another common classification is the New York Heart Association (NYHA) functional classification[28]. Based on symptom severity and exercise capacity, patients may present with NYHA class I to IV heart failure[12]. The NYHA classification is commonly used to identify patients eligible for certain healthcare services[12]. However, given its subjectivity, the American College of Cardiology Foundation/American Heart Association (ACCF/AHA) proposed a complementary, more objective classification that describes four stages of heart failure development based on structural changes and symptoms[29]. The ACCF/AHA stages are mainly used to inform heart failure treatment[29]. In contrast to NYHA classification which may change in both directions depending on patient symptoms, the ACCF/AHA stages are progressive and irreversible[12]. Patients who present with stage-D and NYHA class III or IV despite optimal medical therapy are often described to have *advanced* heart failure[12,18], although definitions vary widely in the literature[30].

Table-1: Classifications of heart failure, adapted from Yancy et al. 2013[12] and McDonagh et al. 2021[18]

Heart failure type	Description
ESC classification	
HFrEF	LVEF ≤40% Systolic dysfunction: failure of the heart to contract and eject blood effectively
HFmrEF*	LVEF 41-49% Mild systolic dysfunction
HFpEF	LVEF ≥50% Diastolic dysfunction: failure of the heart to relax and fill with blood effectively
NYHA classification	
Class-I	No limitation of physical activity; Ordinary physical activity does not cause symptoms
Class-II	Slight limitation of physical activity; Ordinary physical activity causes symptoms
Class-III	Marked limitation of physical activity; Less than ordinary physical activity causes symptoms
Class-IV	Unable to do any physical activity without discomfort; Symptoms at rest
ACCF/AHA classification	
Stage-A	At high risk for heart failure; no structural heart disease or symptoms
Stage-B	Structural heart disease; no symptoms
Stage-C	Structural heart disease; prior or current symptoms
Stage-D	Refractory, end-stage heart failure; requiring specialised interventions

* Formerly called heart failure with mid-range ejection fraction.

1.3.2 Mortality and illness burden

Heart failure is characterised by a poor prognosis[1,2], with a higher mortality risk than common types of cancer[31]. The mortality rate for heart failure is approximately 20% within one year of diagnosis, and 50% to 70% within five years of diagnosis[1,2]. Half of the patients older than 75 years will die within one year of hospitalisation[32]. Most deaths from heart failure are due to worsening disease or sudden death from heart arrhythmias or vascular events[12,33]. Although the risk of sudden cardiac death and all-cause mortality from heart failure has decreased through advances in therapeutics, cardiac devices, and heart transplants, the mortality rate remains high[12,33]. Cardiac devices mainly include implantable cardioverter-defibrillators which monitor and correct heart arrhythmias by delivering electric shocks[12]. Heart transplantation is another option for treating refractory, end-stage heart failure[34]. However, the shortage of donor hearts, high number of patients with end-stage disease, comorbidities, and age restrictions (generally reserved for those aged 70 years or younger) make it a limited option[33,34].

Advancements in heart failure therapy have raised the mean life expectancy, meaning patients may live longer with their advanced disease and accompanied symptoms[18]. Heart failure causes a significant symptom burden that is comparable to that of cancer[35-38], leading to impaired quality of life[3,4]. Typical symptoms include, but are not limited to, breathlessness, fatigue, tiredness, pain, and insomnia[39]. Because of physical frailty, patients experience limitations in their daily activities, leading to care dependency[40,41]. Patients also experience depression and anxiety as they approach death[3,39]. Heart failure is commonly associated with comorbidities such as cancer and kidney failure which further increase the illness burden and affect the prognosis[18].

Heart failure is the most common diagnosis in patients aged 65 years or older admitted to hospitals in developed countries[20]. One million patients are admitted annually for heart failure in the USA and Europe[20]. Health service data for ten European countries, published between 2008 and 2012, showed that hospitalisations with a primary diagnosis of heart failure account for 1-2% of all hospital admissions[32]. In the UK, heart failure accounts for 5% of all emergency hospital admissions[13]. Estimates of health care activity associated with heart failure to the whole UK population showed that about 70% of the total annual cost of heart failure to the NHS is due to the costs of heart failure hospitalisation[42]; with similar results reported in Europe and the USA[43].

Heart failure has an impact on family carers[44-46]. Throughout the thesis, *family carers* will refer to informal, unpaid carers who provide care to patients most of the time, including family members, friends, neighbours, and others[47]. The care provided by family carers is critical for the health and wellbeing of patients with heart failure[44]. However, the caregiving role can be burdensome, physically demanding, and emotionally difficult[48,49]. Family carers have to take on the duties that patients used to do (role reversal), in addition to their own daily activities[50]. They may leave their job to care for their relative which can affect their social and financial circumstances[50,51]. Many family carers are elderly people with morbidities who may prioritise the health of their relative over their own health, which further impairs their quality of life[50,51].

1.4 Palliative care

1.4.1 Definition

Given the progressive nature and significant burden of heart failure on patients and their family carers, the goals of care shift towards improved quality of life[52], which is where palliative care plays an important role[53]. Palliative care is defined by the World Health Organisation (WHO) as an approach that improves the quality of life of patients and their families facing a life-threatening illness, through preventing and relieving suffering by the early identification, assessment, and treatment of physical, psychosocial, and spiritual problems[54]. Palliative care adopts a holistic, patient-centred approach that is applicable from early stages of illness through to bereavement[54,55]. It is a team-based approach and typically classified into *generalist* and *specialist* palliative care[56]. Generalist palliative care is provided by the usual care team, such as General Practitioners (GPs), geriatricians, cardiologists, and heart failure nurses, to address the primary palliative care needs of patients[56,57]. For more complex needs, specialist palliative care is provided by a multidisciplinary team with specialist palliative care training[56,57]. Not all patients with heart failure require specialist palliative care; many have palliative care needs that could be addressed by palliative care generalists[58]. Referral to specialist palliative care is reserved for those with severe and intractable problems that exceed the capability of the usual care team to address them[57].

1.4.2 Evidence of the benefits of palliative care in heart failure

Findings from six systematic reviews showed that palliative care improves patients' quality of life, symptoms, functional status, depression, and satisfaction with care, without affecting mortality rates (**Table-2**)[59-64]**.** Palliative care may also improve patients' spiritual wellbeing as they share their end-of-life wishes[65], and minimise social isolation through fostering communication and open discussions between patients, family carers, and healthcare professionals[66]. Five reviews demonstrated a reduction in medical service utilisation, including hospitalisation, rehospitalisation, hospital length of stay, emergency department visits, intensive care unit admissions, and primary care visits; leading to decreased healthcare costs[59,60,62-64]. Palliative care was found to reduce family carers' caregiving burden and depression, while improving their social needs and confidence in providing heart failure home care[44,67]. Given the benefits of palliative care in heart failure, multiple national and international guidelines have called for integrating palliative care into standard heart failure care[12-16,18].

Table-2: Evidence of the benefits of palliative care in heart failure from six systematic reviews

	Quality of life	**Symptoms**	**Depression**	**Hospitalisation**	**Resource use**
Diop et al. 2017[59]	✓	--	--	✓	✓
Xu et al. 2018[60]	**X**	✓	✓	✓	--
Zhou et al. 2019[61]	✓	--	✓	**X**	--
Datla et al. 2019[62]	✓	✓	✓	✓	✓
Sahlollbey et al. 2020[63]	✓ (modest)	✓ (modest)	--	✓	--
Pedro et al. 2022[64]	✓	✓ (modest)	--	✓	--

✓ Positive effect.
X No effect.
-- Not evaluated.

An important aspect of palliative care is its role in facilitating *advance care planning*; defined as the process of defining patients' goals and preferences for future care, discussing these preferences with family and healthcare providers, and recording and reviewing them if appropriate[68]. Advance care planning enables early exploration of the patients' health-related experiences, concerns, values, and treatments or care they would wish to receive or avoid if they lose the capacity to decide in later stages of their illness[68]. It encourages patient involvement in decision making through discussing their diagnosis, prognosis, and treatment or care options[68,69]. Through advance care planning, patients' preferred place of end-of-life care and death can be explored[70]. Other discussions may include preferences for resuscitation and deactivation of implantable cardioverter-defibrillators at the end of life to prevent repeated shocks and unnecessary suffering[33,71]. Two systematic reviews showed that advance care planning for patients with heart failure improves their quality of life, satisfaction with care, and quality of end-of-life communication; reduces hospitalisation; increases the use of palliative care services; increases documentation of care preferences; and supports deaths in patients' preferred place[72,73].

1.4.3 Barriers to palliative care in heart failure

Despite the significant symptom burden on patients with heart failure and the calls from guidelines to integrate palliative care into standard heart failure care, most patients with heart failure have poor or late access to palliative care compared to those with cancer[5-9]. A UK study showed that only 7% of patients with heart failure in primary care settings were transitioned to palliative care, compared to 48% of those with cancer[7]. Of those 7%, about one third were referred seven days before their death[7]. Similar results were reported in the USA where fewer than 10% of hospitalised patients with heart failure receive palliative care services[74]. Although referral to palliative care has increased, it remains inadequate and substantially lower than that for cancer[8]. Several barriers to providing palliative care to patients with heart failure exist at patient and family, healthcare professional, and organisation levels[75,76], as described below. Understanding these barriers is important to facilitate the integration and implementation of palliative care for all patients who need it.

1.4.3.1 Unpredictable illness trajectory and uncertain prognosis

Three illness trajectories have been described for patients with progressive chronic illnesses (**Figure-1**)[77,78]. In the first trajectory, typically represented by cancer, illness progression is steady with a clear terminal stage. In the second trajectory, typically represented by heart failure and Chronic Obstructive Pulmonary Disease (COPD), illness progression is gradual, with alternating periods of acute exacerbation and partial recovery and a higher risk of sudden, unexpected death. The third trajectory, typically represented by dementia and frailty, is characterised by a prolonged gradual decline. Because of its unpredictable trajectory, clinicians are poor at recognising the appropriate timing for providing palliative care in heart failure[10]. The alternating periods of relapse and remission make it difficult to predict the likely prognosis and identify those at the end of life who may benefit from palliative care[79]. A major barrier is referring patients to palliative care based on their unpredictable prognosis, rather than adopting a patient-centred or needs-based approach[7,80]. This is complicated by a high risk of sudden death which can occur at any point throughout the illness trajectory, including in those with milder symptoms[33]. Patients may die before clinicians recognise that they are deteriorating, and palliative care might be missed. Consequently, patients continue to receive futile treatments and experience poor care and quality of life as they approach death[81].

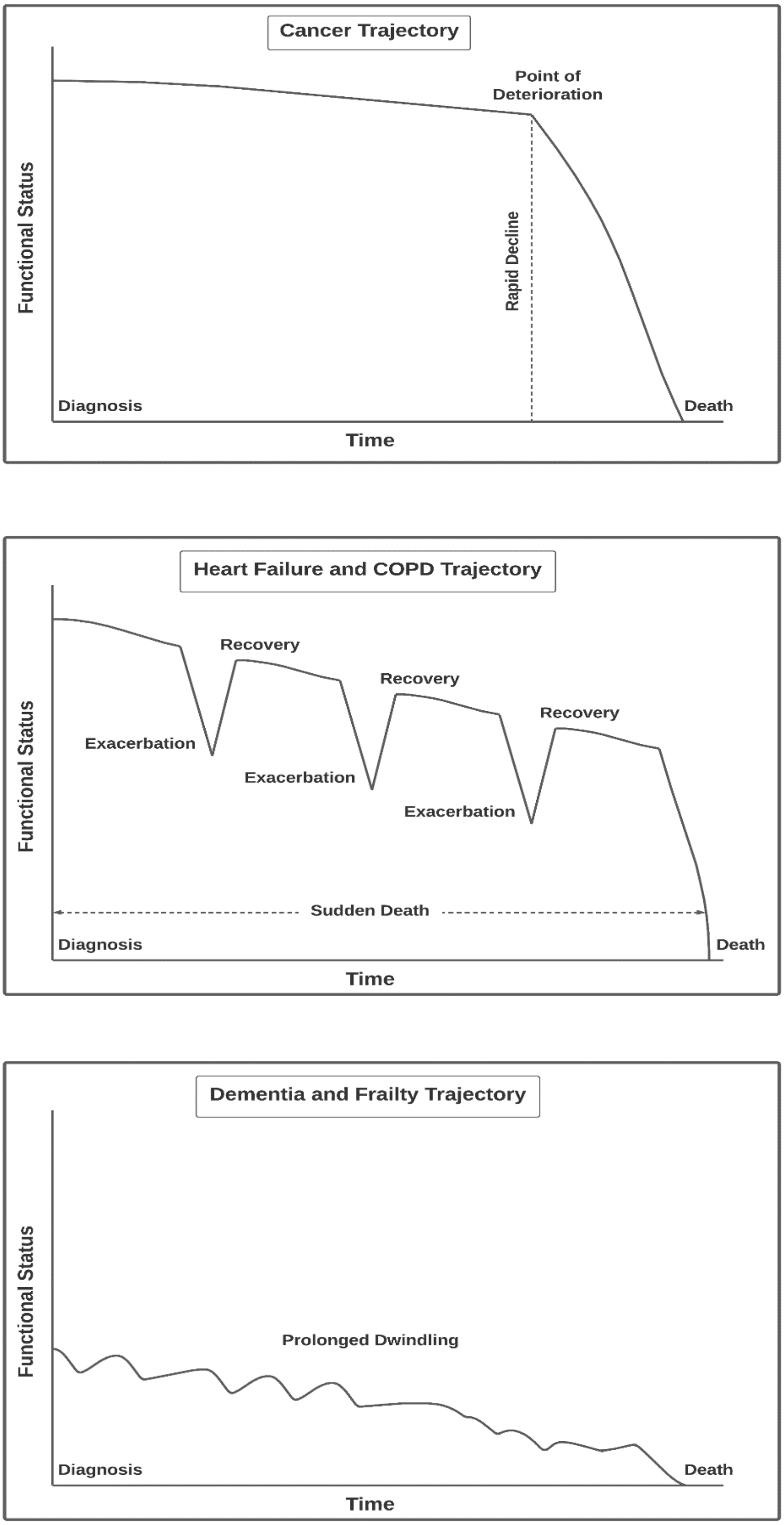


Figure-1: Trajectories of progressive chronic illnesses, adapted from Lynn and Adamson 2003[77]

1.4.3.2 Poor communication with patients and families

Given the prognostic uncertainty and risk of sudden death in heart failure, clinicians may feel unable or reluctant to discuss disease prognosis, palliative care, and future care preferences with patients and families as they fear causing premature alarm and diminishing hope[82,83]. Clinicians often wait for cues from patients before discussing palliative care, while patients wait for clinicians to raise this issue; therefore, these conversations rarely take place[82]. The lack of training and poor communication skills with patients about palliative care, including end-of-life issues and breaking bad news, are significant barriers[76,84]. Some clinicians fail to communicate a heart failure diagnosis to patients to avoid causing anxiety, which further hinders palliative care discussions[85]. Patients may not wish to have palliative care conversations as they perceive heart failure as not life-threatening and attribute their symptoms to ageing; which makes them question the relevance of palliative care to them[82,86]. They may not want to know their prognosis to avoid causing worries to themselves and their families[82]. Enhancing the palliative care communication skills of healthcare professionals and improving their confidence in discussing sensitive end-of-life issues are major facilitators of palliative care in heart failure[84,87].

1.4.3.3 Poor knowledge and attitude about palliative care

Patients, family carers, and healthcare professionals may think palliative care is only for patients with cancer or people who are actively dying, which makes it seem irrelevant for heart failure, especially at the early stages[75,88,89]. Cardiology clinicians often have poor knowledge of palliative care, including what it can offer to patients with heart failure[10], how to identify and address the palliative care needs of patients[11], what services are available and how to access them[10,76], and what role they can play[90]. They can be unwilling to forgo medical treatments and shift towards a more palliative care approach[75]. The dominance of the medical care model, which sees death as a failure[75], is augmented by the range of available therapeutic options in heart failure and the strong evidence on prolonging survival[12,33]. Cardiology clinicians can be reluctant to *hand over* patients to palliative care specialists who may have poor knowledge of heart failure management, leading to suboptimal palliation of symptoms[75,84]. Mutual education is recommended, where cardiology clinicians are trained on palliative care and palliative care clinicians are trained on heart failure management[76,84]. Educating patients and family carers on palliative care is also needed to facilitate palliative care provision[76,84].

1.4.3.4 Poor collaboration between healthcare professionals

Fragmentation of care is common in heart failure[91]. As heart failure is often associated with comorbidities[18], patients have input from several healthcare professionals, move between a variety of settings, and may be admitted to hospital under different healthcare teams[91]. Because palliative care is typically linked to cancer, palliative care specialists have fewer links with cardiology clinicians than with oncologists[91]. The collaboration between palliative care and geriatric medicine is also lacking[92]. There are misunderstandings of the roles and responsibilities of healthcare professionals, including who is the most appropriate to provide palliative care and coordinate overall patient care[11,92]. The poor coordination of services and lack of communication between healthcare professionals are major barriers to providing good-quality, continuing palliative care[11,76,93]. Therefore, several guidelines recommend a patient-centred, multidisciplinary team-based approach to facilitate palliative care provision in heart failure[14-16]. The collaboration between healthcare teams can be achieved through building relationships and establishing mechanisms for joint working[10,75], such as organising joint consultations by palliative care and cardiology clinicians and identifying a palliative care champion in the cardiology team[75,93].

1.4.3.5 Lack of resources

Specialist palliative care services are limited and primarily funded by charities in the UK[75]. A survey of specialist palliative care lead consultants showed that the lack of resources and beds were among the most common reasons for not accepting patients with heart failure in specialist palliative care[94]. The lack of resources and support from specialist palliative care teams and time constraints hinder palliative care provision by GPs[95]. Likewise, cardiology clinicians lack time to discuss palliative care with patients and families and communicate with other healthcare professionals[96]. The lack of resources may be attributed to competing priorities in health care[97], where some services are given a higher priority than palliative care[11]. Given the limited time, personnel, and funding to provide specialist palliative care for all patients with heart failure[93], providing specialist palliative care only to those with the most complex palliative care needs would preserve the limited resources and avoid overwhelming these services[10,57].

1.4.4 Palliative care guidelines and policies

The Heart Failure Association of the European Society of Cardiology (HFA/ESC)[16], the European Association for Palliative Care (EAPC) Task Force[14], and the American Heart Association/American Stroke Association (AHA/ASA)[15] have issued policy or position statements that call for providing palliative care to all patients with chronic life-limiting illnesses, not only cancer. They recommend integrating palliative care into standard heart failure care throughout the whole illness trajectory, based on patient needs rather than illness prognosis[14-16]. To help identify these palliative care needs, some guidelines encourage the use of needs-assessment tools[14,16]. This needs-based approach is considered more appropriate given the unpredictable trajectory of heart failure and the difficulty in recognising patients at the end of life[79]. Waiting until poor prognosis becomes evident or active treatment stops may miss the opportunity to offer palliative care[7,8]. Palliative care is best provided alongside active treatments, starting from diagnosis with a gradual increase in palliative care as the illness progresses, to support patients over a longer period of time[77,78]. Evidence from cancer studies shows that *early* palliative care integration can improve patients' quality of life, depression, and survival and decrease healthcare costs[15,98,99].

In the UK, the current policy calls for providing palliative care to patients with heart failure and access to specialist services as needed[17]. The first UK policy document to recommend access of patients with heart failure to palliative care services is the National Service Framework for coronary heart disease, published in 2000[100]. Eight years later, the End of Life Care Strategy was published by the Department of Health, which emphasised the relevance of palliative care to non-cancer conditions[17]. Nonetheless, the strategy was criticised for applying cancer models to other chronic life-limiting illnesses[82]. The first stage in the strategy's proposed End of Life Care Pathway is the identification of patients approaching the last year of life[17], which is problematic in heart failure. Like the End of Life Care Strategy, the General Medical Council guidance, published in 2010, promotes transition to palliative care and end-of-life care discussions for patients who are likely to die within the next year[101]. This is similar to the USA policy where patients cannot be eligible for hospice care funding unless physicians determine that they have a prognosis of less than six months[102].

In 2018, the UK's National Institute for Health and Care Excellence (NICE) published guidelines for heart failure which recommend a needs-based, rather than prognostic, approach to palliative care[13]. The NICE quality standard for heart failure, last updated in 2018, recommends a holistic assessment for patients within two weeks of hospital discharge[103]. However, one year later, NICE published guidelines for end-of-life care for all adults with a life-limiting illness which recommend identifying those approaching the end of their life, with the aid of prognostic tools, before discussing advance care planning and carrying out a holistic needs assessment[104]. Such tools do not correlate strongly with the palliative care needs of patients with heart failure[105]. It is now a legal requirement to provide palliative care for all who need it in the UK [106]. The National Palliative and End of Life Care Partnership developed a national framework for local action 2021-2026[107]. The framework presents six ambitions for palliative and end-of-life care. It emphasises that each person, including those with non-malignant long-term conditions, gets fair access to care and calls for a palliative care needs assessment. However, the details are vague and guidance is lacking on how to achieve this.

1.5 Mechanism of integrating palliative care in heart failure

Despite the calls from policies and guidelines to provide palliative care to patients with non-cancer illnesses based on their palliative care needs, guidance is still lacking on how best to integrate palliative care into standard heart failure care[63,64]. Consequently, the implementation of palliative care in heart failure is poorly addressed[108]. A systematic review of European guidelines and pathways for integrated palliative care in patients with heart failure and COPD concluded that although the guidelines emphasise aspects such as holistic care and a multidisciplinary team, they do not provide clear recommendations and solutions to existing barriers[108].

In 2015, the UK's Palliative and End of Life Care Priority Setting Partnership published a survey of patients, family carers, and healthcare professionals about palliative and end-of-life care research priorities[109]. One of the top ten ranked priorities was how to identify the palliative care needs and deliver care for patients with non-cancer diseases such as heart failure. In 2020, the James Lind Alliance published a similar survey of patients, family carers, and healthcare professionals about research priorities in advanced heart failure. Similar findings were reported; one of the top 13 ranked priorities was whether patients' palliative care needs can be met by better integration of heart failure and palliative care teams[110].

1.5.1 Need for well-described complex interventions

The identification of the palliative care needs of patients with heart failure, and their family carers, and the integration of palliative care into their standard heart failure care require a *complex* intervention[111]. Although there is no clear line between a simple and complex intervention, the latter has multiple interacting components (outcomes, targeted groups, and behaviours) and can be flexible and adaptable to different settings[112-115]. Palliative care service delivery, including preceding steps such as identifying palliative patients and their needs, is by definition a complex intervention as it typically comprises multiple components, such as symptom management and care planning[111]. A systematic review of palliative care interventions in patients with heart failure concluded that multidisciplinary, multicomponent (complex) interventions are more effective than those with a single discipline or component[62].

Previous palliative care interventions for patients with heart failure are often poorly described and lack guidance on how to identify patients with palliative care needs and implement palliative care in routine clinical practice given the existing barriers[116]. The interventions were generally administered for very specific patients and palliative care was not made available to all who need it. The focus was on *whether* or not the interventions achieved specific outcomes, rather than *how* or *why* they achieved or failed to achieve them, which could be due to implementation failure, genuine ineffectiveness, or inappropriate research outcomes or outcome measures[114,117]. Understanding how and why an intervention works in a specific context can identify possible barriers and resource constraints and enhance implementation[111,114]. Details are also lacking on which specific intervention components were responsible to achieve the outcomes (active ingredients)[116]. Understanding this complexity through detailed intervention description is important to improve transparency, replicability, and implementation in routine world practice and reduce research waste[112,118,119]. Existing palliative care interventions for patients with heart failure differ in team composition and offered services, which range from the assessment of patient and family palliative care needs to care coordination and planning[59,62,63]. This variation, alongside poor intervention description, makes it difficult to compare interventions and identify the most effective models. A key and first step is to understand how to identify patients with palliative care needs[14]. Once identified, palliative care could then be integrated into routine heart failure care.

1.5.2 Need for theory-based interventions

To develop feasible, effective, and implementable interventions, several guidelines call for exploring the active ingredients within complex interventions, understanding how and why they can exert their effects (causal mechanisms or pathways of change), and outlining the contextual factors[112,120]. Authors of systematic reviews of palliative care interventions in heart failure call for further investigation to understand such details in order to know what is required to successfully integrate palliative care into routine clinical practice[55,59,121]. To achieve this understanding, several guidelines advocate using a programme theory when developing and evaluating complex interventions[114,119,122];

defined as a theory that explains how an intervention is expected to work[19]. When applied prospectively in the intervention development stage, programme theories trigger thinking about the choice and rationale of the intervention components and outcomes, hypothetical mechanism of action through which the intervention components achieve those outcomes, and possible implementation barriers[123]. Ultimately, the theory-based intervention would be more effective, implementable, and sustainable[114].

Existing palliative care interventions, including those for heart failure, mostly lack an underpinning theoretical framework and clear understanding of their effective components and mechanism of action[111]. Instead, some interventions used a *logic model* which simply links the inputs with the outputs and provides a minimal description of the intervention components and causal pathways[111]. Most interventions lacked details on the intervention development process; making it difficult to assess the thoroughness of the intervention components[124]. Detailed and systematic intervention development and a good theoretical understanding of how the intervention might cause change are needed to develop effective interventions and identify weak links in the causal pathway[114], which is the focus of my PhD.

In this project, a complex palliative care intervention was developed using the Medical Research Council (MRC) Framework for the Development and Evaluation of Complex Health Interventions[112-115] (see **section-3.3**). A systematic review was firstly conducted to identify the most appropriate palliative care needs-assessment and measurement tools in heart failure. Findings from the review were discussed in group workshops with service providers where a preliminary intervention and underpinning theory were developed. This was followed by a secondary analysis of qualitative interview data about the experiences of patients, family carers, and professional caregivers with integrated palliative care. Findings from the analysis were discussed in follow-up meetings with key service providers where the intervention and underpinning theory were refined and a feasibility study protocol was co-developed. Service users were finally consulted to provide their feedback on the intervention and feasibility study protocol.

1.6 Organisation of thesis

The thesis is organised into ten related chapters:

- **Chapter-1** (Introduction) described the study aim and objectives and motivation behind the research, provided background on heart failure and palliative care, explained the evidence, barriers, and palliative care guidelines and policies, discussed the importance of understanding the mechanism of integrating palliative care into standard heart failure care, and identified the need for well-described and theory-based complex interventions.
- **Chapter-2** (Systematic review) describes a systematic literature review of palliative care needs-assessment and measurement tools used in patients with heart failure.
- **Chapter-3** (Methodology) outlines the philosophical and methodological foundations of the study, including the research paradigm, MRC framework, and adopted theories, and explains the steps of the intervention development.
- **Chapter-4** (Methods) describes the methods of developing the preliminary intervention and underlying theory through group workshops with service providers; methods of a secondary analysis of qualitative interview data about the experiences of patients, family carers, and professional caregivers with integrated palliative care; and methods of refining the proposed intervention and underlying theory through follow-up meetings with key service providers and consultation with service users.
- **Chapter-5** (Results) presents the findings of the group workshops with service providers.
- **Chapter-6** (Results) presents the findings of the secondary qualitative data analysis.
- **Chapter-7** (Results) presents the findings of the follow-up meetings with key service providers and consultation with service users.
- **Chapter-8** (Feasibility study protocol) describes a protocol for a randomised feasibility study to evaluate the feasibility of the proposed intervention and study design.

- **Chapter-9** (Discussion) describes how the study aim and objectives were addressed, provides a review of the study findings and discusses them in the light of the literature, outlines the strengths and limitations of the study, highlights the contribution to knowledge, and ends with personal reflections.
- **Chapter-10** (Conclusion) provides a summary of the study and outlines the implications for future research, practice, and policy.

1.7 Chapter summary

Heart failure is a life-limiting illness, and patients have significant palliative care needs. However, most patients have poor or late access to palliative care because of barriers related to the unpredictable illness trajectory, difficulty to identify palliative care patients, poor communication and knowledge, and lack of resources. Several guidelines call for integrating palliative care into standard heart failure care, but guidance is lacking on how to achieve that. Palliative care interventions often lack an underpinning theory and understanding of the active ingredients and mechanism of action, which are necessary for implementation. This thesis aims to address this issue through developing a palliative care intervention underpinned by a programme theory to explain how and why palliative care integration can work. In the next chapter, a systematic review of palliative care needs-assessment and measurement tools in heart failure is presented.

2 Systematic review of palliative care needs-assessment and measurement tools used in patients with heart failure

In the previous chapter, the research aim and objectives were outlined, a background of palliative care in heart failure was provided, and the issue of identifying patients with palliative care needs and the subsequent integration of palliative care in heart failure was discussed. In this chapter, the methods and findings of a systematic literature review of palliative care needs-assessment and measurement tools in heart failure are described. The review was published in August 2020 in Heart Failure Reviews journal[125]. It was conducted to identify the relevant evidence and inform discussions in subsequent group workshops with service providers about whether and how to incorporate such tools in the intervention (see **section-4.1**). The chapter starts with an introduction to the importance, challenges, and clinical applications of palliative care needs-assessment and measurement tools in patients with heart failure. The knowledge gap is then presented, where a systematic comparison between the tools is lacking, and the review question and objectives are outlined. Next, the methods of the review are described including the search strategy, study and tool screening, data extraction, quality appraisal, and synthesis. Subsequently, the review findings are presented and discussed in light of the wider literature. The chapter ends by highlighting the review strengths and limitations and implications for research, practice, and policy.

2.1 Introduction

As discussed in **Chapter-1**, patients with heart failure have comparable illness burden and palliative care needs to those with cancer[36,37], but few of them are offered timely palliative care[8]. One main barrier is the difficulty in identifying those who require palliative care[79]. Using structured research tools can aid in identifying such patients[126]. Generally, these tools fall into one of two categories: those predicting the end of life (prognostic tools) and those assessing or measuring patient needs (needs-assessment or needs-measurement tools)[126]. Given the unpredictable trajectory of heart failure, prognostic tools are of limited value for identifying patients with a high risk of mortality who can benefit from palliative care[105]. The NICE guidelines do not recommend their use to determine if patients with heart failure need palliative care referral[13]. These tools do not correlate strongly with the palliative care needs of heart failure populations[105], nor do they account for the improvement in their quality of life[127]. Conversely, tools that focus on assessing or measuring patient needs, instead of predicting prognosis, are more appropriate for the timely initiation of palliative care for patients with heart failure[126,128]. These tools can identify patient needs early before evidence of poor prognosis[129], provide a systematic assessment or measurement of patients' needs which are often underreported by patients or assessed differently by healthcare professionals[130,131], facilitate discussion with the care team, and elicit patient preferences and goals of care[132].

Despite their advantages, some challenges exist to the use of palliative care needs-assessment and measurement tools in heart failure populations. These tools require further evaluation to determine their ability to enhance the timely introduction of palliative care in these patients[126]. Most of these tools have not been widely implemented and few have been specifically developed and validated for non-cancer conditions[133,134]. Several factors should be taken into consideration when selecting the most appropriate palliative care needs-assessment or measurement tool, including the aim of assessment, target patients, patient capabilities, clinical settings, administration mode, and its psychometric and practicality properties[133]; the latter defined as the burden of completing the tool on respondents (acceptability) and administrators (feasibility)[135,136].

The intended use of the tools is another important factor to guide the selection of appropriate tools[137]. While some tools are mainly used as screening instruments to identify patients who require palliative care based on their deteriorating health and potential palliative care needs (patient-identification tools), others are primarily used to provide a more holistic evaluation of those unmet needs (needs-identification tools)[138]. Furthermore, while some tools are designed to measure patient needs (needs-measurement tools), others are designed to assess these needs as clinical decision aids (needs-assessment tools)[139]. Needs-measurement tools enable screening, monitoring, and scoring patient needs over time to track changes in health status and evaluate the effectiveness and quality of provided care[140]. When used alone, these tools may not trigger healthcare professionals to act on the identified needs as they may lack the skills and knowledge to interpret the scores[141,142]. Therefore, they may have little contribution to clinical decision making on their own[143]. On the other hand, needs-assessment tools, as clinical decision aids, facilitate the evaluation of patient needs, assignment of actions to address those needs, and understanding of care options and outcomes[139,144]. These tools are ideally used as adjuncts to patient counselling to assist healthcare professionals in making the most appropriate decisions on patient care[139]. They are not intended to be prescriptive or used as an endpoint in themselves, but rather as a support and starting point for patient-centred care[139].

Comparisons between palliative care needs-assessment or measurement tools used in heart failure populations are lacking. It is not known which tools are better for identifying palliative patients and their care needs and which have the best psychometric and practicality evidence in these patients[126]. There are no systematic reviews to critique these tools in identifying patients with heart failure who have palliative care needs. Three systematic reviews demonstrated tools that could be used to identify palliative care patients[134,138,145]. However, these were not specific to heart failure populations and limited to primary care settings. Another review of palliative care needs-assessment tools used in patients with chronic heart failure was not systematic, nor did it compare the psychometric properties in detail[126]. A comprehensive comparison between palliative care needs-assessment or measurement tools used in heart failure populations is needed to determine the most appropriate tools for identifying patients who require palliative care and assessing or measuring their needs. Subsequently, these needs can be acted upon to improve patients’ quality of life.

2.1.1 Review question

What are the most appropriate palliative care needs-assessment or measurement tools for use in patients with heart failure?

2.1.2 Review objectives

1. Identify palliative care needs-assessment or measurement tools used to identify patients with heart failure who have palliative care needs.
2. Compare these tools regarding their content (included items, length, addressed need domains) and context of use (clinical settings, completion method).
3. Compare the development and intended use of the tools.
4. Compare the psychometric and practicality properties of the tools in patients with heart failure.
5. Compare the clinical applications of the tools in identifying patients with heart failure who have palliative care needs.

2.2 Methods

The review protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) on 17th December 2018 under registration number CRD42018118376. Quantitative, qualitative, and mixed-methods studies were included in the review to maximise the evidence on using the tools in patients with heart failure, where limited research is available[146]. The review was written following the guidance of the adapted Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) for reporting systematic reviews of qualitative and quantitative evidence[147]. Covidence online software programme was used to facilitate systematic review management.

2.2.1 Inclusion and exclusion criteria

Studies were included if they met these criteria:

- Included adults 18 years of age or older with a primary diagnosis of heart failure.

- Evaluated palliative care needs-assessment or measurement tools, defined as structured multi-item research instruments developed for identifying palliative care patients or needs.
- Evaluated more commonly used tools, defined as those which were used for identifying heart failure populations with palliative care needs in more than one study retrieved through the review search.
- Aimed to evaluate the tools in terms of development, psychometrics or practicality, or identification of palliative care patients or needs.
- Primary empirical quantitative, qualitative, or mixed-methods studies where quantitative and qualitative data were combined at the stage of data collection and/or analysis.
- Published in English or Arabic.

Studies that evaluated guidelines, pathways, and individual items were excluded. Case reports, opinion pieces, editorials, commentaries, letters, retrospective studies, reviews, and secondary research were also excluded.

2.2.2 Search strategy

A sensitive search strategy was applied to retrieve relevant studies and tools after consulting experienced librarians. Cochrane Library, MEDLINE Complete (EBSCO), AMED (EBSCO), PsycINFO (EBSCO), CINAHL Complete (EBSCO), and EMBASE (Ovid) were searched from inception to 25th June 2020. The following secondary resources were also searched: websites of the retrieved tools where available; EThOS for UK's doctoral research theses; and citing and cited articles of the included studies. Search terms for "palliative care", "heart failure", and "tool" were combined in each database using free-text terms and medical subject headings where available (**Table-3**). The search strategy for EMBASE (Ovid) is presented in **Appendix-1**. Duplicates were removed from the retrieved records using EndNote X8 and Covidence.

Table-3: Key search terms used in the review

Key search terms*	
Concept-1	Palliative care OR Terminal care OR Long-term care OR End of life care OR Hospice OR Advance care planning
Concept-2	Heart failure OR Cardiac failure OR Ventricular dysfunction OR Low cardiac output OR Dilated cardiomyopathy OR Congestive cardiomyopathy OR Cardiogenic shock
Concept-3	Tool OR Survey OR Questionnaire OR Checklist OR Inventory OR Scale OR Instrument OR Indicator OR Measure OR Index OR Model OR Criteria OR Calculator OR Score
Filters/limits	
Population	Human
Language	English or Arabic
Study design	Empirical research
Date	No limits
Settings	No limits

* These terms are not exhaustive. An example of a comprehensive search strategy for EMBASE (Ovid) is shown in **Appendix-1**.

2.2.3 Study and tool selection

Titles and abstracts of retrieved studies were screened by the main author (BR). A second reviewer (IM) screened 10% of them independently. The agreement rate for the studies screened was 97% which demonstrated a high level of agreement. Full texts of potentially relevant studies were screened by BR to determine their eligibility, while IM screened 25% of those independently as the agreement rate was 80%. Discrepancies were resolved through discussion which helped identify screening issues and discuss the inclusion criteria. A third reviewer (my supervisors) was consulted when necessary.

2.2.4 Data collection

Data extraction tables were created for the included studies. They were piloted first on a sample of studies and continuously amended until the final versions were developed. Extracted data included study design, objectives, population, settings, and country; method of and reason for tools' development; results of psychometric and practicality testing; method of identifying patients requiring palliative care and their needs; and results of tools' applications in identifying palliative patients or needs. Relevant data were extracted from the included papers by BR. IM extracted data from about half of the papers independently. All disagreements were resolved through discussion which helped identify extraction issues and refine the data extraction tables. There was no need to refer to the third reviewer. The first authors of the included studies were contacted by email to clarify vague information if necessary, and all of them responded. Data were also extracted from the tools themselves and their associated guides if available. Extracted data included primary instruments from which the tools were adapted, settings of use, completion method and time, and involved items and need domains. The latest edition or version of each tool at the time of synthesising the evidence was compared with the others.

2.2.5 Criteria to assess the tools' psychometrics and practicality

The psychometric and practicality properties of the included tools were assessed by BR using the Oxford Patient-Reported Outcome Measures (PROMs) Group criteria for selecting PROMs in clinical trials[137]. Although the tools in this review were not all PROMs, this seemed the most appropriate tool to use as it provides detailed and evidence-based guidance on how to assess each of these criteria. It also allows the assignment of a score for each criterion to facilitate comparisons[148]. Among the eight criteria suggested by the Oxford PROMs Group, the five which have been more often used and cited on standard checklists and discussions were compared: Acceptability, Feasibility, Reliability, Validity, and Responsiveness[137]. Reliability measures the extent to which the tool is free from random error, validity measures the extent to which the tool measures what it purports to measure, and responsiveness measures the ability of the tool to detect clinically important change over time[137].

2.2.6 Quality appraisal

To assess the quality of the heterogeneous studies (quantitative, qualitative, and mixed methods), Hawker et al.'s tool for appraising disparate data was used[149]. This instrument assesses the quality of studies based on nine criteria which can be scored from one (very poor) to four (good). The minimum and maximum possible scores per study are nine and 36, respectively. Studies were not excluded based on their methodological rigour or assigned scores. Quality assessment of the included papers was performed by BR, while IM assessed the quality of about half of them independently. Disagreements were resolved through discussion which helped identify quality appraisal issues and critique the studies more thoroughly. There was no need to refer to the third reviewer.

2.2.7 Synthesis method

Narrative synthesis, guided by Popay et al.'s framework, was used to synthesise the findings from the heterogeneous studies[150]. Tools were described narratively, and studies were tabulated and grouped according to the evaluated tool and their application to discover patterns within and across the groups. Subsequently, relationships were explored within and between the studies. The synthesis process was then critiqued where the limitations of the synthesis methodology, influence of low-quality studies on the synthesis results, made assumptions, and areas for future research were highlighted. Synthesising the evidence from the included studies was carried out by BR.

2.3 Results

2.3.1 Study selection

The search strategy for the primary and secondary resources retrieved a total of 46,212 records, which were reduced to 33,135 after removing duplicates. The titles and abstracts of these papers were screened for relevance and meeting the inclusion criteria, resulting in 308 papers for full-text screening. Among these, 27 papers were included in the review from 19 studies. Ten studies were quantitative[58,105,151-160], one was qualitative[161], and eight were of mixed-methods design[132,162-174]. All studies were observational except for one interventional study[167-170], one pilot study[165], and one feasibility study[132,162]. The PRISMA flow diagram of study selection is presented in **Figure-2**[175].

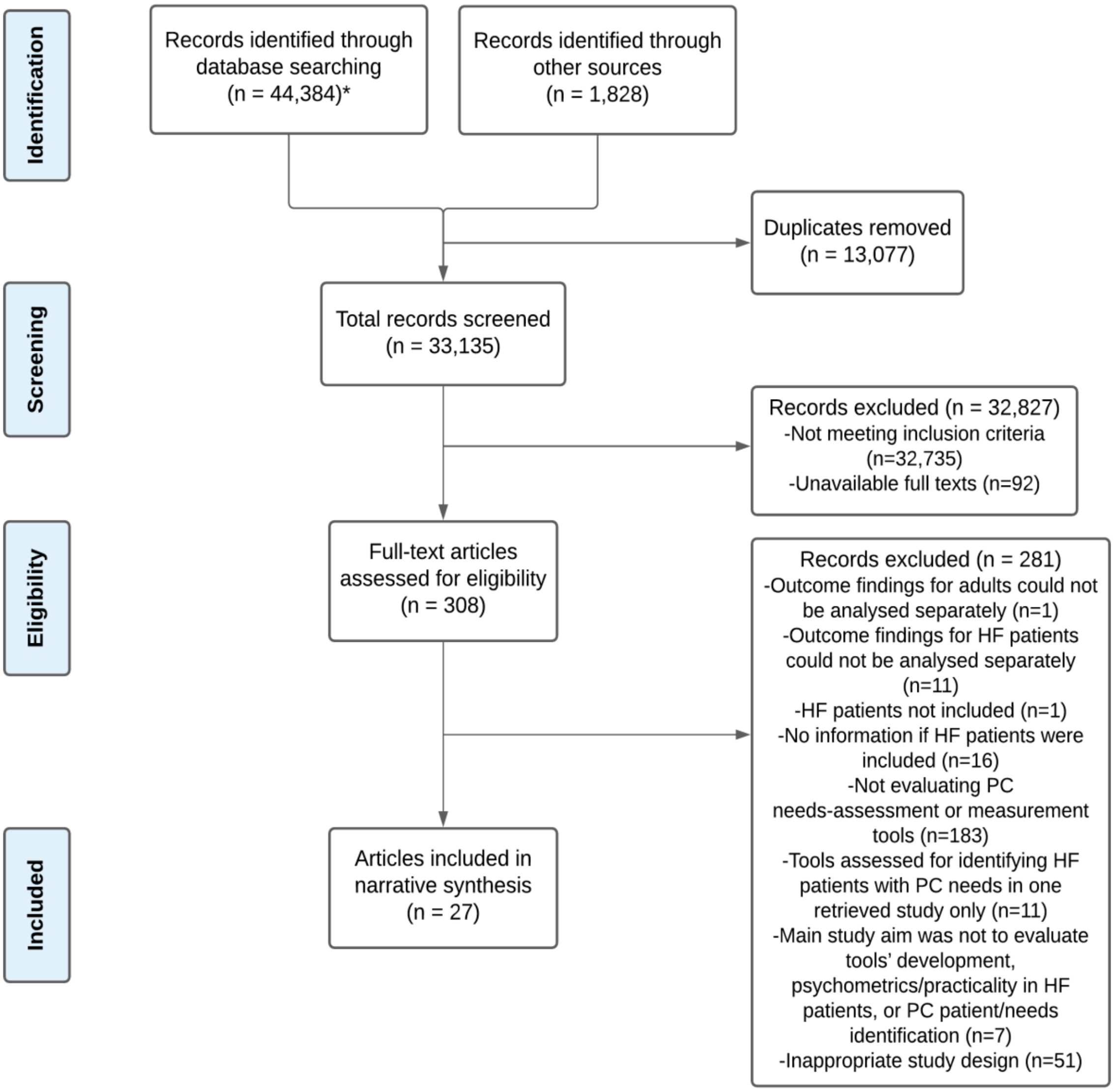


Figure-2: PRISMA flow diagram of study selection

HF: Heart Failure, PC: Palliative Care.
* Cochrane Library, MEDLINE Complete, AMED, PsycINFO, CINAHL Complete, and EMBASE were originally searched from inception to 4th January 2019. The latest search update was run in these databases on 25th June 2020 except for CINAHL Complete because of end of subscription.

The included papers were classified into three categories based on how the included tools were evaluated: studies assessing the tools' development, studies assessing the tools' psychometric or practicality properties, and studies assessing palliative care patient or needs identification (**Table-4**). Some studies fitted into more than one category as they were used for more than one purpose. There were five studies assessing the tools' development, five studies assessing psychometrics or practicality, and 17 studies assessing palliative care identification. Quality scores of studies ranged from 22 to 35 with a median of 29, indicating moderate to good quality.

2.3.2 Identifying palliative care needs-assessment or measurement tools used to identify patients with heart failure who have palliative care needs

Several tools were found that had been or could be used for identifying patients with heart failure who require palliative care. Among these, six palliative care needs-assessment or measurement tools were identified as per the inclusion criteria and compared:

1. Gold Standards Framework - Proactive Identification Guidance (GSF-PIG)[176].
2. Radboud Indicators for Palliative Care Needs (RADPAC)[166].
3. Supportive and Palliative Care Indicators Tool (SPICT)[171].
4. Necesidades Paliativas - Palliative Needs (NECPAL)[172].
5. Integrated Palliative care Outcome Scale (IPOS)[161].
6. Needs Assessment Tool: Progressive Disease - Heart Failure (NAT:PD-HF)[164] (**Appendix-2**).

Table-4: List of the included tools and corresponding evaluation studies with their overall quality scores using Hawker et al.'s tool

Tool	Development study	Quality score*	Psychometrics or practicality study	Quality score*	Identification study	Quality score*
IPOS	Schildmann et al. 2016[161]	32	Kane et al. 2017[162]	29	Kane et al. 2017[162]	29
					Kane et al. 2018[132] *(follow-up paper)*	30
			Roch et al. 2020[163]	28	Roch et al. 2020[163]	28
GSF-PIG	not found	--	not found	--	Milnes et al. 2019[151]	27
					Haga et al. 2012[105]	30
					Gardiner et al. 2013[153]	28
					Ryan et al. 2013[152] *(follow-up paper)*	30
					Pandini et al. 2016[154]	24
RADPAC	Thoonsen et al. 2012[166]	27	not found	--	Thoonsen et al. 2011[167] *(protocol)*	--
					Thoonsen et al. 2015[168]	32
					Thoonsen et al. 2019[169] *(follow-up paper)*	32
					Thoonsen et al. 2016[170] *(follow-up paper)*	29
SPICT	Highet et al. 2014[171]	27	not found	--	Highet et al. 2014[171]	27
					Hamano et al. 2018[155]	26
					Hamano et al. 2019[156]	29
NAT:PD-HF	Waller et al. 2013[164]	30	Waller et al. 2013[164]	30	Waller et al. 2013[164]	30
			Janssen et al. 2019[165]	35	Janssen et al. 2019[165]	35
			Campbell et al. 2018[58]	28	Campbell et al. 2015[157] *(protocol)*	--
					Campbell et al. 2018[58]	28
NECPAL	Gómez-Batiste et al. 2013[172]	24	not found	--	Gómez-Batiste et al. 2013[172]	24
					Gómez-Batiste et al. 2014[173] *(follow-up paper)*	30
					Amblàs-Novellas et al. 2016[174] *(follow-up paper)*	29
					de-la-Rica-Escuín et al. 2019[158]	30
					Orzechowski et al. 2019[159]	23
					Gastelurrutia et al. 2019[160]	22

* Scores are out of 36.

2.3.3 Comparing the tools regarding their content and context of use

The main features and comparisons of the tools are displayed in **Table-5**. All tools were based on previous tools that informed their development except RADPAC, which was informed by extracting indicators used for identifying patients with palliative care needs from the literature[166]. Some tools were derived from each other which explains their similarities.

2.3.3.1 Included items

The tools include different items to identify patients with palliative care needs. GSF-PIG and NECPAL include the *surprise question* (would you be surprised if the patient dies in the next year?) as the first step for identification[177], followed by general and disease-specific indicators of health decline. SPICT does not have the surprise question but includes general and disease-specific indicators, while RADPAC has only disease-specific indicators. In all these tools, a set of indicators specific to heart failure, or heart disease, exists. IPOS and NAT:PD-HF do not have indicators for patient identification. Instead, they include items that evaluate a variety of patient needs. IPOS consists of open-ended questions about patient main problems and unlisted symptoms alongside closed-ended questions on patient and family carer needs which are answered using a Likert scale. It gives a total score that measures the overall patient needs. NAT:PD-HF consists of four sections that address patient and family carer needs: Priority referral for further assessment, Patient wellbeing, Ability of caregiver or family to care for patient, and Caregiver wellbeing. Needs identified in the last three sections can be rated according to their significance: None, Some/Potential, and Significant. Moreover, actions are suggested for these needs: Directly managed (by the healthcare professional), Managed by other care team member, and Referral required (to members outside the team).

Table-5: Main features and comparisons of the tools

Tool	**IPOS** ***version-1***	**NAT:PD-HF** ***original version***	**GSF-PIG** ***6th edition***	**RADPAC** ***original version***	**SPICT** ***April 2019***	**NECPAL** ***version-3.1***
Tools from which the tool was derived	POS, POS-S, APCA African POS	PC-NAT	NHPCO tool	none	NHPCO tool, GSF-PIG, PPS, PPI	GSF-PIG, SPICT
Clinical settings						
Generic vs HF-Specific tool	Generic	HF-Specific	Generic	Generic	Generic	Generic
Clinical settings for tool use	Multiple	Multiple	Multiple	Primary care/ General practice	Multiple	Multiple
Completion method						
Completed by	Healthcare professionals (staff version), Patients (patient version)	Healthcare professionals	Healthcare professionals	Primary care practitioners	Healthcare professionals (staff version), Family carers (SPICT-4ALL)	Healthcare professionals
Objective or Subjective*	Subjective	Subjective	Objective, Subjective	Objective, Subjective	Objective, Subjective	Objective, Subjective
Items						
Surprise Question	**X**	**X**	✓	**X**	**X**	✓
General indicators of health decline or PC need	**X**	**X**	✓	**X**	✓	✓
Disease-specific indicators of health decline or PC need	**X**	**X**	✓	✓	✓	✓
Open questions	✓	**X**	**X**	**X**	**X**	**X**
Likert scale questions	✓	✓	**X**	**X**	**X**	**X**

Tool	**IPOS** ***version-1***	**NAT:PD-HF** ***original version***	**GSF-PIG** ***6^{th} edition***	**RADPAC** ***original version***	**SPICT** ***April 2019***	**NECPAL** ***version-3.1***
Length						
Number of items (for HF patients)	17 (+2 open questions)	20	17	7	9	18
Average time for completion	Staff version: 2–5 minutes Patient version: 8 minutes	5–10 min. (Dutch version: 26 minutes)	not assessed	not assessed	Older staff versions: 5–7.5 minutes	Older version: 2–8 minutes
Minimal criteria to identify HF patients who require PC	not applicable	not applicable	SQ+, or general indicators, or two HF-specific indicators	not clear	Any general indicator or the HF-specific indicator	SQ+ plus any other parameter
Need domains						
Physical	✓	✓	✓	✓	✓	✓
Psychological	✓	✓	✓	**X**	**X**	✓
Social	✓	✓	**X**	**X**	**X**	✓
Spiritual	✓	✓	**X**	**X**	**X**	**X**
Others	Family carer, Information, Financial and personal	Family carer, Information, Financial and legal, Treatment regimens	--	--	Family carer	--

APCA: African Palliative Care Association, HF: Heart Failure, NHPCO: National Hospice and Palliative Care Organisation, PC: Palliative Care, PC-NAT: Palliative Care-Needs Assessment Tool, POS: Palliative care Outcome Scale, POS-S: Palliative care Outcome Scale-Symptoms, PPI: Palliative Prognostic Index, PPS: Palliative Performance Scale, SQ+: a negative answer to the Surprise Question (healthcare professionals would not be surprised if the patient dies within the next year).

* Objective: medical records. Subjective: clinical judgement or patient/family carer input.

2.3.3.2 Clinical settings

Only NAT:PD-HF is specific for use in patients with heart failure[164]. All other tools can be used in multiple diseases. RADPAC was developed for use in primary care[166], while the other tools can be used in different healthcare settings.

2.3.3.3 Completion method

Other than IPOS and SPICT which have a version for staff completion and another for patient or family carer completion, respectively, all tools were designed to be completed by healthcare professionals with interaction from patients or family carers. All tools have a subjective element of completion where healthcare professionals use their clinical judgement (for example, to assess symptoms severity or health decline) or where patients or family carers provide their input (for example, to ask for palliative care or rate their symptoms). GSF-PIG, RADPAC, SPICT, and NECPAL require information from patients' medical records such as the number of hospitalisations and weight.

2.3.3.4 Length

The length of tools varies with a range of seven items for completion (RADPAC) to 20 items (NAT:PD-HF). IPOS and NAT:PD-HF contain more items than other tools and although they may take longer to complete, they provide a more comprehensive evaluation of patient needs. SPICT and NECPAL need less than eight minutes to complete[178-180]. IPOS patient version takes about eight minutes to complete while the staff version takes about two to five minutes[181]. NAT:PD-HF needs about five to ten minutes[133], although its Dutch translation needed an average of 26 minutes to be completed by heart failure nurses who were untrained in palliative care[165].

2.3.3.5 Addressed need domains

NAT:PD-HF covers more palliative care needs than any other tool, including the key need domains advocated by the WHO: physical, psychological, social, and spiritual[54]. It is the only tool that asks if patients have problems in managing their medication and treatment regimens, which is important in heart failure as patients commonly have comorbidities and take several medications[18]. IPOS is also comprehensive and addresses most of the need domains contained in NAT:PD-HF. NECPAL misses the spiritual issues, while GSF-PIG, RADPAC, and SPICT address mainly the physical symptoms of patients.

In a summary for **section-2.3.3**, NAT:PD-HF and IPOS outweigh other tools regarding the content and context of use. Both can be used in multiple clinical settings, completed in a reasonable timeframe without reviewing patient medical records, provide a comprehensive assessment or measurement of patient and family carer needs, and address more palliative care needs than other tools. Compared with NAT:PD-HF, IPOS has a patient version for completion which can decrease staff burden, includes open questions which enable patients to outline their main problems and unlisted symptoms, and requires less time for completing. However, unlike NAT:PD-HF, IPOS does not explicitly address treatment complexity among patient needs, nor does it have a corresponding action to be taken for the identified concerns.

2.3.4 Comparing the development and intended use of the tools

None of the tools was originally developed for use in patients with heart failure. Only NAT:PD-HF was adapted specifically for use in these patients from a similar tool for patients with cancer[164]. All other tools are generic but have been used for patients with heart failure. A heart failure-specific version of IPOS has not been formally tested yet[182]. All tools were developed in high-income countries, and half of them (IPOS, GSF-PIG, SPICT) were developed in the UK. The clinical expertise of healthcare professionals contributed to the tools' development. Literature reviews were conducted to aid in the development of all tools except GSF-PIG[176]. Notably, all tools have an original development paper except GSF-PIG.

GSF-PIG, RADPAC, SPICT, and NECPAL were developed to identify patients who require palliative care (patient-identification tools)[166,171,172,176], while IPOS and NAT:PD-HF were developed to provide a more comprehensive evaluation of the palliative care needs of patients (needs-identification tools)[161,164]. The patient-identification tools were mainly developed as *clinical decision aids* which can be used during patient consultation to decide whether patients require palliative care and subsequently to prompt more holistic needs assessment or measurement. SPICT, for example, is recommended to be used alongside IPOS to get a more complete picture of patient needs[183]. IPOS was developed as an *outcome measure* to identify and score patient symptoms and concerns. It does not provide recommendations on how to address the identified needs and thus, clinical decision support tools are needed to interpret its scores[139]. NAT:PD-HF is not an outcome measure. It is mainly used as a clinical decision aid during patient consultation to classify the level of concern (none, some/potential, significant) and assign actions for each identified need (directly managed, managed by other care team member, referral required). The main purpose and intended use of the tools are summarised in **Table-6**.

Table-6: Main purpose and intended use of the tools

Tool*	IPOS	NAT: PD-HF	GSF-PIG	RADPAC	SPICT	NECPAL
Patient identification			✓	✓	✓	✓
Needs identification	✓	✓				
Needs assessment/ Decision aids		✓	✓	✓	✓	✓
Needs measurement	✓					

* This classification should not be considered rigid as there can be some overlap in these applications.

2.3.5 Comparing the psychometric and practicality properties of the tools in patients with heart failure

In the general population, IPOS and SPICT have the best evidence of validity, reliability, and practicality[161,171,178,179,184-190], followed by NECPAL and RADPAC[166,172], while no formal validation studies were found for GSF-PIG. Still, the psychometric and practicality properties of the tools were rarely assessed in heart failure populations (**Table-7**). Only NAT:PD-HF, its Dutch translation, IPOS, and its German translation had their practicality properties tested in these patients[162-165]. Only NAT:PD-HF and its Dutch translation had some of their psychometric properties tested in this population[58,164,165].

Table-7: Psychometric and practicality properties of the tools in patients with heart failure, using the Oxford PROMs Group criteria

Tool	Acceptability	Feasibility	Reliability	Validity	Responsiveness
IPOS (original)	+++	+++	0	0	0
IPOS (German)	++	0	0	0	0
NAT:PD-HF (original)	+	+++	+	++	0
NAT:PD-HF (Dutch)	–	–	0	–	0
GSF-PIG	0	0	0	0	0
RADPAC	0	0	0	0	0
SPICT	0	0	0	0	0
NECPAL	0	0	0	0	0

– = evidence does not support criteria.
0 = not reported or no evidence in favour.
+ = some limited evidence in favour.
++ = some good evidence in favour, but some aspects do not meet criteria or are not reported.
+++ = good evidence in favour.

2.3.5.1 Acceptability

Acceptability of the tools to patients was only tested for original NAT:PD-HF, Dutch NAT:PD-HF, original IPOS, and German IPOS. Overall, IPOS and original NAT:PD-HF were acceptable, with more evidence in favour of IPOS[162-164]. On the contrary, Dutch NAT:PD-HF had negative evidence of acceptability[165].

2.3.5.2 Feasibility

Feasibility of the tools for healthcare professionals was only tested for original NAT:PD-HF, Dutch NAT:PD-HF, and original IPOS. While original IPOS and original NAT:PD-HF were feasible (easy to complete in a short time)[162,164], Dutch NAT:PD-HF had negative evidence of feasibility[165].

2.3.5.3 Reliability

Reliability was only assessed for original NAT:PD-HF[164]. Results of testing inter-rater reliability showed good agreement between the raters for each tool item. Internal consistency and test-retest reliability were not tested.

2.3.5.4 Validity

Validity was only assessed for original NAT:PD-HF and Dutch NAT:PD-HF. Original NAT:PD-HF showed good face, content, and concurrent (construct) validity[58,164]. Construct validity was tested in one study by identifying the correlation between the items in the NAT:PD-HF *patient wellbeing* section and corresponding items from the Heart Failure Needs Assessment Questionnaire (HFNAQ)[164]. In another study that was not designed to test the tool psychometrics, a statistically significant relationship was found between having a significant concern on any item in the NAT:PD-HF *patient wellbeing* section and the construct of specialist palliative care needs as defined by the authors (persistently severe impairment of any of four PROMs without improvement, or severe impairment immediately preceding death)[58]. The other tool sections were not tested for construct validity in both studies. In contrast to original NAT:PD-HF, Dutch NAT:PD-HF showed poor construct and criterion validity[165]. These were tested by identifying the correlation between some items of Dutch NAT:PD-HF and three outcome measures: Dutch Edmonton Symptom Assessment System (ESAS), Australia-modified Karnofsky Performance Scale (AKPS), and Family Appraisal of Caregiving Questionnaire for Palliative Care (FACQ-PC). Of note, the evaluating study was a pilot study and not designed to test the tool's validity.

2.3.5.5 Responsiveness

Responsiveness was not evaluated for any tool.

In a summary for **section-2.3.5**, original NAT:PD-HF is the most extensively tested and psychometrically robust tool in heart failure populations. It is the only tool validated in this population and has some evidence of reliability. It is feasible for healthcare professionals and has some evidence of acceptability to patients. Although IPOS has more acceptability evidence than NAT:PD-HF, its psychometrics has not been tested in heart failure populations. Psychometrics and practicality of the other tools were not tested at all in this population.

2.3.6 Comparing the clinical applications of the tools in identifying patients with heart failure who have palliative care needs

The characteristics of the palliative care identification studies are shown in **Appendix-3**. Detailed results of the tools' applications in identifying heart failure populations with palliative care needs are presented in **Appendix-4**.

2.3.6.1 Breadth of tools' application in heart failure populations

Few identification studies were found for each tool. GSF-PIG and NECPAL were the most commonly evaluated (four studies each)[105,151-154,158-160,172-174], followed by SPICT and NAT:PD-HF (three studies each)[58,155-157,164,165,171], IPOS (two studies)[132,162,163], and lastly RADPAC (one study)[167-170]. GSF-PIG was evaluated in more countries than other tools (four countries), followed by NAT:PD-HF (three countries). NECPAL was evaluated in diverse healthcare settings, while IPOS, GSF-PIG, SPICT, and NAT:PD-HF were evaluated for inpatients and outpatients. More patients with heart failure were screened by NAT:PD-HF and NECPAL compared with other tools. Baseline data for the tools-screened patients were described in more detail in NAT:PD-HF and IPOS studies. While NAT:PD-HF was evaluated for several types and classes of heart failure and was the only tool evaluated for those with acute on chronic heart failure, patients who lacked the cognitive capacity to participate or consent were excluded from NAT:PD-HF studies.

2.3.6.2 Use for palliative care patient or needs identification

All tools were used to identify palliative patients (patient identification) and evaluate their needs (needs identification), although these were not always reported. When used for patient identification, GSF-PIG (in one study) and RADPAC were combined with a more comprehensive needs-assessment or measurement tool[152,153,167,168].

2.3.6.3 Ability and appropriateness of the tools for palliative care identification

The proportion of patients with heart failure identified by the tools for palliative care among those screened was considered an indicator of their *identification ability*. This could not be calculated in many studies because of missing or vague data and the lack of a clear gold standard of what a palliative care patient is. RADPAC-trained primary practitioners identified only 6% of patients with heart failure in a randomised controlled trial[168]. One year after training, these trained practitioners did not identify any patient, while those untrained identified more patients shortly after RADPAC administration[169]. SPICT identified only a few patients with heart failure although the proportion in one study was misleadingly high because of the small sample size[155]. GSF-PIG identified 86% of patients with heart failure in one study[105], while NECPAL identified 32%, 55%, and 91% in three studies[159,160,173]. IPOS and NAT:PD-HF identified 56% and 26% of patients with heart failure for specialist palliative care, respectively[58,163]. NAT:PD-HF identified 100% of patients for palliative care in another study[165].

The baseline health characteristics and morbidity outcomes of identified patients were considered an indicator of the *appropriateness of identification* by the tools. However, this was not adequately reported in most studies. The tool is robust if the patients it identified for palliative care had evidence of poor health. Poor health at baseline, evidenced by poor scoring in patient outcome measures, long or frequent hospitalisations, old age, and/or NYHA class III-IV, was shown for many patients identified by IPOS[163], GSF-PIG[105,152,153], NAT:PD-HF[58,165], and NECPAL[159,160]. Likewise, better health at baseline, evidenced by NYHA class I-II, was observed in many patients who reported few significant psychological, social, and spiritual concerns in NAT:PD-HF[164]. Morbidity outcomes at follow-up periods of identified patients were only presented briefly in one GSF-PIG study, where identified patients did not have significantly more hospitalisations within a one-year follow-up period as would have been expected[105].

2.3.6.4 Impact of the tools

Three tools were incorporated into palliative care interventions where healthcare professionals were trained on using the tools to identify, and subsequently act on, the palliative care needs of patients[162,165,167,168]. IPOS, RADPAC, and Dutch NAT:PD-HF had no significant positive impact on patients with heart failure or their family carers. The IPOS-based intervention resulted in mild improvement in patients' quality of life, symptom burden, and depression, though this was often transient and got worse at further follow-up periods[162]. Similarly, symptom burden, physical functioning, care dependency, and caregiving burden were not significantly improved after the Dutch NAT:PD-HF intervention and health status got significantly worse[165]. Additionally, it did not influence the recording of advance directives or hospital and emergency room visits. Of note, the studies that evaluated the intervention effect of IPOS and Dutch NAT:PD-HF were pilot or feasibility studies and not designed to test their effectiveness[162,165]. In contrast, the RADPAC intervention effect was evaluated in a cluster-randomised controlled trial where primary care practitioners used the tool to identify patients with palliative care needs[167,168]. RADPAC intervention did not result in a significant difference between deceased patients of RADPAC-trained practitioners and those of untrained practitioners in the number of contacts with out-of-hours primary care service (primary outcome measure), contacts with own primary care practitioner, hospitalisations, and place of death (secondary outcome measures). In a post-hoc analysis, identified patients from the trained group (only two with heart failure) had significantly better secondary outcome measures compared with all other patients, but the primary measure was not different.

2.3.6.5 Perspectives of healthcare professionals and patients on using the tools for palliative care identification

The three interventions described above were followed by interviews with healthcare professionals and/or patients to evaluate their perspectives on using the tools for identification[132,165,170]. The emerged themes were mainly positive for IPOS and RADPAC and negative for Dutch NAT:PD-HF. A common positive theme on IPOS and RADPAC was the identification of palliative care needs (IPOS) and patients (RADPAC), though identifying those with heart failure was considered difficult by RADPAC. Dutch NAT:PD-HF was not found helpful to communicate about palliative care, while IPOS was found to facilitate patient communication with nurses although many patients did not consider it to have any clinical effect. Patient perspectives were only evaluated for IPOS while healthcare professionals were interviewed in all studies.

In a summary for **section-2.3.6**, NAT:PD-HF outperformed other tools in the clinical applications in identifying palliative patients or needs though this needs further testing. NAT:PD-HF has relatively wide application in heart failure populations and it was used for both patient identification and needs identification. NAT:PD-HF was able to identify high proportions of patients with heart failure who have palliative care needs. More importantly, those identified had poor health at baseline, indicating a proper identification. The original NAT:PD-HF was not incorporated into an intervention in contrast to its Dutch translation. Like IPOS and RADPAC, Dutch NAT:PD-HF lacked a significant positive impact on patients and family carers. Unlike these two tools, healthcare professionals were not positive in their comments on Dutch NAT:PD-HF and they listed many barriers to its use.

2.4 Discussion

This is the first systematic review that comprehensively compares palliative care needs-assessment or measurement tools used in patients with heart failure. The main review question was to determine the most appropriate palliative care needs-assessment or measurement tools for use in heart failure populations. Six tools were identified and compared according to their content and context of use, development, psychometrics and practicality, and applications in identifying patients with palliative care needs. Based on the limited available evidence, NAT:PD-HF is the most appropriate palliative care needs-assessment tool for heart failure populations, though more studies are needed to confirm this. IPOS is promising and shares many advantages of NAT:PD-HF but it is less commonly studied in this population. The generalisability of the review results is limited by the small number of tool-evaluating studies and the heterogeneity of populations, interventions, outcomes, and healthcare settings.

2.4.1 Comparing the review findings to the literature

The results of this review are concordant with the 2020 EAPC position statement on heart failure that calls for using a comprehensive palliative care needs-assessment tool to identify patients with unmet needs[14]. NAT:PD-HF, being validated for patients with heart failure, was suggested as an example of such a tool but this was not based on detailed comparisons with other tools. IPOS was also suggested as a trigger to initiate palliative care but categorised separately as a symptoms-assessment tool. SPICT was considered a patient-identification tool that does not detail individual needs. Although SPICT was recommended over other tools in one review to identify palliative patients, this was concluded for the general population in primary care, and neither NAT:PD-HF nor IPOS was included in that review[145].

NAT:PD-HF was not identified in three previous systematic reviews that looked for tools used to identify general populations with palliative care needs in primary care[134,138,145]. It was probably seen as a needs-identification rather than a patient-identification tool. Indeed, NAT:PD-HF was developed for identifying patient needs rather than screening patients who require palliative care, although it has been used for both purposes[58,164,165]. Another non-systematic review of palliative care needs assessment in patients with chronic heart failure included NAT:PD-HF but it did not seek which tool is the most appropriate for this population[126].

Shortly after the publication of this review[125], Ament et al. published a similar systematic review of tools to help healthcare professionals recognise palliative care needs in patients with advanced chronic heart failure[191]. Both reviews aimed to identify and describe the tools and compare their development and intended use, psychometric and practicality properties, and clinical applications in patients with heart failure. However, my review aimed to synthesise the findings to identify *the most appropriate* tools for use in this population (Review question), while Ament et al.'s review focus was more descriptive. Although Ament et al. identified NAT:PD-HF, IPOS, RADPAC, and NECPAL, both GSF-PIG and SPICT were not identified although they were included in this and other similar reviews[125,126,134,138,145]. Similar to this review, Ament et al. concluded that despite the limited evidence on the use of the tools to recognise the palliative care needs of patients with heart failure, NAT:PD-HF and IPOS are the most promising given their robust psychometric properties[191]. Methodologically, the quality of included studies was appraised in my review, but not in Ament et al.'s review, which strengthens the evidence of my review findings.

2.4.2 Tools' content and context of use

The tools have different items to identify patients with palliative care needs, including the surprise question, indicators of deterioration, and reported symptoms and concerns. The surprise question was suggested as a simple method for identifying patients with palliative care needs[192,193]. However, RADPAC developers did not recommend it to trigger end-of-life discussions[166], and although it was included in SPICT original versions, it was removed later. Apart from this question, the items of some tools (GSF-PIG, RADPAC, and SPICT) address mainly patient physical symptoms. Consequently, these tools may not be able to identify relatively asymptomatic patients with a high risk of dying[194,195].

The length of time to complete the tools should be accounted for to prevent staff and patient burden[133]. Reasons for the differences between the tools in time for completion include the tool purpose, number of items, and completion method[133,145]. NAT:PD-HF and IPOS aim to identify the multidimensional palliative care needs of patients and hence, they have the largest number of items to complete. All items require clinical judgement or patient or family carer input which may increase completion time[145]. The *action taken* section of NAT:PD-HF may contribute to the longer time needed to complete the tool compared with IPOS, but it may also prompt staff to think about how to act on the identified needs. IPOS does not have such a section and it may just be filled and filed without having a clinical effect[132].

IPOS patient version (PROM) can be used outside the consultation time where each question is answered to provide a score measure for each concern and symptom. Conversely, although NAT:PD-HF takes a relatively few minutes to complete the form itself, it represents information obtained throughout a longer clinical assessment. This may explain the long time needed to complete its Dutch translation (26 minutes)[165]. Interestingly, the original cancer version of NAT:PD-HF did not prolong the average consultation time (18 minutes) indicating that the tool items are normally evaluated during consultations[196]. The other tools (GSF-PIG, RADPAC, SPICT, and NECPAL) are clinical consultation aids, like NAT:PD-HF, but they require screening medical records in addition to subjective judgements. No data about the time for completion were available on the latest version of these tools at the time of synthesising the evidence.

2.4.3 Tools' development and intended use

GSF-PIG, SPICT, and NECPAL were derived from prognostic tools but the focus has been shifted from determining prognosis to assessing needs for recognising eligible patients for palliative care. This is supported by the results of a study where a high level of need was observed among patients identified by GSF-PIG although few of them died within a 12-month follow-up period[105]. Indeed, GSF-PIG was renamed from "Prognostic Indicator Guidance" to "Proactive Identification Guidance" although the tool content only showed minimal changes[176]. Likewise, the aim of SPICT was changed from "identifying people at risk of deteriorating and dying" to "identify people whose health is deteriorating [and] assess them for unmet supportive and palliative care needs"[183]. Despite these endeavours, these tools are still used to determine prognosis which informs patient eligibility for palliative care[105,184,197].

The tools are not necessarily mutually exclusive; they can be used for different, and possibly complementary, purposes. One scenario is the use of one tool to screen for patients who require palliative care (patient identification), followed by another tool to evaluate their needs more comprehensively (needs identification)[138]. In this case, the patient-identification tool provides a quick snapshot of patient needs, while the needs-identification tool provides a more complete picture and holistic evaluation of these needs[133]. Another scenario is the use of one tool to measure general patient needs over time (needs measurement) and another tool to identify specific needs and assign actions to meet those needs (needs assessment)[198]. IPOS, as a generic outcome measure that provides a total score and individual scores of patient needs, could provide a general summary of patient needs which could be then assessed in more detail using the heart failure-specific tool NAT:PD-HF by determining the level of concern for each need and assigning actions to address those needs.

2.4.4 Tools' psychometric and practicality properties in patients with heart failure

Given that the tools serve different purposes, their psychometric properties are not directly comparable. Nonetheless, no tool had been tested as widely as NAT:PD-HF. Original NAT:PD-HF has good validity and inter-rater reliability and was acceptable to staff and patients[58,164]. After the publication of this review[125], two studies were conducted to further assess the psychometric and practicality properties of NAT:PD-HF[199,200]. In one study, the construct and concurrent validity of NAT:PD-HF were tested by identifying the correlation between items in NAT:PD-HF and corresponding items from IPOS, AKPS, Zarit Caregiver Burden Interview, and Hospital Anxiety and Depression Scale (HADS)[200]. NAT:PD-HF showed adequate to good construct and concurrent validity as indicated by a moderate agreement for patient and family carer physical symptom needs and substantial agreement for patient and family carer psychological symptoms and information needs. In the other study, NAT:PD-HF was translated to German, using a forwards-backwards translation procedure and cultural adaptation, and tested for its psychometric and practicality properties[199]. The German NAT:PD-HF showed good face validity, internal consistency, inter-rater reliability, test-retest reliability, feasibility, and acceptability. The findings of these two studies add to the psychometric and practicality evidence of the tool and support the findings of this review where NAT:PD-HF was recommended over other tools for patients with heart failure.

The poor psychometric and practicality properties of Dutch NAT:PD-HF have several possible reasons[165]. Firstly, although the tool was translated using a forwards-backwards procedure, cultural adaptation was not adopted upon translation. Cultural adaptation is needed when a tool is used in another country and language to maintain its content validity, and poor translation may create an inequivalent tool to the original one[201,202]. Secondly, the evaluating study was not designed as a primary psychometric study and its focus was not to test construct and criterion validity. Nonetheless, the correlation between some Dutch NAT:PD-HF items and three outcome measures was examined in an exploratory secondary analysis, and the results provided information on both validity types. Thirdly, the small sample size was a possible contributor to the lack of relationship between the constructs. Lastly, the heart failure nurses who administered the tool to patients lacked skills, knowledge, training, and experience in palliative care which led to difficulties in understanding the tool questions.

2.4.5 Tools' clinical applications in identifying patients with heart failure with palliative care needs

Two approaches were suggested in this review to evaluate the tools for identifying patients with palliative care needs. The first approach is to assess their identification ability by calculating the proportion of identified palliative patients (the more patients identified, the better is the tool). It was noted that a high proportion of identified patients may not always reflect a good tool's identification ability. Proportions may be misleadingly high or low if the tool is used by untrained or unskilled staff or if few patients are screened[155,156]. Also, a low proportion may reflect less severe disease rather than weak identification ability. Therefore, a better approach to evaluate the tools is to assess the appropriateness of identification by evaluating the health status of identified patients. Identification issues were observed in RACPAC and NECPAL studies. RADPAC-trained primary care practitioners identified a few patients for palliative care[168], most likely because the tool covers only physical patient needs so it could not identify those with psychosocial and spiritual needs. For NECPAL, more than 90% of patients with a negative answer to the surprise question were identified by the tool across all the evaluating studies[158-160,173], which may suggest a little added value of the detailed NECPAL compared with the surprise question alone.

The lack of intervention effect of IPOS and Dutch NAT:PD-HF on health outcomes has many possible reasons[162,165]. Firstly, the evaluating studies were not designed to test effectiveness. Secondly, worsening of health status over time is expected in patients with heart failure[203]. Without a control group, it is not possible to see a signal of benefit over time; deterioration may have happened faster without the intervention. Lastly, the actions taken by the nurses to address the identified patient needs might be inappropriate. The interviews with heart failure nurses and patients after the IPOS intervention revealed that it could not trigger the nurses to act on the identified needs[132]. The several barriers listed for Dutch NAT:PD-HF by the interviewed heart failure nurses indicate the improper translation of the tool and lack of palliative care knowledge[165]. For RADPAC intervention, the lack of significant effect was justified by the small proportion of identified patients and identifying practitioners[167,168]. The difficulty in identifying palliative patients with heart failure as reported by the interviewed primary care practitioners after the intervention revealed a tool identification problem[170].

To be clinically relevant, palliative care needs-assessment and measurement tools should be successfully implemented in practice by healthcare professionals. Barriers to implementation include the high workload of healthcare professionals and limited resources; lack of expertise, education, and training about palliative care in heart failure; and lack of communication skills with patients and family carers[138,165,204]. Additional barriers adopted from similar discussions on implementing advance care planning in heart failure care, where needs assessment is a key element[68], exist at different levels. These include the lack of support at the institutional level; lack of an electronic information-recording and exchange system; lack of public education about palliative care; fear of losing hope and causing concern if palliative care is discussed with patients; lack of trustful relationship with patients and family carers to enable palliative care discussions; unstable physical, cognitive, and emotional patient condition; emotional impact on healthcare professionals when discussing palliative care; misconception that palliative care discussions reflect treatment failure; poor collaboration between healthcare professionals; and lack of consensus on who should complete needs-assessment tools[69,70,205]. It is essential to overcome these barriers because no matter how well-developed, valid, acceptable, and feasible the tools are, they would be ineffective in clinical practice if no attention is paid to implementation issues. Successful implementation of the tools would facilitate the timely identification of patients with palliative care needs and subsequent access to palliative care services[138].

2.4.6 Strengths and limitations

This review adopted a systematic method to search for relevant evidence, screen retrieved studies and tools, extract data from included ones, assess their quality, and synthesise their findings. A broad search strategy was used to retrieve relevant studies. The review was not restricted to quantitative or qualitative studies as both were sought. It was written following the adapted PRISMA reporting guideline to enhance transparency[147]. The choice of the most appropriate tool was based on comprehensive comparisons according to predetermined criteria. Although NAT:PD-HF was suggested as an example of a good needs-assessment tool in the EAPC position statement and another review[14,126], this was not based on such comparisons.

The review has some limitations. Firstly, tools were excluded if they were not developed for palliative care patients or needs identification. Tools were also excluded if they were used for identifying heart failure populations with palliative care needs in a single study retrieved through the review search. Including these tools in the review could have altered its findings. Secondly, the second reviewer was only partly involved in study screening, data extraction, and quality appraisal. He was not involved in assessing the tools' psychometric and practicality properties and synthesising the evidence. Thirdly, the psychometric and practicality properties of the tools were assessed using the Oxford PROMs Group criteria although all tools, except IPOS patient version, were clinical decision aids rather than PROMs. Needs-assessment tools are distinct from needs-measurement tools and they have different, though overlapping, purposes; therefore, the psychometric approaches for each are not directly comparable. The purpose and method of validation differ between these tool types and the psychometric items of responsiveness, although not assessed, may not apply to clinical decision aids. Fourthly, despite adopting a sensitive search strategy, some studies and tools might be missed as with any systematic review. Palliative care and heart failure studies are difficult to retrieve because of their inconsistent terminology[206,207]. The term “heart disease” was used in some included studies and this was assumed to be equivalent to “heart failure” unless indicated otherwise. Studies published in non-English or non-Arabic languages were not searched, and few grey literature sources were sought.

One methodological issue of the review is the subjective nature of narrative synthesis which may affect transparency[208], though this was mitigated by adapting Popay et al.’s framework. Another issue is the lack of consensus on the best tool for concomitantly appraising quantitative, qualitative, and mixed-methods studies[209], especially that qualitative research could be judged differently from quantitative research[149]. This is complicated by debates about the appropriateness of assigning a total score for each study, especially if used as a threshold to include or exclude studies[210]. For this review, the commonly cited Hawker et al.’s tool was used to describe the quality of the studies, rather than to include or exclude studies based on their assigned quality score. Excluding lower quality studies would not have changed the answer to the review question, especially that NAT:PD-HF and IPOS studies scored in the upper range of the scale and would not have been excluded.

2.4.7 Implications for research, practice, and policy

The tools need further assessment of their psychometric and practicality properties in patients with heart failure. Further evaluation of the tools for identifying heart failure populations with palliative care needs is also needed. Future studies should include a larger number of patients, evaluate patients with different types of heart failure and in multiple health settings, adequately report the baseline data and health outcomes for identified patients, and assess the tools' effect on relevant outcomes in a randomised controlled trial. Cultural adaptation should be included in the tools' translation to create tools equivalent to the original ones. Healthcare professionals should be aware of the different roles that needs-assessment and measurement tools can play and consider combining them where appropriate. Until more data become available, they are advised to use NAT:PD-HF to identify heart failure populations with palliative care needs. This should be followed by acting to address these needs and consequently improve health outcomes. Policymakers should adopt a needs-based approach for identifying patients requiring palliative care and integrate needs-assessment or measurement tools into the practice of healthcare professionals. Particular attention should be paid to implementation issues to enhance the clinical effectiveness of the tools in practice.

2.5 Chapter summary

This review aimed to identify the most appropriate palliative care needs-assessment or measurement tools for patients with heart failure. Six tools were identified from 27 papers and compared according to their content and context of use, development, psychometrics and practicality, and applications in identifying palliative care patients and needs. The tools are not necessarily mutually exclusive as they may serve different purposes including patient identification, needs identification, needs measurement, and needs assessment (decision aids). Comparison results suggested that NAT:PD-HF is the most appropriate palliative care needs-assessment tool for use in heart failure populations. It covers most of the patient needs and has the best psychometric properties and evidence of identification ability and appropriateness. However, this conclusion is based on limited evidence. Four retrieved tools lack studies on their psychometric and practicality properties in heart failure populations, and one of these (GSF-PIG) even lacks a research development paper. Nevertheless, NAT:PD-HF is preliminarily recommended for use in patients with heart failure, but it requires further testing and validation. IPOS has some similar advantages to NAT:PD-HF but less evidence is available on its use in heart failure populations. In the next chapter, the methodological foundations of the study are discussed.

3 Methodology

In the previous chapter, a systematic review of palliative care needs-assessment and measurement tools used in patients with heart failure was presented. The aim was to identify the most appropriate tools and discuss them with service providers to see whether and how they could be incorporated into the intervention. In this chapter, the design and methodological foundations of the study which informed the development of the complex palliative care intervention are described. The adopted research paradigm is first outlined, before explaining the steps of co-designing the intervention and underpinning theory with stakeholders using the MRC framework. For this study, *stakeholders* refer to service providers and service users who were involved in the development and refinement of the intervention[114]. The chapter ends with self-reflexivity and an outline of the congruence across the methodological framework.

3.1 Methodological framework

The congruence between the research question, ontology, epistemology, methodology, and methods is essential for good research[211]. Ontology is the nature of being and reality, the study of what exists, and the assumptions in which researchers operate in their search for knowledge[212,213]. Epistemology is the nature of knowledge and a way of understanding how we know what we know, what counts as knowledge, how knowledge claims are justified, and what the relationship is between the knower (researcher) and the known (research participants)[211,212,214]. Methodology is the research approach underlying the choice of methods, while Methods are the techniques used to collect and analyse data to answer the research question[211]. Ontological, epistemological, and methodological questions are addressed by philosophical paradigms or worldviews, defined as a set of beliefs and practices that orient thinking, guide action, and conceptualise research[213,215]. The methodological framework for this study is described in the following sections, while the congruence between the methodological choices is summarised in **section-3.9**.

3.2 Pragmatic paradigm

3.2.1 Philosophical assumptions

Pragmatism was the adopted paradigm for the study[216-219]. Pragmatism is not committed to a system of philosophy or reality[215,219]. It rejects the either/or choice between paradigms and opposes the *paradigm wars* arising from the philosophical and methodological conflict between paradigms[220]. Pragmatists believe we should stop asking questions about reality, truth, and laws of nature[215,218,220]. For them, reality is what is useful and practical[212]. Ontologically, pragmatists believe in the existence of a single, objective, and external reality independent of our minds and influence, but deny that the *Truth* regarding this reality can be determined as people will have their own interpretations and perspectives of that reality[214,217,219]. Thus, pragmatists endorse diverse viewpoints regarding social realities (multiple realities) and believe that reality is socially constructed, which means that individuals seek understanding of the world they live in and develop subjective, varied, and multiple meanings of their lived experiences through their personal histories and social interaction with others[212,214]. The truth in pragmatism is "what works at the time"[215,221].

Epistemologically, pragmatists endorse both subjective points of view, where researchers work with participants to co-construct social realities, and objective points of view, where researchers distance themselves from the research topic or participants, depending on the stage of the research process[214,217]. Knowledge is viewed as being both constructed and based on the reality of the world that a person experiences[221]. Pragmatists endorse inductive thinking to develop theories and deductive thinking to test these theories[214,217]. Language and meaning, and the actual interactions that people use to negotiate them, are important[217]. Pragmatists emphasise the researcher's values in choosing a topic of, and methods for, research and interpreting its results based on their personal values[212,214,217,221]. They endorse shared values and believe that knowledge reflects the views of both the researcher and participants[212,214,221].

The methodological orientation of pragmatism is its rejection of the *incompatibility thesis* which assumes that qualitative and quantitative approaches cannot be mixed because of the incompatibility of the underlying paradigms[214]. Instead, pragmatism calls for *peaceful coexistence* and asserts that the two approaches are not dichotomous, but rather exist along a continuum[220]. Pragmatism focuses on the research problem and applies multiple methods, perspectives, and theories to understand it[215,217,221]. The research question is central and drives the methods of data collection and analysis that best address the research objectives (qualitative, quantitative, or mixed methods)[212,220,222].

Pragmatism emphasises actions, outcomes, causal relations, workability, and consequences over philosophising[212,217,219]. It provides practical solutions to problems by emphasising communication and shared-meaning making, addressing what works through experience and experimenting, and addressing how to research based on the intended consequences[212,217,223]. This fits with the purpose of palliative care which takes a problem-oriented and goal-oriented care approach to assess and address the multidimensional care needs of patients and families[54]. Pragmatism is oriented to real-world practice; focusing on the practical implications of research, programme's workability in specific contexts, and transferability of results to similar settings[212,220,223].

3.2.2 Limitations and critiques

One argument is whether pragmatism can be considered a paradigm because of its apparent focus on practicality over philosophical underpinnings[217,218,224]. Proponents of pragmatism questioned what the term "paradigm" really implies as it has different meanings in the literature[217]. Pragmatism does not ignore the ontological and epistemological issues as it emphasises their connection with the methods used to generate knowledge[217]. However, pragmatism focuses more on the process of inquiry about the nature of human experience through which the researcher's beliefs and actions continually interact to create meaning and underlie the production and philosophy of knowledge (**Figure-3**)[218]. Hence, pragmatism does not lack a philosophy of knowledge and goes well beyond practicality and problem solving[218].

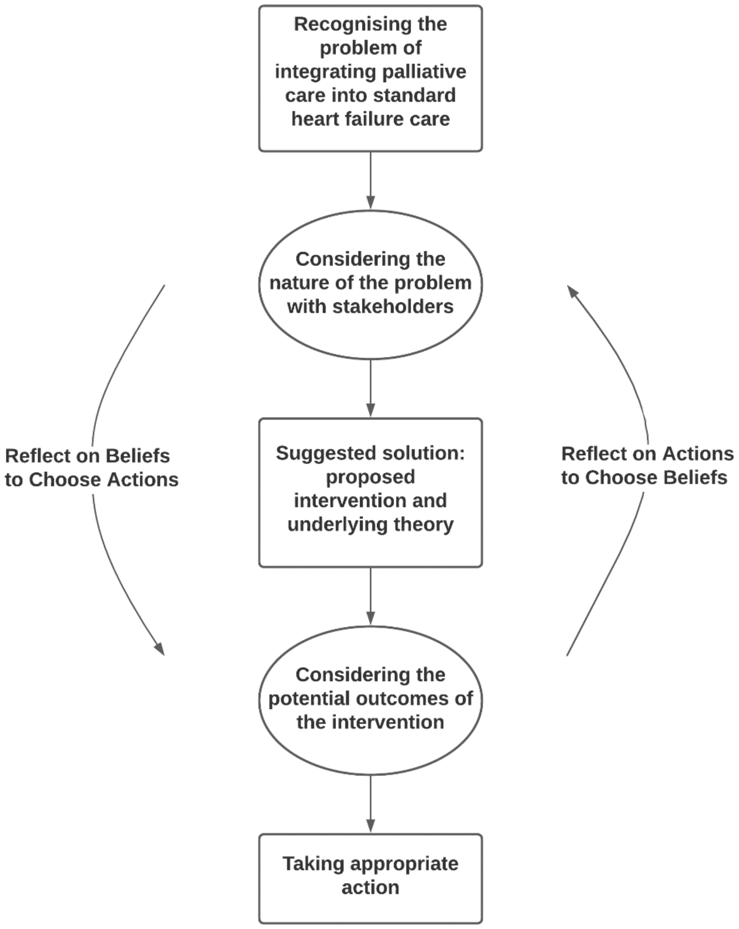


Figure-3: A model of enquiry for pragmatism, adapted from Morgan 2014[218]

Most other critiques of pragmatism are based on misunderstandings of its basic features or failure of researchers to be explicit about their assumptions[214,221]. For example, pragmatists were criticised for not specifying *whose values* are involved and what they mean by usefulness or workability[221,224]. For this study, both my values and the values of stakeholders were involved to produce knowledge, while workability comprises the ability to integrate palliative care into standard heart failure care. Another critique is that pragmatism is *solely* related to mixed-methods research[218,221]. Indeed, pragmatism adopts a needs-based approach to research methods where researchers are free to use qualitative, quantitative, or mixed methods based on their research question[218,221].

3.2.3 Applications in the study

In congruence with pragmatism's focus on joint actions, outcomes, causality, context, and practice, this study aims to identify the key intervention *activities* required by service providers and delineate the hypothetical *causal* pathways through which these activities interact to achieve specific *outcomes* within a particular *context* and real-world *practice*. In congruence with the ontological, epistemological, and methodological orientations of pragmatism, a multi-method qualitative approach was used to inductively develop a programme theory in participation with service providers to explore what changes are possible in their clinical practice, what intervention might make them happen, and how it can work; thus, endorsing multiple realities and subjective viewpoints as well as my values. Later, in a future planned post-PhD experimental study, a quantitative approach will be applied, within a mixed-methods study, to deductively test the theory through evaluating the intervention feasibility and measuring its outcomes in a full trial; thus, endorsing a single and objective reality.

3.3 Medical Research Council framework

The study aim was to develop a complex palliative care intervention informed by the MRC Framework for the Development and Evaluation of Complex Health Interventions[112-115]. Complex interventions have inherent challenges including the difficulty in describing the intervention components, complexity of the causal pathway through which interventions lead to outcomes, standardisation of intervention design and delivery, sensitivity to the local context, and integration into existing services[114]. Consequently, guides were developed to help researchers develop and evaluate such interventions[119]. The MRC framework was developed in 2000 to guide the adoption of appropriate methods for developing, evaluating, and implementing complex interventions to improve health[112,113]. It was updated in 2008 in response to critiques of the previous guidance for adopting a linear drug-evaluation model to illustrate the sequential stages from intervention development to implementation and for providing limited guidance and evidence for the recommendations[114,115]. The updated framework demonstrates a flexible and iterative approach and outlines four stages that do not follow a linear or cyclic sequence: development, feasibility testing and piloting, evaluation, and implementation (**Figure-4**). For the development stage, three elements are suggested: identifying the evidence base, identifying or developing theory, and modelling process and outcomes.

The MRC-2008 framework is the most cited guidance that uses an iterative approach to develop and evaluate complex health interventions[119]. It fits with pragmatism as it aims to involve *multiple viewpoints* (stakeholders) in designing complex interventions, address the *practical* difficulties of evaluating and implementing such interventions, identify and assess the most appropriate *outcomes*, and clarify *causal mechanisms* and processes of change in specific *contexts*[114]. However, the framework was critiqued for providing limited information on how to incorporate theories into the development and evaluation of complex interventions, model the intervention and conduct process evaluation, and evaluate the implementation context[119,123,225-227].

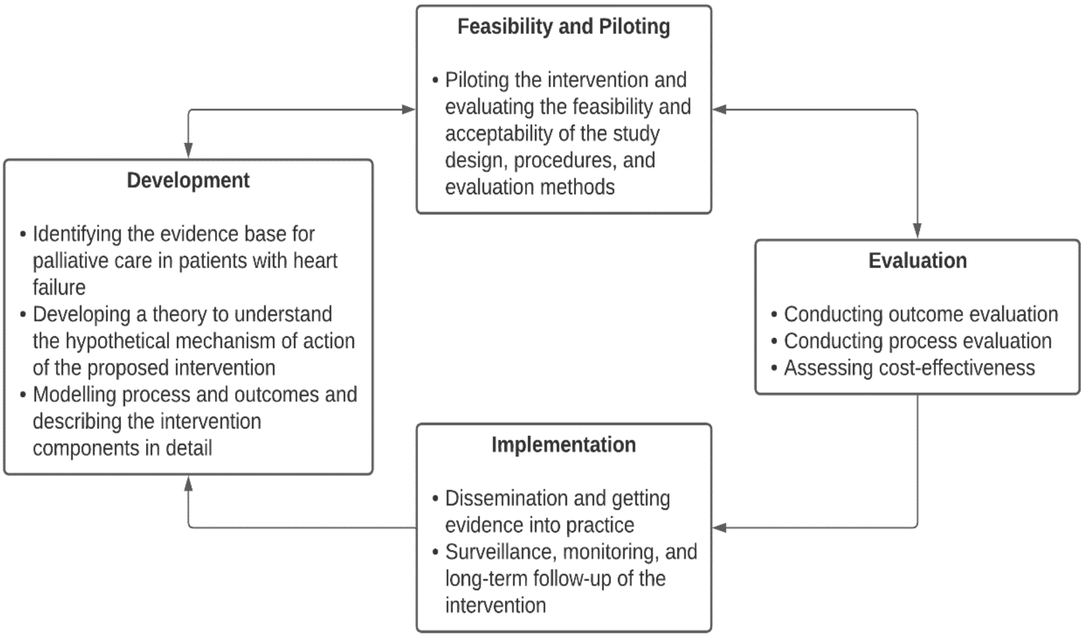
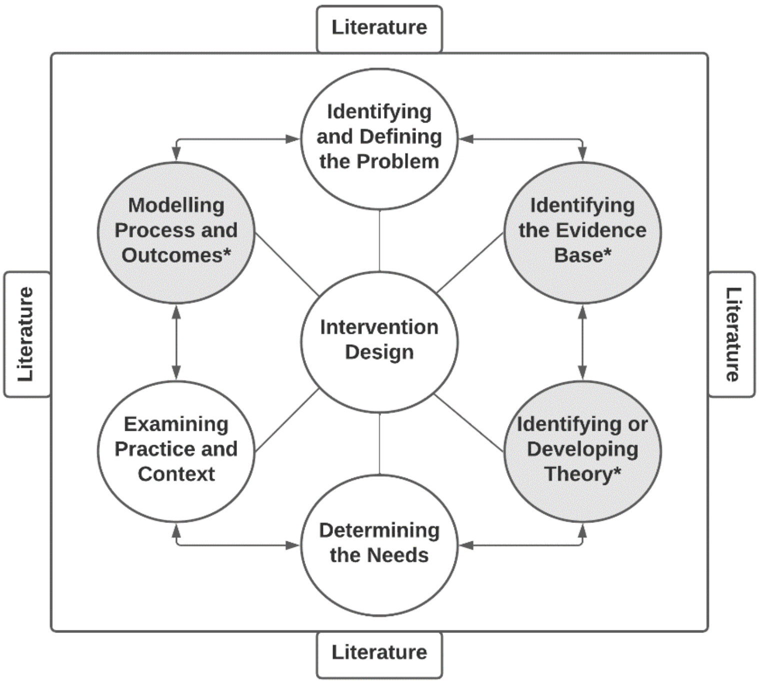


Figure-4: MRC-2008 framework for developing and evaluating complex health interventions, adapted from Craig et al. 2008[114]

In response to these limitations, the MRC framework was further updated in 2021 to address the new conceptual, methodological, and theoretical developments since the last framework was developed[228,229]. The MRC-2021 framework recommends asking questions beyond whether an intervention is effective at achieving certain outcomes, including how it works and interacts with the implementation context, what impacts and value it has considering the required resources, and how to use the generated evidence to support decision making[228]. It recommends considering six core elements when developing, assessing the feasibility, evaluating, and implementing complex interventions: evaluating the context, developing and refining a programme theory, engaging stakeholders, identifying key uncertainties, refining the intervention, and economic considerations. By the time the MRC-2021 framework was published, the intervention was in its final modelling and refinement stage and it was too late to adopt the newest guidance. However, its elements were found to be already covered in the complementary guides that were used for this intervention (see next).

3.3.1 Complementary guides

Given the limitations of the MRC-2008 framework, Bleijenberg et al. argued that it may not be enough to design effective interventions that fit within the implementation context[119]. Therefore, they created more comprehensive guidance to enrich the development stage of the MRC framework. The guidance aims to increase the value and decrease the waste of health research by designing more effective and well-adopted interventions that have a high chance of success and fit the local context and clinical practice. It was developed through a literature review and expert experience by combining the three elements of the development stage of the MRC framework with elements of other intervention development guidelines. Ultimately, four elements were added: problem identification and definition, determination of the needs of service providers and users, examination of current practice and context, and intervention design (**Figure-5**). For each element, reviewing the literature is necessary to inform how to proceed or determine the need for further data collection.



*** The main steps of the development stage in the MRC-2008 framework**

Figure-5: Bleijenberg et al.'s guidance on intervention design and adaptation of the MRC development stage, adapted from Bleijenberg et al. 2018[119]

Although Bleijenberg et al.'s guidance added value to the design of this palliative care intervention, it was generic and developed using published reports and expert opinion[119]. Therefore, the Methods of Researching End of Life Care (MORECare) guidance was also followed to help develop the intervention[122]. The MORECare guidance was developed through systematic reviews, expert consultations, and stakeholder workshops to identify main issues and best practices in end-of-life care research. It was built on the MRC framework but is more comprehensive as it provides 36 evidence-based recommendations on ethics, recruitment, attrition, mixed methods, outcome measures, and health economics[230-237]. Key recommendations include outlining the intervention's theoretical framework; involving patients, family carers, and clinicians in developing the intervention; testing the feasibility of both the intervention and evaluation methods; considering the analysis of existing datasets; using comprehensive, short, and psychometrically robust outcome measures for evaluation; and considering implementation implications in all stages of the study[122]. The guidance has some limitations including identifying only the key methodological difficulties in end-of-life care research, providing few recommendations on recruitment methods, and giving less attention to early palliative care[122]. Nevertheless, the recommendations from this guidance, when combined with those from the MRC framework and Bleijenberg et al.’s guidance, provided one coherent guideline to develop this complex palliative care intervention.

3.3.2 Steps of the intervention development

The intervention was developed following the steps recommended by the MRC framework, Bleijenberg et al.’s guidance, and MORECare statement in an iterative, non-linear approach[112-115,119,122]. As discussed above, these steps were found to be incorporated in the newest MRC-2021 framework. **Table-8** shows the followed steps and the parallel recommendations and core elements from the MRC-2021 framework[228,229].

Table-8: Steps of the intervention development and parallel recommendations from the MRC-2021 framework, adapted from the MRC framework[112-115,228,229], Bleijenberg et al.'s guidance[119], and MORECare statement[122]

Steps	Description	Parallel recommendations from MRC-2021 framework#
Identifying and defining the problem	Exploring the nature and impact of the problem of integrating palliative care into standard heart failure care in the research setting from different stakeholder perspectives to provide insights into the current gaps and investigate who is affected.	**Engaging stakeholders:** Exploring the perspectives of diverse stakeholders from the outset to identify key research questions. **Identifying key uncertainties:** Exploring the key uncertainties and research questions through the programme theory, given what is already known and what is identified as being most important to discover.
Examining current practice and context	Investigating the existing intervention practice and research setting to enhance the delivery and implementation of the intervention within its context and discussing the facilitators and barriers of the proposed intervention with stakeholders to adapt it to the current practice.	**Evaluating context:** Understanding the context in which the intervention will be implemented.
Determining service providers' and users' needs	Exploring the perceptions of stakeholders regarding the problem of palliative care integration, the palliative care needs of patients with heart failure and their families, and the preferences and capacities regarding the proposed intervention to produce a feasible and effective intervention.	**Engaging stakeholders:** Involving patients, practitioners, and policy makers from early stages to identify practical barriers and investigate the acceptance, implementation, cost-effectiveness, and transferability of the intervention across contexts. **Economic considerations:** Identifying the required resources to implement the intervention in light of its intended outcomes to help decide whether the potential benefits outweigh the expected costs.

Steps	Description	Parallel recommendations from MRC-2021 framework#
Identifying the relevant existing evidence*	Identifying the relevant existing evidence by conducting a systematic review of palliative care needs-assessment and measurement tools in heart failure and finding systematic reviews of similar palliative care interventions to investigate their effectiveness.	Reviewing published research evidence throughout the intervention development process to identify existing interventions and understand their evidence base.
Developing appropriate theory*	Developing a theory to understand the mechanism and process of the intervention (how it works and causes change and what the active ingredients are), identify possible barriers and reinforce weak links in the causal pathways, and subsequently create an effective, implementable, pragmatic, and sustainable intervention.	**Developing and refining a programme theory:** Developing a theory to promote shared understanding among stakeholders on how an intervention brings about change. This includes explicating the key components of the intervention and how they interact to achieve specific outcomes in an underlying context (mechanisms of change). The theory should be co-developed with diverse stakeholders from early stages based on scientific evidence and relevant theories, and then refined in subsequent stages.
Modelling process and outcomes*	Refining the intervention and delineating the key intervention components in detail, and the mechanisms through which they interact to achieve specific outcomes, to allow comparisons and create an implementable, replicable, and transparent intervention.	**Refining the intervention:** Modifying the preliminary intervention based on the collected data, programme theory, and potential intervention users' perspectives to enhance its feasibility and acceptability.
Intervention design	Describing the output and final product of the development process including the final content, components, and duration of the intervention.	Designing the intervention, describing its content and delivery method with stakeholders, and writing up the intervention development process.

* The main steps of the development stage in the MRC-2008 framework.
# The core elements of the MRC-2021 framework are written in bold.

3.4 Qualitative methodology

The MRC framework, Bleijenberg et al.’s guidance, and MORECare statement call for incorporating qualitative methods in designing complex interventions[112,114,119,122]. Multiple qualitative methods were used for this intervention, from group workshops with stakeholders to a secondary qualitative data analysis. Using a qualitative approach helped to explore the perceptions of service providers and users on the problem under investigation, understand their complex and diverse needs, examine the current practice and contextual factors, and identify relevant outcomes and implementation challenges[119,238,239]. Qualitative methods also helped to understand how and why the intervention could work by generating a theory that explains how the key components of the intervention interact within its context to produce the desired outcomes (process of change)[112,113,226]. This informed which elements are essential, and which ones are less important, to achieve the intervention effect. Qualitative methods are congruent with pragmatism where research questions can be answered using the best methods: qualitative and/or quantitative[214]. Both pragmatism and qualitative research focus on the meanings and viewpoints that participants hold about the problem, use inductive and deductive logic in developing and testing theories, endorse the researcher’s role in shaping interpretations, and emphasise the importance of context[221,240].

3.4.1 Co-design

In response to calls from the MRC framework, Bleijenberg et al.’s guidance, and MORECare statement, the intervention was co-designed with service provider and service user stakeholders[112,114,119,122]. Service providers were included throughout all stages of the intervention development: from initial *practitioner engagement meetings* where clinicians asked for a service to enhance palliative care provision for patients with heart failure, through group workshops where the preliminary intervention was co-developed, to follow-up meetings where the proposed intervention was refined. The voice of service users was included from existing interview data and Patient and Public Involvement (PPI) to refine the developed intervention.

Co-design is compatible with pragmatism that endorses diverse viewpoints regarding social realities[214]. It empowers and reveals the perspectives of stakeholders; ensures the proposed intervention is responsive to the needs of service providers and users; allows recognising mutual benefits; reduces research waste by developing relevant, acceptable, feasible, and implementable interventions; ensures the ethics and validity of research; encourages study commitment; and improves health outcomes and cost savings[119,232,233,241-244]. Despite these benefits, and the calls from national funding organisations to involve stakeholders in setting research priorities[110], co-designing complex interventions is not common within the MRC framework[243]. Challenges include time and resource constraints, the need for commitment from all stakeholders, tendency to prioritise the preferences of stakeholders over scientific rigour, and increased complexity of study design[241,242,245]. In response to these challenges, the service providers were keen to develop a palliative care service for their patients as they initiated the discussions and were willing to invest time and resources to achieve that. Most had good research experience and could understand the value of scientific rigour, basic study designs, and the wider implication of the research beyond their department. The PPI group (service users) were also motivated and aware of the value of research.

3.5 Normalisation Process Theory

Normalisation Process Theory provided the overarching theoretical framework for this study[246,247]. It was rigorously developed in 2009 from empirical studies of implementation and integration processes of real-world complex healthcare interventions to provide a robust theoretical basis for planning and evaluating implementation programmes[246,248]. Normalisation Process Theory is a theory that identifies, conceptualises, and evaluates mechanisms and factors that promote and inhibit the routine incorporation of an organisational practice (a complex intervention) into everyday life and thus helps to understand how and why a complex intervention works[246,248-251]. It aims to explain the mechanisms that motivate and shape the work of enacting new complex interventions in real-life settings (implementation), and how these are normalised and made routine elements of everyday work (embedding), and sustained in practice and existing social contexts (integration)[246]. Normalisation Process

Theory is a *sociological theory* that emphasises the importance of social collective action (what people do together) to implement a new practice and is concerned with the interaction between agents (people interacting in clinical encounters), objects (practices and procedures employed by agents), and contexts (technical and organisational structures in which agents and objects are implicated)[248,251-253]. It is a *middle-range theory* that guides empirical inquiry, addresses a discrete sociological question (mechanisms of implementation), and has limits to its scope and the explanations it can provide[246,247,253].

3.5.1 Propositions and core constructs

Normalisation Process Theory has three formal propositions[246,247]:

1. Complex interventions become routinely embedded in their social contexts as the result of people working, individually and collectively, to implement them. The routine embedding of a complex intervention is the result of *action*; not only people's attitudes or intentions.
2. Implementation work is operationalised through four generative mechanisms of social action: coherence, cognitive participation, collective action, and reflexive monitoring. These represent the core constructs of Normalisation Process Theory (see below).
3. Implementation and integration of a complex intervention need ongoing investment by people in ensembles of action that are carried forward in time and space. Consequently, the intervention becomes a routine practice that disappears into the everyday world of normal activities that people do (normalised).

Normalisation Process Theory is built up around four constructs that explain the different types of work that people do when encountering and implementing a new practice[246,247]:

1. **Coherence** (What is the work? Investments in meaning): the *sense-making work* that people do, individually and collectively, when encountering the problem of operationalising a new practice.

2. **Cognitive participation** (Who does the work? Investments in commitment): the *relational work* that people do to engage and enrol individuals and groups in a new practice.
3. **Collective action** (How is the work done? Investments in effort): the *operational work* that people do to enact a new practice.
4. **Reflexive monitoring** (How is the work understood? Investments in appraisal): the *appraisal work* that people do to assess and understand how a new practice affects them and those around them.

These constructs interact non-linearly with each other, and with the intervention's context, and may occur simultaneously[247]. Each construct has four components (sub-constructs) which were translated by the developers of the theory into simple statements to create the 16-item user-friendly Normalisation Process Theory toolkit[254,255]. This toolkit was used in the study to inform the analysis of the group workshops with service providers, where the intervention was initially developed, and to optimise the trial design in the planned feasibility study (see **section-3.5.4**). A general model of the Normalisation Process Theory constructs, showing how they operated simultaneously and flexibly throughout this study to help understand the implementation processes, is illustrated in **Figure-6**[256].

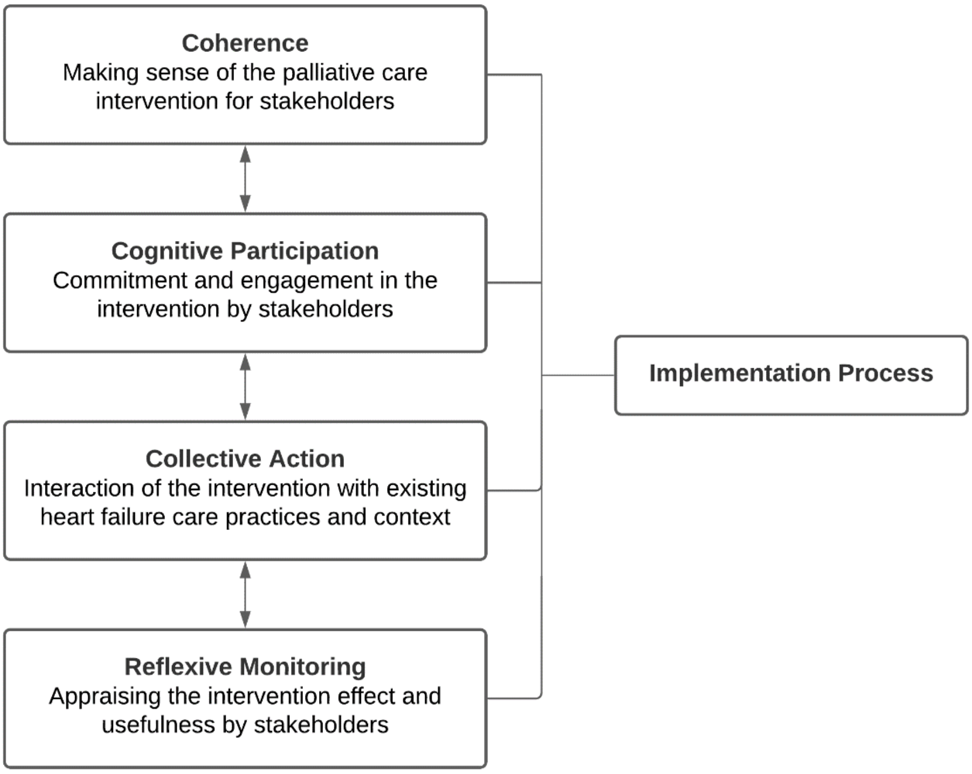


Figure-6: Model of Normalisation Process Theory core constructs, adapted from May et al. 2018[256]

3.5.2 Congruence with pragmatism

Both Normalisation Process Theory and pragmatism, which views theories as instrumental in research[221], focus on practical solutions, actions, joint actions, outcomes, and methodological flexibility. The emphasis of Normalisation Process Theory on collective action and collaborative implementation mirrors pragmatism's focus on joint actions, shared meanings and values, and diverse viewpoints regarding social realities[217,247,253]. Normalisation Process Theory is method-neutral as it does not prescribe a specific epistemological and theoretical perspective, methodology, or method for doing research and can be used in both qualitative and quantitative research[253,256]. Normalisation Process Theory is characterised by its flexibility as it is applied dynamically, rather than prescriptively or rigidly, and adapted to the specific research needs. It is not a protocol or methodology for how to do research, but it helps to sensitise critical thinking about implementation processes throughout the research project.

3.5.3 Limitations and critiques

Normalisation Process Theory has some limitations and critiques. The theory does not provide precise predictions of the implementation potential of new interventions[251,257,258]. It does not assume that normalisation is an automatic outcome of the implementation-embedding-integration process nor a permanent state[251]. Collective action could either lead to normalisation (new interventions are embedded in everyday work), adoption (new interventions are taken up but not routinely embedded), rejection (new interventions are disregarded or refused), or de-normalisation (formerly normalised interventions are replaced or abandoned)[250,251]. Normalisation Process Theory is not a theory of everything or panacea to all research questions[248,259]. It does not offer a *comprehensive* theoretical model of implementation processes, as these cannot be fully captured, but it provides a conceptual framework to understand and evaluate them.

Normalisation Process Theory was critiqued for the overlap between its constructs[256,260]. Nevertheless, the theory is fluid and flexible and the constructs were developed to work together, rather than compete with each other, to explain implementation processes. Normalisation Process Theory was also critiqued for its complex terminology although this is addressed by developing training packages and user-friendly tools[256]. Lastly, there is a misunderstanding that Normalisation Process Theory places more emphasis on service providers than service users[256,261]. Indeed, Normalisation Process Theory recommends a whole-system perspective on implementation and focuses on the work of all stakeholders to enhance the implementation of complex interventions[256,260,261].

3.5.4 Applications in the study

Normalisation Process Theory aims to inform and underpin empirical prospective studies that have practical relevance[246,247]. It was used in this study to inform the development and optimise the design of an implementable intervention. Normalisation Process Theory complements the MRC framework which calls for adopting a theory in developing complex interventions[112,114]. While the MRC framework provides a *methodological* approach to developing, evaluating, and implementing complex interventions, Normalisation Process Theory offers an *explanatory* approach to understanding these processes[252]. Normalisation Process Theory is widely used in the health literature for similar applications to those in this study: for developing complex interventions, within the MRC framework, in qualitative research to understand implementation processes and individuals' experiences, and in heart failure literature[256,260]. However, its use in the palliative care field is scarce and it has not been used before to develop a palliative care intervention for patients with heart failure[262-264].

The Normalisation Process Theory constructs and components were used as research directives to shape thinking about implementation issues from the outset and at different points in the project[250,255]; from the group workshops with service providers, through the secondary analysis of qualitative interview data, to the development of the feasibility study protocol. First of all, Normalisation Process Theory triggered thinking about data collection methods[253]. As the theory focuses on what goes on (practice), it encourages using observation, even sparingly, to examine how people work. Thus, I was engaged before the workshops in two shadowing activities in the participants' practice to observe and examine how the new intervention could fit with the existing settings (see **section-4.1.2**). Moreover, Normalisation Process Theory informed the choice of the workshops' participants who were involved in developing the intervention[250,253,255]. Recruited participants were those healthcare professionals who were considered vital for enacting and normalising the new intervention, those whose routine work practice would be affected by the new intervention, and those for whom the intervention would be relevant.

During the workshops, Normalisation Process Theory informed the in-depth discussions with service providers, including how the new intervention will affect their routine work practices and how feasible it is going to be given the human, organisational, and resource changes that it requires and whether its likely benefit justifies making them[250,255,256]. This triggered thinking about the individual components of the complex intervention and their fit with the existing context and routine ways of working. In this way, Normalisation Process Theory was used to assess whether the intervention is implementable and can proceed to a full trial evaluation, or one that is better to be abandoned if it seems to have a low chance of implementation (trial killer)[250]. The workshops' analysis was informed by the Normalisation Process Theory constructs and components, simplified in the theory toolkit (see **section-3.7.1.1**). Following the workshops, the secondary qualitative data analysis was conducted in the light of Normalisation Process Theory, which triggered thinking about the issue of implementing palliative care in clinical practice[260] (see **section-3.7.2.5**). In a future study, Normalisation Process Theory will underpin the feasibility and process evaluation of this complex intervention to understand why it works or fails to work, understand its mechanism of action and outcomes, and refine the programme theory that explains its effects[255,256] (see **section-8.3.6.1**).

3.6 Theory of Change

In response to the MRC framework's call to use a theory in developing complex interventions[114], this intervention was developed using a *theory-driven approach to programme evaluation*; the Theory of Change[265-267]. The Checklist for Reporting Theory of Change in Public Health Interventions was used to report the Theory of Change approach where applicable to ensure transparency, credibility, and replicability[124]. This checklist was developed based on three reviews to help authors report the essential elements of the Theory of Change, together with other intervention reporting checklists[117,124,268]. The elements covered in the checklist include defining the Theory of Change approach, describing the Theory of Change development process, depicting and illustrating the Theory of Change *map* (a diagram that displays what the intervention comprises), and describing the use of the Theory of Change in intervention development and evaluation.

A programme-theory evaluation is a theory explaining how the programme causes the expected or observed outcomes and an evaluation guided by this theory[19]. Theory of Change is dated back to the 1930s, with further development in the 1990s by the Aspen Institute which defined it as a theory of how and why a programme works[117,265]. It is often developed with stakeholders and represented graphically in a Theory of Change map that illustrates the mechanisms of change and hypothetical causal pathways through which the intervention components interact within a specific context to achieve specific outcomes and a realistic impact[123,267,269]. Theory of Change is flexible as it does not prescribe a rigid linear structure but rather allows for several causal pathways, feedback loops, and intervention levels[123]. It aims to develop a feasible, acceptable, and implementable intervention by involving stakeholders in the intervention development, agreeing on a real-world impact of the intervention within the local context and available resources, and identifying implementation barriers from the outset[123]. Later on when the intervention is evaluated; if the intervention worked, Theory of Change can identify the active ingredients necessary for replication, while if it failed to work, Theory of Change can identify whether this is due to implementation failure or theory failure (genuine ineffectiveness)[117].

3.6.1 Congruence with pragmatism and Normalisation Process Theory

The Theory of Change approach fits well with the epistemological and theoretical underpinnings of this project. Being described as a "pragmatic framework" that explains how the intervention causes a change[123], Theory of Change fits with pragmatism that views theories as instrumental in research[221]. In congruence with pragmatism, this approach endorses diverse viewpoints and shared values through stakeholder engagement, acknowledges the researcher's values and role in analysing the findings, endorses a method-neutral approach for data collection and analysis, provides practical solutions to problems, addresses what intervention activities are required to achieve the outcomes (action-oriented and outcome-oriented), seeks to explore causal relations between the intervention components in specific contexts, and acknowledges the transitory nature of these causal relations, which makes it subject to continuous change throughout the intervention development and evaluation as implementation challenges and new evidence arise[265-267,270,271].

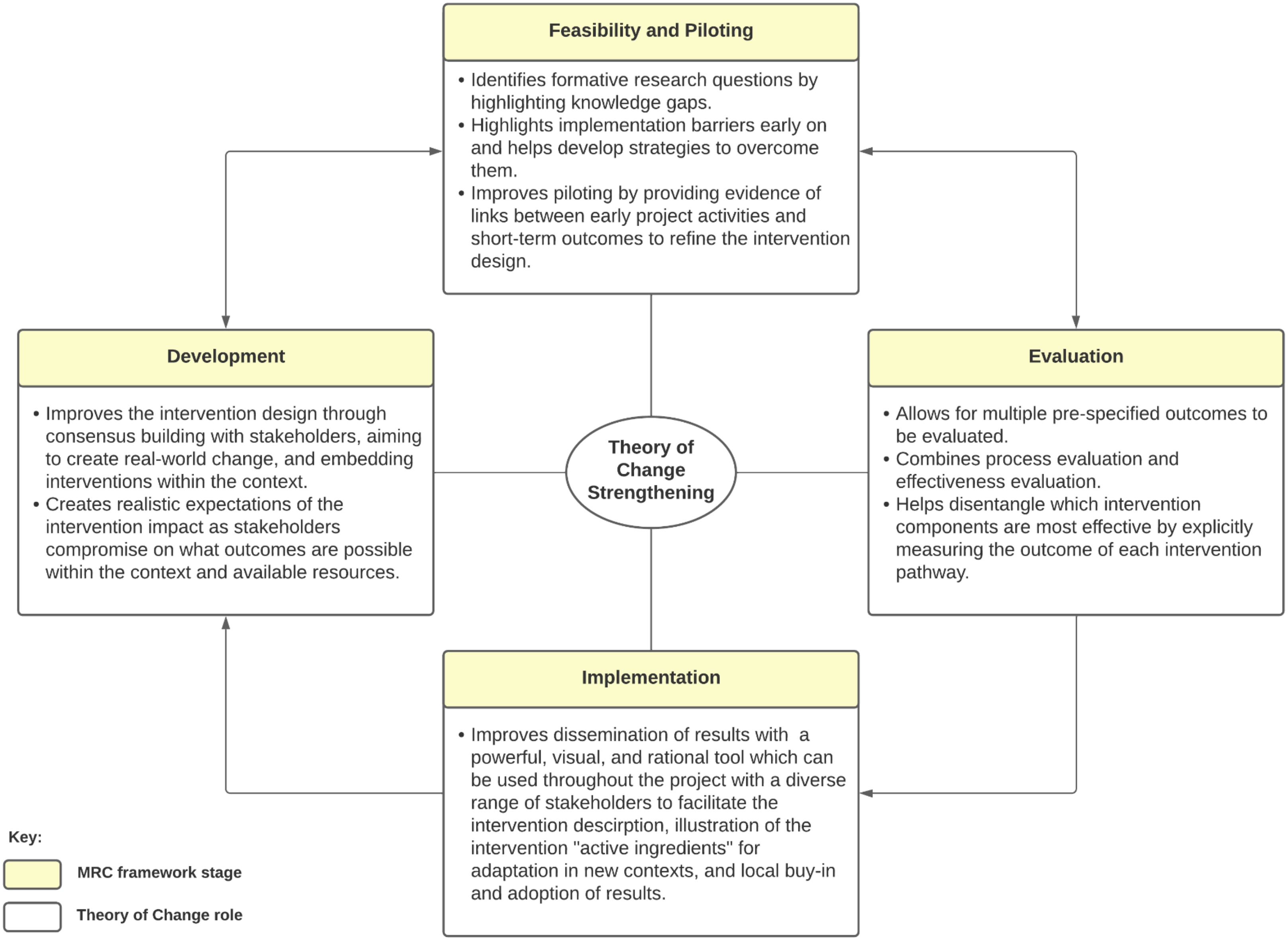
Theory of Change is complementary with Normalisation Process Theory, with a few examples from the literature where both were used together, mostly within the MRC framework[272-275]. Both theories were designed to work with other theories to optimise the development, evaluation, and implementation of complex interventions[123,256]. They focus on understanding the mechanism of action of interventions; how and why they work or fail to work[123,249]. While Normalisation Process Theory explains how implementation processes are motivated and shaped and provides a set of questions to develop an intervention that could be normalised into routine practice, Theory of Change provides explanations to answer these questions[123]. Indeed, Theory of Change has been described as having two components: a *programme theory* focusing on the mechanisms of achieving the intervention outcomes, and an *implementation theory* focusing on the activities needed to achieve the outcomes[270]. The latter corresponds to the Normalisation Process Theory's focus on the actions that people do to implement interventions in practice.

3.6.2 Limitations and critiques

Theory of Change has some critiques. Firstly, it could be difficult to engage all affected stakeholders in developing and evaluating the Theory of Change (achieve total ownership)[271]. This was addressed through engaging *key* service provider leaders to develop and implement the theory (achieve elite ownership)[271], and working with willing service providers who desire change and see the relevance of the theory[276]. Although service users were not directly involved in developing the theory, their voice was brought in through the secondary qualitative data analysis and PPI consultation in later stages. Secondly, developing effective Theories of Change may need time and intensive effort by stakeholders and evaluators[266]. The developed theory can be complex, and the subsequent evaluation in a busy clinical practice can be difficult if the theory includes several outcomes, each of which should be individually measured[123,265]. Apart from the inherent complexity of developing the Theory of Change, this issue was managed by identifying the *key*, rather than all, outcomes necessary to achieve the intervention impact[123,265]. Thirdly, it could be difficult to reach a consensus among stakeholders on the developed Theory of Change[265]. This was mitigated by good facilitation to build trust and resolve confrontation between stakeholders[277]. Finally, during my work in developing the Theory of Change underpinning this intervention, I noted the lack of guidance to analyse the Theory of Change workshops and had to develop my own analysis approach (see **section-4.1.3**). This could be related to the methodological flexibility of Theory of Change[124].

3.6.3 Applications in the study

The Theory of Change approach is widely used within evidence-based medicine to develop and evaluate complex health interventions in experimental trials[124], although it has been rarely used in palliative care research[278-280]. When used within the MRC framework, it enables understanding how and why an intervention is expected to work[123,278-284]. Evidence from projects that used Theory of Change to develop and evaluate complex health and palliative care interventions showed its potential to strengthen all stages of the MRC framework, from development to implementation, and identify the key components and mechanism of action of complex interventions (**Figure-7**)[123,278-280,285]. Nevertheless, this approach has not been used before to develop a palliative care intervention for patients with heart failure. Hence, Theory of Change was adopted in this study to address the frequent calls for further investigation of the active ingredients and mechanism of action of such palliative care interventions which often lack details on the development process and adopted theory[55,59,62,116,121].



Feasibility and Piloting

- Identifies formative research questions by highlighting knowledge gaps.
- Highlights implementation barriers early on and helps develop strategies to overcome them.
- Improves piloting by providing evidence of links between early project activities and short-term outcomes to refine the intervention design.

Development

- Improves the intervention design through consensus building with stakeholders, aiming to create real-world change, and embedding interventions within the context.
- Creates realistic expectations of the intervention impact as stakeholders compromise on what outcomes are possible within the context and available resources.

Theory of Change Strengthening

Evaluation

- Allows for multiple pre-specified outcomes to be evaluated.
- Combines process evaluation and effectiveness evaluation.
- Helps disentangle which intervention components are most effective by explicitly measuring the outcome of each intervention pathway.

Implementation

- Improves dissemination of results with a powerful, visual, and rational tool which can be used throughout the project with a diverse range of stakeholders to facilitate the intervention descirption, illustration of the intervention "active ingredients" for adaptation in new contexts, and local buy-in and adoption of results.

Figure-7: Use of Theory of Change to strengthen the MRC framework, adapted from De Silva et al. 2014[123]

3.7 Development of the Theory of Change

The Theory of Change for the palliative care intervention was developed through an ongoing process of reflection and adaptation, allowing multiple iterations and modifications of the theory as appropriate (**Figure-8**). **Table-9** outlines the methods used to develop the theory and underpinned intervention and the corresponding steps from the MRC framework and complementary guides (see **section-3.3.2**). To construct an effective Theory of Change, it was developed at early stages through interactive group workshops with a variety of service providers, including two key members of the prospective implementation team[228,269]. As preparatory work, practitioner engagement meetings with service providers, shadowing a key service provider in clinical practice, and findings from the systematic review of palliative care needs-assessment and measurement tools in heart failure, provided the necessary background and contextual data and informed the development of the Theory of Change. Next, the Theory of Change was developed in two stages:

1. **Group workshops with service providers**: This method is commonly used in developing Theories of Change for health interventions[124], and is congruent with pragmatism that endorses diverse viewpoints regarding social realities[214]. A participatory approach was adopted by including healthcare service providers in developing the intervention from the outset to have a shared vision on how it may work and ensure their ownership of and buy-in to the project[123,271]. A preliminary Theory of Change was developed by the end of the workshops.
2. **Secondary analysis of qualitative data**: The second stage would have been testing the feasibility of the preliminary Theory of Change and proposed intervention developed after the workshops, but that was not possible due to COVID-19 restrictions. Therefore, a secondary analysis of relevant interview data was conducted to refine the intervention and underlying theory by including the patient and family carer voice which was missing in the workshops. These data were collected from a multinational European project aiming to evaluate the perspectives of patients with advanced heart failure, COPD, and cancer; family carers; and professional caregivers on integrated palliative care[47]. The analysed data were confined to those collected in the UK and relevant to heart failure.

Findings from the secondary data analysis were discussed in follow-up meetings with key service providers who participated in the Theory of Change workshops to enhance and adapt the developed intervention and underpinning theory. Subsequently, a PPI group was consulted to provide their feedback on the proposed intervention. Throughout the whole Theory of Change process, regular fortnightly meetings with the academic supervisors were conducted and the relevant literature was reviewed to aid in the theory development and refinement. The refined Theory of Change, developed after the secondary data analysis and follow-up meetings, is subject to continuous modification when the intervention undergoes feasibility testing, evaluation, and implementation in future work.

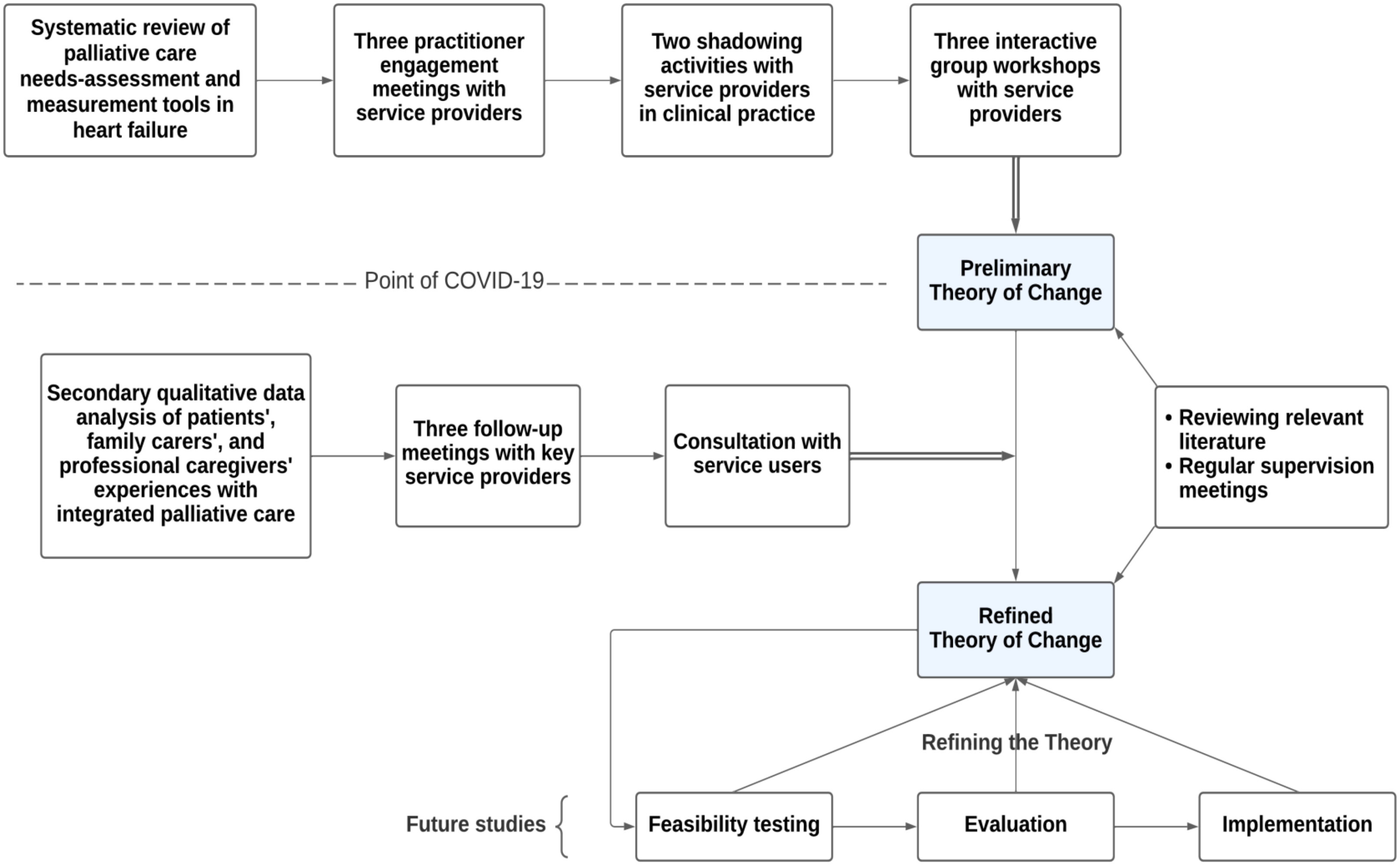


Figure-8: Stepwise development of the Theory of Change underpinning the intervention

Table-9: Methods for developing the Theory of Change and underpinned intervention and the corresponding steps from the MRC framework and complementary guides

Steps/Methods	Systematic review of PC needs-assessment tools in HF	Practitioner engagement meetings	Shadowing service providers	Workshops with service providers	Secondary qualitative data analysis	Follow-up meetings with service providers	Consultation with service users
Identifying the problem		✓	✓				
Examining current practice		✓	✓				
Determining stakeholder needs		✓	✓		✓		✓
Identifying the relevant evidence	✓						
Developing appropriate theory	✓	✓	✓	✓	✓	✓	✓
Modelling process and outcomes				✓		✓	✓
Intervention design						✓	✓

HF: Heart Failure, PC: Palliative Care.

3.7.1 Group workshops with service providers

To develop the Theory of Change for the intervention using group workshops with service providers, the Aspen Institute's and De Silva et al.'s practical guides to Theory of Change development were followed[267,269]. The Theory of Change map was developed using a backwards mapping approach, starting by identifying the ultimate *impact* of the intervention that stakeholders hope to attain, then working backwards to identify the *long-term outcomes* and *preconditions* necessary to achieve that impact. Other steps included identifying the *interventions* required to achieve the outcomes and preconditions, the *rationales* for the links in the causal pathway, and the *assumptions* necessary to achieve the outcomes. *Ceiling of accountability*, the level at which the intervention is no longer responsible for the target impact, was also determined. A further illustration of these commonly used terms in the Theory of Change approach, including how they can be represented graphically in a Theory of Change map, is presented in **Figure-9**[123,269].

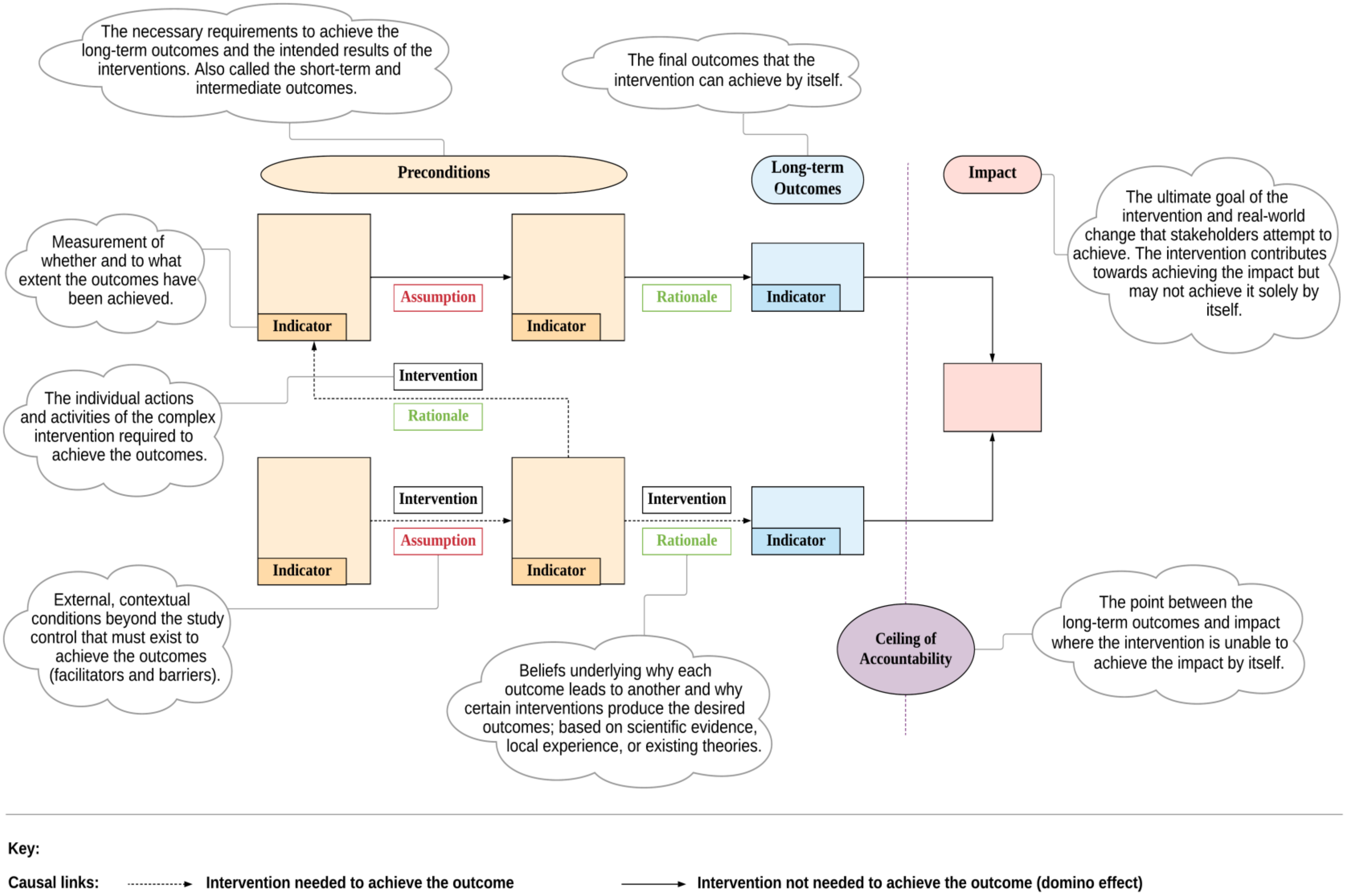


Figure-9: Illustrative representation of a Theory of Change map showing its key components and a hypothetical causal pathway, adapted from De Silva et al. 2014[123,269]

3.7.1.1 Analysis of the workshops

As the Theory of Change approach does not prescribe a certain method for analysing the data collected throughout the intervention development process[266], the literature was searched to find how authors analysed their workshops' data. Nothing specific was found and a Theory of Change expert had to be consulted who advised that the Theory of Change is the output of the group workshops and the content is often not formally analysed[286]. Consequently, the analysis of the group workshops represents the process through which the preliminary Theory of Change is produced. This is consistent with the description of the Theory of Change as both a *process* and a *product*[287]. Nonetheless, the workshops and their analysis were informed by the Normalisation Process Theory constructs and components represented in the theory toolkit (**Table-10**). This interactive, online toolkit was developed through intensive item-development and user feedback activities as a heuristic device to predict and critically think about implementation, embedding, and integration problems throughout all stages of the intervention development and evaluation[254,255].

Table-10: The application of the Normalisation Process Theory toolkit in informing and analysing the workshops, adapted from May et al. 2011[254] and May et al. 2015[255]

Toolkit items*	Applications
Coherence	
Differentiation: Participants distinguish the intervention from current ways of working.	The intervention was co-designed with service providers, described in detail, and broken down into individual intervention activities. Service providers could see how it is distinct from the routine heart failure care provided in their settings as it includes introducing new training materials, assessment tools, group meetings, and other activities.
Communal specification: Participants collectively agree on the purpose of the intervention.	Service providers had a consensus and shared understanding of the intervention aims, expected outcomes, and desired impact; all of which were depicted in the Theory of Change map.
Individual specification: Participants individually understand what the intervention requires of them.	Service providers understood how the intervention could affect the nature of their work. The specific tasks and responsibilities were explained to participants by breaking down the complex intervention into individual activities.

Internalisation: Participants construct the potential value of the intervention for their work.	The intervention was developed in response to the service providers’ willingness to improve how they work with palliative patients. They asked for a service that enables better integration of palliative care into patients’ standard care.
Cognitive Participation	
Initiation: Key individuals drive the intervention forward.	The intervention was championed by two key service providers who attended all the workshops and supplementary meetings. Both have a team leader position in their practice and are therefore able to support the intervention and get others involved.
Legitimation: Participants agree that the intervention should be part of their work.	Service providers were aware that palliative care needs better integration in their practice and were willing to be involved in the new intervention.
Enrolment: Participants' buy-in to the intervention.	Service providers were willing to adopt the intervention, open to working with colleagues in new ways, and prepared to challenge expected difficulties.
Activation: Participants continue to support the intervention.	Service providers were willing to keep the intervention going by addressing the contextual conditions that may facilitate or impede the long-term survival of the intervention (time, resources, skills).
Collective Action	
Interactional workability: Participants perform the tasks required by the intervention.	As service providers were involved in developing the intervention and discussing the contextual conditions, they believed they could integrate it into their existing work.
Relational integration: Participants maintain their trust in each other’s work and expertise through the intervention.	Service providers had confidence in each other’s ability to use the intervention based on their knowledge, skills, and experience. They believed that the intervention would enhance their communication with each other, rather than disrupt their working relationships.
Skill set workability : The work of the intervention is appropriately allocated to participants.	The intervention will be delivered by healthcare professionals with appropriate skills. Training will be provided to enhance participants’ skills in palliative care, communication, and use of needs-assessment tools.
Contextual integration: The intervention is adequately supported by its host organisation.	The intervention was designed with service providers considering the available resources and support. Unfeasible intervention elements which were beyond the capacity of the available resources were excluded.
Reflexive Monitoring	
Systematisation: Participants access information about the intervention effects.	Service providers will be provided with reports about the effects of the intervention after being evaluated.

Communal appraisal: Participants collectively assess the intervention as worthwhile.	Service providers will be asked to provide their feedback on the intervention feasibility and its effect on their practice after being implemented.
Individual appraisal: Participants individually assess the intervention as worthwhile.	Service providers will be asked to provide their feedback on the intervention feasibility and effect on their work after being implemented.
Reconfiguration: Participants modify their work in response to their appraisal of the intervention.	Service providers' feedback will be used to improve the intervention.

* The items correspond to the Normalisation Process Theory sub-constructs.

3.7.1.2 Nominal group technique

To establish a consensus on the desired impact of the intervention among participants, the nominal group technique was used in the first workshop[288,289]. The process started by asking participants about the impact they desire to achieve through the intervention. They were given five minutes for generating ideas and asked to write their answers independently on provided cards. Next, each participant was asked to present one answer to the group in a round-robin fashion. This continued until no new suggestions were forthcoming. After that, the whole group discussed the answers and grouped similar ones. These groups were written on a flip chart where everyone could see them. Following the workshop, the potential impacts, preconditions, and interventions were sorted and identified. In the second workshop, the potential impacts were discussed with participants who were asked to rank them in terms of importance, but this was not necessary as they all agreed on one impact.

The nominal group technique is a widely used consensus method in health research[290]. It is an interactive approach that helps to explore ideas on a specific question and facilitate in-person debate[289]. The nominal group technique was used to provide structured discussion and rapid answers to the proposed question, enable balanced participation from stakeholders, and explore different views from a small group of multidisciplinary experts[289,291,292]. It is congruent with pragmatism, Theory of Change, and co-design as it endorses a participatory process for problem solving[288]. Issues of anonymity and power differentials, where participants may feel uncomfortable discussing their ideas in the presence of senior colleagues, were addressed during and after the workshops (see **section-4.1.4**).

3.7.1.3 Quality of the Theory of Change

The quality of the proposed Theory of Change was evaluated through its plausibility, feasibility (doability), and testability[267,269]. *Plausibility* refers to whether the hypothetical pathway of change makes sense and is evidence-based, and whether implementing the intervention activities would lead to the desired intermediate and long-term outcomes and ultimate impact. This was addressed by identifying the evidence base (rationales) for the causal links in the hypothetical pathway from the scientific literature, local experience of service providers, and existing theories. *Feasibility* refers to whether the intervention can be implemented with the available capacities and resources. This was addressed with the service providers through discussing the assumptions and contextual conditions necessary to achieve the outcomes, where implementation issues and availability of resources were brought centre-stage to create a realistic pathway of change. Further feasibility testing of the developed intervention and underlying Theory of Change is subject to a future study (see **Chapter-8**). *Testability* is the ability to measure the progress towards the intervention impact and is evaluated by defining indicators for the outcomes in the causal pathway (outcome measures). Indicators were identified for key outcomes in the Theory of Change to measure the effect of the intervention in a subsequent trial.

3.7.2 Secondary analysis of qualitative data

The qualitative interview data about patient, family carer, and professional caregiver experiences with integrated palliative care were analysed using reflexive thematic analysis[293,294] (see **section-3.7.2.5**). The analysis was reported using the Best Practice for Reporting Reflexive Thematic Analysis guidance to enhance transparency and show the conceptual and design thinking for thematic analysis[295]. The following items were reported, as per the guidance recommendation: the rationale and contextualisation of research, research question, conceptual and theoretical underpinnings, particular approach of reflexive thematic analysis, reflexive practices, ethical issues, sample size justification, analysis process, quality check, analysis findings (the relationship between the themes and an analytic narrative with quotes), analytic conclusions and implications, and study limitations.

3.7.2.1 Motivation and justification

Secondary data analysis is the reuse of existing data, collected from a previous study, for a different research interest to that of the original study[296]. As stated in **section-1.1**, the plan for this project was to test the feasibility of the proposed Theory of Change and intervention after the workshops as advocated by the MRC framework to address the assumptions identified in the development stage and refine the intervention accordingly[114], but this was not possible due to COVID-19. This made me think about how to continue my PhD project within my limited funding period. After discussions with my supervisory team, the plan was changed from testing the intervention feasibility to conducting a secondary analysis of extant and relevant data. This was the best solution as it allowed me to look back at the proposed intervention and underlying theory and think about how to enhance them before testing their feasibility. The choice of secondary data analysis is congruent with pragmatism that focuses on "what works at the time" to provide a practical solution to problems[215,220,221].

The secondary data analysis provided an opportunity to include the patient and family voice as they were not directly involved in the intervention development. It aimed to evaluate the perceptions of patients with heart failure, family carers, and professional caregivers on the holistic palliative care needs of patients and families in the community, the key healthcare professionals involved in addressing these needs, and how to address them. As the group workshops were conducted in a hospital and thus focused on patients visiting the hospital clinics (see **section-4.1.1.1**), it was important to assess the palliative care needs in the community where palliative care is mostly delivered for patients with heart failure[7]. These needs were not widely investigated in the literature from the patient, family, and healthcare professional perspectives. Following the secondary data analysis, its findings were discussed with key service providers in follow-up meetings to refine the proposed intervention to better meet these needs.

3.7.2.2 Summary of the primary study

The primary study, that provided the data for the secondary analysis, was a part of the EU-funded research project Integrated Palliative Care in Cancer and Other Chronic Conditions (InSup-C) which aimed to identify the best practices in integrated palliative care across Europe[297]. It was conducted across different European countries over five years (2012-2016) to investigate the experiences of patients, family carers, and professional caregivers with palliative care provision in order to understand the mechanisms of successful palliative care integration[47]. It employed questionnaires and semi-structured individual and group interviews over three months to address questions about the organisation of the patients' care network, patients' symptoms and quality of life, caregiving burden and reward, and perceptions of the continuity and quality of provided care.

The primary study findings showed the high burden and unmet needs of family carers, poor patient communication with palliative care specialists, importance of professional networking for integrated palliative care, and importance of continuous multidisciplinary care for patient satisfaction[298-301]. All these findings were not specific to patients with heart failure, but rather to the whole cohort of patients. The data related to patients with heart failure had not been analysed separately and therefore they were subject to further, more specific, analysis. Only the data collected inside the UK were analysed for my study because of the lack of access to data in other countries and differences in healthcare structures[302]. Among the primary researchers who conducted the UK study, one was my academic supervisor and another was my adviser, while I was not involved in the original study.

The dataset that was analysed is relevant to my study and rich as it contains more data than I could have collected in the timeframe left for my PhD, as further ethics approval would have been required and online recruitment might have been challenging. Patients, family carers, and professional caregivers were recruited for the primary study from multiple sites. Patients and family carers were interviewed twice over a three-month period which provided insight into their care needs and how they changed over time. Their interviews also involved taking photos of graphical representations of the experiences of patients and family carers with patient care needs, care network, and collaborative working (see **section-4.2.1.2**). Combining visual methods with verbal data enhances meaning and helps participants to express their ideas and reflect on their experiences[303]. The multiplicity of recruitment sites, involvement of different participants (patients, family carers, and professional caregivers), longitudinal data collection, and availability of supplementary photos added quality, richness, depth, and detail to the data.

3.7.2.3 Epistemological and practical challenges

One issue in secondary data analysis is that the data collected for the primary study may not fit the purpose of the secondary study, and hence the variables of interest may not have been collected[304,305]. By examining the primary study, it was found congruent with my study objectives, focus (integrated palliative care), variables of interest (palliative care needs), and UK study sites (north of England, including the site where service providers were recruited to develop this intervention). A second challenge concerns the quality and completeness of the primary data[306]. This was checked using the Assessment Tool: Criteria for Use in a Secondary Analysis of Qualitative Data (**Table-11**). Briefly, the audio-recorded interviews were conducted by well-trained, experienced researchers and had a clear agenda, while the interview transcripts and associated photos were intact, comprehensible, and interpretable. A third challenge is the currency of the primary dataset, as some contexts may change with time[306]. Although the interviews were conducted five years before the secondary data analysis, the practice of palliative care for patients with heart failure in the UK study sites has not changed considerably since then[307].

A final issue is that secondary analysts interpret data which are collected by other researchers and co-constructed through their interaction with participants[304,306,308]. Thus, secondary analysts are less familiar with the study context and did not encounter the emotions and cognitions experienced by primary researchers and participants. This was particularly relevant as I was not involved in the primary study and conducting the interviews, nor did I have access to the audio recordings because of limitations of ethics approval. Nevertheless, this issue was mitigated through communicating with the primary researchers who familiarised me with the context and experienced feelings during the interviews and by reading the journal papers of the primary study to get background information[306,309]. It is argued that it may not be problematic if secondary analysts do not have a full picture of the context as they should not aim to recreate the primary study context, but rather to recontextualise and reconstruct data[310]. Having a *distant* look at the study can provide new insights and alternative perspectives by secondary analysts and bring up critical and less biased knowledge[305,308,311,312].

Table-11: Criteria for determining the general quality of primary study dataset, adapted from Hinds et al. 1997[306]

Criteria	**Options**		
Ready access to study documents and team	**Yes**		**No**
Tapes of interviews	--		✓
Hard copies/transcripts of interviews	✓		--
Field notes	--		✓
Memos or interpretive notes	Not relevant as I did my own analysis		
Principal investigator or team members	✓		--
Training of primary team	**Satisfactory**	**Unable to determine**	**Unsatisfactory**
Credentials of team members to conduct the primary study	✓	--	--
Training of members for roles in the primary study	✓	--	--
Completeness of dataset	**Yes**		**No**
Available documents are complete	✓		--
Accuracy of transcription	Cannot assess		
Minimal or insignificant typographic errors	✓		--
Appropriate use of software	Not relevant as I did my own analysis		
Ability to assess interviewing quality	**Satisfactory**	**Unable to determine**	**Unsatisfactory**
Interviewing quality	--	✓	--
Interviewing format allowed responses of descriptive depth	✓	--	--
Focus, meaning, and subject of responses can be determined	✓	--	--
Ability to assess sampling plan	**Yes**		**No**
Type of sampling plan (for example, convenience, purposive, theoretical) is clear	✓		--
Criteria for determining the fit of the secondary research question	**Present in sufficient depth**	**Unable to determine**	**Not present in sufficient depth**
Ability to determine the extent to which the concept of interest is reflected in the dataset	✓	--	--

Ability to estimate the validity of the new question	**Likely**	**Unsure**	**Unlikely**
Study sample could be expected to experience this concept or situation	✓	--	--
	Similar	**Somewhat similar**	**Dissimilar**
Proposed research question is similar to that in the primary study	✓	--	--
Aggregate impression	**Yes**		**No**
Dataset of sufficient quality, completeness, and fit with the secondary research question	✓		--

3.7.2.4 Ethical challenges

Ethics approval for the secondary data analysis was obtained (see **section-4.2.2.3**). There are several arguments about the ethics of conducting a secondary analysis of qualitative data. One main issue is whether and when informed consent should be obtained to share and reuse data for a different study purpose[304,313]. Asking the participants for their consent for this study was unfeasible because all patients had probably died by the end of the primary study period according to the primary researchers. Even if the consent for secondary data analysis was obtained at the time of the primary study, it would lack information on how, by whom, and for what purpose the data will be reused. Although the implied consent of the research participants cannot be always assumed, given the unfeasibility of reconsenting participants an ethical judgement was made to justify reusing the data based on the fit between the purpose of the primary study and that of the secondary analysis[296,311]. It was also concluded that participants consented to the general analysis purpose and process, rather than specific research questions or analysis contexts, and therefore reanalysing their data for that purpose without their consent was justifiable. Besides, data from the primary study are still analysed and recent papers had been published during the secondary data analysis[314,315].

Another argument is that qualitative data are co-constructed by respondents and researchers through mutual trust, and therefore using these data by other researchers would break this trust[308,316]. However, this secondary data analysis was supervised by one of the primary researchers who felt that the analysis was congruent with the original research and just an extension. Proponents of secondary data analysis say that researchers have an ethical responsibility to use available datasets to answer their research questions[304,316]. They argue that secondary data analysis reduces the burden of participation in research on vulnerable populations and enables using data from those who are difficult to reach and recruit, such as patients with advanced heart failure[122,296,317]. In summary, the ethical, epistemological, and practical limitations of the secondary data analysis were surmountable and the advantages were perceived to outweigh the residual limitations. Glaser summarised it all: “secondary data analysis can help save time, money, career, degrees… and myriads of data from untimely, unnecessary and unfortunate loss”[318].

3.7.2.5 Reflexive thematic analysis

The interviews were analysed following Braun and Clarke's approach to reflexive thematic analysis[293,294]. Reflexive thematic analysis is an interactive and subjective process that reflects the data, researcher’s positionality, and research context[319]. Themes are analytic outputs developed from codes through the researcher’s engagement with the data, and each theme captures a common, recurring pattern of shared meaning across participants, underpinned by a central organising concept[319-321]. This contrasts with other thematic analysis approaches where themes and meanings are supposed to exist within the data waiting to be discovered by the researcher (themes *emerging* from data), and each theme simply summarises what participants said in response to a specific interview question[293,319,321].

In reflexive thematic analysis, researchers move backwards and forwards between semantic (explicit) and latent (interpretative) coding, as well as inductive and deductive coding[294]. Semantic coding stays close to the participants’ terms as it presents a more descriptive account of their experiences (reality is knowable and language reflects thoughts and feelings), while latent coding goes beyond the surface meanings of the data and presents a more conceptual account of the assumptions underpinning the data (knowledge and experiences are socially constructed and language creates, rather than reflects, reality)[293,322-324]. Inductive coding aims to develop themes from the data content (bottom-up, data-driven approach), while deductive coding aims to develop themes based on existing concepts (top-down, theory-driven approach)[293].

The main thematic analysis approach used in this study was inductive and semantic as I wanted to capture patterns in what people said about their experiences with integrated palliative care and to stay close to how they made sense of their experiences. To a lesser extent, I used deductive and latent coding which involved coding *in the light of* Normalisation Process Theory, where its core constructs were applied *as a lens* through which to code the data and critically think about integrating palliative care in healthcare practice[256] (see **section-3.5.1**). This approach did not constrain my thinking as I was aware that some findings can fall outside the theory. Nonetheless, it allowed me to map the inductively generated themes onto the Normalisation Process Theory constructs. The combination of experiential-inductive-semantic coding and critical-deductive-latent coding is concordant with pragmatism which views knowledge as being both constructed and based on the reality of the world that a person experiences[221].

Reflexive thematic analysis is a flexible method for collecting and analysing data rather than a methodology that prescribes a theoretically-informed framework for how to do research[293]. It is used across a wide range of ontological, epistemological, and theoretical approaches, and for a wide range of research questions (including people's experiences and perspectives), most types of qualitative data (including secondary and visual data[325-330]), and both small and large datasets[323]. In congruence with pragmatism, reflexive thematic analysis is method-neutral, endorses the role of theory in research, endorses the role of research context and researcher values for interpreting results, and combines inductive and deductive coding approaches[220,294,331]. It is also compatible with

Normalisation Process Theory which does not specify a certain research method and aids in assessing people's experiences[253,256,260].

One critique of thematic analysis is related to its flexibility, which poses a challenge in achieving coherence between the research objectives, philosophical and theoretical assumptions, and chosen methods, and could therefore affect the research methodological integrity[295,332]. This was addressed by explaining my epistemological position and its fit with reflexive thematic analysis and the approach used, and how they both are appropriate to answer my research question (see above). Thematic analysis is also criticised for its simplicity, descriptive focus, and lack of interpretative depth[333,334]. The approach itself is not inherently simple or complex; this depends on how analysts implement it[333]. Reflexive thematic analysis always has an element of interpretation, regardless of the approach used (semantic or latent), and can produce unexpected insights[293]. A related critique is the false assumption that thematic analysis is an a-theoretical method[324,331]. Reflexive thematic analysis is rather theoretically flexible, as researchers choose the theoretical framework that best answers their research questions[293]. A final critique is that thematic analysis is a poorly demarcated and unstructured method[293]. However, there are now several papers that provide a distinctive set of procedures and tools on how to do thematic analysis rigorously, including the widely used Braun and Clarke's six-phase approach[293,322] (see **section-4.2.2.2**). Still, these guidelines were misunderstood and criticised for creating rigid rules for doing thematic analysis, rather than seen as flexible starting points for analysis[333].

The analysis quality was checked by evaluating the validity and rigour of its findings. In qualitative research, validity refers to the procedures taken by researchers to check the accuracy of findings and show that their interpretations and inferences are supported by the data[335,336]. The strategies used to improve the validity of my analysis findings were: creating themes using multiple converging sources of data and types of evidence (interview transcripts and supplementary photos), providing an in-depth description of the findings through discussing the context and providing several perspectives about the themes, and reviewing my findings and coding procedure by the primary researchers who conducted and facilitated the interviews[240,337]. The continuous feedback that I received from my experienced supervisors on my analysis helped to discuss my ideas and reflect on how I coded the data, guide me back to the data when I was overinterpreting and speculating, and reflect on the assumptions I made in coding and the ideas I might have missed in the data[338]. Moreover, I documented all phases of the research and analysis process in adequate detail to ensure following the procedures[240,337]. A more comprehensive check of the quality of the thematic analysis is provided in **Table-12** using Braun and Clarke's Checklist of Criteria for Good Thematic Analysis[293].

Table-12: Checklist of criteria for good thematic analysis, adapted from Braun and Clarke 2006[293]

Process	Quality criteria	Notes
Transcription	Transcribing the data to an appropriate level of detail and checking the transcripts against the tapes for accuracy.	• This was not applicable as I did not transcribe the interviews nor did I have access to tapes. However, all interviews were transcribed verbatim by a transcription company and checked by experienced, well-trained researchers[47].
Coding	Giving equal attention to each data item in coding.	• I coded all the interviews systematically. The professional caregiver group interviews were coded under codes created from the patient and family interviews to compare their opinions. However, where data in the group interviews could not be associated with existing codes, new codes were created.
	Thorough, inclusive, and comprehensive coding (themes not generated from a few vivid examples).	• I combined coding small chunks of data to open up the data and not miss important meanings and nuances in the text (mainly for the first few interviews) with coding longer segments of data to investigate broad and overarching discussion areas and not lose the context[339,340]. • I checked the data under each code to explore both exemplars and outliers that oppose the theme's general perspective. • I created a tally mark chart for each theme to ensure that data extracts from different participants were provided to support the themes' prevalence in the data.
	Collating all relevant extracts for each theme.	• I used computer software to facilitate managing data and collating coded extracts for each theme.
	Checking the themes against each other and the original dataset.	• I compared the themes with the coded extracts and interview transcripts to confirm their presence in the data.
	Internally coherent, consistent, and distinctive themes.	• I compared the themes against each other to evaluate if each has a distinctive central organising concept (core idea) and little overlap.

Process	Quality criteria	Notes
Analysis	Analysing rather than just paraphrasing or describing the data.	- I combined semantic and latent approaches to generate the themes. In both cases, the analysis went beyond the data content to explore meanings.
	Matching between data extracts and analytic claims.	- I chose data extracts that best illustrate the themes.
	Telling a well-organised story about the data and topic.	- Data extracts were embedded within an analytic narrative to tell a coherent story. - I created a thematic map that shows how themes relate to each other to tell a convincing story about the data and answer the research question.
	Good balance between data extracts and analytic narrative.	- I supported each theme with a range of data extracts.
Overall	Allocating enough time to complete all analysis phases.	- It took me about one year to complete the analysis which provided an in-depth understanding of the data.
Written Report	Explicating the assumptions about and approach to thematic analysis.	- I discussed my assumptions and illustrated the rationale of my analysis approach (mainly inductive and semantic).
	Consistency between the described method and reported analysis.	- I checked the final report against the adopted method and epistemology to make sure that I have done what I claimed to do.
	Consistency between the report language and concepts and the analysis epistemological position.	- I explained how reflexive thematic analysis is concordant with my philosophical and theoretical assumptions (pragmatism and Normalisation Process Theory), which were reflected in the report language.
	Positioning the researcher as active in the research process.	- Throughout the analysis process, I reflected on how my assumptions, past experiences, and possible biases shaped my interpretation of the results (see **section-9.6.2**). Consequently, themes were developed, rather than emerged, from the data.

3.8 Self-reflexivity

Reflexivity describes the researcher's role throughout all steps of the research and the implications of their values, biases, and decisions on knowledge construction[337]. Researchers are required to reflect on their theoretical assumptions and past experiences with the research problem, setting, or participants, including how these experiences shape their interpretations of results[240,294]. Throughout my research, I wrote reflective notes about my personal experiences and used them throughout the intervention development, which aided in analysing the Theory of Change workshops and the qualitative interview data[240,341]. I received continuous feedback from my supervisors to evaluate my interpretations and challenge my assumptions. I maintained a balance between my preconceived ideas and participants' concepts, including those different from my own[341]. The value and involvement of the researcher in the research process are endorsed by pragmatism, qualitative research, Theory of Change, and reflexive thematic analysis[123,214,240,294].

My professional experience and orientation influenced the research topic and the adopted philosophical paradigm and theory. I was trained and worked as a clinical pharmacist; focusing on addressing treatment issues of patients with chronic conditions, including those with advanced heart failure. My understanding of this context enhanced my awareness and sensitivity to the palliative care needs of patients and their families. It also ignited my interest in the topic and prompted me to do this study to seek the best way of identifying and addressing those needs. My desire to make a difference in practice and solve the consequences of advanced heart failure on patients and families prompted me to adopt pragmatism, Normalisation Process Theory, and the Theory of Change approach as all provide practical solutions to problems and are outcome-oriented[223,251,265,270]. As a pragmatist, I decided what I wanted to study, and how to study it, based on what I value as important[214]. More details on how I reflected on my own experiences throughout all stages of the intervention development are presented in **section-9.6**.

3.9 Congruence across the methodological framework

Pragmatism informed the choice of the MRC framework to develop this intervention[112-115], and both informed a qualitative methodology for the development stage. The MRC framework triggered thinking about theories to underpin the intervention and guide the research, with the choice of the theories being affected by my philosophical and personal inclinations[212]. Normalisation Process Theory was adopted as a middle-range theory to provide an overarching theoretical framework for this study[246,247], and to direct the choice and application of a programme theory (Theory of Change)[265-267]. Ultimately, the methods of data collection included group workshops with service providers, secondary 'reflexive thematic' analysis of qualitative interviews, and follow-up meetings with service providers. These methods were informed by the research objectives, my values, adopted paradigm, qualitative methodology, and adopted theories, in addition to practical considerations related to the COVID-19 pandemic restrictions on clinical research[222,342].

The congruence between my methodological choices was discussed throughout this chapter and summarised in **Table-13**. The value of multiple viewpoints and stakeholder involvement, the flexibility of adopted methods to answer the research question, and the importance of theory and context in research are endorsed by the MRC framework, qualitative methodology, Normalisation Process Theory, Theory of Change, and data collection methods. The role of inductive and deductive reasoning to develop and test theories and the value of the researcher to interpret research findings are mainly endorsed by the qualitative methodology, Theory of Change, and reflexive thematic analysis. Both the MRC framework and adopted theories share a similar purpose of providing practical solutions to research problems by focusing on the actions and outcomes.

Table-13: Congruence across the methodological framework

Philosophical paradigm	Research framework	Methodology	Theory		Data collection/analysis methods	
Pragmatism*	MRC framework	Qualitative	NPT	Theory of Change	Group workshops and meetings with stakeholders	Secondary ‘reflexive thematic’ data analysis
Diverse viewpoints regarding social realities	✓	✓	✓	✓	✓	✓
Inductive and deductive reasoning		✓		✓		✓
Theories are instrumental in research	✓	✓	✓	✓		✓
Researcher’s values in interpretation		✓		✓		✓
Methods driven by the research question (qualitative and/or quantitative)	✓	✓	✓	✓	✓	✓
Practical solutions to real-world problems	✓		✓	✓		
Action-oriented	✓		✓	✓		
Outcome-oriented	✓		✓	✓		
Causal relations (although transitory)	✓			✓		
Context is important	✓	✓	✓	✓		✓

NPT: Normalisation Process Theory.

* The characteristics of pragmatism were derived from multiple resources including Teddlie and Tashakkori 2009[214], Johnson and Onwuegbuzie 2004[221], and Creswell and Poth 2018[212].

3.10 Chapter summary

In this chapter, the philosophical and methodological foundations of the study were outlined. Pragmatism was the adopted paradigm, with its focus on what works in practice. Normalisation Process Theory provided an overarching theoretical framework for the study, while the Theory of Change approach underpinned the intervention development. The intervention was developed using the MRC framework, alongside Bleijenberg et al.'s guidance and the MORECare statement. A co-design approach was adopted where stakeholders were involved from the outset to create a feasible and implementable intervention. The steps for the intervention development included identifying the problem, examining current practice, determining stakeholder needs, identifying the relevant evidence, developing appropriate theory, modelling process and outcomes, and designing the intervention. Multiple qualitative methods were used to achieve these steps, including group workshops with service providers, secondary qualitative data analysis, follow-up meetings with service providers, and consultation with service users. These methods are discussed in detail in the following chapter.

4 Methods

In the previous chapter, the methodological foundations of the study were discussed. This chapter describes the methods of three studies. Firstly, the methods of Theory of Change group workshops with service providers, during which the preliminary intervention and underpinning theory were developed, are outlined. This is followed by describing the methods of a secondary analysis of qualitative interview data about the experiences of patients, family carers, and professional caregivers with integrated palliative care. Finally, the chapter outlines the methods of follow-up meetings with key service providers during which the findings of the workshops were discussed against the findings of the secondary data analysis, the proposed intervention and underlying theory were refined, and a protocol for a future feasibility study was co-developed. The chapter ends by describing how service users were consulted to provide feedback on the intervention and feasibility study protocol.

4.1 Methods: Theory of Change workshops with service providers

4.1.1 Study sample

4.1.1.1 Settings

Study participants were healthcare providers who were involved in at least one Theory of Change group workshop. They were recruited from the heart failure multidisciplinary team of a tertiary teaching NHS hospital in a coastal community area in northwest England. All members of the heart failure multidisciplinary team were approached by email to participate in the Theory of Change workshops and identified as potential participants. On the day of each workshop, the team members who were available at the preceding multidisciplinary team meeting were invited to participate in the workshop which followed.

The hospital has a specialist cardiac centre where most patients with heart failure are seen. The hospital heart failure multidisciplinary team work cooperatively and hold weekly meetings to discuss patients. The team is composed of consultant cardiologists, heart failure nurse specialists (hospital and community), and a heart failure occupational therapist. Other team members, such as palliative care specialists, are consulted as needed. The heart failure team provide medical and generalist palliative care for patients with heart failure and refer them to specialist palliative care services when required. The team had initiated discussions about how to improve palliative care provision in their practice, which is congruent with the aim of this study.

4.1.1.2 Inclusion criteria

Study participants took part in the Theory of Change workshops if they met the inclusion criteria:

- Healthcare professionals.
- Members of the hospital heart failure multidisciplinary team.
- Providing informed consent for the workshops.

4.1.1.3 Sample size

There is no agreement on the recommended number of participants in a Theory of Change workshop. The Aspen Institute's practical guide to Theory of Change development recommends a maximum of eight to ten participants[267], though the sample size ranged from five to 54 in previous studies[278,279,281,282,343]. Similarly, whilst no agreement exists on the ideal number of participants in the nominal group technique (used in the first workshop), it ranged from two to 14 in previous research in line with some guidelines' recommendations[289,291,292]. For this study, eight service providers participated in the first workshop (plus three facilitators), four in the second (plus three facilitators), and five in the third (plus two facilitators). This sample size was convenient as it reflected the numbers attending the heart failure team meetings. Three key participants attended all the workshops: a consultant cardiologist and heart failure specialist (team leader), lead heart failure nurse specialist, and heart failure occupational therapist.

4.1.1.4 Recruitment

The workshops were conducted between October 2019 and January 2020. A recruitment email was sent to the hospital heart failure team leader one week before the first workshop which she forwarded to all team members. An invitation to participate, participant information sheet, consent form, and workshops' schedule were attached. The team members willing to participate were asked to sign the consent form before the start of the workshops. Participation in the workshops was voluntary and participants could attend as many workshops as they could. Although the possibility of coercion from the team leader cannot be excluded, team members were informed that non-participation would not affect their employment status in any way. No participation incentives were paid, and travel reimbursements were not necessary as the workshops were conducted at the participants' workplace.

4.1.2 Data collection

The group workshops with service providers were the central stage in building the Theory of Change map. Before that, three one-hour practitioner engagement meetings were conducted with service providers over six months (February to July 2019) to set the scene for the Theory of Change workshops and engage them in the design and development of the research through exploring what sort of research was possible and discussing the barriers and facilitators of integrating and implementing palliative care in their daily practice. These meetings were initiated by key service providers who were willing to enhance palliative care provision for patients with advanced heart failure in their practice. The discussions shaped the next stage and were explored later in the Theory of Change workshops. Following the meetings, the lead heart failure nurse specialist was shadowed on two separate occasions to observe the clinical practice in a hospital heart failure nurse-led clinic and inpatient wards and understand the operating system. The workshops were next conducted to build a preliminary Theory of Change. After the workshops and the subsequent secondary data analysis, three one-hour follow-up meetings were held with key service providers to refine the proposed theory, and a PPI group was consulted about the intervention (see **section-4.3**).

Reviewing the literature and supervision meetings provided important data and input throughout all the theory and intervention development steps. Searching the literature retrieved relevant systematic reviews that showed positive evidence for palliative care interventions in patients with heart failure[59-63] (see **section-1.4.2**). The wider literature on palliative care in heart failure was reviewed to provide background information, guide focused discussions with the service providers, aid in constructing the Theory of Change map, and provide scientific evidence of the causal links in the hypothetical pathway of change (rationales). Findings from my systematic review were presented to the workshop participants to discuss the possible incorporation of palliative care needs-assessment and measurement tools in the intervention[125]. On the other hand, meetings with the academic supervisors provided feedback on the Theory of Change map drafts proposed following each workshop. The map was continuously refined based on their comments and experience both in and out of the field. At least one supervisor was present in each workshop as a second facilitator, making their feedback relevant to the workshops' discussions. Both supervisors have good clinical and research experience in palliative care for patients with chronic conditions. One supervisor is an academic nurse while the other is a palliative medicine consultant.

4.1.2.1 Group workshops with service providers

Three interactive in-person workshops were conducted with service providers in a private room in the hospital after their routine multidisciplinary team meetings. A two-month period separated each workshop from the next one to suit stakeholders' busy schedules and allow time for reflection and discussion. For each workshop, a schedule and PowerPoint presentation were prepared to guide discussions. A flip chart, markers, small cards, and pens were used to write and discuss participants' ideas and draft the Theory of Change map. I facilitated the workshops with one or two of my supervisors. Participants who deviated from the focus of the workshops were politely guided back to the main topic. The three workshops lasted for 38, 75, and 65 minutes. They were audio-recorded using a digital voice recorder and transcribed by myself.

At each workshop, participants were asked to provide demographic data including gender, profession, and year of graduation. These data served to describe the sample, provide contextual background, and allow comparisons with participants in similar interventions. All workshops started with encouraging participants to comply with the ethical principles of group workshops (confidentiality, anonymity, right to withdraw) and follow the ground rules of the Theory of Change approach, including considering participants' input as equally important, encouraging participants to think outside the box, and confirming that what is written can be modified[278]. Next, participants were introduced to the Theory of Change approach for developing complex interventions. They were then provided with an overview of what was achieved in the last workshop/s, where applicable, and what is planned to be achieved in the current workshop. The Theory of Change map was then constructed step by step in collaboration with participants.

4.1.3 Data analysis

The workshops' analysis was informed by the Normalisation Process Theory constructs and components represented in the theory toolkit (see **section-3.7.1.1**). Data analysis occurred concurrently with data collection and is represented by the process of constructing the Theory of Change map throughout the workshops. Before the workshops, drafting the map was practised with the supervisors based on their experience. During the workshops, the map was built in a stepwise fashion, beginning with determining the impact of the intervention and ending with discussing what is needed to achieve the impact. Multiple versions of the map were drafted until a consensus was reached on a last preliminary version that illustrates the key intervention components and its possible mechanism of action. The content of the workshops' transcripts was not analysed. Instead, it served to remember what was said and decided and extract the Theory of Change components that came out through the discussions, which helped to create the map. The preliminary Theory of Change map was built using Lucidchart diagram software and described narratively. The intervention was systematically reported using the Template for Intervention Description and Replication (TIDieR) guidelines; addressing the following items: intervention's name, why (rationale), what (procedures and materials), who provides it, how, where, when and how much, tailoring, and planned fidelity assessment[118].

The following discussion provides an overview of how the workshops were analysed to construct a preliminary Theory of Change and represent it in a map:

- **Workshop-1:**

In response to the question on the intervention's desired impact, the ideas that were generated from participants in the nominal group process were gathered, including both the answers written individually on the provided cards and those grouped on the flipchart. After the workshop, those ideas (individual and grouped answers) were synthesised and merged where appropriate to better reflect the workshop discussion. Each idea was then evaluated whether it fits better as an ultimate impact (as participants were asked), long-term outcome, or an earlier precondition. The discussed ideas were made sense of and linked to create a *first draft* of the Theory of Change map that shows how preconditions could interact to achieve specific long-term outcomes and a potential impact (suggested pathway of change). Next, a few more preconditions, apart from those arising from the workshop discussion, were added from the literature to fill in some gaps in the suggested Theory of Change map, tell a more coherent story of the intervention process of change, and trigger discussion in the following workshops. Lastly, potential intervention activities, rationales, and assumptions that came out implicitly through the workshop discussion were extracted from the workshop's transcript.

- **Workshop-2 and Workshop-3:**

In the second workshop, the impact of the intervention was agreed upon by participants. Potential long-term outcomes, preconditions, intervention activities, rationales, and assumptions were extracted from the workshop discussion and associated transcript. These elements were added to the first draft of the Theory of Change map to create a *second draft* that was less complex and more focused; comprising only the essential potential preconditions needed to achieve the agreed impact. In the third workshop, the second draft of the map was presented and discussed with the workshop participants for refinement. Again, potential long-term outcomes, preconditions, intervention activities, rationales, and assumptions were extracted from the workshop discussion and associated transcript. These elements were added to the second draft of the map to create a *third draft*. The relevant literature was reviewed to assess the evidence for the proposed causal links in the hypothetical pathway of change and revise the third draft to create a *preliminary* Theory of Change map. This preliminary map was the eventual outcome of the workshops; comprising the essential components of a Theory of Change map. It was evaluated in terms of plausibility and feasibility (see **section-3.7.1.3**) and emailed to all workshop participants for validation and agreement. It was later modified following the secondary data analysis and follow-up meetings with key service providers.

4.1.4 Ethical considerations

Ethics approval for the group workshops was obtained from the Research Ethics Committee in the Faculty of Health and Medicine at Lancaster University on 9th August 2019 (reference number: FHMREC18098). A letter of access for conducting the workshops and an honorary contract for the shadowing activities were obtained from the hospital on 12th August 2019 and 11th September 2019, respectively. During the practitioner engagement meetings and shadowing, no actual data were obtained and hence no ethics approval was needed from the university. The ethical considerations of the study regarding consent and recruitment were discussed in **section-4.1.1.4**. Other ethical considerations include data management and storage, confidentiality and anonymity, and risk and benefit.

For research data management, the EU General Data Protection Regulation and the UK Data Protection Act 2018 were complied with[344]. The workshops were audio-recorded on an encrypted digital voice recorder which was stored securely before the immediate transfer of the data to a personal password-protected laptop computer and encryption.

The audio data were also stored in OneDrive for backup. Next, they were deleted permanently from the voice recorder. The transcripts were anonymised, stored on the same laptop, encrypted, and backed up in OneDrive. Hard copies of demographic sheets were temporarily stored in a locked place only accessible to me. After that, they were written in a Word document on the laptop, encrypted, and backed up in OneDrive. The papers were then immediately destroyed.

The nature of group workshops does not guarantee confidentiality and anonymity, because the material is shared with others in the group and participants may disclose information outside the group. However, the participants in this study were healthcare professionals who understand the importance of these ethical principles and were expected to adhere to them. Steps taken to enhance confidentiality and anonymity were: encouraging participants to respect the privacy of each other, not to repeat what is said in the workshop to outside parties, and not to link certain information to a specific person; storing data securely; transcribing audio by myself; analysing data at the group level; and anonymising the transcripts. Participants were informed that confidentiality and anonymity cannot be completely guaranteed in the participant information sheet.

The workshops did not cause discomfort or inconvenience to participants, although some might have felt uncomfortable expressing and sharing their ideas in their workplace in the presence of senior colleagues with more power and impact or thought that their opinion is not worthwhile. This was mitigated by the nominal group technique where all participants wrote their ideas independently, good facilitation and confirming that everyone’s input is equally important, encouraging the group to share their ideas openly and respectfully, and asking participants to commit to the confidentiality of the workshop discussion. Plans were put in place if participants experienced significant distress, including directing them to counselling services and providing a debriefing sheet with sources of support at the end of the study. Participants could withdraw from the workshops at any time, although their contribution to the discussion could not be withdrawn. The workshops have not caused me any harm. I conducted all the workshops with at least one supervisor and did not share personal contact information with participants. While the study might not provide direct benefits to the participants, it might affect their future practice if they adopt the developed intervention. Also, it might benefit the patients and family carers to whom the intervention will be delivered.

4.2 Methods: Secondary qualitative data analysis

In **section-4.1**, the methods of developing the preliminary intervention and underlying Theory of Change through group workshops with service providers were discussed. The current section outlines the methods of a secondary analysis of qualitative interviews through which the voice of service users (patients and family carers) was included in the intervention development. The secondary data analysis aimed to evaluate the perceptions of patients with heart failure, family carers, and professional caregivers on the holistic palliative care needs of the patients and their families in the community and how, and by whom, they can be addressed. This section starts with an outline of the primary study methods, before discussing the secondary data analysis methods. In the next section, I explain how the findings of the secondary data analysis were discussed in light of the findings of the workshops in follow-up meetings with key service providers to refine the proposed intervention and underlying theory (see **section-4.3**).

4.2.1 Methods of the primary study

4.2.1.1 Design and settings

The primary study is an international, multi-centre, prospective, longitudinal, mixed-methods, and multiple-embedded case study[47]. It was conducted in 23 integrated palliative care initiatives across five European countries including five initiatives in the UK. These initiatives represent the *cases* in the study and were selected based on these criteria: established local palliative care collaborations, involving at least two different organisations, and providing direct palliative care for patients with advanced heart failure, COPD, or cancer by collaborative multidisciplinary healthcare professionals. The *embedded subunits* of these cases are the patients, family carers, and professional caregivers. The study was approved by the relevant research ethics committees.

Patients were recruited from each initiative by a treating healthcare professional. Those who were at different timepoints in their disease trajectories were purposefully sampled. Each patient was asked to identify one family carer for recruitment. Patients and family carers were included if they were adults (≥18 years) and able to communicate in the national language, complete questionnaires, and participate in interviews. Patients should also have advanced heart failure, COPD, or cancer and a negative answer to the question (Would you be surprised if the patient died within the next year?) by the attending doctor. Patients were asked to identify professional caregivers involved in their care network for recruitment. Professional caregivers who had different roles in the selected initiatives were conveniently sampled. Across Europe, 152 patients (19 with heart failure) and 92 family carers participated in individual interviews, while 142 professional caregivers in total participated in 19 group interviews[298,300]. In the UK, 35 patients (seven with heart failure) and 13 family carers (five carers of patients with heart failure) participated in individual interviews between July 2014 and July 2015, while 23 professional caregivers participated in four group interviews between March and October 2015.

4.2.1.2 Data collection and analysis

Demographic characteristics were collected from the patients, family carers, and professional caregivers at baseline. Semi-structured, individual, in-person interviews with patients and family carers were conducted at baseline and after three months to assess the problems and needs of patients, relationships of patients and family carers with professional caregivers, and perceived collaboration between professional caregivers[298]. Patients and family carers were interviewed separately in most cases. If the patient died during this time, family carers were asked if they wished to participate in the second interview (bereavement interview). Semi-structured, group, in-person interviews with professional caregivers involved in the patients' care network were conducted at the end of data collection to provide multiple insights on how integrated palliative care was implemented across the content of care, patient flow, information logistics, and availability of resources[300]. All interviews were conducted by experienced researchers, audio-recorded, transcribed verbatim, and guided by an interview protocol.

Patient and family carer interviews lasted for an average of one hour while professional caregiver interviews lasted for an average of one and a half hours. All interviews were analysed using qualitative content analysis with the help of qualitative data software[345].

During the patient and family carer interviews, a prompt card method (Pictor technique) was used to trigger discussions about patient needs and who, in the care network, meets these needs[346]. This involved four steps: writing down patient problems and needs on separate cards and ordering them according to their priority to the patient; writing down the caregivers who had contact with the patient on separate cards and ordering them according to their contact frequency and importance to the patient and family carer; placing the cards of the three highest priority problems and needs on the cards of caregivers who address them; and drawing lines between the cards of caregivers to show who work, and do not work, together in patient care. Throughout this process, photos of the cards were taken.

4.2.2 Methods of the secondary study

4.2.2.1 Data collection

The data from the primary study that were analysed in this study are confined to those collected in the UK and relevant to patients with heart failure. They were available electronically and collected directly from the primary researcher. The collected data include transcripts of individual interviews with patients with heart failure and family carers, transcripts of group interviews with professional caregivers, card photos used during the patient and family carer interviews, and demographic characteristics of interviewed participants which served to describe the sample. The patient and family carer interviews were conducted by my adviser mostly in patients’ homes, while the group interviews were facilitated by both my supervisor and adviser and lasted for 90 to 120 minutes. The group interviews were not limited to discussing a particular disease, but several stories were told about patients with heart failure.

Overall, there were 20 individual interviews with patients with heart failure and family carers recruited from three community hospice-based palliative care initiatives in the north of England, in addition to four group interviews with professional caregivers carried out in four different initiatives (**Table-14**). Although this study is a secondary data analysis where determining the sample size was beyond control, these numbers of interviews agree with Braun and Clarke's recommendations of more than ten interviews for relatively broad-scope studies that address sensitive topics in a heterogenous sample of participants using a more inductive analytic approach across a dataset[295].

Table-14: Number of patients with heart failure, family carers, and professional caregivers interviewed in the UK

Individual interviews	**Baseline**	**Month-3**
Patients	7	5 (2 patients died)
Family carers	5	5 (including 2 bereavement interviews)
Total	11 (one joint interview)	9 (one joint interview)

Group interviews	**Group interview-1**	**Group interview-2**	**Group interview-3**	**Group interview-4**
Professional caregivers	6	6	5	6

4.2.2.2 Data analysis

Following the Pictor technique's guide that does not specify a particular photo-analysis approach[346], the card photos that accompanied the patient and family carer interviews were not analysed separately. Instead, they were examined in the context of the accompanying interview transcript to make sense of the participants' stories and produce richer, more integrated analysis. The analysis of the interviews was reflective, mostly inductive and semantic, aiming to develop themes from the interviews' data[294]. It was aided by NVivo-12 Plus qualitative data analysis software. The six phases for thematic analysis described in Braun and Clarke's guidance were followed in an iterative, non-linear, back-and-forth fashion[293,320-322,324]:

1. **Data familiarisation:** Intimate immersion in, and deep engagement with, the data through actively reading and re-reading the interviews' transcripts, examining the associated card photos, and writing annotations and initial analytic observations to highlight items of interest and notice patterns in the data (reading data *as data*).
2. **Systematic data coding:** Creating succinct codes across the entire dataset to identify common meanings throughout the transcripts that are relevant to the research questions and collating all data extracts relevant to each code. Where appropriate, existing codes were modified and coded data were recoded as coding evolved throughout the analysis.
3. **Generating initial themes:** Examining the codes and coded extracts to identify areas of similarity and broader meaning patterns, clustering the codes to create potential subthemes and candidate themes on patient and family needs and how and by whom they can be addressed, and exploring the relationship between the themes.
4. **Reviewing initial themes:** Checking the candidate themes against the coded extracts and all interviews to ensure that the themes exist and reflect the meanings in the data and tell a convincing and coherent story that answers the research questions. At this stage, themes were refined (for example, relocating codes under another theme), some were combined, and others were split into distinctive themes.
5. **Defining and naming themes:** Analysing the themes in detail, describing their scope and focus, creating a thematic map to show how the themes relate to but do not overlap with each other, and giving them informative and concise names.
6. **Writing up:** Writing the report, including presenting the themes in a logical order to tell a compelling story of the data and providing vivid data extracts from various interviewees to capture the essence and support the prevalence of the created themes. In **Chapter-9**, an argument was made in relation to the research questions and literature.

4.2.2.3 Ethical considerations

Ethics approval for the secondary data analysis was obtained from the Faculty of Health and Medicine Research Ethics Committee on 26th May 2020 (reference number: FHMREC19099). The data for this study were directly collected from the primary researchers (my supervisor and adviser). An approval from the chief investigator was gained to use the data for secondary analysis. Consent for the secondary data analysis from research participants was not sought in the primary study as it was seen as aligned with the original consent (see **section-3.7.2.4**).

For research data management, the EU General Data Protection Regulation and the UK Data Protection Act 2018 were complied with[344]. According to the act, using research data for different purposes to those of the primary study is permitted as in the public interest. The study data (interview transcripts, card photos, and demographics) had been already anonymised by the primary researchers. I did not have access to the audio recordings of the interviews as they were destroyed after the primary data analysis, neither did the photos taken during the interviews contain people; only the cards could be seen. The study data were stored securely in a personal password-protected laptop computer, encrypted, and backed up in OneDrive.

There was no risk to participants in the primary study as their data were not misused, but rather analysed for a similar purpose to that of the primary study for which they provided their consent. The project did not cause me any harm. Given that I did not listen to the interview recordings with the patients and families, I did not experience emotional distress or need debriefing. However, plans were put in place if I had experienced distress from reading the transcripts, including debriefing with my adviser who conducted the interviews. While the study might not provide direct benefits to the primary study participants, its findings might benefit the patients and family carers who will receive the intervention.

4.3 Methods: Follow-up meetings with service providers and PPI group consultation

This section describes how the findings of the secondary qualitative data analysis were discussed in light of the findings of the workshops in follow-up meetings with key service providers. The aims were to refine the proposed intervention and underlying Theory of Change, co-design a feasibility study protocol, and discuss the design of the definitive trial. This section also outlines a PPI group consultation where service users provided feedback on the intervention and feasibility study protocol.

4.3.1 Follow-up meetings with service providers

Following the secondary data analysis, three one-hour follow-up online meetings were conducted with two key service providers who participated in the Theory of Change workshops: the hospital heart failure team leader and the lead heart failure nurse specialist. Ethics approval was obtained from the Research Ethics Committee in the Faculty of Health and Medicine at Lancaster University on 20th July 2021 (reference number: FHMREC20170). The meetings were conducted in July, September, and November 2021, during which the UK was still under the COVID-19 pandemic. The aims were to discuss the secondary data analysis findings to refine the preliminary theory and intervention which were developed in the Theory of Change workshops, and to explore if and how the heart failure team's clinical practice had been changed after the pandemic to judge if it was still feasible to evaluate the intervention and what changes were necessary (**Table-15**).

The sampling, inclusion criteria, recruitment procedure, and ethical considerations were similar to those for the group workshops (see **section-4.1.1** and **section-4.1.4**). However, this time participants had an option to fill out an electronic consent form via an online secure method (Qualtrics) or provide verbal consent before the start of the meetings. No one, except the two key service providers, attended the meetings because of COVID-related staff shortage, work pressure, and illness. Because of COVID-imposed social restrictions, the meetings were conducted online via Teams when participants were in their workplace. I facilitated the meetings with one of my supervisors. The meetings were video-recorded; auto-captions were generated by Teams and checked by myself afterwards. The transcripts served to remember what was said. The refined Theory of Change map was emailed to the participants following the last meeting.

The follow-up meetings started by reminding the participants of the developed intervention, including how it was co-developed in the workshops, its aims, and required intervention activities. Then, participants were informed about the change of the project's plan due to COVID-19; from testing the intervention feasibility in practice to analysing secondary interview data which provided an opportunity to include the voice of patients receiving palliative care in the community and enhance the developed intervention. Next, participants were provided with an overview of the analysed interviews to see their relevance to the intervention; emphasising that they were conducted with patients with advanced heart failure, their family carers, and professional caregivers in four nearby UK hospices including a hospice that operates within their work area. Subsequently, the main themes generated from the secondary data analysis were presented with a brief definition of each.

The most relevant findings of the secondary data analysis that could help in refining the intervention were discussed with the team. One table was created for each theme where the workshops' findings were discussed against corresponding findings from the secondary data analysis. Following the first two meetings, a protocol for a planned feasibility study was developed and this was then discussed with the same key service providers in the third meeting. Discussions included the feasibility trial design, study settings and duration, eligibility criteria of study participants, methods of recruiting patients and family carers, required intervention activities and provided training, data collection (types of data, who collects data, and collection timepoints), and study outcomes and outcome measures.

Table-15: Focus of the follow-up meetings with key service providers

Follow-up meeting-1	Follow-up meeting-2	Follow-up meeting-3
Discussing the impact of COVID-19 on heart failure team's clinical practice		
Discussing the findings from the secondary data analysis against the findings of the Theory of Change workshops		
		Discussing the feasibility study protocol
Refining the intervention and underlying Theory of Change		

4.3.2 Consultation with service users

After the follow-up meetings with the key service providers, a one-hour online consultation was conducted with two PPI heart failure group members from the James Lind Alliance[110]. They were first approached by my supervisor who worked with them on previous projects. Both are patients with heart failure but one was also a family carer. The consultation was conducted on 11th January 2022. Ethics approval was not required as this was a PPI group consultation that aimed to get feedback from service users on the intervention and feasibility study protocol. Because of the high risk of COVID-19 transmission, the consultation was conducted online via Teams for safety concerns. I facilitated the consultation with my supervisor. Three weeks before, a one-page study summary was emailed to participants outlining the aims of the study, suggested intervention activities, and study design. Participants were also emailed the patient and family carer outcome measures planned to be used in the feasibility study. They were encouraged to complete the outcome measures beforehand to evaluate their acceptability on the consultation day.

The consultation started with a brief overview of the study and proposed intervention. Participants were asked about their perceptions of palliative care, and if they had questions about it and what it can offer, before proceeding. Next, they were asked to provide feedback on the proposed study and whether it is relevant. Feedback was sought for the proposed intervention activities, study design, target study sample, and outcome measures including whether they found them appropriate and easy to complete, how long it took them to complete each, how they preferred to complete them (in person, on phone, mail), and in what order they would like to complete them. Participants were also asked about the use of the terms “palliative care” and “advanced heart failure” when discussing the study with patients and in study participant documentation. Following the consultation, the intervention and feasibility study protocol were revised to address the PPI group feedback.

4.4 Chapter summary

In this chapter, the methods of developing and refining the intervention and underpinning theory were outlined. The preliminary intervention and underpinning Theory of Change were developed through group workshops with service providers. A secondary analysis of qualitative interview data about the experiences of patients, family carers, and professional caregivers with integrated palliative care was then conducted to include the voice of service users in the intervention and theory development. The preliminary intervention and underpinning Theory of Change were then refined through follow-up meetings with key service providers during which the workshops’ findings were discussed against the secondary data analysis findings and a protocol for a future feasibility study was co-developed. A PPI group consultation was finally conducted, where service users provided their feedback on the intervention and feasibility study protocol. In the next chapter, the findings of the Theory of Change workshops, during which the preliminary intervention was developed, are outlined.

5 Results: Theory of Change workshops with service providers

In the previous chapter, the methods of developing and refining the intervention and underpinning theory were outlined. In this chapter, the findings of the group workshops during which the preliminary intervention and underlying Theory of Change were developed, are described. The chapter starts by outlining the flow chart of recruitment and demographic characteristics of workshops' participants. Next, the preliminary Theory of Change that was agreed upon in the workshops is described, including the impact of the intervention that participants desire to achieve; long-term outcomes of the intervention; preconditions, intervention activities, and contextual factors (assumptions) required to achieve the outcomes; and rationales for why the preconditions and intervention activities are required to achieve the desired outcomes. A graphical representation of these components in a preliminary Theory of Change map is then provided, showing how they interact in a hypothetical pathway of change. The chapter ends with a detailed description of the preliminary intervention proposed following the Theory of Change workshops.

5.1 Participants in the Theory of Change workshops

The group workshops with service providers were conducted on 1st October 2019, 26th November 2019, and 28th January 2020. The flow chart of the recruitment process is outlined in **Figure-10**. All heart failure team members who attended the preceding multidisciplinary team meetings took part in the workshops that followed, which demonstrated good recruitment. The workshops were attended by ten different service providers. Among these, three attended all the workshops, each with a different profession. The demographic characteristics of the participants are displayed in **Table-16**. The participants had an average duration of professional experience of 20 years. Most participants were females and heart failure nurse specialists from the acute hospital team.

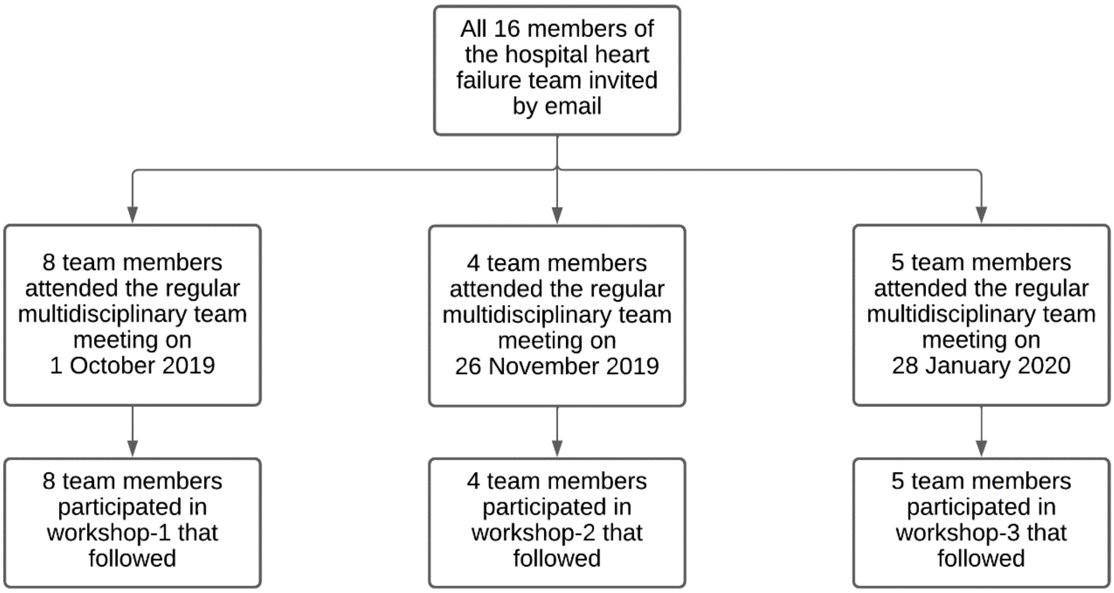


Figure-10: Flow chart of recruitment process for the Theory of Change workshops

Table-16: Demographic characteristics of the Theory of Change workshops' participants

	Workshop-1	**Workshop-2**	**Workshop-3**	**Total***
Facilitators, n	3	3	2	3
Participants, n	8	4	5	10
Female gender, n	7	4	4	8
Profession, n				
Consultant cardiologist	1	1	2	2
Heart failure nurse specialist (acute hospital team)	4	2	2	5
Heart failure nurse specialist (community team)	1	0	0	1
Heart failure occupational therapy specialist	1	1	1	1
Clinical fellow	1	0	0	1
Years of professional experience, mean	16.4	18.8	24.4	20

* As some people attended more than one workshop, the numbers do not add up.

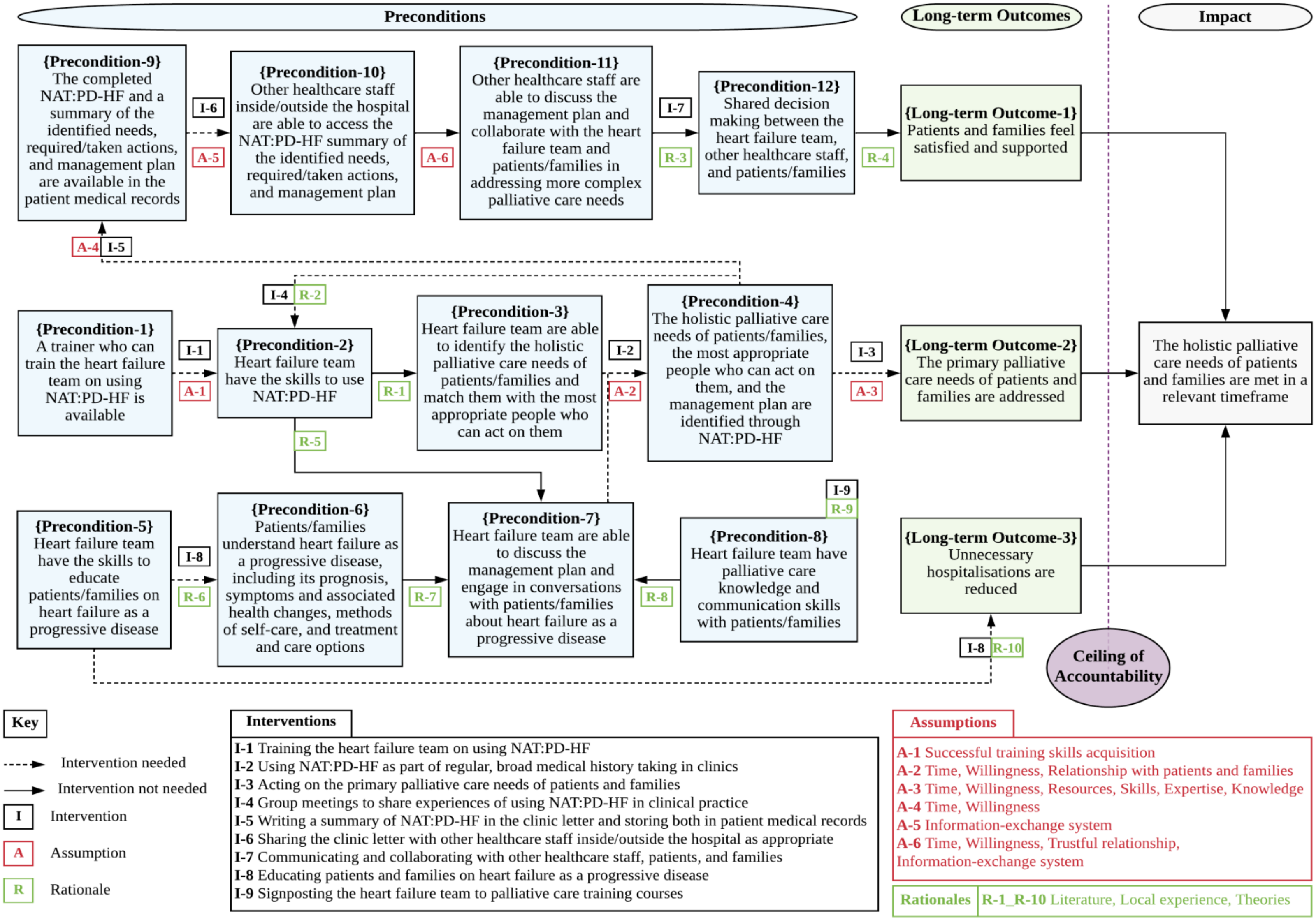
5.2 Preliminary Theory of Change

The outputs of each Theory of Change workshop are summarised in **Table-17**. The preliminary Theory of Change map constructed throughout the workshops is depicted in **Figure-11** and described narratively in the following subsections. The map shows the intervention's impact, long-term outcomes, preconditions, activities, assumptions, and hypothetical pathway of change (see **section-5.2.4** for the rationales). While these Theory of Change components came out through all workshops' discussions, they were identified and sorted following the workshops to help in building the map. The intervention was proposed to be delivered to patients with heart failure attending the hospital (and possibly community) outpatient clinics of doctors, heart failure nurse specialists, and heart failure occupational therapists (see **section-5.3**).

Table-17: Outputs of the Theory of Change workshops

Workshop	Main outputs*
Workshop-1	Four potential impacts. Potential long-term outcomes. Potential preconditions (identification, communication, and education). Suggested intervention activities, rationales, and assumptions. First draft of the Theory of Change map (**Appendix-5**).
Workshop-2	Agreed impact. More long-term outcomes. More preconditions (identification). More intervention activities, rationales, and assumptions. Second draft of the Theory of Change map (**Appendix-6**).
Workshop-3	Agreed long-term outcomes. More preconditions (communication and education). Agreed intervention activities, rationales, and assumptions. Third draft of the Theory of Change map (**Appendix-7**). Preliminary Theory of Change map (**Figure-11**). Quality check (plausibility and feasibility). Validation by service providers.

* These represent the outputs of the workshop itself and the analysis work afterwards.



Interventions

I-1 Training the heart failure team on using NAT:PD-HF
I-2 Using NAT:PD-HF as part of regular, broad medical history taking in clinics
I-3 Acting on the primary palliative care needs of patients and families
I-4 Group meetings to share experiences of using NAT:PD-HF in clinical practice
I-5 Writing a summary of NAT:PD-HF in the clinic letter and storing both in patient medical records
I-6 Sharing the clinic letter with other healthcare staff inside/outside the hospital as appropriate
I-7 Communicating and collaborating with other healthcare staff, patients, and families
I-8 Educating patients and families on heart failure as a progressive disease
I-9 Signposting the heart failure team to palliative care training courses

Assumptions

A-1 Successful training skills acquisition
A-2 Time, Willingness, Relationship with patients and families
A-3 Time, Willingness, Resources, Skills, Expertise, Knowledge
A-4 Time, Willingness
A-5 Information-exchange system
A-6 Time, Willingness, Trustful relationship, Information-exchange system

Rationales **R-1_R-10** Literature, Local experience, Theories

Figure-11: Preliminary Theory of Change map

5.2.1 Impact

In the first workshop, participants were asked about the real-world fundamental change and overall goal (impact) that they desire to achieve through the intervention. Overall, 41 answers were written independently on the provided cards. These were discussed by participants and merged into 21 answers that were written on a flip chart where everyone could see them. Following the workshop, the individual and merged answers were re-examined, reworded, refined, and reduced to 19 answers (see **Table-18** for examples). After examining those, it was noted that although participants were asked about the impact of the intervention, many answers were thought to fit more as long-term outcomes or preconditions for the impact to be achieved. Ultimately, four potential impacts were identified:

- *Patient quality of life is improved.*
- *Patient and family palliative care needs are met (physical, psychological, social, spiritual...).*
- *Multidisciplinary holistic palliative care is integrated early into curative heart failure therapy.*
- *Unnecessary hospital admissions and interventions are avoided or reduced.*

Table-18: Examples of grouping and classifying the ideas generated from participants in the nominal group process

During the workshop		**After the workshop**	
Individual answers on provided cards	**Merged answers on flip chart**	**Refined groups**	**Classification**
• Reduce breathlessness and pain. • Reduce anxiety. • Provide good quality of sleep. • Provide opportunity for spiritual support. • Look at needs of family/carers as well as patients.	• Early symptom control even when waiting for active management. • Look at needs of family and carers.	• Patient and family/carer palliative care needs are met (physical, psychological, social, spiritual...).	Potential impact or long-term outcome
• Opportunity to speak about one's needs. • Patients share fears/emotions as standard (broader history taking; time lets clinical history taking only). • Improved communication with patients and families. • Good communication to reinforce messages to patient. • Improve communication with palliative patients and families; better understanding of prognosis. • Improve communication about palliative care with the patients.	• Improve communication between healthcare professionals and palliative care patients/families... • Patients share (as standard) feelings, emotions, fear, anxieties…	• Communication with patients and families is improved.	Potential precondition

In the second workshop, the four potential impacts were displayed to participants to refine them if needed and agree on one impact for the intervention. Participants thought that the suggested impacts were encompassing to some extent but agreed that the second one (*Patient and family palliative care needs are met: physical, psychological, social, spiritual…*) incorporates the others as it addresses the four main palliative care domains. However, they suggested adding the phrase "in a relevant timeframe" to emphasise the importance of time in meeting the palliative care needs. This was preferred over "early" or "in a timely manner" because these imply that meeting the needs should be done urgently. Rather, participants preferred to be realistic, rather than rushed, and meet the needs as soon as they can; not too quick, nor too early, nor too late (see **section-5.3.4** for more discussion on the timing of intervention delivery). Ultimately, the impact agreed upon was stated as:

- **Impact:** The holistic palliative care needs of patients and families are met in a relevant timeframe.

5.2.2 Long-term outcomes

Three long-term outcomes of the palliative care intervention were identified:

- **Long-term outcome-1:** Patients and families feel satisfied and supported.
- **Long-term outcome-2:** The primary palliative care needs of patients and families are addressed.
- **Long-term outcome-3:** Unnecessary hospitalisations are reduced.

Ceiling of accountability was situated between these long-term outcomes and the impact. That is; the intervention will contribute to meeting the palliative care needs of patients and families in a relevant timeframe (impact), but it cannot achieve it solely on its own because of the presence of other contributing factors out of control (for example, factors related to the healthcare system). However, the intervention will be responsible to achieve the three long-term outcomes on its own.

Long-term outcome-1 was derived from three answers written on the participants' cards when asked about the impact in the first workshop: *Patient feels in control and involved in all discussions*, *For heart failure patients to feel that they are supported*, and *For patients' families to feel that they are supported*. These were depicted in the first draft of the Theory of Change map as preconditions and then moved forward in the second map draft as one long-term outcome: *Patients and families feel involved, supported, and in control as they participate in the shared decision-making process*. In the third workshop, participants broke this down as they believed that shared decision making is a precondition to achieving patient and family satisfaction which was agreed as the first long-term outcome.

Long-term outcome-2 was derived from three answers written on the flip chart when participants were asked about the impact in the first workshop: *Identifying palliative care needs*, *Integrating multidisciplinary holistic palliative care into active management*, and *Meeting palliative care needs*. These were depicted in the first draft of the Theory of Change map as a sequential process: *Identifying needs* [precondition] → *Integrating palliative care* [precondition] → *Meeting needs* [long-term outcome]. As participants agreed that *Meeting palliative care needs* is an impact rather than a long-term outcome, an alternative long-term outcome was suggested in the second map draft: *Staff are able to act on the identified needs*. As participants thought that they may not have the resources to act on all identified palliative care needs, they preferred to use the phrase "primary palliative care needs".

Long-term outcome-3 was derived from three answers written on the participants' cards when asked about the impact in the first workshop: *Keep them out of hospital*, *Avoid unnecessary admissions and interventions*, and *Reduce or avoid unnecessary hospital admissions*. These were depicted in the first draft of the Theory of Change map as one precondition which was then moved forward in the second and third map drafts as a long-term outcome: *Unnecessary hospital admissions and interventions are avoided or reduced*. As "hospital admissions" and "hospital interventions" are two different, though related, terms, the latter was omitted for simplicity as participants thought that "hospital interventions" could be difficult to define.

5.2.3 Preconditions

Twelve interconnected preconditions were identified as necessary to achieve the long-term outcomes. These preconditions apply to three different levels: healthcare professionals, patients and families, and organisations. The preconditions that came out through the discussion in the first workshop were classified into three broad categories, though overlapping, to trigger discussion in the next workshops:

- *Identification* of patients with heart failure who have palliative care needs.
- *Communication* with patients and families and between healthcare professionals.
- *Education* of patients and families about progressive heart failure and healthcare professionals about palliative care.

5.2.3.1 Preconditions of Identification

In the second workshop, the potential preconditions of *Identification* were displayed to participants to discuss, determine if they are necessary to achieve the impact, and suggest more. These included:

- *Staff are able to identify patients who require palliative care and recognise their -and their family- needs early (physical, psychosocial, spiritual...).*
- *Staff are able to use a palliative care needs-assessment tool as a part of regular, broad medical history taking.*
- *A trainer who can train staff about the palliative care needs-assessment tool is available.*

The first precondition emerged from the first workshop's discussion, while the last two were suggested to participants based on the systematic review (see **Chapter-2**) and the value of palliative care needs-assessment tools for identifying the palliative care needs of patients and families[126,128,129].

In the second workshop, the systematic review findings were presented, demonstrating the two most appropriate palliative care needs-assessment and measurement tools for patients with heart failure: NAT:PD-HF and IPOS. Participants were given a hard copy of both tools and a comparison table was presented to trigger discussion on the most appropriate tool they wanted to adopt in their practice. Participants debated the advantages and disadvantages of each tool. They thought that the tools could help them in identifying the level of patient needs (needs identification), rather than screening patients who require palliative care (patient identification). The *action taken* section of NAT:PD-HF was considered helpful in prompting staff to discuss the management plan with patients and families and act on the identified needs, although this commitment to action was also seen as a burden on staff. Conversely, as IPOS does not have such a section, participants thought that it could be just filled and filed. They believed that many NAT:PD-HF items are already covered by staff during their regular patient needs assessment in clinics and can be answered by instinct. Some IPOS items were considered less relevant for patients with heart failure such as vomiting, constipation, and sore or dry mouth. Participants liked the multi-coloured background of NAT:PD-HF and believed that it will enhance their clinical practice.

An advantage of IPOS over NAT:PD-HF as perceived by participants is having a patient version that enables patients to address the issues more relevant to them. Other perceived concerns on NAT:PD-HF were the difficulty to ask some questions and the availability of resources, skills, and time to identify and act on the identified needs. However, participants believed that with adequate training, these issues are surmountable. One aspect of tool training asked for was how to complete the *level of concern* and *action taken* sections for each identified need to achieve consistency across the staff using the tool. This involves differentiating between some/potential and significant concern, and knowing when to manage the needs directly, when to manage by other care team member, and when to refer. Eventually, it was agreed that participants need training on the needs-assessment tool in addition to other palliative care training to enhance the use of the tool for identification.

The decision on the most appropriate tool was not reached in the second workshop. One suggestion was to combine them, by using the IPOS patient version first to get patient perspectives and main concerns, followed by further exploring their needs by a staff member through NAT:PD-HF. In this case, IPOS would inform the NAT:PD-HF-based discussion and consultation in the clinic. After the second workshop, participants discussed the two tools with other heart failure members who did not attend the workshop to get more opinions. In the third workshop, the suggestion to combine the tools was disregarded as participants thought that this would increase the burden on both staff and patients. Rather, participants preferred to use NAT:PD-HF alone as it is streamlined and would fit their clinics more. After the workshop, a copy of NAT:PD-HF was provided to the heart failure team leader to share with other colleagues upon her request. Following these discussions, four preconditions of *Identification* were identified:

- **Precondition-1:** A trainer who can train the heart failure team on using NAT:PD-HF is available.
- **Precondition-2:** Heart failure team have the skills to use NAT:PD-HF.
- **Precondition-3:** Heart failure team are able to identify the holistic palliative care needs of patients and families and match them with the most appropriate people who can act on them.
- **Precondition-4:** The holistic palliative care needs of patients and families, the most appropriate people who can act on them, and the management plan are identified through NAT:PD-HF.

5.2.3.2 Preconditions of Communication

In the second workshop, participants discussed how to integrate the palliative care needs-assessment tool into their clinical practice and share it with other healthcare professionals. Integrating the tool in a paper form, with paper notes or clinic letters, and an electronic form, by scanning and uploading the tool to the system, were both considered feasible. In the third workshop, participants suggested writing a summary of NAT:PD-HF in the clinic letter, so that it could serve both as a permanent record of the tool and communication aid. They thought that sharing this letter would make other healthcare professionals inside and outside the hospital aware of the palliative care needs of patients and families. This, in turn, would trigger them to communicate and collaborate to act on more complex needs. Following this conversation, four preconditions of *Communication* that emerged from the first workshop were displayed to participants for discussion:

- *Staff are able to communicate with patients and families, engage in discussions about palliative care and heart failure, and introduce some elements of advance care planning.*
- *Advance care planning is systematically recorded on patient medical records, made accessible to all staff, and updated regularly.*
- *Staff within and across multidisciplinary teams communicate and collaborate in patient care.*
- *Patients and families feel involved, supported, and in control as they participate in the shared decision-making process.*

Participants thought that advance care planning (the first two preconditions) is a large multicomponent task that could not be completely addressed with the available resources. However, they acknowledged that some of its elements will naturally be discussed and addressed when NAT:PD-HF is used. Participants believed that they, as well as patients, might feel uncomfortable discussing palliative care openly, especially at early stages, as patients may think they are dying when the word “palliative” is mentioned. Instead, participants preferred to use the phrase “heart failure as a progressive disease” with patients (see **section-7.2.3** for more discussion on the use of potentially distressing terms). Still, these conversations were considered important and some participants argued for conducting them as a continuous process that starts early during the disease to enable building a good relationship with patients. Other participants thought that the decision of when to start the conversations should be patient-centred and individualised.

The third precondition (*Collaboration with other staff*) was seen as reasonable while the fourth was broken down into a precondition (*Shared decision making*) and a long-term outcome (*Patients and families feel satisfied and supported*) (see **section-5.2.2**). Ultimately, six preconditions of *Communication* were identified:

- **Precondition-7:** Heart failure team are able to discuss the management plan and engage in conversations with patients and families about heart failure as a progressive disease.
- **Precondition-8:** Heart failure team have palliative care knowledge and communication skills with patients and families.
- **Precondition-9:** The completed NAT:PD-HF and a summary of the identified needs, required and taken actions, and management plan are available in the patient medical records.
- **Precondition-10:** Other healthcare staff inside and outside the hospital are able to access the NAT:PD-HF summary of the identified needs, required and taken actions, and management plan.
- **Precondition-11:** Other healthcare staff are able to discuss the management plan and collaborate with the heart failure team, patients, and families in addressing more complex palliative care needs.
- **Precondition-12:** Shared decision making between the heart failure team, other healthcare staff, patients, and families.

5.2.3.3 Preconditions of Education

Some preconditions of *Education* overlapped with those of *Identification* (such as identifying the information needs of patients and family carers using NAT:PD-HF) or *Communication* (such as having communication skills to engage in conversations with patients and family carers about progressive heart failure), and these were discussed above. While such preconditions are related to educating healthcare professionals, another precondition that emerged from the first workshop was related to educating patients and families. This was presented to participants in the third workshop to discuss:

- *Patients and families understand palliative care and heart failure, including its prognosis, the health changes it causes, treatment and care options, and methods to self-care and manage symptoms.*

Participants thought that it would be difficult to start talking explicitly about palliative care with patients as this might cause unnecessary worry. Consequently, they suggested changing the content of education from “palliative care and heart failure” to “heart failure as a progressive disease”. Ultimately, two preconditions of *Education* were identified:

- **Precondition-5:** Heart failure team have the skills to educate patients and families on heart failure as a progressive disease.
- **Precondition-6:** Patients and families understand heart failure as a progressive disease, including its prognosis, symptoms and associated health changes, methods of self-care, and treatment and care options.

5.2.4 Interventions, rationales, and assumptions

The intervention activities, rationales, and assumptions underlying the preliminary Theory of Change developed after the three workshops are presented for each causal link in the hypothetical pathway of change (**Table-19**). These elements came out through the workshops’ discussions and some were retrieved from the scientific literature. Overall, nine intervention activities that are required to achieve certain preconditions and long-term outcomes were identified. Ten rationales for the intervention activities and causal links in the Theory of Change map were identified. Where no rationale was found, assumptions exist instead. Assumptions were identified for six causal links in the Theory of Change map. The lack of these contextual conditions may create barriers to achieving the long-term outcomes.

Table-19: Intervention activities, rationales, and assumptions underlying the preliminary Theory of Change

<table>
<tr><th colspan="2">Precondition-2: Heart failure team have the skills to use NAT:PD-HF</th></tr>
<tr><td>Required Intervention</td><td>[I-1]* Training the heart failure team on how to use NAT:PD-HF to identify patient and family palliative care needs, assess their level of concern, and assign actions to address them.</td></tr>
<tr><td>Assumption</td><td>[A-1] The heart failure team should acquire the necessary skills from the NAT:PD-HF training session to use NAT:PD-HF effectively.</td></tr>
<tr><td>Required Intervention</td><td>[I-4] Facilitated group meetings between heart failure team members to share experiences of using NAT:PD-HF in clinical practice.</td></tr>
<tr><td>Rationale for the intervention</td><td>[R-2] Participants suggested that group meetings following the use of NAT:PD-HF in clinics will help them to reflect on using the tool, learn more from each other, and resolve any issues. A systematic review showed that practice-based small group learning, which includes discussing patient cases, improves the knowledge and skills of learners and contributes to their professional development[347]. This approach is well-accepted by learners and can be adapted based on their learning needs[347]. Practice-based learning is supported by educational adult learning theories that indicate that individuals learn better and are more willing to change when they begin with problems that they have experienced in practice (problem-based learning)[348].</td></tr>
<tr><th colspan="2">Precondition-3: Heart failure team are able to identify the holistic palliative care needs of patients and families and match them with the most appropriate people who can act on them</th></tr>
<tr><td>Required Intervention</td><td>no intervention required</td></tr>
<tr><td>Rationale for:
Precondition-2
→
Precondition-3</td><td>[R-1] Research shows that needs-assessment tools, like NAT:PD-HF (Precondition-2), can facilitate the timely recognition and holistic assessment of the palliative care needs of patients with heart failure[126,128,129,132,164]. The systematic review findings demonstrated some evidence that patients with heart failure who have palliative care needs can be identified by NAT:PD-HF[125]. When NAT:PD-HF was displayed to workshop participants, they were confident that it would prompt them to match the identified needs with the appropriate services to address them.</td></tr>
<tr><th colspan="2">Precondition-4: The holistic palliative care needs of patients and families, the most appropriate people who can act on them, and the management plan are identified through NAT:PD-HF</th></tr>
<tr><td>Required Intervention</td><td>[I-2] Using NAT:PD-HF as part of regular, broad medical history taking during patient consultation in the clinics of the heart failure team.</td></tr>
</table>

<table>
<tr><td>Assumption</td><td>[A-2] The heart failure team should have time, willingness, and good relationships with patients and families to use the tool during the clinic consultation.</td></tr>
<tr><td colspan="2">Precondition-6: Patients and families understand heart failure as a progressive disease, including its prognosis, symptoms and associated health changes, methods of self-care, and treatment and care options</td></tr>
<tr><td>Required Intervention</td><td>[I-8] Educating patients and families on heart failure as a progressive disease, including its prognosis, symptoms, self-management, and care options using existing educational materials and other resources.</td></tr>
<tr><td>Rationale for the intervention</td><td>[R-6] Educational interventions for patients with heart failure have been shown to improve their knowledge and understanding of the disease, medication, diet, and rationale for symptom monitoring[349,350]. Topics included in such education programmes were diagnosis and prognosis, pathophysiologic effect of heart failure, aims of treatment, management and symptom monitoring, medications and side effects, and prompts to call the GP. Service providers were confident about their ability to educate patients and families as they do this routinely in their practice.</td></tr>
<tr><td colspan="2">Precondition-7: Heart failure team are able to discuss the management plan and engage in conversations with patients and families about heart failure as a progressive disease</td></tr>
<tr><td>Required Intervention</td><td>no intervention required</td></tr>
<tr><td>Rationale for:
Precondition-6
→
Precondition-7</td><td>[R-7] The lack of knowledge on heart failure among patients and families (Precondition-6) is a well-documented barrier to palliative care communication[351]. A prospective study showed that patients with advanced illness who were educated about their illness, symptoms, and treatment had significantly better communication with healthcare professionals about their concerns[350]. A randomised controlled trial demonstrated a significantly higher quality of end-of-life communication between healthcare professionals and patients with heart failure who were educated about their disease[352].</td></tr>
<tr><td>Required Intervention</td><td>no intervention required</td></tr>
<tr><td>Rationale for:
Precondition-2
→
Precondition-7</td><td>[R-5] Palliative care needs-assessment tools (Precondition-2) have been shown to facilitate patient communication with healthcare professionals when completed by patients with heart failure before their clinic consultation[132]. NAT:PD-HF, although typically completed during the clinic consultation, has also been suggested to enhance the conversation between patients and the healthcare team[164]. Although the Dutch translation of NAT:PD-HF were not found helpful to communicate about palliative care, this was attributed to the lack of palliative care knowledge and communication skills among the staff rather than an issue with the tool itself[165].</td></tr>
</table>

<table>
<tr><td>Required Intervention</td><td>no intervention required</td></tr>
<tr><td>Rationale for:
Precondition-8
→
Precondition-7</td><td>[R-8] The lack of palliative care knowledge and communication skills among healthcare professionals (Precondition-8) is a well-documented barrier to palliative care communication with patients and families[165,353]. Systematic reviews showed that enhancing the communication skills of healthcare professionals was positively associated with the quality of communication with patients and can improve and increase palliative care discussions[354-356].</td></tr>
<tr><td colspan="2">Precondition-8: Heart failure team have palliative care knowledge and communication skills with patients and families</td></tr>
<tr><td>Required Intervention</td><td>[I-9] Signposting heart failure team members to palliative care training courses such as communication skills and advance care planning.</td></tr>
<tr><td>Rationale for the intervention</td><td>[R-9] Systematic reviews provided evidence that training healthcare professionals on end-of-life communication, advance care planning, and palliative care in general improves their communication skills with patients about end-of-life issues[355,357-359]. Workshop participants were aware of some palliative care training programmes and showed a willingness to attend them.</td></tr>
<tr><td colspan="2">Precondition-9: The completed NAT:PD-HF and a summary of the identified needs, required and taken actions, and management plan are available in the patient medical records</td></tr>
<tr><td>Required Intervention</td><td>[I-5] Writing a summary of NAT:PD-HF in the clinic letter (including the identified needs, required and taken actions, and management plan), and storing NAT:PD-HF and the letter in patient medical records.</td></tr>
<tr><td>Assumption</td><td>[A-4] The heart failure team should have time and willingness to write a summary and store it, together with NAT:PD-HF, in patient records.</td></tr>
<tr><td colspan="2">Precondition-10: Other healthcare staff inside and outside the hospital are able to access the NAT:PD-HF summary of the identified needs, required and taken actions, and management plan</td></tr>
<tr><td>Required Intervention</td><td>[I-6] Sharing the NAT:PD-HF summary in the clinic letter with other healthcare professionals inside and outside the hospital as required.</td></tr>
<tr><td>Assumption</td><td>[A-5] An electronic or paper-based information-exchange system should exist to share the NAT:PD-HF summary with other healthcare staff.</td></tr>
<tr><td colspan="2">Precondition-11: Other healthcare staff are able to discuss the management plan and collaborate with the heart failure team, patients, and families in addressing more complex palliative care needs</td></tr>
<tr><td>Required Intervention</td><td>no intervention required</td></tr>
</table>

Assumption	**[A-6]** An information-exchange system should exist to facilitate communication between the heart failure team and other healthcare staff. Time, willingness, and trustful relationships are needed to collaborate in patient care.
Precondition-12: Shared decision making between the heart failure team, other healthcare staff, patients, and families	
Required Intervention	**[I-7]** Communication and collaboration with other healthcare staff inside and outside the hospital, patients, and families.
Rationale for the intervention	**[R-3]** The lack of multidisciplinary communication and trustful relationship was perceived by patients and families as a major barrier to shared decision making[360,361]. Communication interventions aimed at healthcare professionals were shown to improve shared decision making with patients[362,363]. The Conceptual Framework for Individual and Family End-of-Life Decision Making indicates that shared decision making is facilitated through an interdisciplinary team approach and by enhancing information sharing between patients, families, and healthcare providers[364].
Long-term outcome-1: Patients and families feel satisfied and supported	
Required Intervention	no intervention required
Rationale for: Precondition-12 → Long-term outcome-1	**[R-4]** Two systematic reviews showed that patient and family involvement in decision making (**Precondition-12**) is associated with their satisfaction with palliative care[365,366]. For patients with heart failure, those who had shared decision making had high *satisfaction with decision* scores and felt supported[367].
Long-term outcome-2: The primary palliative care needs of patients and families are addressed	
Required Intervention	**[I-3]** Acting on the primary palliative care needs of patients and families identified by the heart failure team.
Assumption	**[A-3]** To address the palliative care needs of patients and families, the heart failure team members should have time, willingness, resources, and necessary skills, expertise, and knowledge.
Long-term outcome-3: Unnecessary hospitalisations are reduced	
Required Intervention	**[I-8]** Educating patients and families on heart failure as a progressive disease, including its prognosis, symptoms, self-management, and care options using existing educational materials and other resources.
Rationale for the intervention	**[R-10]** Systematic reviews showed that educational interventions for patients with heart failure and their families significantly reduce hospitalisation and rehospitalisation[368-370].

* The numbers are concordant with those in the preliminary Theory of Change map in **Figure-11.**

5.3 Describing the preliminary intervention

A systematic description of the preliminary intervention proposed following the Theory of Change workshops is presented according to the TIDieR checklist below. As with the underlying Theory of Change, this was not the final version of the intervention as it was modified and refined after the secondary data analysis, follow-up meetings with service providers, and consultation with service users.

5.3.1 Intervention activities and materials

This theory-based, complex palliative care intervention for patients with heart failure and their family carers has nine intervention activities. These were described in detail alongside their rationales in **Table-19** above. Several materials are needed to deliver the intervention. These include:

- NAT:PD-HF to communicate with patients and families, identify their palliative care needs, and match the needs with those who can address them. NAT:PD-HF will be completed for each patient, and family carer if present, during the clinic consultation at baseline and monthly or with change in patient condition (functional status) as per the NAT:PD-HF user guide (see **Appendix-2**).
- Clinic letters to record a summary of NAT:PD-HF for each patient.
- Information-exchange systems to share the NAT:PD-HF summary with as many healthcare staff as needed, refer patients and families to other services, and communicate with other staff to address more complex needs.
- Training material on using NAT:PD-HF (**Table-20**). This will be prepared using several resources including the systematic review, NAT:PD-HF user guide, and a training module about patient-centred care and a similar tool (IPOS) which was delivered to heart failure nurses in a previous intervention[371]. The hospital specialist palliative care team will be asked to participate in the training to provide input on how to address the palliative care needs. A one-hour, in-person interactive group training session was planned.
- Palliative care training courses running in the hospital and available online.
- Educational materials to educate patients and families on heart failure as a progressive disease during regular patient consultation time.

- Other materials as required to act on the primary palliative care needs of patients and families, such as medications and information sheets. The heart failure team will be advised to address the needs based on their clinical expertise. Clinical guidelines will not be administered, but some of this can be explored at NAT:PD-HF training.

Table-20: Outline of NAT:PD-HF training material

Theme	Topics
Palliative care needs assessment	What palliative care needs assessment comprises.
	Holistic, patient-centred needs assessment.
	Palliative care needs assessment in heart failure.
Palliative care needs-assessment tools	Advantages over prognostic tools.
	Implementation barriers and facilitators.
NAT:PD-HF	Superiority over other palliative care needs-assessment tools for patients with heart failure.
	Purpose of NAT:PD-HF.
	Main features (clinical settings, items, length, completion time, palliative care need domains).
	How to complete NAT:PD-HF.
	What after completing NAT:PD-HF? (addressing needs directly, by another team member, through referral)*
	Available local healthcare services for referrals.
	Case studies.

* Input from the hospital specialist palliative care team.

5.3.2 Intervention providers

The intervention will be provided by the hospital heart failure team, including doctors, heart failure nurse specialists, and heart failure occupational therapists, some of whom were involved in developing the intervention. Doctors involve both cardiology consultants and junior doctors, while heart failure nurse specialists involve the acute hospital team and possibly the community team. Apart from one community heart failure nurse specialist who attended the first workshop, the community heart failure team did not participate in the workshops and therefore it was not confirmed if they would provide the intervention at this stage (see **section-7.1.3.3** for more discussion about this issue). Three intervention activities will be provided by the main researcher: training the heart failure team on using NAT:PD-HF (in cooperation with the hospital specialist palliative care team), signposting the heart failure team to available palliative care training courses, and facilitating the monthly, one-hour group meetings to discuss the use of NAT:PD-HF in practice.

5.3.3 Intervention settings

There was a debate on the settings where the intervention should be delivered. Suggested places included hospital inpatient wards, hospital heart failure and cardiology outpatient clinics, community heart failure clinics, and patient homes. The latter two were advocated because patients seen in their homes or nearby community clinics were considered frail with significant palliative care needs which prevent them from coming to hospital clinics. Therefore, administering the intervention to those patients was thought to increase the chance of demonstrating a significant benefit of the intervention. However, given that the community heart failure nurse specialists were not present in the last two workshops when these issues were mainly discussed, these options remained open at this stage. Another suggested option was to see patients seven days or more after their hospital inpatient admission, despite concerns that patients may still be in an acute condition and not ready to discuss their palliative care needs. Eventually, workshop participants agreed that the intervention should be delivered in hospital, and possibly community, outpatient clinics. Patients attending these clinics were considered in a relatively stable condition which would facilitate communication, discussions, education, and using NAT:PD-HF.

5.3.4 Intervention duration and timing

The intervention was proposed to be delivered for a few months, although the exact duration was not determined at this stage. There was another debate on when along the heart failure trajectory the intervention should be delivered. Suggestions included at the first patient visit to the clinic (newly diagnosed patients), early stages of the disease, and advanced stages. Proponents of delivering the intervention to new patients or at early stages thought it would be easier to start with patients from the very beginning and alluded to the difficulty and subjectivity in identifying those with advanced heart failure. Conversely, other participants thought it would be difficult to deliver the intervention at early stages as they will not know the patients and families well. They believed that having a long relationship with patients will facilitate the conversations and expressed their comfort in providing the intervention when they see signs of deterioration and non-response to treatments. Eventually, participants agreed that the intervention could be delivered to every heart failure patient visiting their clinics, knowing that there will be few exceptions. Although participants recognised that this could be burdensome, they wanted to explore what kind of patients it is possible to deliver the intervention to.

5.4 Chapter summary

In this chapter, the findings of group workshops with service providers, during which the preliminary intervention and underlying Theory of Change were developed, were outlined. The agreed intervention impact was to meet the holistic palliative care needs of patients and families in a relevant timeframe. Three potential long-term outcomes were suggested: patients and families feel satisfied and supported, the primary palliative care needs of patients and families are addressed, and unnecessary hospitalisations are reduced. To achieve these outcomes, 12 preconditions were proposed focusing on identifying patients with palliative care needs, communicating with patients and families and between healthcare professionals, and educating patients and families about progressive heart failure and healthcare professionals about palliative care. Several assumptions were identified including the availability of time and resources, information-exchange systems, relationships, and expertise. Nine intervention activities were suggested, focusing on using NAT:PD-HF to identify patient and family palliative care needs and sharing a summary of it with other staff to address these needs. Ten rationales that showed why each intervention or precondition may lead to the subsequent precondition were identified from the scientific literature and stakeholders' local experience. All these components were linked and represented in a preliminary Theory of Change map that shows a hypothetical pathway of change. The preliminary intervention was proposed to be delivered by the heart failure team, but there was a debate on where and when along the disease trajectory it should be delivered. In the next chapter, the results of a secondary qualitative data analysis, through which the voice of patients and family carers was included in the intervention development, are outlined.

6 Results: Secondary qualitative data analysis

In the previous chapter, the results of the group workshops with service providers, during which the preliminary intervention and underlying Theory of Change were developed, were outlined. In this chapter, the findings of a secondary analysis of qualitative interview data about the experiences of patients, family carers, and professional caregivers with integrated palliative care are described. The analysis provided an opportunity to include the voice of service users in developing the intervention at the time of the COVID-19 pandemic. The chapter starts by describing the demographic characteristics of the interviewed patients, family carers, and professional caregivers. Next, the themes and subthemes generated from the analysis are outlined, represented graphically in a thematic map, and mapped onto the Normalisation Process Theory constructs. The themes and subthemes are then described narratively and supported with data extracts.

6.1 Participant characteristics

The demographic characteristics of the interviewed patients and family carers are displayed in **Table-21**. The mean age of patients and family carers was 70 and 71 years, respectively. One patient-family carer dyad was interviewed jointly both at baseline and follow-up. Two patients did not have a family carer and two other patients died before their follow-up interview. Bereavement interviews were conducted with the family carers of those who died. The demographic characteristics of the interviewed professional caregivers are displayed in **Table-22**. All interviews were attended by participants from different professional backgrounds. Nurses, including community nurses and matrons, hospice staff nurses, district nurses, and clinical nurse specialists, were a majority in all group interviews.

Table-21: Demographic characteristics of interviewed patients and family carers

	Age (years)	Gender	Relationship	Follow-up interview	Joint interview
Patient-1	75	Male	Spouse	Died	No
Carer-1	73	Female		Yes (bereavement)	
Patient-2	70	Male	Spouse	Died	No
Carer-2	69	Female		Yes (bereavement)	
Patient-3	53	Female	Spouse	Yes	No
Carer-3	55	Male		Yes	
Patient-4	71	Female	no family carer	Yes	--
Patient-5	89	Female	Spouse	Yes	Yes
Carer-5	90	Male		Yes	
Patient-6	86	Female	no family carer	Yes	--
Patient-7	48	Female	Mother	Yes	No
Carer-7	70	Female		Yes	

Table-22: Demographic characteristics of interviewed professional caregivers

Group interviews	Interview-1	Interview-2	Interview-3	Interview-4
Participants, n	6	6	5	6
Age (years), mean	48	48	44	51
Female gender, n	6	6	5	4
Profession, n				
Palliative medicine consultant	1	0	0	1
GP	1	1	0	1
Nurse	3	4	4	3
Physiotherapist	0	0	1	0
Occupational therapist	0	0	0	1
Social worker	0	1	0	0
Chaplain	1	0	0	0
Years of qualification, mean	22	20	16	25
Years in post, mean	6	6	5	9

6.2 Themes

6.2.1 Themes and subthemes

Codes were created from both the patient and family carer interviews and the professional caregiver group interviews. These codes were collated into subthemes, which were further clustered together to generate four major themes of the experiences of patients, family carers, and professional caregivers with integrated palliative care (**Table-23**). The themes were shared across the patient, family carer, and professional caregiver interviews. Theme-1 and Theme-2 were more prominent in the patient and family carer interviews, while Theme-3 and Theme-4 were more prominent in the professional caregiver interviews. A comparison of the findings to those of other qualitative interview studies with patients with advanced heart failure is provided in **section-9.3.8**.

Table-23: Themes and subthemes of the experiences with integrated palliative care

Themes	Subthemes
Theme-1: Impact of heart failure	Impact of heart failure on patients
	Impact of heart failure on families
Theme-2: Coping and support	Patient coping
	Patient support
Theme-3: Recognising palliative phase	Identifying palliative patients
	Palliative care conversations
Theme-4: Coordination of care	Networking
	Continuity of care

Merging patient, family carer, and professional caregiver interviews to generate the themes enabled exploring multiple perspectives and different views on integrated palliative care, which added breadth and depth to the analysis. This combination of interview data provided a comprehensive view of the palliative care needs for patients with heart failure and the experiences with palliative care. It enabled comparing similar, different, and complementary data from different perspectives to get a more complete picture and better understanding of palliative care experiences. Exploring the perspectives of multiple stakeholders would enhance the transferability of the findings and provide insight into clinical practice. However, combining the interview data had a few limitations. The interview topic guides for patient and family carer interviews (focusing on problems, needs, relationships, and communication) were a bit different from those for professional caregiver interviews (focusing on content of care, patient flow, information logistics, and availability of resources). Thus, the first two themes were more prominent in the patient and family carer interviews, while the last two were more prominent in the professional caregiver interviews. Exploring the perspectives of a bigger sample of one group would have added more depth to the analysis, albeit on the expense of the breadth of the analysis.

6.2.2 Thematic map

The relationship between the four themes is represented in a thematic map (**Figure-12**). Theme-1 describes the significant impact of heart failure on patient and family lives. To relieve such an impact, the need for coping and support (Theme-2), recognising palliative phase (Theme-3), and coordination of care (Theme-4) became evident. Theme-2 describes the coping strategies developed by patients and the provided professional and family support. Theme-3 describes the recognition of patients with palliative care needs and the initiation of palliative care conversations with patients and families to discuss the care plan. Theme-4 describes the coordination of care around the patients and families along the whole disease trajectory. These three themes are interconnected: once the palliative phase is recognised, patients and families can be provided with tailored, coordinated support. In turn, care coordination is needed for optimal patient and family support and for timely palliative care conversations.

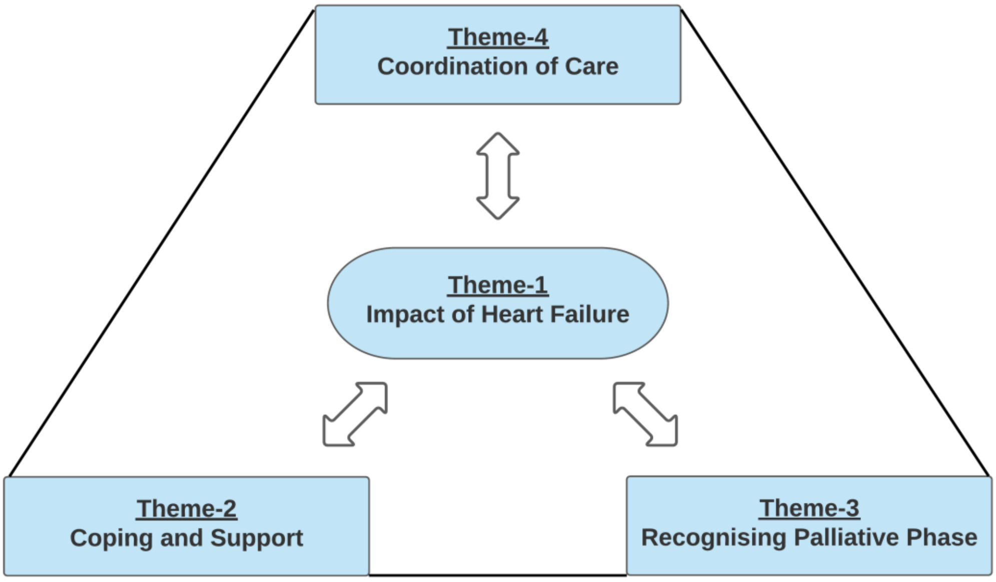


Figure-12: Thematic map of the experiences with integrated palliative care

6.2.3 Mapping the themes onto Normalisation Process Theory constructs

Table-24 shows how the four inductively developed themes map onto the four Normalisation Process Theory constructs. In response to the multidimensional impact of heart failure on patients and families (Theme-1), the *value* of identifying and addressing their palliative care needs became evident to relieve this impact (Coherence). As a result, patients developed coping strategies with the help of families, while professional caregivers provided support (Theme-2) and played their role to *operationalise* palliative care and address the unmet needs (Collective action). Professional caregivers had the duty to identify palliative patients and engage in difficult palliative care conversations (Theme-3); they agreed that this should be *part of their work* despite the expected challenges (Cognitive participation). Patients, family carers, and professional caregivers commented on the quality of professional support (Theme-2), communication, and continuity of care (Theme-4); they assessed and provided *feedback* on the palliative care services and pointed to areas where further support is needed (Reflexive monitoring).

Table-24: Mapping the themes onto Normalisation Process Theory constructs

Normalisation Process Theory constructs	Corresponding themes*
Coherence (sense-making work, meaning)	Theme-1: Impact of heart failure
Collective action (operational work, effort)	Theme-2: Coping and support
Cognitive participation (relational work, commitment)	Theme-3: Recognising palliative phase
Reflexive monitoring (appraisal work, feedback)	Theme-2: Coping and support Theme-4: Coordination of care

* Theme-2 was mapped onto two constructs given the overlap between the Normalisation Process Theory constructs (see **section-3.5.3**).

6.2.4 Theme-1: Impact of heart failure

This theme reflects the significant impact of heart failure on the daily lives of both patients and families and the needs that emerged from this impact. Heart failure affected patients and families in several dimensions: physical, psychological, social, financial, legal, and practical, while the spiritual impact was less evident in the interviews. Patients also had limitations in activities of daily living, medication-related issues, and information needs. Patient problems were fluctuating, although mostly getting worse with time:

"(Patient-7_Baseline): Yeah, it's a roller-coaster, that's what it is, of emotion, feelings and physical stuff, and feeling you're missing out on things or… zooming downhill with no brakes. There's all sorts of things going on…"

Besides heart failure, patients experienced comorbidities such as cancer and kidney failure which had an additional impact on patients and further exacerbated the physical symptoms of heart failure.

6.2.4.1 Impact of heart failure on patients

Patients experienced ongoing physical symptoms with fluctuating or worsening severity over time, which caused frequent hospitalisations and healthcare professional visits. Patients reported feeling "poorly" and "bad" all the time. They complained of general slowing down and weakness that predisposed them to fall. Because of their limited mobility, patients needed support from carers in addition to mobility aids and special hospital beds. Leg cramps, swelling, fatigue, and tiredness made patients' lives difficult:

"(Patient-7_Baseline): …and the Consultant said… on my tests results, when they tested how my heart works, every flight of stairs my heart has done the equivalent of a marathon, and that's how hard it's had to work."

Patients reported bowel and bladder problems, palpitations, dizziness, sexual dysfunction, and communication and concentration difficulties which made them unable to describe their symptoms and express their needs. They experienced breathlessness and accompanied sleeping issues during rest and activity. Pain was mostly persistent, severe, and difficult to manage. This suffering made bereaved family carers grateful that their relative's pain was over after their death:

"(Family carer-1_Bereavement): It was the pain that… that… was there all the time and the only thing now I can think is he has no more pain. He was a very brave, courageous man and at least his pain is over."

Because of physical limitations, heart failure affected the patient's ability to do basic things in life; making them dependent on carers. Personal care needs were evident as patients experienced difficulties in dressing, eating, taking medication, toileting, and doing tasks around the house:

"(Patient-5_Joint interview_Baseline): There was a bath at that end of the bathroom. Well, we never take a bath. Who wants a bath at this age? We're all frightfully good at getting in it but [chuckling] we can't get out."

Patients' ability to go out and drive was restricted; making them housebound. Some were embarrassed about using mobility aids, while others could not go to their medical appointments. Some patients had to leave their jobs because of their physical disability, advice from healthcare professionals, or forced retirement by employers, which affected their wellbeing and sense of self.

Patients experienced significant and ongoing psychological and emotional issues because of heart failure and needed mental health support. Fear, worry, anxiety, stress, and overthinking were prominent symptoms. Patients were afraid of the unknown and experienced feelings of uncertainty and insecurity as they were facing an ambiguous future and expecting death at any time. This uncertainty prevented them from planning effectively for the future:

"(Patient-2_Baseline): it's the whole thing of not knowing what's going to happen when you wake up in a morning, how the day's going to be. We can't book anything because you just don't know… what the future's going to be."

Patients were concerned about the impact of heart failure on their relationships and being a burden on their families. They got frustrated from asking for help from others and experienced poor self-confidence as their role changed from a working person to a dependent person. Some patients described spiritual issues including hopelessness, isolation, and withdrawal from life, and others experienced depression because of physical suffering:

"(Patient-3_Baseline): …because I sometimes get really bad days where, despite taking all my painkillers and doing all the right things, I'm in extreme agony and I can't get out of bed or I can't get dressed or, you know, I just go into kind of a depression because I'm just in too much pain, I just want to be left alone."

Patients needed reassurance to overcome their fear, worry, and uncertainty. They wanted information and regular monitoring to know what is happening with their illness. Patients needed compassion, empathy, and caring from family and professional caregivers, especially when broaching end-of-life discussions:

"(Palliative medicine consultant): …[we] start some of those (end of life) conversations in a much more generic way. You know, 'How do you feel things are going? You know, 'you don't seem to be bouncing back each time,' so that, rather than it being this kind of cliff that we throw people off, we're trying to be a bit more gentle about it…" (Group interview-1).

Patients needed family, friends, and professional caregivers to understand their suffering. They did not want their disease to be ignored, neither did they want to be seen as a disabled person who always needs help. They wanted normality in their life and to feel in control over their disease:

"(Family carer-7_Baseline): Very independent. You see I'll say… I'd love to come down and do things for her, but I try not to because I think she doesn't really want me. You can be too interfering as a parent. She's got to live her life, her own life."

The physical and psychological impact of heart failure caused loneliness and social isolation. Patients' inability and lack of confidence to go out restricted their opportunities to meet people and increased the sense of being disconnected, which exacerbated their psychological suffering. Patients wanted more social interaction and peer support and to talk about their disease. Their relationship with family and friends were affected by sexual dysfunction, sleeping issues, lack of self-esteem, and not going out:

"(Family carer-3_Follow-up): …she's had problems sleeping and particularly with her sinuses and stuff, and it means that she ends up being quite noisy in bed and I shouldn't do but I sometimes lose my temper and then she gets irate because I lose my temper and she can't really cope with it that well. I know that's my… sort of my problem. So we end up falling out over that..."

Patients experienced a lack of financial security and felt a drain on their families as they had to leave work due to their physical limitations. Financial problems were exacerbated as family carers left their work to look after their relative:

"(Patient-3_Follow-up): …some of my issues, like the sense of security, because my husband doesn't work at the moment, he's – as you know, he's trying to be a day trader – and my fear is that our savings are running out and we're going to end up homeless…"

Paying for mobility aids, home adaptations, medications, housekeeping services, and some healthcare services put an additional financial strain on patients. Because of this financial struggle, patients and family carers endeavoured to claim benefits although this was a difficult and bureaucratic process. Professional caregivers talked about the need for continuing healthcare funding for terminally ill patients to provide 24-hour care. Patients also described legal and practical issues such as difficulties in filling out legal forms and getting travel insurance because of their disease. Besides, because of multimorbidity, patients were on several medications which caused interactions, toxicities, and patient confusion, especially when healthcare professionals changed their already complicated treatment regimen:

"(Patient-2_Baseline): They (Healthcare professionals) changed it (medication for anxiety), yes, because it was… it interacted with the heart stuff (medication) and so they changed it to… I'm on a shed-load of stuff, I really am."

Heart failure left the patients with several questions to ask about their condition and symptoms. Patients wanted up-to-date information about what is happening with their heart in clear and simple language. Some did not know whether their symptoms were caused by heart failure, other conditions, or medications, while others attributed them to ageing or worrying. Patients needed information on how to self-care and manage symptoms, including what adjustments they should make, what activities they could safely perform, and what they should avoid. They wanted information about their medications, including their beneficial and adverse effects and which ones to avoid. Patients were not fully aware of the available care services and their role, including what palliative care and hospices could offer, and whether they are eligible for hospice care. They wanted to know whether, when, and whom to call for professional help when they have symptoms. Some did not approach healthcare professionals at the right time as they thought that their symptoms were not related to heart failure or might improve by themselves or with medicines:

"(Palliative medicine consultant): I think there's another potential problem – not particular to palliative care – but for people with long-term conditions… of services tending to become only reactive to them […] because a lot of patients and [family] carers don't know how bad a problem needs to get to justify calling someone…" (Group interview-4).

6.2.4.2 Impact of heart failure on families

Caring for patients with heart failure had a physical impact on family carers. Because of caring responsibilities that took most of their time, family carers needed help with their daily activities, and some had to give up work to care for their relative:

“(Patient-4_Follow-up): He (patient’s husband) used to sit up the hospital eight or ten hours a day and he was doing all the housework, he was cooking my meals – everything… He had to give his job up as a postman to look after me.”

Families experienced psychological and emotional issues because of heart failure. They were worried about the patient’s physical and emotional wellbeing, health deterioration, and death. Waiting for patients’ test results caused additional stress and fear. Family carers were worried about not being able to cope with the patient needs anymore. Some felt they were living in a separate world as they employed all their time caring for their relative and consequently overlooked themselves:

“(Family carer-1_Bereavement): I was in a different world really. I’d been caring for him for so long that I think my… my own self had kind of gone into the background […] and I’m, you know, I’m under 8 stone now, which is… I’ve lost a lot of weight because I suppose I haven’t been looking after myself at all. I mean I’m not aware that I’m not looking after myself but obviously it’s taken its toll...”

Bereaved family carers experienced mixed feelings of hope and hopelessness before their relative’s death. They needed compassion and empathy from clinicians when talking about the impending death of their relatives as they suffered at the end of life. Grief was experienced following the patient's death. Bereaved family carers described the initial trauma they experienced when their relative died. They expressed anger at professional caregivers and blamed them for patient suffering and death. They also blamed themselves for not making the right decisions before their relative’s death:

“(Family carer-1_Bereavement): He (hospice specialist doctor) said, ‘If it is a chest infection, we can’t…’ because he couldn’t swallow orally, ‘…we can’t treat this chest infection at the hospice. He would have to go to (Hospital)’. […] we immediately said, ‘No, there is no way he could cope even getting to (Hospital), you know, transferred from bed to a whatever and have injections there,’ [...] And if I… another question is to myself: why didn’t I say, ‘Yes, let him go’? Would that have made any difference?”

The nature and quality of the relationship between patients and family carers were affected by heart failure. The family role changed to a caring role to help patients cope with their illness, while patients were busy dealing with their illness and did not have time to look after their family carers:

"(Patient-7_Follow-up): …so it's (relationship with husband) become… it's become more caring I suppose than… Yeah, than physical. But I just think that relationships go that way anyway. I think that's a natural progression for a relationship…"

Some patients preferred to deal with their illness alone and refused to share their disease experiences with family carers. Consequently, family cares felt intrusive and rejected when they were talking with their relatives about their illness or trying to provide support. Eventually, they stepped aside as they believed that their relative's disease is their own thing which further impacted their relationship.

Families were not fully aware of the available care services and their roles. They did not know what palliative care could offer and that hospices provide a range of free services such as respite care and advice lines. Before the referral of their relatives to hospices, some families thought that patients are ineligible for hospices as they presumed that they are only for cancer, terminally ill, or dying patients. Families were uncertain about the role and remit of some healthcare professionals and had unrealistic expectations that conflicted with what care services could offer:

"(Palliative care clinical nurse specialist): I think, going back to what makes good integrated palliative care for patients, again it is about services but it's also about making… ensuring that the family know what services are available and what their expectations can be, because it can be just as equally as detrimental by misinforming people about services and then you can't deliver. And certainly there have been a couple of instances where things have broken down because families' expectations have exceeded way over what could possibly be given." (Group interview-3).

6.2.5 Theme-2: Coping and support

This theme describes the coping process of patients and the professional and family support provided to relieve the impact of heart failure on their lives. Patients developed different coping strategies in response to the heart failure impact although some were struggling to cope effectively. Professional caregivers supported the patients in their disease journey. Because of patients' diverse care needs, multiple professional caregivers were involved from multiple care settings. They used multiple approaches to address patient issues although the outcomes were not always perceived as successful. Families had a key role in providing most of the patient care. However, most were not coping and found it burdensome. As a result, professional caregivers assessed family needs and supported them to care for their relatives although this was sometimes lacking.

6.2.5.1 Patient coping

Patients coped with the physical, psychological, and other consequences of heart failure to relieve its impact on their life. Some thought that they could manage without certain professional caregivers and refused referral to some healthcare services. However, other patients found it difficult to cope and needed more professional and non-professional support. In either case, patients developed multiple coping strategies. They acknowledged and accepted the reality of being ill with heart failure and recognised that their illness will last "forever". They were aware of the progressive, life-limiting nature of heart failure; accepting that death is an inevitable reality, wherever and whenever it happens:

"(Patient-7_Baseline): But I suppose… and I know you're born with a terminal illness, aren't you? You're gonna die whatever… whatever anybody thinks, everybody's gonna die. We don't know when it is… you're born for that."

Patients had to live with their physical symptoms and limitations and were convinced that nothing more could be done to eliminate these symptoms and cure their disease. They accepted that they had to live a different life with frustration and loneliness as they could not go out, have holidays, and exercise as before.

As patients accepted the reality of heart failure, they adapted and adjusted to their limitations and made constant changes to live with their illness, although some changes were frustrating. Some patients adapted by doing other things which they did not have time to do while they were working before their illness, such as going out for little trips.

Those unable to go out shopped online and interacted remotely with people. One patient described how she could get another life through online gaming and having a virtual character that makes her appear healthy:

"(Patient-3_Follow-up): And I must admit I do rely a lot on social activity on the internet… because on the internet I can give myself this image that I'm not ill… The people that know me on the internet don't realise how seriously ill I am. To them I'm just healthy and an idiot and have a great sense of humour."

Patients adjusted by planning and setting up a safe environment before doing things, such as having the phone nearby while bathing. They did their daily activities at a slow pace, in small stages, and with regular resting periods:

"(Patient-2_Baseline): The flesh is weak, yes. The brain says you can do it and, like a lot of things, and I've learnt you can do mammoth tasks if you take it in tiny bits."

Patients did not give up on their symptoms and limitations but rather tried to cope with and work through them. While having a willing spirit and an urge to do things, patients were aware that they cannot achieve too much in one day. Therefore, they were setting attainable goals and pushing themselves to achieve them to feel accomplishment. Patients strived to keep independent and did not ask for help as they did not want to worry their families, bother professional caregivers, or be a drain on the health system:

"(Patient-3_Follow-up): I'm independent. The main theme is [chuckling] I like to stay independent as much as I can. My husband calls it being stubborn, but I just feel like I have to keep fighting. If I […] stop fighting, I'm going to give up. […] I'm still reluctant to let my husband help me, but that's just me being stubborn."

Patients looked ahead and tried to carry on with their lives rather than just sitting and worrying about things. They did not regret having a bad day but rather looked forward to a better tomorrow. While realising that their condition will worsen, patients looked forward to doing things before further deterioration. They did not want to stop their life because of their illness, so they tried to keep doing their usual activities. Some patients were hiding their suffering, while others used humour to get on with their life. Some felt that they had developed maladaptive coping strategies:

"(Patient-3_Follow-up): The way I cope with things is I put them in boxes in my head and shove them away and then switch off, and I need to stop doing that because it is damaging me and it's damaging my relationship."

Patients reinterpreted the meaning of heart failure and thought about its positive aspects. Being diagnosed with this life-limiting disease put death in front of patients which triggered them to prepare for it and sort things out before they die. Spirituality enabled patients to overcome the physical impact of heart failure. Some patients used mindfulness meditation to cope with breathlessness and palpitations. Others were tied to faith and religion, committed to going to prayer meetings and worship places, and engaged in rituals to find inner peace and comfort and make sense of their life:

"(Community matron): My particular patient, it (ritual) really has allowed that person to explore some needs, some fears, some experiences, and to resolve some life experiences that she never lifted the lid on." (Group interview-1).

Patients searched for information about heart failure to enhance their understanding of the illness and self-care approaches. They sought information about their illness diagnosis, prognosis, causes, symptoms, medications, and available treatment options. As patients educated themselves, they were able to discuss their treatments with healthcare professionals and have an informed decision about treatment options. Ultimately, gathering information provided reassurance and patients became experts on their condition:

"(Patient-7_Follow-up): I'll think [when I got chest pain]: Ooh… I don't feel very comfortable. Right, I'll take my spray. […] then I'm timing myself, then I take it again and I think: Right, I'll go have a lie down. And you do all… you do all these things before you have to go to t'next level, and sometimes it goes away. It might be angina pain, it might be summat else that does get… does go away with your spray or some painkillers."

6.2.5.2 Patient support

Multiple professional caregivers, including healthcare and non-healthcare professionals, provided patient support in different settings to manage the impact of heart failure on their lives. Non-healthcare professionals comprised a small group that involved faith leaders such as chaplains and priests, while healthcare professionals comprised a larger group that involved doctors, nurses, allied healthcare professionals, and homecare workers. Patients and families did not feel that there were too many professional caregivers involved in patient care. However, having multiple carers was confusing for patients and families as they did not know whom to call when there is a problem or emergency. When several professional caregivers were involved in patient care, it was difficult for them to work together, communicate, share information, and coordinate care. This resulted in poor awareness of the holistic patient care needs and conflicts in healthcare decisions. Patients who had several specialists experienced disintegrated and non-holistic care. Their GPs took a backseat as they felt that their care needs were addressed by the specialists and there was nothing they could do:

"(Family carer-3_Follow-up): I think she (patient) would, from her perception, would move the (GP) down [in terms of importance] because it's… it seems to only be… the contact with the (GP) is primarily, it would seem, a kind of function of the bureaucracy of it all, of having to go through a certain person to organise certain other things, rather than it seems to me him adding any value to the process."

Professional caregivers played different roles in addressing the impact of heart failure on patients. Doctors and nurses were mainly involved in addressing the physical impact of heart failure and medication-related issues, although nurses had more role in addressing psychological and emotional issues. Hospice teams were highly valued by patients and families as they were key in addressing patient needs and providing holistic care. Hospice teams managed patient's physical problems, helped with activities of daily living, addressed information needs, relieved uncertainty and fear, offered complementary therapies, addressed spiritual needs, and provided social outlets:

"(Patient-4_Follow-up): Oh, I love coming here (hospice). It's just the company and, believe it or not, somebody to make you a cup of tea. I know it sounds, you know, I say to the cat [at my home] sometimes, 'Go and make Mummy a cup of tea.' Yeah."

Patients and family carers described cases where professional caregivers did not intervene to address patient care needs, but rather ignored them or left them to other carers, because of the lack of time, knowledge, skills, and experience. Consequently, patients and families had to push for things to be done, live with their unresolved issues, or rely on other carers to address them. Patients and family carers described other examples where professional caregivers intervened to manage patient symptoms, but failed to resolve the problem which left patients suffering:

"(Family carer-1_Bereavement): I said, 'The whole thing (patient's pain and breathlessness before death) was just horrendous.' And do you know what she (spiritual adviser) said to me? She said, 'Well, sometimes it takes… it's a real battle for the soul to leave the body.' And I thought: What? What are you telling me? I have seen the failure of medicine – nothing to do with souls or bodies."

In advanced stages of heart failure, healthcare professionals did not intervene further to manage the disease because of irreversible deterioration and a shift towards a more palliative care approach. It was difficult for healthcare professionals to explain that sometimes active treatments are worse for the patients or that there is nothing they can do. Professional caregivers stressed that patients should understand that other things can be done that can improve their quality of life (palliative options) as opposed to active treatments. Nevertheless, they acknowledged the difficulty in giving up such treatments and moving towards palliative care when medical options are available:

"(Palliative care clinical nurse specialist): …sometimes it's harder to do nothing than to do something…

(Palliative medicine consultant): There's a, I think, a big cultural issue around end of life care is that we've still not got right and may never get right […]. Cardiologists, because they, you know, they've got lots of exciting things Cardiologists can do, so I think that's… the other thing is, the more things you can possibly do, the more likely you are to do them." (Group interview-1).

Patients were supported by friends and volunteers who helped them to go out and provided social outlets, and charities that provided educational materials and signposted patients to available care services. Families had a more significant role as they provided most of their relative's care. Caring expectations were placed by patients and professional caregivers on family carers; some of whom were complaining of chronic diseases and needed help themselves. Some family carers put expectations on themselves to care for their relative because they are in a relationship. Consequently, they thought that they did not need, or even refused, professional support as they felt they are coping well. However, most families were struggling to cope with patient care which they perceived as a burdensome and 24-hour job that caused tiredness and emotional stress:

"(Social worker): With long-term illnesses you kind of… you get sucked into the caring role as well, don't you? So you don't actually realise the stresses until it can really build up to quite a significant level…" (Group interview-2).

Professional caregivers supported family carers to cope with the patient disease, relieve the caring burden, and manage their grief following the patient death. Although families were supported by doctors, nurses, and psychologists, it was the hospices that provided the most support through providing mental health counselling, relaxation therapies, social gatherings, shared information classes, referral to services, and respite care. Hospice support to families continued during and after patient death as they provided bereavement care and counselling. Family carers described examples of poor professional support because of the limited staff and resources and poor information sharing about the family need for support. One family carer reported poor bereavement support from the GP:

"(Family carer-2_Bereavement): The only person that surprised me [after patient death] is our own doctor (GP), who I've not had a word from. […] I was just gobsmacked actually. I mean I know in the olden days your local (GP) always used to come round and contact you and whatever – nothing, not a word."

6.2.6 Theme-3: Recognising palliative phase

This theme describes the process of recognising the palliative phase of patients with heart failure and the subsequent initiation of palliative care conversations with patients and families. Recognising the palliative phase starts with identifying patients with heart failure who require palliative care, using a prognostic or needs-based approach. This is followed by a holistic assessment of the palliative care needs of patients and families and the timely introduction of palliative care. Once this recognition happened, professional caregivers engaged with patients and families in palliative care conversations to discuss patient preferences and care plans. However, these conversations were difficult and infrequent because of the prognostic uncertainty of heart failure, patient and family misconception of heart failure and palliative care, and lack of time and communication skills of healthcare professionals. Although open and individualised conversations were recommended to help patients and families in care planning and goals-of-care discussions, the timing of and staff responsible for these conversations were highly debated.

6.2.6.1 Identifying palliative patients

Professional caregivers described two main approaches to identifying palliative patients with heart failure: the prognostic approach and the needs-based approach. The prognostic approach was considered unreliable for patients with chronic heart failure because of poor understanding of the dying process, prognostic uncertainty, and unpredictable trajectory. Nonetheless, professional caregivers believed that recognising the palliative phase could be facilitated by having a long relationship with the patients. Patients described experiences of alternating periods of deterioration and stabilisation, and some explained how they outlasted the life expectancy given by their doctors:

"(Patient-3_Baseline): …it (heart) was so badly damaged. And they even put me on a heart transplant list – well, a pre-heart transplant list – and I had to go down to (Hospital1) for 18 months every six months to be checked. But, luckily for me, I stabilised…"

The needs-based approach was advocated by professional caregivers to recognise palliative patients with heart failure and introduce palliative care services. Professional caregivers preferred an "in and out" approach to specialist palliative care where it is provided as needed for patients with complex palliative care needs. Subsequently, specialist services are withdrawn to allow generalist palliative care services to take the lead and manage less complex needs. Although all patients were receiving specialist palliative care services, hospice day care was provided for a limited period. Professional caregivers acknowledged that this could be emotionally difficult for patients, but they argued that this would free up the resources to cover more patients:

"(GP): …palliative care's got to be more and more dynamic and more in and out. It depends on the need rather than [prognosis]… […] if you're looking at what the patient's needs are, so they might have dreadful lot of needs at the point, but then… so we should look at palliative care from that point of view but then discharge them [from the Day Care]. […] we need the resources to cover a lot more patients, that's what we've got to do." (Group interview-4).

Professional caregivers acknowledged that more patients with heart failure were provided palliative care as it is no longer limited to those with cancer. However, they realised that the number is still low and variable across care settings. Professional caregivers believed that palliative care should be introduced early in the disease trajectory to prepare patients for palliative care conversations, facilitate early care planning, provide the necessary services, build relationships, and improve care quality. However, an early approach was not always possible as some patients were afraid or reluctant to receive palliative care as they linked it to dying:

"(Palliative medicine consultant): What does concern me a lot is the number of people who have their first contact with palliative care services in hospital, an acute hospital, and I mean often within only one or two days of dying, and then it really is too late to either address their physical problems and provide emotional support to them or the family and they end up dying in hospital, which was clearly not what they would have wanted, but it's just far too late to try and make any sensible plans..." (Group interview-4).

Patients and family carers needed a more holistic and integrated approach to assessment and care. While this was provided by hospices, other healthcare professionals focused on physical symptoms and treatments. Patients and family carers needed healthcare professionals to show respect and concern for them as unique individuals with a whole set of distinctive care needs. They wanted to feel that they are important and be treated as a person rather than names or numbers:

“(Patient-7_Follow-up): I think they’re (consultants) a bit too important for their own importance, and the importance of your actual life and what it’s (heart failure) doing to your life isn’t really an issue for them.”

6.2.6.2 Palliative care conversations

Palliative care and end-of-life conversations were perceived as necessary to discuss patient care plans and help them to make decisions in their life, confront their fears, reflect, and make sense of their life. However, these conversations were difficult for patients, families, and professional caregivers for different reasons. Because of the unpredictable heart failure trajectory, healthcare professionals lacked the confidence to have an end-of-life conversation with deteriorating patients who might get better unexpectedly. They were concerned that patients would no longer trust their clinical judgements if they told them they are deteriorating but that did not come true. Therefore, they waited for the patients to open the conversations, although this rarely happened. The lack of time, communication skills, palliative care knowledge, and experience of healthcare professionals were other perceived barriers to palliative care conversations. Educating healthcare professionals through end-of-life care training programmes was therefore deemed vital. Another described barrier was the patient and family misperceptions of palliative care (for dying patients) and heart failure (not life-threatening):

“(GP): …they (patients with chronic disease) go [to the hospital] with an exacerbation, they come with end of life drugs, and it’s a complete shock it’s something they’ve lived with for 20 years, so they’re like: ‘Well, why is it any different now than it was last time I went in?’ And I think that’s quite a stumbling block to actually get that across to the patients and to the carers…” (Group interview-1).

Patients, families, and professional caregivers favoured open and honest conversations about heart failure diagnosis, prognosis, and available treatment options. By telling the patients and families all the facts, they knew what to expect and felt in control and were able to make informed decisions about their life and future care. Patients and families placed expectations on healthcare professionals to give them answers based on their skills and knowledge. However, healthcare professionals were not able to provide accurate prognostic information because of the unpredictable disease trajectory. Some were reluctant to disclose full prognostic information to avoid distressing patients:

"(Patient-4_Follow-up): Yeah, I would [prefer straight-talking from professionals], yeah, because half the time I come out and I don't believe what they tell me. […] I think by doing that (telling me the whole story) they are thinking of me really, thinking: Well, if we tell her that, she'll worry; if we don't tell her, she won't know, sort of thing. But I think that's the wrong thing to do when you're on your own."

In a few cases, patients and families did not want to know the facts about their diagnosis and prognosis nor talk about care planning, or they were trying to hide the facts from each other. While professional caregivers acknowledged the right of patients and families to avoid the information or the whole conversation, they were worried if they were avoiding them "out of ignorance" or because "that's the right thing for them to do". Therefore, they called for an individualised and patient-led approach to the conversations. That is; not every patient needs all information or "vigorous conversations", and the information that is right for one patient or family at a particular time might not be right for others:

"(Palliative medicine consultant): I think the most important thing for me is that you're not hiding things from people […] I would argue quite strongly that most patients need to know their diagnosis; and I would argue quite strongly that they need to know a little bit about the natural process of that diagnosis – in very broad terms, you know – […] So at least people know a little bit – whether they want to know the ins and outs of all of it, that's then for the patient to take you in that journey. […] So it's patient-led. We give that key bit of initial information and then they lead us as far, how far they want to go with that." (Group interview-1).

The timing of palliative care conversations, who broaches it, and how it is communicated to other professional caregivers and followed up had a big impact on patients and families. Professional caregivers preferred to have early and regular conversations during patient assessments to have time for care planning. However, early conversations were thought to be difficult if patients were not emotionally prepared to have them until later in their disease trajectory, or if patients improved afterwards and the same conversation had to be repeated. Consequently, professional caregivers thought that late conversations might be preferred in a few instances:

"(Physiotherapist): I think, as we touched on before, that with people with COPD and heart failure, because you can't predict how the disease is going to pan out and what timescale you've got, it sometimes is harder to make sure that people are having the right conversations at the right time…" (Group interview-3).

Palliative care conversations were considered a collective responsibility that should be initiated by one professional caregiver and then communicated to the others to follow them up as patients move between different healthcare settings. It was agreed that those involved in the conversations should have experience, training, communication skills, palliative care knowledge, and good relationships with patients. Professional caregivers placed expectations on GPs to start the conversations as they know the patients best, and on community nurses as patients would be more comfortable having these conversations at home. However, many conversations were initiated by palliative care specialists, which was perceived as difficult because these are the people dealing with dying.

In palliative care conversations, advance care planning was conducted with patients and families where the goals and preferences for future care and treatment were defined, discussed, documented, and reviewed regularly. This included discussions about available treatment options, preferred place of end-of-life care and death, resuscitation, who to care for the patient if the family carer gets unwell, living wills, and ritual practice after patient death. Conducting and documenting advance care planning facilitated shared decision making and enhanced the concordance between patient preferences and the received care. In some examples, patients were not involved in care planning nor were they provided with enough information to help them decide. Even when patients were reluctant to discuss care planning, once they did it they felt empowered and more comfortable:

"(Patient-3_Follow-up): It (Advance care planning at the hospice) was actually quite cathartic because I hadn't really thought about it, but it let me have my voice. If I couldn't speak, my voice is down in black and white, so it was actually quite good… My (Cardiac nurse specialist) was a bit concerned when I handed it in to her to put into my file till I

explained to her that I knew I wasn't dying at this moment from heart failure: this was something that I wanted to be taken into consideration down the line."

Discussions around the preferred place of end-of-life care and death were prominent in the interviews. Patients did not want to die in hospital because of the poor care quality. They wanted to die in the hospice where they felt welcome and their care needs were addressed:

"(Patient-6_Baseline): …if I [get ill]… I definitely don't want to go into hospital, but if I had to go anywhere I would go to the hospice. […] there's such a peace and a comfort there and, as I say, I don't know, I just go and I just feel I'm at home and I mean I know when I've gone to the Prayer Meeting, I've also gone in and visited people, you know, but they're such… there's such a calm atmosphere, there's such a wonderful feeling there, you know… and that, so that's just the way I feel and that's just the way I want."

Patients also preferred to be cared for and die at home. However, professional caregivers argued that patients and families could have unrealistic expectations of what services are available as 24-hour home care might not be feasible because of limited financial and staff resources. Families might also be unable to cope with their relatives' care needs at home. Home care needed several aids of daily living and adaptations and interfered with the privacy of patients and families because of frequent healthcare professional visits.

6.2.7 Theme-4: Coordination of care

This theme describes the organisation of care between professional caregivers across different care settings to meet the palliative care needs of patients and families along the whole trajectory of heart failure. Patients and families had a care network of professional caregivers who were expected to communicate, share information, and collaborate between each other and with patients and families to provide high-quality, timely, consistent, integrated, patient-centred, and holistic care. However, this communication was affected by cultural, organisational, environmental, and patient-related factors in addition to the availability of resources and information-exchange systems. Educating professional caregivers about palliative care, the available care services, and their role was perceived as necessary to improve care coordination. Patients and families needed continuous care that is provided by a team of professional caregivers across different settings from the moment of diagnosis into death and bereavement. They wanted ongoing management and follow-up of their disease, timely response to their care needs, and consistency of professional caregivers over time. The role of a care coordinator was perceived by patients, family carers, and professional caregivers as important to link patients to healthcare services and ensure appropriate palliative care delivery.

6.2.7.1 Networking

Patients and family carers were not completely aware of the connections between the professional caregivers involved in their care. Nevertheless, poor and one-way communications were perceived to be more common than two-way communications. Nurses had predominantly two-way communications with each other and with other professional caregivers. Hospice workers communicated well as a "team", but their communication with other professional caregivers was generally perceived as less good. Patients and family carers indicated a need for integration, communication, and information sharing between all professional caregivers, particularly doctors. They wanted healthcare professionals to use the available information-sharing technology and access their medical history before seeing them in clinics:

"(Family carer-3_Baseline): Sorry, but it's just a pet hate and I just think it's… it's just silly. Like many things, you know, human body and its care and health are a marvellously, complicated thing, but the rest of it, why not just talk to each other… about the right stuff?"

Professional caregivers emphasised the importance of collaborative working and joint palliative care meetings, which were an "eye-opener" and a "good refresher" to know which patients needed palliative care conversations or referrals to go through their care needs. Such meetings aided to reflect on the quality of provided care and triggered communication and integrated care. However, some healthcare professionals were too busy to attend or thought they do not have many palliative patients to discuss. Patients and families valued joint working between healthcare professionals:

"(Family carer-3_Baseline): …I know she (patient) had experience that they do with oncologists and cancer patients, is they have a team, they don't just have one person who makes a decision, they have a team of consultants and surgeons who sit down in a meeting and discuss the various patients they have on the list, what the appropriate treatment for them is… […] but it frustrates her that they don't have something similar across the various… medical areas…"

The communication between professional caregivers was perceived to be affected by several factors. These include cultural differences between health care and care agencies in talking openly about death; organisational difficulties for care agencies to let their homecare workers do joint home visits with other healthcare professionals; use of different palliative care pathways, policies, and assessment tools; staff consistency; severity of patient disease; availability of financial and staff resources; and information-exchange systems. In three of the group interview sites, professional caregivers used to write their medical notes in documents kept in the patients' homes, including patients' personal details, care needs assessment, and care plan. The home documents were mostly accessible to other professional caregivers who could see what assessments and care plan discussions had been done.

The experience of using computer systems was different among the group interview sites depending on the quality of the available system. In one site where the system had advanced features, professional caregivers had a positive experience as the system enabled gathering all patient information in one confidential place, flagging patients having a care plan, alerting that patients are at the end of life, and tasking clinicians to manage specific patient problems. In other sites where computer systems were not networked, professional caregivers complained of the complicated systems, time-consuming information sharing, difficult access to medical records, using different computer systems across organisations, and distancing professional caregivers from each other. Consequently, they preferred in-person and phone contact as these would enable detailed conversations and build personal connections, despite the difficulty to get hold of busy clinicians:

"(Palliative medicine consultant): …it surprised me for ages how rare it seems that GPs will ring up the Consultant and have a conversation about something, but they write a letter about quite straightforward things, you know, asking for somebody to be seen or asking a question in a letter that then takes two weeks before anybody gets round to answering it. And you think: Why could you not just have a five-minute conversation about it?" (Group interview-4).

The communication between professional caregivers was perceived to have important consequences. Poor information sharing made professional caregivers unaware of the patient condition, care needs, and current care plan, which made patients argue for their preferences again or left clinicians acting in contrast to these preferences. Poor awareness of patients' medical histories triggered patients and families to reiterate them or act as a "conduit of information" between professional caregivers which was time-wasting and frustrating:

"(Palliative care clinical nurse specialist): …a lot of the information we get is very poor, not very much at all. We spend a lot of our time digging for information, trying to ascertain exactly what's happened, what they've (patients) had done, what they haven't had done, what they understand, what they don't understand, what the plan is. It can take us a couple of hours." (Group interview-3).

Poor communication made professional caregivers unaware of what each other is doing; leading to duplication. It created feelings of frustration, worry, isolation, and upset which in turn exacerbated patients' physical symptoms:

"(Patient-7_Follow-up): …I think with a heart problem especially, when you're anxious, it heightens everything that's going on, so it makes you feel unwell, because they (healthcare professionals) say try and reduce anxiety, try and stay out of stressful situations because it makes your heart beat faster and… but they're creating it [by not communicating with each other]."

Conversely, good communication provided reassurance for patients, built trust between clinicians, resolved medical decision conflicts, facilitated patient referrals and timely access to healthcare services, and enhanced integrated, patient-centred, and holistic care.

The need for joint palliative and end-of-life care education among professional caregivers was considered important to increase the awareness of palliative care, develop communication skills, build relationships, provide good-quality care, and deal with complex patient needs. In one group interview, professional caregivers gave an example of mutual training sessions between the hospice team and heart failure nurses when the heart failure service was set up in the hospice. However, joint palliative care training programmes were difficult to conduct because of workload and limited resources. It was also important for professional caregivers to know the available care services and their roles to seek their advice, refer patients, and avoid conflicts and duplication. However, this was problematic with the high staff turnover and in the presence of locum GPs.

The communication between professional caregivers and patients was variable, with experiences of two-way communication with hospice workers and nurses and poorer communication with GPs and consultants. Family carers had poor communication with most professional caregivers. Patients wanted to be copied into consultant letters and informed about their test results, appointments (if cancelled or rescheduled), management plan, and if there is a change in their professional caregivers. The communication with patients and families was perceived to be affected by several factors. These include environmental factors (better communication in areas with small healthcare teams), severity of patient disease and care needs, availability of financial and staff resources, how patients perceive the care network around them, and ease of contact:

"(Lymphoedema nurse specialist): …we've discovered patients often have difficulty accessing the GP and, if they've got a Specialist Nurse that they've built that rapport with and they can rely on, they will ultimately go back to you rather than then going to the GP. You can encourage them to do that but whether they will or not… can be difficult, because they will always go to the person who will give them the answers and things that they want." (Group interview-2).

6.2.7.2 Continuity of care

Continuity of care was fulfilled when palliative care was provided across different healthcare settings from the point of diagnosis, along the whole disease trajectory, into death and bereavement. Participants valued the flexibility of healthcare services where professional caregivers rotate to meet patient needs, although they did not want the specialist services to completely replace their primary care team. Continuous monitoring was considered necessary to relieve patient symptoms and anxiety and reduce hospitalisations. Patients asked for more frequent monitoring of their condition and long-running services. One issue was the quick hospital discharge before weekends and poor follow-up in the community, which highlighted the importance of "discharge coordinators" to facilitate seamless discharges. Another issue was about lacking, late, or futile referrals:

"(Family carer-2_Baseline): It's just you keep getting put off or pushed onto somebody else… You know, every time some new problem comes up, 'Oh, send him to So-and-So,' send him to somebody else and never seem to get to the root of anything. It just… just keeps on going and going."

Patients' follow-up by professional caregivers gradually decreased once they were stabilised or referred to other services. Some patients and families did not mind as long as professional caregivers were still in the background and accessible. However, patients were worried about being crossed off the lists of their consultants and heart failure nurse specialists as their heart failure is "still there" and may relapse anytime:

"(Patient-3_Baseline): I am now getting to the stage where I feel like they're (consultants and nurse specialists) sort of thinking about signing me off because I'm no longer urgent. They don't realise that it's actually quite a scary thought when you've got the conditions that I've got, that if they sign you off and something happens, I might not be able to get the treatment that I want."

Premature discharge from healthcare services resulted in the loss of relationships with professional caregivers, feelings of abandonment and isolation, and worries about what is going to happen next. Patients and families wanted professional caregivers to be available all the time and when needed, as this provided reassurance. However, the high cost and lack of staff and time made it difficult for professional caregivers to visit patients frequently, organise seamless discharges, and provide 24-hour long-term care.

Patients and families asked for more responsive health services to their care needs. Responsiveness of health services was dependent on the workforce commitment, availability of time and staff resources, and ease of access to other services. Where resources were limited, late response resulted in unresolved or worsened symptoms, health deterioration, hospitalisation, missed care, and frustration. Some patients reported long waiting times to get their medications or prescriptions:

"(Patient-3_Baseline): …I'll just come off it (old painkiller) and go on the new thing (painkiller), but the thing is it will take a few days to get into my system so I have to prepare myself for a few days of extreme pain."

Other patients had problems with booking, cancelling, rearranging, and postponing appointments and referrals. Patients and families needed timely and easy access to doctors as they struggled and had to wait a long time to get appointments, especially with the same GP. They complained of the need to get re-referral through GPs if discharged from specialist services.

While multiple professional caregivers were needed to provide continuous care across different healthcare settings, it was considered important to have consistent professional caregivers over time. Staff consistency enabled professional caregivers to work and train together and strengthened the relationships and communication among them and with patients. Nevertheless, lack of staff consistency was a common problem caused by the presence of locum GPs and staff turnover:

"(Family carer-7_Follow-up): And he (GP) died a few weeks ago, but they (surgery) haven't sent a letter saying 'You are now under this doctor,' because they don't have any… they don't have any long-time doctors. (GP1), they're all locums and come-and-go doctors, so you don't know who the heck you're seeing. You haven't a clue."

New staff often had poor communication with other professional caregivers, insufficient knowledge of the available care services, and poor awareness of the patients' condition which affected the care quality and follow-up plan.

A care coordinator was perceived to be a key and responsible carer who organises patient care and acts as a single point of contact for patients to communicate their healthcare needs to other professional caregivers, ensure that their care preferences are met, and ensure that timely palliative care is delivered at the right level. There was no common understanding among professional caregivers of who should be the coordinator of patient care, especially when multiple healthcare professionals were involved. Some thought it would be unrealistic to allocate one identified key worker who follows the patient throughout the whole course of their illness. Others suggested that GPs, district nurses, or palliative care clinical nurse specialists could be the care coordinators as they spend more time with patients. However, they acknowledged that they could not do that alone if they had a big caseload or were isolated from other caregivers. Some patients were completely reliant on community matrons and heart failure nurse specialists to organise their care. Where no care coordinator was available, patients or their families took the responsibility to organise patient care, which was a big task that not all could cope with:

"(Patient-5_Joint interview_Baseline): Where do I fit in? Oh, I'm Queen Bee, sitting in the middle. [All chuckle] I mean I set it up. I decided because… I used to be what they called 'a good secretary'. I set things up and I organise and I'm good at human resources. You might not think so: you might I'm argumentative…"

6.3 Chapter summary

In this chapter, the findings of a secondary analysis of qualitative interview data about the experiences of patients, families, and professional caregivers with integrated palliative care were outlined. Four themes were generated from the analysis. Theme-1 (Impact of heart failure) described the significant impact of heart failure on the daily lives of both patients and families and the needs that emerged from this impact. Theme-2 (Coping and support) described the coping process of patients and the professional and family support provided to relieve the impact of heart failure on their lives. Theme-3 (Recognising palliative phase) described the process of identifying the palliative phase of patients with heart failure and the subsequent initiation of palliative care conversations with patients and families. Theme-4 (Coordination of care) described the organisation of care between professional caregivers across different care settings to meet the palliative care needs of patients and families along the whole trajectory of heart failure. These themes were represented graphically in a thematic map and mapped onto the Normalisation Process Theory constructs. In the following chapter, the results of follow-up meetings with key service providers, where the secondary data analysis findings were discussed against the Theory of Change workshops' findings, are outlined.

7 Results: Follow-up meetings with service providers and consultation with service users

In the previous chapter, the findings of a secondary qualitative data analysis, through which the voice of service users was included in developing the intervention, were outlined. In this chapter, the results of follow-up meetings with key service providers, where the secondary data analysis findings were discussed in light of the workshops' findings, are described. The meetings provided an opportunity to refine the preliminary intervention and underlying theory, which were developed with service providers in the Theory of Change workshops, and co-design a feasibility study protocol. The findings of a PPI group consultation, where patients with heart failure provided feedback on the intervention and feasibility study protocol, are also outlined. Subsequently, the main modifications to the preliminary intervention are presented, the refined Theory of Change is depicted, and the refined intervention is described in detail.

7.1 Follow-up meetings with service providers

7.1.1 Participants in the follow-up meetings

The flow chart of the recruitment process for the follow-up meetings is outlined in **Figure-13**. The meetings were only attended by two key service providers who participated in all of the Theory of Change workshops because of staff shortages due to COVID-19. The demographic characteristics of the participants are displayed in **Table-25**.

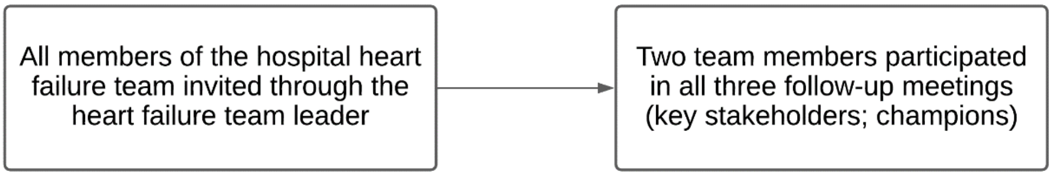


Figure-13: Flow chart of recruitment process for the follow-up meetings with service providers

Table-25: Demographic characteristics of the follow-up meetings' participants

	Three follow-up meetings
Facilitators, n	3 (each meeting was facilitated by two researchers)
Participants, n	2
Female gender, n	2
Profession, n (years of professional experience)	
Consultant cardiologist (heart failure team leader)	1 (25 years)
Lead heart failure nurse specialist	1 (23 years)

7.1.2 Discussing the impact of COVID-19

In the first follow-up meeting, the impact of COVID-19 on the clinical practice of the heart failure team was discussed with the key service providers to explore the feasibility of the proposed intervention and any possible changes required to adapt to the ongoing situation where COVID-19 is endemic. The service providers acknowledged the initial impact of the pandemic on their heart failure clinics, patient waiting lists, palliative care conversations, and time and resources. They explained how the heart failure team had been working to adapt to the new situation, despite staff shortages due to self-isolation. For example, although heart failure clinics stopped initially, they were restarted later, firstly remotely and then in person, and the heart failure team had more clinics to cover patient waiting lists which increased pressure on staff. Similarly, although palliative care conversations with patients declined initially, and some were done in virtual clinics, the heart failure team quickly restarted in-person conversations for better interaction with patients.

7.1.3 Discussing findings from the secondary data analysis

In the first two follow-up meetings, the findings of the secondary data analysis were presented to the key service providers and discussed against the findings of the Theory of Change workshops to refine the proposed intervention and underlying theory. This was accomplished by presenting one table for each of the four themes from the secondary data analysis (see **Table-26, Table-27, Table-28,** and **Table-29** below). The first column of each table contained specific findings from the Theory of Change workshops' discussions (for example, heart failure team are reluctant to engage in open palliative care conversations), while the second column contained corresponding findings from the themes (for example, healthcare professionals, patients, and families favour open conversations). The main modifications to the intervention following these discussions, the refined Theory of Change, and the refined intervention are presented at the end of the chapter.

7.1.3.1 Theme-1 findings

Table-26: Discussing relevant findings from Theme-1 (Impact of heart failure)

Findings from Theory of Change workshops	**Finding from secondary data analysis**
Heart failure team use NAT:PD-HF to assess the palliative care needs of patients and families.	Patients and families had multidimensional palliative care needs: physical, psychological, social, spiritual, practical, medication issues, and information needs.
Heart failure team educate patients and families about heart failure as a progressive disease, including prognosis, symptoms, methods of self-care, and care options.	Patients and families also needed information about medications; available care services and what they can offer (including palliative care services); whether, when, and whom to call for professional help in illness and emergencies; and financial issues. Patients and families wanted the use of lay language in education.

Commenting on the first point, the service providers acknowledged the ability of NAT:PD-HF to assess the holistic palliative care needs of patients with heart failure and their families, including information needs, although they had concerns about the time it could take if used routinely for all patients (see **section-7.1.3.3**). In response to the second point, they believed that the heart failure team have the necessary expertise and skills to educate patients on heart failure in simple language. They confirmed that the team use two booklets from the British Heart Foundation and an associated website to educate patients on heart failure in the clinics. The booklets contain information on heart failure medications; available care services; whether, when, and whom to call for professional help; and prognosis and palliative care, although these are not discussed in detail with patients. Therefore, it was suggested to the service providers to signpost the heart failure team to such patient education resources and topics that patients can use to enhance their understanding of *advanced* heart failure and palliative care. They agreed while acknowledging that patients with complex information needs would require a referral to specialist palliative care services. Stickers will be attached to the booklets to inform patients about local health services and who to call if their condition deteriorates.

7.1.3.2 Theme-2 findings

Table-27: Discussing relevant findings from Theme-2 (Coping and support)

Findings from Theory of Change workshops	Finding from secondary data analysis
Heart failure team communicate and collaborate with other healthcare staff inside and outside the hospital.	Multiplicity of healthcare professionals caused GPs to take a backseat and made it difficult to collaborate, communicate, share information, and coordinate care.
Heart failure team act on the primary palliative care needs of patients and families.	Most healthcare professionals did not adopt a holistic, patient-centred palliative care approach.

Regarding the first point, the assignment of a care coordinator for patients was suggested to the service providers. They thought it would be difficult to assign a healthcare professional who could act as a single contact point to communicate patients' palliative care needs and ensure appropriate care delivery, as most patients have comorbidities. There was a debate on which long-term condition group should coordinate patient care or whether it should be a shared responsibility. The service providers doubted that the heart failure team would have enough time, experience, and connections with other staff to do it. They thought that coordination is a complex role that needs investment and should be fulfilled by experienced staff with strong communication links and relationships with their colleagues. Although GPs and extensive care frailty services were used to fulfilling this role, this was for a limited period and for a few patients due to poor resources. Concerning the second point, service providers believed that the pandemic is not a barrier for the heart failure team to address the holistic palliative care needs of patients and families, signpost them to available care services, and engage in palliative care conversations. They thought that NAT:PD-HF could help in adopting a holistic approach to care.

7.1.3.3 Theme-3 findings

Table-28: Discussing relevant findings from Theme-3 (Recognising palliative phase)

Findings from Theory of Change workshops	Finding from secondary data analysis
Heart failure team are able to discuss the management plan and engage in conversations with patients and families about heart failure as a progressive disease (reluctance to engage in open advance care plan discussions).	Most patients, families, and professional caregivers favoured open conversations about diagnosis, prognosis, and end of life. Although open conversations could cause initial worry to patients and families or could be difficult due to prognostic uncertainty and poor understanding of heart failure and palliative care, they enable discussing patient wishes and care plans and prompt patients to reflect, confront fears, and make decisions in their life. Some healthcare professionals favoured individualised conversations that are led by patients for what, how much, and when to have information.
The intervention should be delivered to all patients attending the hospital, and perhaps community, heart failure clinics.	Early palliative care and advance care planning build relationships, make patients more prepared for conversations, reduce the chance of missing health services, address palliative care needs, and improve quality of life.

Concerning the first point, the service providers acknowledged that the heart failure team do not have enough open and early palliative care conversations with patients and families and some were waiting for patient triggers to start the conversations. The team found it difficult to broach these subjects on time, especially as patients may look well before deterioration. Nonetheless, the service providers believed that the heart failure team are more willing than before to have advance care planning conversations. Rather than having open conversations for all patients, the team favoured individualised conversations while referring more complex ones to specialist palliative care services. The service providers expected that NAT:PD-HF would help to open and structure the conversations and give them the confidence to conduct earlier and more frequent palliative care discussions. However, they acknowledged the time constraints and difficulty in asking some of the tool questions which could come as a surprise for the patients they have known for a long time. Therefore, familiarity with NAT:PD-HF and asking the questions sensitively were considered necessary.

In response to the second point, the service providers believed that it would be ideal for the intervention to be standard care in the everyday practice of *all* heart failure team members. They assumed that community heart failure nurse specialists should be involved in delivering the intervention in community clinics as they see frailer patients who are most likely to have palliative care needs. They believed that the intervention should ideally be routine for *all* patients in their clinics. However, they thought that this could be unfeasible and time-consuming especially if NAT:PD-HF is used as a tool to help open up palliative care conversations, identify and address patient and family concerns, and signpost them to other services**,** rather than just as a checklist. Therefore, they suggested delivering the intervention randomly (for example, to the first two consenting patients in each clinic); acknowledging that this selective approach would weaken the intervention. This was discussed in more depth in the last follow-up meeting when the target sample for the planned feasibility study was debated (see **section-7.1.4.2**).

7.1.3.4 Theme-4 findings

Table-29: Discussing relevant findings from Theme-4 (Coordination of care)

Findings from Theory of Change workshops	Finding from secondary data analysis
Other healthcare staff inside and outside the hospital are able to communicate and collaborate with the heart failure team, patients, and families. The heart failure team share the NAT:PD-HF summary in the clinic letter with other healthcare staff as appropriate.	Poor communication and information sharing between healthcare professionals and with patients and families.
Heart failure team are signposted to available palliative care training courses. Heart failure team conduct group meetings to share experiences of using NAT:PD-HF in practice. Heart failure team are informed of the available local healthcare services for referrals as part of the NAT:PD-HF training.	Collaborative education is important including joint training, joint visits to patients' homes, shadowing, and multidisciplinary palliative care meetings. Healthcare professionals needed information about the available care services and their role as this would help in role clarification, avoiding conflicts, seeking advice, and offering referrals to address patient and family care needs.
Heart failure team store the NAT:PD-HF summary and management plan in the clinic letter and share it with other healthcare staff using an appropriate information-exchange system.	A common practice was to store medical documents in patients' homes in an accessible place so that other staff can see them.
Heart failure team complete NAT:PD-HF monthly or with a change in patient condition (functional status).	Patients need continuous follow-up and monitoring.
Heart failure team aim to meet the palliative care needs of patients and families in a relevant timeframe.	Patients need a timely response to their care needs.
Trustful relationships between healthcare professionals and with patients and families are important contextual factors.	Staff consistency improves relationships, communication, and continuity of care.

Commenting on the first two points, the service providers perceived the communication between the heart failure team and other healthcare professionals as generally good. With COVID-19, the heart failure team correspondence had become more accessible to teams across the hospital and local primary and secondary care. However, communication with primary care and within the heart failure team (hospital acute and community teams) is mainly through posted paper copies as they use different electronic information-exchange systems. The need for collaborative education was endorsed by the service providers who had plans to restart the group training courses that stopped with COVID-19. Heart failure nurse specialists shadow consultants in their clinics, and there is a 24-hour palliative care clinical helpline which was activated during COVID-19. The weekly multidisciplinary team meetings were considered an opportunity for mutual education as patient cases are discussed. Still, dedicated palliative care meetings are lacking due to time constraints. The service providers acknowledged that awareness of the up-to-date available care services and their scope is problematic because services keep changing, especially with COVID-19. Nevertheless, the heart failure team are familiar with a few key services and some visit the nearby hospice to learn and see what they provide.

Concerning the next two points, the service providers thought that copies of care plan discussions could be shared directly with the patients and kept in their homes if they would like to do that. When asked about the frequency of NAT:PD-HF completion, they thought it would be unfeasible and too frequent to complete NAT:PD-HF monthly as not all patients have monthly clinics and some would be stable or in the early stages of heart failure. They favoured completion at baseline, with a change in patient condition (functional status), and six months after the baseline, although stable patients might have been discharged by then. Conversely, patients with an unstable, progressive disease may have the tool completed regularly as they will have more frequent clinic visits.

In response to the last two points, the service providers confirmed that responsiveness to care needs is enhanced by dedicated helpline numbers for patients run by the heart failure team. Those known to the nearby hospice can use their helpline number, out-of-hours service, and Hospice at Home. These numbers will be printed on stickers which will be attached to the patients' heart failure booklets (see **section-7.1.3.1**). Regarding staff consistency, the service providers believed that it would be realistic to make the intervention part of what is expected of new staff and part of their training, culture, and routine practice, despite the increased staff turnover with COVID-19. They wanted the intervention to be structured and standardised for all team members.

7.1.4 Discussing the feasibility study protocol

In the final follow-up meeting, the key service providers were introduced to the concept of a *feasibility study* and the importance of conducting it before the definitive trial. A preliminary draft of a feasibility study protocol prepared in advance was then discussed including a suggested study design, settings, sample, recruitment, data collection, intervention duration, intervention activities and preceding training, study outcomes, and outcome measures (**Table-30**). The service providers were asked to provide their feedback and suggest modifications where needed.

Table-30: Feasibility study items suggested to service providers

Items	Suggestions to service providers
Study design	Parallel cluster-randomised controlled trial.
Study settings	Hospital heart failure and cardiology outpatient clinics.
Target study sample	• New patients. • Patients with symptoms despite optimal therapy. • Patients who score a specific value in IPOS patient version. • Patients who meet the SPICT criteria for palliative care needs.
Recruitment of participants	By research nurses.
Data collection	Mostly by research nurses, except for NAT:PD-HF data.
Intervention duration	Six months per patient.

Intervention activities and preceding training	- Training staff on using NAT:PD-HF. - Signposting staff to palliative care training courses. - Signposting staff to patient education resources. - Completing NAT:PD-HF in clinics. - Acting on primary palliative care needs. - Writing a NAT:PD-HF summary in clinic letter and storing it in medical records. - Sharing the clinic letter with other staff. - Monthly group meetings to share experiences of using NAT:PD-HF in practice.
Study outcomes and outcome measures	- Hospitalisations (primary outcome). - Hospital service use. - Patient symptom burden, measured by ESAS-r[372]. - Patient illness perception, measured by Brief IPQ[373,374]. - Family carer burden, measured by HF-CQ[375,376].
Timepoints for collecting outcome measures	Baseline, 6 weeks, 12 weeks, and 24 weeks.

ESAS-r: Revised Edmonton Symptom Assessment System, HF-CQ: Heart Failure Caregiver Questionnaire, IPQ: Illness Perception Questionnaire.

7.1.4.1 Feasibility trial design

Following the MRC framework's recommendation of using a study design that is best suited to answer the research question[114], a parallel, two-arm cluster-randomised controlled trial design was suggested to the service providers for evaluating the intervention[377]. In this design, clusters (heart failure and cardiology units) would be randomised into intervention and control groups, rather than individuals being randomised to decrease the risk of contamination in the control group (**Figure-14**). The service providers had a few concerns about the parallel cluster design as not all patients would get the intervention. They thought it would be difficult to explain to patients in the control group that there is an intervention aiming to address patients' palliative care needs that will not be delivered in their centre, which could ultimately result in poor recruitment as patients may not accept allocation to the control group.

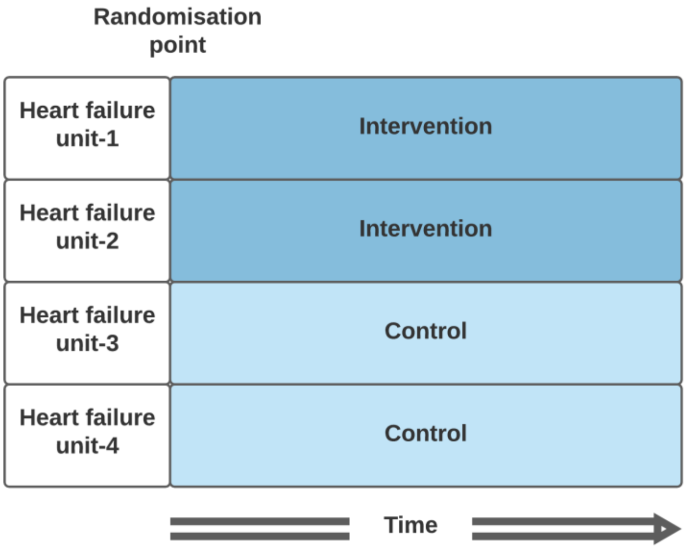


Figure-14: Parallel cluster-randomised controlled trial design, adapted from Hemming et al. 2015[378]

After the follow-up meetings with the service providers, other trial designs were sought where all randomised patients will eventually receive the intervention. One discussed design was the stepped-wedge cluster-randomised controlled trial[378,379]. This would include the transition of the participating heart failure and cardiology units sequentially and randomly from control to intervention groups until all units are exposed (**Figure-15**). This design was dismissed as it is more complicated, time-consuming, and has more risk of bias than parallel cluster-randomised trials which may threaten the strength of the generated evidence[114,380]. One source of bias could result from exposing more clusters to the intervention towards the end of the study than in its early stages, leading to confusion about whether an apparent intervention effect is a result of natural changes over time[380]. Another bias could arise from exposing each cluster to both control and intervention conditions, which might lead to within-cluster contamination and misestimation of the intervention effect. Ethical concerns could also arise as patients allocated to receive the intervention towards the end of the study (Heart failure unit-4 in **Figure-15**) may not be alive at this time.

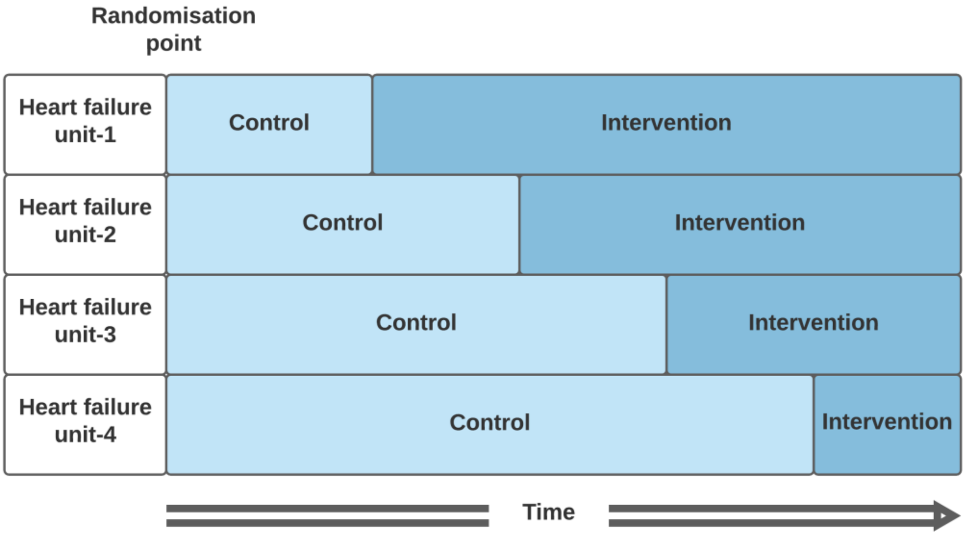


Figure-15: Stepped-wedge cluster-randomised controlled trial design, adapted from Hemming et al. 2015[378]

Given the limitations of the stepped-wedge cluster design, another design was proposed: the fast-track randomised controlled trial[381]. This comprises two periods: in the first period, individuals are randomised into intervention and control groups just like the conventional randomised controlled trial, while in the second period, the control group also receive the intervention (**Figure-16**). This design has the rigour of a traditional randomised trial as it randomly allocates participants into the study arms and thus reduces selection bias[381,382]. It is often more ethical and acceptable to patients, families, and healthcare professionals as all patients will eventually receive the intervention, leading to improved trial recruitment and retention. Because only half of the patients will receive the intervention in the first period (fast-track group), this would decrease the burden on the heart failure team. In the subsequent period when the other half also receive the intervention (standard group), the heart failure team will have gained more skills for completing NAT:PD-HF from the initial period, and thus they would be more prepared to complete the tool with more patients. These advantages were thought to outweigh the risk of contamination that may arise from delivering the intervention and standard care by the same healthcare provider. This trial design was approved by the key service providers. It was agreed that the optimal duration for the first period is 12 weeks; after which the control group receive the intervention (see **section-8.3.5.1**).

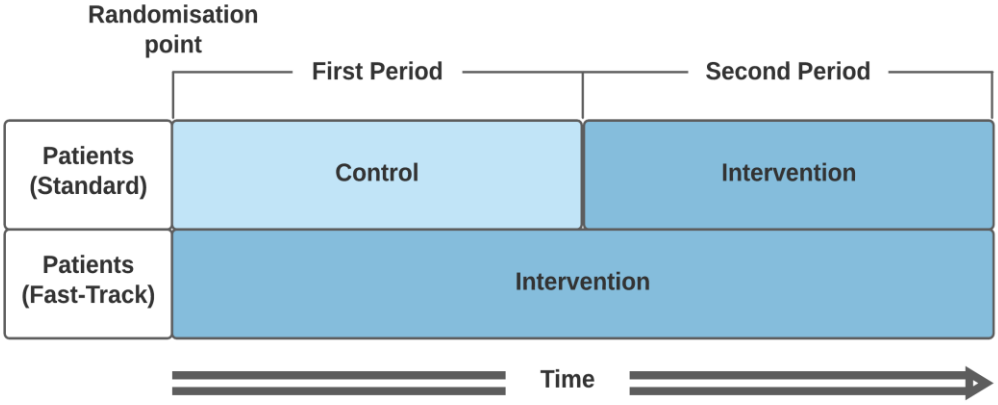


Figure-16: Fast-track randomised controlled trial design, adapted from Higginson and Booth 2011[381]

7.1.4.2 Target study sample

The type of patients for whom the intervention should be delivered was highly debated (see **section-7.1.3.3**). The service providers were advised that their previous suggestion of randomly selecting a few patients from each clinic to participate in the study could mean that the intervention is already not feasible to be implemented in their daily practice. Four alternative options were presented to them for discussion: including only new patients, including patients with persistent symptoms despite optimal medical therapy, including patients who score a specific value in IPOS patient version (to be administered by research nurses for patients to complete before the clinic in the waiting room), or including patients who meet the SPICT criteria for palliative care needs (see **Table-5**). The first two options were disregarded. Selecting new patients was considered problematic as the heart failure team do not see them frequently in their clinics and they were unsure if they can answer NAT:PD-HF questions and meet the patients' palliative care needs when they do not understand their condition and its trajectory. Conversely, selecting those with symptoms despite medical therapy was considered too late, vague, and subjective.

The service providers were hesitant with the last two options as they wanted to deliver the intervention to patients before they score highly on IPOS or meet SPICT criteria.

Instead, they reconfirmed that the NAT:PD-HF intervention should *ideally* become part of everyday life and apply to all outpatients with heart failure to encourage better relationships, communication, and support for everybody. However, they were aware that this would be unfeasible. After the follow-up meetings, the issue of the target study sample was further investigated. Ultimately, the service providers suggested including patients two weeks after their hospital discharge as they are committed to a specialist review of all admissions in their clinics at this time (a national mandate)[103]. This is similar to an earlier suggestion made in the Theory of Change workshops to include patients seven days or more after their hospital *admission*, although this was dismissed as patients may still be in an acute condition (see **section-5.3.3**). The new suggestion of including patients two weeks after their hospital discharge seemed the best solution given the available resources. The intervention will not be delivered to all patients visiting the clinics, which would decrease the staff burden. The intervention will not be provided too early when patients may not be ready to discuss palliative care, nor too late when they may have little time to live.

7.1.4.3 Recruitment method, data collection, intervention duration, and intervention activities

To decrease the burden on heart failure teams delivering the intervention, it was suggested to the service providers to include research nurses for recruiting patients and family carers and collecting most of the study data. This suggestion was welcomed. The service providers also agreed with the suggested duration of the intervention (six months per patient) considering that NAT:PD-HF will be completed at least twice in this period for most patients (baseline, change in patient condition, and six months after the baseline), which would enable tracking the changes in their palliative care needs over time. A longer intervention period was not favoured as most patients would be discharged from the heart failure service or died, and because outcomes need to be quick in palliative care interventions. The list of the required intervention activities and preceding training was revisited with the service providers. For instance, it was suggested to them to conduct the monthly NAT:PD-HF group meetings, which aim to discuss using the tool in practice, for the first two months of the intervention instead of the whole intervention period to decrease the burden on heart failure teams. This was endorsed by the service providers.

7.1.4.4 Study outcomes and outcome measures

The final discussion with the service providers was about the outcomes and outcome measures for the full definitive trial. Although the outcomes of the intervention were discussed in detail in the Theory of Change workshops, there was no agreement about which outcomes are the most important to measure in a randomised controlled trial and which outcome measures should be used. Informed by the preliminary Theory of Change, specific outcomes were suggested to the service providers alongside outcome measures and timepoints for collection. These outcomes were related to hospitalisations (primary outcome), hospital service use, patient symptom burden, patient illness perception, and family carer burden. The service providers agreed, as they found the outcomes relevant and the resource use data would be available to collect through shared patient records. They were also willing to assess the longitudinal change in the *level of concern* of the palliative care needs identified by NAT:PD-HF and acted upon (none, some/potential, significant). This would capture their sense of the value of the intervention and motivate them to complete NAT:PD-HF to see if their actions will have an effect. After discussing the outcomes for the full trial, the outcomes for the feasibility study were then discussed to agree on a priori criteria thresholds for measuring success in achieving these outcomes, for example, what is considered acceptable for NAT:PD-HF completion rate (see **section-8.3.6.2**).

7.2 Consultation with service users

7.2.1 Participants in the PPI group consultation

Two of three invited PPI heart failure group members from the James Lind Alliance provided feedback on the planned intervention. The James Lind Alliance is a non-profit-making initiative, partly funded by the National Institute for Health Research (NIHR), which ensures that people most affected by a condition are involved in prioritising research[110]. One participant was an older female with lived experience of heart failure and a family carer, while the other was a younger male who considered himself in a stable condition. Both participated on previous PPI group consultations and had some research experience which influenced their responses about the proposed intervention activities and study design. For example, they were aware of some palliative care barriers, value of palliative care conversations and family involvement, and importance of randomisation in clinical trials (see below). Although it could be argued that their responses are likely to be representative of other patients with heart failure in the James Lind Alliance, they could be different from the responses of a less experienced PPI group. A more diverse group (for instance, involving people with different educational backgrounds and research experiences) could have added more insight and variable perspectives but this was difficult with the COVID-19 pandemic situation. Further PPI group consultation is planned in the future feasibility study (see **Chapter-8**).

7.2.2 Discussing intervention activities

The PPI group agreed with the suggested intervention activities and thought that it would be ideal if all these activities work smoothly. However, they were aware of certain barriers, equivalent to some preconditions and assumptions identified in the intervention's Theory of Change, such as the poor communication between clinicians which could impede the integration of medical care with psychological and social care. The group talked about the public misperception of what palliative care is, as most people confuse it with end-of-life care; an issue that would be addressed in the intervention as heart failure teams signpost patients to relevant educational resources. The group also supposed that some palliative care conversations may need to be conducted separately for patients and family carers as their relationship may be complicated or they may prefer to say something privately. The PPI group were reassured that such conversations would be individualised in the intervention as everybody has unique needs and experiences. The group welcomed the idea of targeting family carers in the intervention as they may be severely ill or exhausted by the burden of caregiving and need more support than the patients themselves.

7.2.3 Discussing study design, participant documentation, and target sample

The group agreed with the proposed fast-track study design, as all patients would ultimately receive the intervention. They were aware that randomisation is necessary to have a control group to compare the intervention with. They agreed that 12 weeks, the timepoint at which the control group receive the intervention, is appropriate and not too long as patients are likely to be alive at this point. The group advised against the use of the terms “palliative care” and “advanced heart failure” when discussing the study with patients and in the study participant documentation, as people have different perceptions of what these terms mean. As clinicians do not use these terms commonly with patients, the group believed that researchers should not be the first to introduce such potentially distressing terms, but rather they should use the language used by the clinicians.

When asked about the target study sample, whether they would prefer including all patients visiting the heart failure and cardiology outpatient clinics or those with more advanced disease (recently admitted), one patient who considered his heart failure as stable and medically managed thought he would be a bad choice for the study and would not benefit from palliative care. However, the group believed that palliative care should not be offered too late to patients, at the very end of life, as they emphasised the importance of providing palliative care concurrently with standard care. Including recently admitted patients seemed a reasonable option, not too early when illness is stable, nor too late when the patient is dying.

7.2.4 Discussing study outcome measures

The group found all the study outcome measures appropriate, easy to complete, and important for research. It took them up to four minutes to complete the Revised Edmonton Symptom Assessment System (ESAS-r), four to seven minutes to complete the Brief Illness Perception Questionnaire (IPQ), and seven to eight minutes to complete the Heart Failure Caregiver Questionnaire (HF-CQ). Although they thought that some questions in HF-CQ may be difficult for some family carers to answer as it touches on sensitive and emotional issues, such as the feeling of guilt for the time spent on caregiving, they believed that this is still a very important questionnaire given the perceived importance of family carers in the intervention. The group advised to inform study participants about the importance of the outcome measures and introduce them in a way that reassures people to complete them. When asked about the order they would like to complete the patient outcome measures, both wanted to complete the ESAS-r first, as it addresses patient symptoms and would empower patients to be more reflective and prepared to discuss illness perception issues covered by the Brief IPQ.

The group favoured completing the outcome measures by themselves when they have a clinic. They wanted the researchers to give them the questionnaires by hand, leave them alone to complete except where they request help or support, and then collect back the questionnaires. If that is not possible, they do not mind completing the outcome measures on the phone, especially as during the COVID-19 pandemic they got used to having medical appointments and completing questionnaires on the phone. They advised that skilled researchers are needed who should be sensitive while reading out the questions to people on the phone and able to offer support if needed; a role which will be fulfilled by trained research nurses in the future study. Posting by mail was suggested to the group but they had concerns about the low response rate as many people may not post back the sent questionnaires.

7.3 Modifications to the preliminary intervention

After the follow-up meetings with the key service providers and PPI group consultation, the preliminary intervention developed after the Theory of Change workshops was refined. The modifications to the intervention are summarised in **Table-31**.

Table-31: Modifications to the preliminary intervention after the follow-up meetings with service providers and consultation with service users

Criteria	Preliminary intervention	Refined intervention
Intervention activities	Nine intervention and training activities (see **Table-19**).	Five intervention activities required by heart failure team staff, preceded by three training activities provided in one training session (see **Table-32** below).
Education materials for patients and family carers	Undetermined.	Two British Heart Foundation booklets and an associated website; stickers of the local health services and helpline numbers will be attached to the booklets.
Focus of patient education	Heart failure as a progressive disease.	More general (for example, heart failure, available care services, who to call if condition deteriorates, palliative care); refer patients to existing educational resources.
Team's willingness for advance care planning	Reluctance; favouring discussing the management plan instead.	More willingness; aided by NAT:PD-HF.
Staff responsible for palliative care conversations	Mostly not the heart failure team.	Mostly the heart failure team; referring patients for exceptional, complex conversations.
Open versus individualised conversations	Debated.	Individualised; looking actively for patient triggers.
NAT:PD-HF completion frequency	Monthly or with a change in patient condition (functional status).	Baseline, after six months, and with a change in patient condition (functional status).
NAT:PD-HF group meetings	Monthly throughout the intervention period.	Monthly in the first two months of the intervention.
Study design to evaluate the intervention	Undetermined.	Multi-centre, fast-track randomised controlled trial.

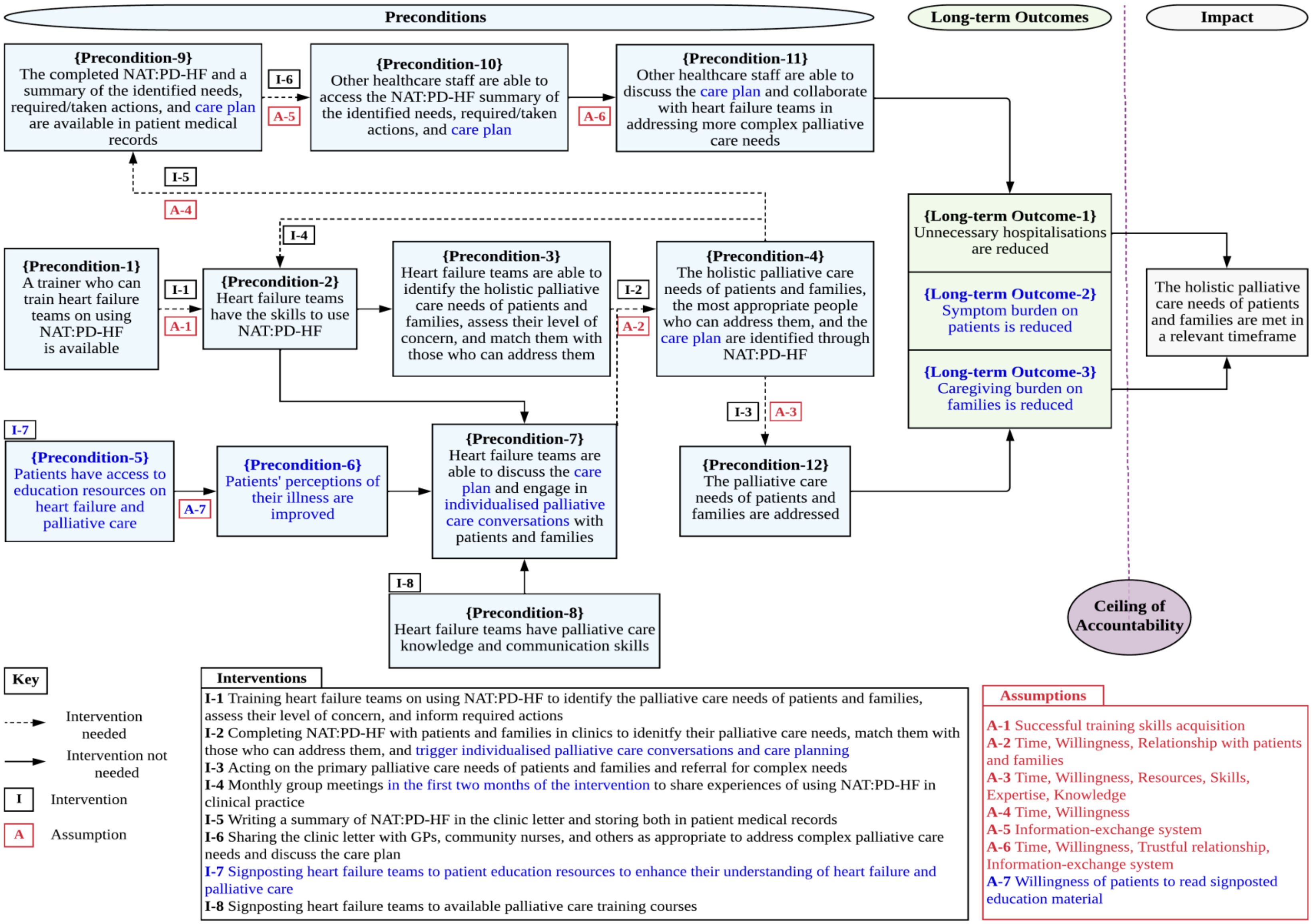
Criteria	Preliminary intervention	Refined intervention
Study settings where the intervention is delivered	Hospital heart failure and cardiology outpatient clinics; possibly community clinics and patient homes (undecided if community heart failure nurse specialists will be involved).	Hospital and community heart failure and cardiology outpatient clinics; all heart failure team members will be involved.
Target patient sample	All patients with heart failure attending the heart failure and cardiology outpatient clinics.	Patients with heart failure referred to the heart failure and cardiology outpatient clinics for a specialist review two weeks after hospital discharge.
Intervention duration	Undetermined; a few months per patient.	Six months per patient or until patient death, whichever is earlier.
Study outcomes to measure success of the intervention	Twelve preconditions and three long-term outcomes (see **Figure-11**); undetermined outcome measures (or indicators in the Theory of Change terminology).	Two preconditions and two long-term outcomes were modified (see **Figure-17** below); outcome measures determined for specific key outcomes related to hospitalisations, hospital service use, patient symptom burden, patient illness perception, family carer burden, and the level of concern of the palliative care needs identified by NAT:PD-HF.

7.4 Refined Theory of Change

After the follow-up meetings with the key service providers and PPI group consultation, the preliminary Theory of Change developed after the group workshops was refined (see **Figure-11** for the preliminary version and **Figure-17** below for the refined version). Irrelevant long-term outcomes and preconditions and redundant interventions were discarded and replaced where appropriate, while the intervention impact, underlying assumptions and rationales, and hypothetical causal pathway of change stayed almost the same. The main modifications to the preliminary Theory of Change included:

- **Long-term outcome-1** (patients and families feel satisfied) in the preliminary Theory of Change map was discarded as it was deemed difficult to change through the intervention because it may depend on subjective patients' expectations.
- **Long-term outcome-2** (primary palliative care needs are addressed) was moved back on the map as a precondition.
- Two key measurable long-term outcomes of the intervention were added: (symptom burden on patients is reduced) and (caregiving burden on families is reduced).
- **Precondition-12** (shared decision making) was deleted as it would be covered in **Precondition-7** (discussing the care plan).
- **Intervention-7** (communicating and collaborating with other staff) was deleted as it would be covered in and triggered by **Intervention-6** (sharing the NAT:PD-HF summary).
- **Intervention-8** (educating patients and families on heart failure) was considered part of standard care rather than a novel activity. Thus, it was replaced with a new intervention activity (signposting heart failure teams to patient education resources on heart failure and palliative care) which would enhance patient perceptions of their illness.

The refined Theory of Change map is displayed in **Figure-17**, showing the intervention's impact, long-term outcomes, preconditions, activities, assumptions, and hypothetical pathway of change. Changes from the preliminary Theory of Change map are written in blue colour. The refined version is subject to further refinements based on the feasibility study findings.



Interventions

I-1 Training heart failure teams on using NAT:PD-HF to identify the palliative care needs of patients and families, assess their level of concern, and inform required actions
I-2 Completing NAT:PD-HF with patients and families in clinics to idenitfy their palliative care needs, match them with those who can address them, and trigger individualised palliative care conversations and care planning
I-3 Acting on the primary palliative care needs of patients and families and referral for complex needs
I-4 Monthly group meetings in the first two months of the intervention to share experiences of using NAT:PD-HF in clinical practice
I-5 Writing a summary of NAT:PD-HF in the clinic letter and storing both in patient medical records
I-6 Sharing the clinic letter with GPs, community nurses, and others as appropriate to address complex palliative care needs and discuss the care plan
I-7 Signposting heart failure teams to patient education resources to enhance their understanding of heart failure and palliative care
I-8 Signposting heart failure teams to available palliative care training courses

Assumptions

A-1 Successful training skills acquisition
A-2 Time, Willingness, Relationship with patients and families
A-3 Time, Willingness, Resources, Skills, Expertise, Knowledge
A-4 Time, Willingness
A-5 Information-exchange system
A-6 Time, Willingness, Trustful relationship, Information-exchange system
A-7 Willingness of patients to read signposted education material

Figure-17: Refined Theory of Change map (changes written in blue colour)

7.5 Describing the refined intervention

The preliminary intervention developed after the Theory of Change workshops was refined after the follow-up meetings and PPI group consultation. A systematic description of the refined intervention according to the TIDieR checklist is presented in **Table-32** below. As with the underlying Theory of Change, the refined intervention is subject to further refinements based on the feasibility study findings.

Table-32: Systematic description of the refined intervention according to the TIDieR checklist, adapted from Hoffmann et al. 2014[118]

Item	Description
Name	A theory-based, complex palliative care intervention for patients with heart failure and their family carers.
Who?	The intervention will be provided by hospital and community multidisciplinary heart failure teams.
What 'procedures'? How?	**Training session for the heart failure teams:** • Training heart failure teams on using NAT:PD-HF to identify the palliative care needs of patients and families, assess their level of concern, and inform required actions in a one-hour, in-person or online interactive group training session per each study centre. • Signposting heart failure teams to available palliative care training courses at the end of the session. • Signposting heart failure teams to patient education resources on heart failure and palliative care at the end of the session.
	Intervention activities required by the heart failure teams: • Completing NAT:PD-HF with patients and families in clinics at baseline, after six months, and with change in patient functional condition to identify their palliative care needs, match them with those who can address them, and trigger individualised palliative care conversations and care planning. • Acting on the primary palliative care needs of patients and families based on clinical expertise and referral for more complex needs. • Writing a summary of the identified needs, required actions, and care plan for each completed NAT:PD-HF in the clinic letter, and storing NAT:PD-HF and the clinic letter in patient medical records. • Sharing the clinic letter with GPs, community nurses, and others as appropriate using available information-exchange systems to address complex palliative care needs and discuss the care plan. • Monthly one-hour in-person or online interactive group meetings in the first two months of the intervention to share experiences of using NAT:PD-HF in clinical practice.

Why?	• The intervention was developed in response to the poor and late access of patients with heart failure to palliative care and the lack of guidance on how to integrate palliative care into standard heart failure care. • The overall goal (impact) of the intervention is to meet the holistic palliative care needs of patients and families in a relevant timeframe. • The rationales for the intervention components were outlined in **Table-19**.
What 'materials'?	• Training material on using NAT:PD-HF for heart failure teams (see **Table-20**). • List of available palliative care training courses for heart failure teams. • Patient education resources (two British Heart Foundation booklets, an associated website, and a list of local healthcare services) to enhance their understanding of heart failure and palliative care. • NAT:PD-HF to identify the palliative care needs of patients and families, assess their level of concern, match the needs with those who can address them, and trigger palliative care conversations and care planning. • Clinic letters to record a summary of NAT:PD-HF. • Information-exchange systems to share the NAT:PD-HF summary, refer patients and families to healthcare services, and communicate with other staff. • Other materials as required to act on the primary palliative care needs of patients and families, such as medications and information sheets.
Where?	The intervention will be delivered in hospital and community heart failure and cardiology outpatient clinics in the UK.
When? **How much?**	• The intervention will be provided to patients with heart failure referred to the heart failure and cardiology outpatient clinics for a specialist review two weeks after hospital discharge. • In the first study period, the intervention will be delivered only to patients in the fast-track group; at a later point of time (12 weeks), it will also be delivered to patients in the standard control group. • The intervention will be delivered over six months per patient or until patient death, whichever is earlier.
Tailoring	To meet the individual needs of heart failure teams in different settings and enhance the intervention feasibility and implementation, flexibility and tailoring of the intervention would be allowed without compromising its core components; for example, the teams could use any suitable information-exchange system to share the NAT:PD-HF summary with other staff, but they should not use a different needs-assessment tool.
How well?	The plan for assessing the intervention adherence and fidelity is explained in **Chapter-8**.

7.6 Chapter summary

In this chapter, the findings of the follow-up meetings with service providers and consultation with service users, both of which aimed to refine the intervention and underpinning Theory of Change, were outlined. In the follow-up meetings, participants endorsed the use of NAT:PD-HF for the intervention and were more willing to conduct individualised advance care planning conversations. However, they found it difficult to assign a care coordinator for patients and conduct dedicated multidisciplinary palliative care meetings. A fast-track design was agreed upon for the planned feasibility study, where half patients receive the intervention immediately following randomisation while the other half receive it after 12 weeks. The PPI group endorsed the intervention activities and feasibility study protocol. The refined intervention differs from the preliminary version regarding the focus of patient education, willingness for advance care planning and palliative care conversations, and frequency of NAT:PD-HF completion and group meetings. It will be provided over six months by hospital and community heart failure teams to patients referred to the heart failure and cardiology outpatient clinics for a specialist review two weeks after hospital discharge. The refined Theory of Change differs from the preliminary version regarding certain long-term outcomes, preconditions, and intervention activities, while the other theory components stayed almost the same. In the next chapter, a protocol for a future planned study is presented to evaluate the feasibility of the refined intervention and fast-track design before testing them in a full definitive trial.

8 Developing a feasibility study protocol

In the previous three chapters, findings were outlined from the Theory of Change workshops, secondary qualitative data analysis, follow-up meetings, and PPI group consultation, through which a complex palliative care intervention was developed and refined for patients with heart failure and their family carers. This chapter presents a protocol for a multi-centre, fast-track randomised controlled feasibility trial with embedded process evaluation to evaluate the feasibility of the intervention before a full definitive trial. The protocol is reported using the Consolidated Standards of Reporting Trials (CONSORT) 2010 Statement: Extension to Randomised Pilot and Feasibility Trials where applicable to enhance transparency, replication, and reporting quality[383].

8.1 Background

Randomised controlled trials are recommended by the MRC framework as the gold standard for evaluating complex interventions, including palliative care interventions, to provide the evidence base to underpin clinical practice[114,384]. Nonetheless, palliative care trials are difficult to conduct because of multiple practical and ethical difficulties with recruitment, randomisation, retention, and outcome measurement[122,207,385]. These obstacles are mainly related to the complex and multi-component nature of interventions, multiple domains and sensitive nature of palliative care, and involvement of patients with short or unpredictable prognosis[207,232,236,386]. Given these difficulties, a feasibility study is needed to identify and overcome barriers to conducting the definitive trial, assess and enhance the potential for successful implementation of the proposed intervention, and reduce research waste resulting from failed expensive trials[387-389].

A *feasibility study* is a study conducted before the main trial to explore whether and how it can be done[390,391]. Testing the feasibility of the developed intervention and evaluation design before conducting a definitive full-scale evaluation is advocated by the MRC framework, MORECare statement, and Bleijenberg et al.'s guidance to address the main uncertainties and assumptions identified in the development stage and refine the intervention accordingly[114,119,122,228]. Given the paucity of research on NAT:PD-HF interventions, a feasibility study is needed to establish the best way of delivering this complex intervention.

This feasibility study will have an embedded process evaluation element, as advocated by the MRC framework, to assess the feasibility of and experiences with the intervention, explain the differences between anticipated and observed outcomes, understand the effect of context on outcomes and implementation, and evaluate the fidelity and quality of implementation[114,226,228]. Fidelity in this context refers to the delivery of the intervention as intended; process evaluation enables distinguishing between permissible adaptations made to fit the intervention into different contexts, and prohibited changes of the core intervention components that compromise its fidelity. Process evaluation will inform why the intervention works and how it can be improved, or why the intervention fails or has unexpected consequences (poor design or poor implementation)[114,226,392]. It will aid in understanding the hypothetical causal mechanisms of the intervention in practice (how it works and causes change) and the interactions among the inputs and outcome measures, to better explain the complex pathways and identify unexpected mechanisms.

The feasibility study and embedded process evaluation will be informed by Normalisation Process Theory and the Theory of Change approach. Both theories informed the development of the intervention and are widely used as theoretical frameworks for feasibility studies and process evaluations of complex healthcare interventions[124,256]. For this feasibility study, Normalisation Process Theory will explain the mechanisms of implementation processes, success or failure of the intervention, and observed outcomes. The intervention's Theory of Change will inform questions to address the identified assumptions and knowledge gaps about how the intervention will work in practice, which would help to identify unanticipated outcomes and side effects of the intervention, test its hypothetical causal pathways, identify and strengthen weak links in the causal pathways, and identify possible breakdowns such as inappropriate context, barriers to intervention delivery, implementation failure, or theory failure[117,123,124]. Ultimately, the evaluation results from the feasibility study will help in validating and further refining the Theory of Change and intervention to enhance implementation.

8.2 Aim and objectives

The study aims to evaluate the feasibility and acceptability of the intervention, study design, study procedures, and evaluation methods to refine the intervention and underlying Theory of Change and inform a full definitive trial.

8.2.1 Primary objectives

Evaluating the:

- Feasibility, acceptability, and safety of the intervention activities and materials.
- Adherence and fidelity to the intervention protocol.
- Feasibility and acceptability of a multi-centre, fast-track randomised controlled trial.
- Appropriateness of patients' eligibility criteria.
- Feasibility and acceptability of patients' recruitment procedure and materials.
- Acceptability of self-reported outcome measures and assessment timepoints.
- Feasibility of collecting hospital service use data.

8.2.2 Secondary objectives

- Identifying the palliative care needs of patients and family carers and actions taken by healthcare professionals to address the identified needs.
- Providing preliminary evidence of the intervention effect on trial outcomes.

8.3 Methods

8.3.1 Trial design

8.3.1.1 Fast-track randomised controlled trial

A feasibility study, comprising a multi-centre, fast-track randomised controlled trial with embedded process evaluation will be conducted (see **section-7.1.4.1)**. Conducting the study in multiple centres would enable testing the intervention in other sites with similar contexts to the site where it was initially developed, enhance the generalisability of study findings, and explore any differences in the intervention delivery between the study sites. With the fast-track design, patients with heart failure will initially be randomised into intervention (fast-track) and control groups. During this period, the developed palliative care intervention in the fast-track group will be compared with the standard care in the control group. After 12 weeks of study entry, those in the control group will crossover to the intervention group so that all study participants would receive the intervention.

Although sometimes called a “wait-list” design, the term “fast-track” design is preferred because patients are not denied access to the intervention, but are either randomised to receive the intervention faster than they would normally (fast-track group) or receive it after a waiting period during which they receive the best standard care (control group)[382]. Randomised fast-track trials were used successfully and proved acceptable and feasible in palliative care interventions for patients with cancer, multiple sclerosis, and COPD[393-398]. This design has been suggested for use within the MRC framework for patients who are not at the end of life, similar to this study population, to ensure that study participants in the control group are likely to be alive to receive the intervention after a short wait period[393,399]. Nevertheless, this design was not used before in a palliative care intervention specifically for patients with heart failure.

8.3.1.2 Intervention and standard care

Patients allocated to the control group will receive standard care before crossing over to the intervention group. While in the standard control group, patients will attend their regularly scheduled outpatient clinics and receive care from the heart failure teams as usual. They will be asked to provide demographic information and complete data collection questionnaires at specific timepoints (see **section-8.3.5.1**), but will not be assessed using NAT:PD-HF until they crossover to the intervention group.

The intervention was described in detail according to the TIDieR checklist in **section-5.3** (preliminary intervention) and **section-7.5** (refined intervention). The intervention will be integrated with and complement the standard heart failure care, rather than duplicate or replace it. It will be based on NAT:PD-HF to identify patient and family carer palliative care needs, inform actions to meet the identified needs, trigger palliative care conversations, and encourage communication between healthcare staff. This will be preceded by training staff on NAT:PD-HF and signposting them to palliative care training courses and patient education resources. An illustration of the intervention activities and timepoints of data collection within the feasibility fast-track randomised trial design is demonstrated in **Figure-18**.

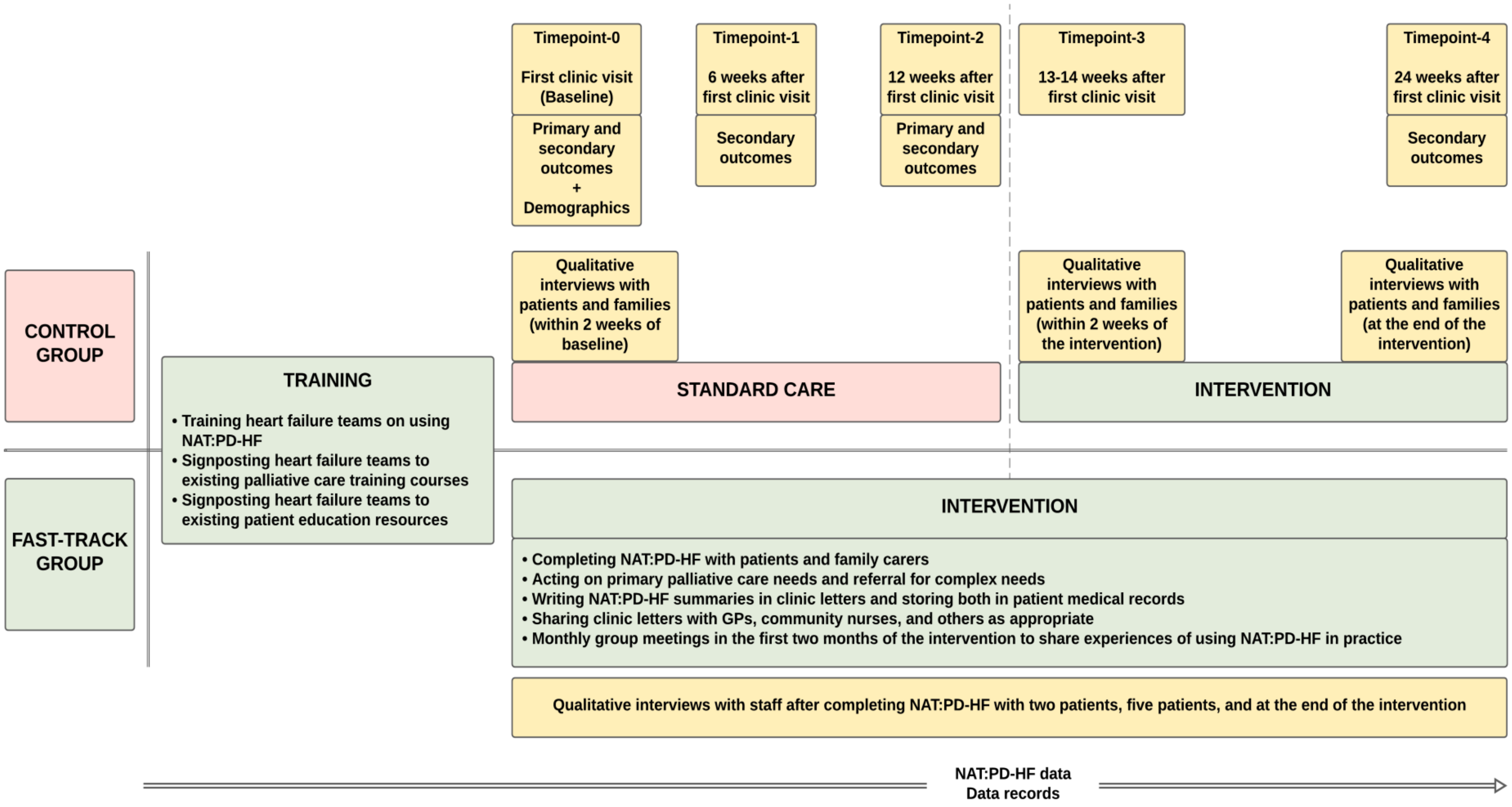


Figure-18: Fast-track randomised feasibility trial design

8.3.1.3 Mixed-methods approach

A mixed-methods approach will be used in the feasibility study and embedded process evaluation, based on recommendations from the MRC framework and MORECare statement[114,122,226,228,235]. Quantitative data will be collected and qualitative interviews will be conducted with heart failure teams' staff, patients, and family carers to assess their experiences with the intervention and evaluation methods. Mixed methods are embraced by and most frequently associated with pragmatism; the adopted paradigm for this research[214,215,223]. Combining and integrating quantitative and qualitative methods is valuable in the development and evaluation of complex palliative care interventions[238]. For this study, mixed methods will enable answering the diverse feasibility study objectives, enhance the validity of the findings, and provide a deeper and broader understanding of the research problem including how the intervention works and will be delivered in practice[221,226,238,400].

A *parallel mixed design* will be adopted, where quantitative and qualitative data collection and analysis occur simultaneously or with some time-lapse to answer related aspects of the same research question (**Figure-19**)[401,402]. Ultimately, the inferences from the findings of each strand (quantitative and qualitative) are integrated to form a meta-inference or general conclusion. Although typically the analysis of one strand is conducted independently from the other, the two strands can *cross-talk* during the analysis, which means that the findings from the quantitative data analysis could inform the qualitative data analysis, and vice versa[402]. This design would enable comparing and contrasting the conclusions from each strand to develop a more comprehensive understanding of the research question[400,401]. It would also enable the qualitative interviews with patients, family carers, and staff to take place as close to NAT:PD-HF completion as possible to help them recall their experiences.

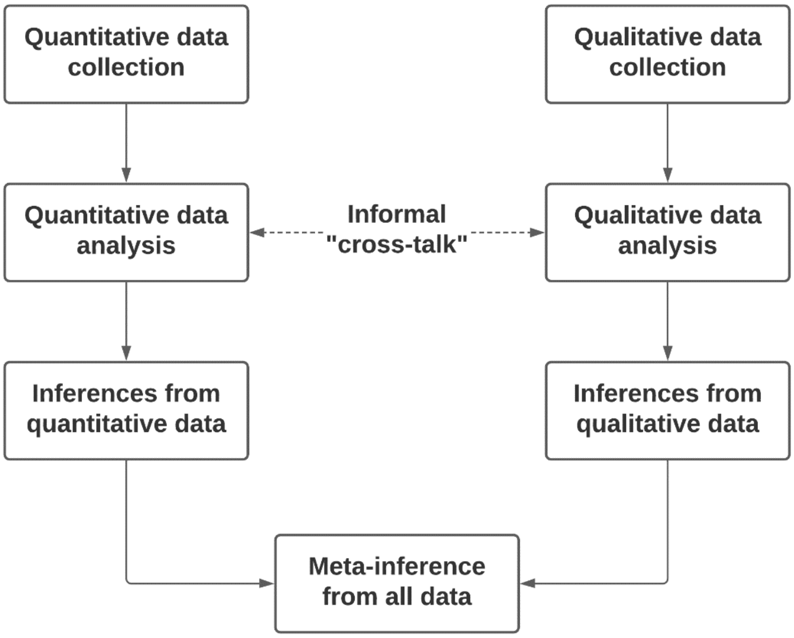


Figure-19: Parallel mixed design, adapted from Teddlie and Tashakkori 2009[401,402]

8.3.2 Study population

The intervention will be provided by multidisciplinary heart failure teams in hospital and community heart failure and cardiology outpatient clinics in the UK. Identifying patients with heart failure who would most benefit from palliative care interventions is difficult[207]. Therefore, patients' eligibility criteria were made relatively broad, clear, and applicable to the population group and clinical settings to enhance the representativeness of the study sample to the target population, ensure a high proportion of screened patients meets the eligibility criteria, and improve recruitment of those who may benefit most from the intervention and are difficult to reach[383,384,403].

8.3.2.1 Eligibility criteria for patients

- Adults ≥18 years.
- Heart failure diagnosis according to the hospital criteria.
- Scheduled for a specialist review by a multidisciplinary heart failure team member at hospital or community heart failure or cardiology outpatient clinics two weeks after hospital discharge.

- Fluent in English.
- Sufficient cognitive capacity and willingness to consent and interact with staff and researchers based on the clinical judgement of a heart failure team member.

Patients involved in another palliative care research study and those receiving hospice or specialist palliative care services will be excluded.

8.3.2.2 Eligibility criteria for family carers

- Identified by a consenting patient as a family or non-family member who provides informal, unpaid care.
- Adults ≥18 years.
- Fluent in English.
- Able and willing to consent and interact with staff and researchers.

Family carers involved in another palliative care research study will be excluded.

8.3.2.3 Eligibility criteria for heart failure teams' staff for the qualitative interviews

- Healthcare professionals from a hospital or community multidisciplinary heart failure team.
- Working in heart failure or cardiology outpatient clinics.

8.3.3 Sample size

There is no guidance on the minimum number of patients required to answer the feasibility objectives of a palliative care needs-assessment intervention. The sample size in similar palliative care randomised feasibility trials ranged from 30 to 50 patients with heart failure recruited from one or two medical centres[404-406]. Considering a 25% drop-out rate in line with other palliative care studies[407], this feasibility study will randomise 60 patients on a 1:1 basis for participation in three sites within 12 to 18 months of an enrolment period. The feasibility study will also inform the sample size calculation for the main trial from the effect size of the primary outcome (hospitalisations)[389,408] (**Appendix-8**).

8.3.4 Recruitment and randomisation

8.3.4.1 Expected barriers and steps to mitigate them

Recruitment, randomisation, and consenting are challenging in randomised trials, including those evaluating palliative care interventions, with less than half of trials achieving their recruitment targets[232,384,409]. Recruitment to this study could be affected by several factors, including patients' inability to participate or consent because of health deterioration, patients' perception that the offered intervention is palliative and for end of life, general perceptions that research is burdensome and unnecessary, patients' unawareness of their heart failure diagnosis and prognosis, increased workload of staff and lack of time to recruit patients, and gatekeeping role of clinicians and families in recruiting patients with palliative care needs based on assumptions that they are too vulnerable to participate in research[122,207,230,232,233,235]. Randomisation issues could arise as staff and patients in the control group may not be happy to wait for their turn to receive the intervention in the randomised fast-track design, despite the relatively short waiting period[381].

Steps to enhance recruitment of study participants and mitigate clinicians' gatekeeping had already been taken through working with stakeholders throughout all stages of the intervention development and involving them in designing the feasibility study protocol[207,384]. The PPI group consultation provided important insights to enhance recruitment as they provided feedback on the proposed intervention, agreed with the suggested feasibility study design and patients' inclusion criteria, and advised on avoiding the use of potentially distressing terms in study participant documentation. Adopting a randomised fast-track design, where all patients would ultimately receive the intervention, and targeting post-discharge patients for whom a specialist review is nationally mandated are expected to significantly improve recruitment[381]. Other steps to aid recruitment would include developing short participant information sheets to reduce the burden of consenting, informing study participants about the possible research benefits, assigning dedicated on-site research nurses to help in identifying and recruiting eligible patients, emphasising to clinicians that the intervention and trial were designed to be sensitive to patients' needs, and advising that it could be unethical not to offer patients and families the opportunity to participate in research[122,233,384].

8.3.4.2 Recruitment of study participants

The flow chart of the recruitment and follow-up process is shown in **Figure-20**. Recruitment will start with in-person or online meetings with leaders of heart failure teams from NHS hospital trusts to discuss the study and assess their capacity to deliver the intervention, with the aim of recruiting three centres. Sixty patients, and their family carers if available, will be recruited from these centres over a 12 to 18-month period. This was based on stakeholders' conservative estimates that each week eight hospitalised patients with heart failure will have a specialist review at the hospital or community outpatient clinics two weeks after hospital discharge. Patients scheduled for this review will be identified and recruited by research nurses before their discharge. If patients were discharged before being approached, the research nurses will contact them over the telephone. Research nurses will discuss the study with eligible patients, and patient-identified family carers if present, and provide them with a study pack (patient and family carer participant information sheets, invitations to participate, and consent forms). If the family carer was not present, permission will be asked from the patient to contact their relative about the study.

In the scheduled patient visit to the clinic two weeks after hospital discharge, research nurses will obtain signed consents from interested patients and family carers, collect baseline demographics and outcome measures, and obtain their contact details to complete follow-up outcome measures and qualitative interviews by phone or online if necessary. Consenting participants will then be randomised by an independent clinical trials unit using a simple computer-generated random number sequence to either the intervention (fast-track) or control group on a 1:1 allocation ratio. Blinding the staff and study participants to the allocation status is not possible due to the nature of the multi-component complex intervention and its delivery[385]. Study participants will be followed up for 24 weeks after baseline data collection or until patient death, whichever is earlier.

A sample of the heart failure team staff delivering the intervention from each participating centre will be asked to participate in qualitative semi-structured interviews to assess their experiences with the intervention and evaluation methods. Those interested will be provided with a study pack (staff participant information sheet, invitation to participate, and consent form) at least one day before the interviews and asked for their contact details to conduct the interviews by phone or online if necessary. Signed consent forms will be obtained from staff on the interview day or online before the interview.

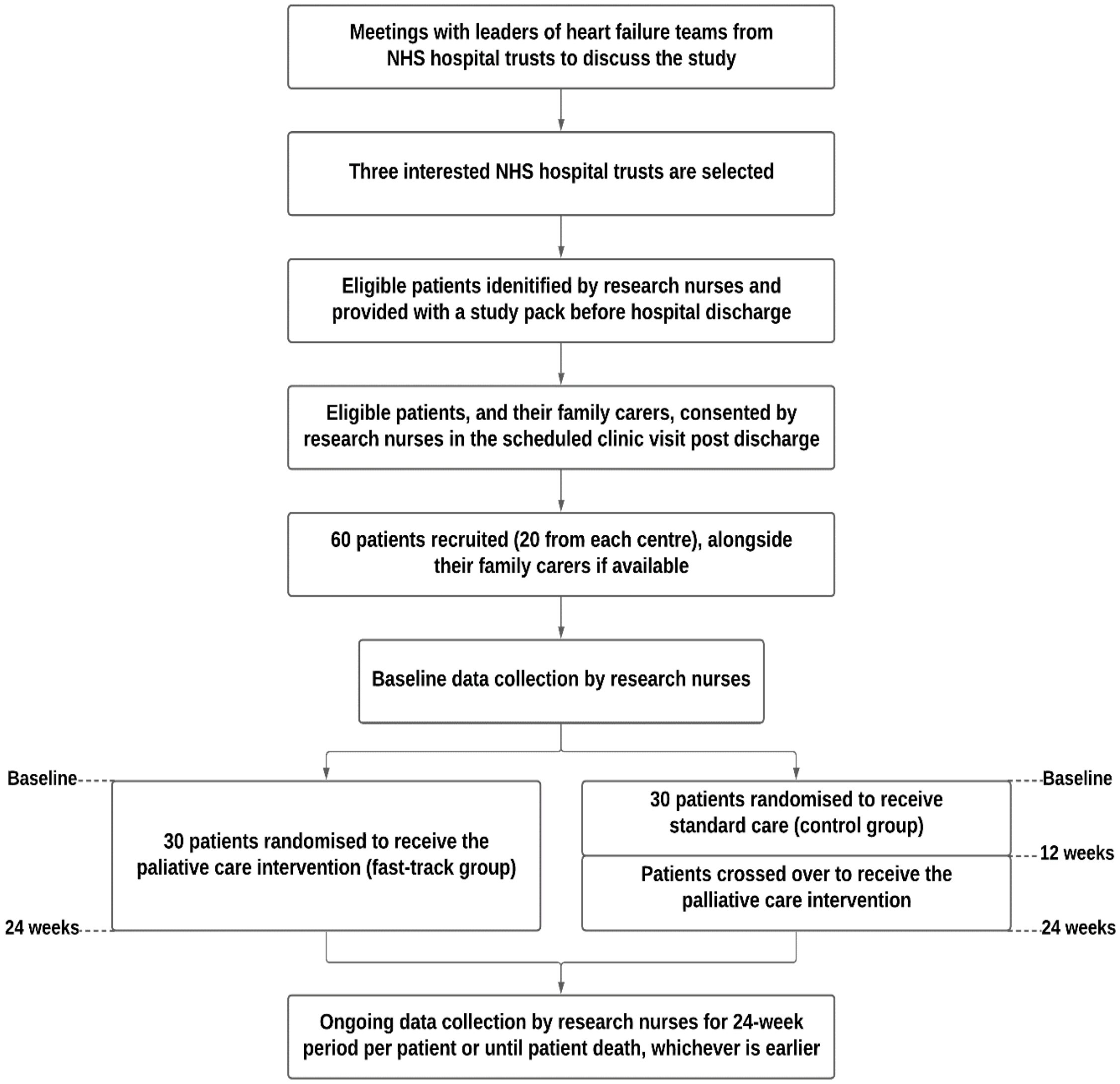


Figure-20: Flow chart of recruitment and follow-up process for the feasibility study

8.3.5 Data collection

Data will be collected for 24 weeks per patient or until patient death, whichever is earlier, using a mix of quantitative and qualitative methods. If a patient dies during the study period, the family carer will be contacted in a sensitive manner, not too close to the death, to offer consolation and ask if they would like to continue the study. All family carers will be informed about this in the participant information sheet provided during recruitment. A summary of the quantitative and qualitative data to be collected and timepoints for data collection are shown in **Table-33** and **Table-34**, respectively. Patients' qualitative data will only be collected from those in the control group.

Table-33: Quantitative data to be collected in the feasibility study

Data for collection	**Tool**	**Data collection timepoints**				**Respondent**			**Who collects data**		
		Baseline	6 weeks	<12 weeks*	24 weeks						
Demographics	Data records	✓				Patient	Family		Research nurses		
Full trial outcomes											
Hospitalisations (primary outcome)	Data records	✓#		✓					Research nurses		
Hospital service use	Data records			✓					Research nurses		
Symptom burden	ESAS-r	✓	✓	✓	✓	Patient			Research nurses		
Illness perception	Brief IPQ	✓	✓	✓	✓	Patient			Research nurses		
Caregiving burden	HF-CQ	✓	✓	✓	✓		Family		Research nurses		
Severity of palliative care needs	NAT:PD-HF	Throughout the study period						Staff			Staff
Other feasibility data (for instance, completion rate of data collection tools, missing data, patients' study flow)	NAT:PD-HF, Data records	Throughout the study period							Research nurses	Main researcher	Staff

* Timepoint at which the control group crossover to the intervention group; the trial outcomes will be collected from the control group just *before* they receive the intervention to enable comparison with the intervention group.
# Within a six-month period before baseline.

Table-34: Qualitative data to be collected in the feasibility study

Data for collection	**Tool**	**Data collection timepoints**			**Respondent**			**Who collects data**
		Baseline	>12 weeks*	24 weeks				
Experiences with the intervention and trial design								
Patient and family experiences	Qualitative interviews	✓	✓	✓	Patient#	Family#		Main researcher
Staff experiences	Qualitative interviews	After completing NAT:PD-HF with 2 and 5 patients		✓			Staff	Main researcher

* Timepoint at which the control group crossover to the intervention group; the qualitative interviews will be conducted with participants from the control group just *after* they receive the intervention (within two weeks) to assess their experiences.

Control group only.

8.3.5.1 Outcomes and outcome measures for the full trial

Outcome measures will be collected in the feasibility study to evaluate their completion rate and acceptability, provide an estimate of the required sample size for the full trial, and provide preliminary evidence of the intervention effect on the trial outcomes. Most study outcomes will be collected and measured by research nurses to decrease the burden on staff delivering the intervention. Among these, patient and family-reported outcome measures will be collected in person on the day of the patients' clinic visit or by phone if not possible. Using a telephone to collect PROMs is acceptable to patients with heart failure as it could minimise burden and missing data[371].

The outcomes for the full trial were informed by the refined Theory of Change underpinning the intervention. While there are multiple outcomes postulated in the refined theory, only those deemed to be key outcomes will be measured to decrease the burden on patients and family carers and minimise attrition and missing data[235]. Most outcomes will be measured using patient and family-reported outcome measures as they are the gold standard in evaluating palliative care services[236]. The outcome measures were selected considering the MORECare guidance on the selection and use of outcome measures in palliative care research, including their psychometric properties in patients with heart failure or their family carers; length, complexity, burden of completion, and ease of interpretation; potential to capture the multidimensional components of palliative care; and ease of integration into clinical practice[122,236]. The outcomes and outcome measures were discussed with the stakeholders in the workshops, follow-up meetings, and PPI group consultation and have been widely used in similar palliative care interventions which will allow for comparisons[55,59-63].

- **Primary outcome:**
    - All-cause hospitalisations within 12 weeks of study entry: This was informed by one of the long-term outcomes suggested in the refined Theory of Change (Unnecessary hospitalisations are reduced). Hospitalisation is a common consequence of heart failure and is associated with a high cost burden to the healthcare system[20,42].

- **Secondary outcomes:**
  - Hospital service use: This includes hospital length of stay, intensive care unit admissions, and emergency department visits within 12 weeks of study entry. Medical resource use is the most widely reported outcome in palliative care interventions for patients with heart failure, where a reduction was associated with a significant decrease in the overall cost of care[59].

  - Patient symptom burden, measured by ESAS-r: Heart failure causes a range of symptoms in patients[33]. ESAS is a generic validated PROM that is appropriate for use in patients with heart failure[410]. The revised version (ESAS-r) was found easy to follow and understand in patients with advanced heart failure[371]. ESAS-r asks patients to rate the severity of their symptoms *now* and is more user friendly[372]. It assesses nine physical and non-physical symptoms on a scale of 0 (no symptom) to 10 (worst possible severity), with an optional tenth symptom, giving a total possible score of 0-100.

  - Patient perception of heart failure, measured by Brief IPQ: Patients' perception of their illness affects the way they react to and cope with it, and is associated with their wellbeing and disease outcomes[373,374,411]. The Brief IPQ is a short, easy to interpret, generic, and widely used PROM that demonstrated good psychometric properties in different populations including those with heart failure[373,374,411,412]. It is a 9-item sale that measures nine dimensions of patients' cognitive and emotional perceptions of their illness: effect on life, timeline, personal control, treatment control, symptoms, concern, understanding, emotional effect, and causes. The first eight items are answered on a scale from 0 (weakest perception) to 10 (strongest perception), while the ninth item (causes) can be answered by choosing one answer (the main cause) from seven categories[374].

  - Family carer burden, measured by HF-CQ version 5.0: Family carer burden results from the physical, emotional, and financial challenges of providing care to patients with heart failure[44]. HF-CQ is a valid and reliable, heart failure-specific, self-reported outcome measure that assesses the physical wellbeing, emotional wellbeing, and lifestyle of family carers of patients with heart failure during the past four weeks[375,376]. It contains 21 items answered on a severity response scale ranging from 0 (not at all) to 4 (a lot). The score for each domain (physical, emotional, and lifestyle) is the sum of scores for its items divided by their total possible score and multiplied by 100, giving a possible domain score of 0-100. The total score is the mean of the sum of the three-domain scores.

- Severity of patient and family carer palliative care needs, identified by NAT:PD-HF: Although not developed as an outcome measure[164], NAT:PD-HF copies will be collected to assess the longitudinal change in the severity (level of concern) of the palliative care needs of patients and family carers as suggested by the service providers in the third follow-up meeting (see **section-7.1.4.4**). This will only be applicable to study participants who complete NAT:PD-HF more than once.

- **Timepoints of collecting trial outcomes:**

Secondary outcomes will be collected at specific timepoints: baseline, six weeks, 12 weeks (just immediately *before* the control group receive the intervention), and 24 weeks. These timepoints were selected to minimise the burden on patients and family carers, enable early recording to reduce attrition, enable short and long-term detection of the intervention effect, account for symptom fluctuation in heart failure, and provide long-term safety data[122,207,236,381]. The selected timepoints were agreed upon by the service providers in the third follow-up meeting.

The primary outcome will be collected at baseline and 12 weeks, just before the control group receive the intervention. This would be the primary point of analysis; the intervention must have made the expected difference by that time and the study will be powered at this point[381]. It is expected that a 12-week period is long enough for the intervention to have an effect in the fast-track intervention group to enable comparison with the control group, but not too long for patients in the control group to receive the intervention before death or deterioration. Patients are expected to be alive for 24 weeks from the point of recruitment, which corresponds to the whole intervention duration. The same *wait* period (12 weeks) was chosen in a palliative care intervention for patients with multiple sclerosis who were not at the end of life which is similar to this study population[393].

8.3.5.2 Other quantitative data collection tools

Data from NAT:PD-HF will serve to assess the tool completion rate and missing items to evaluate its acceptability. Clinic letters will be assessed by research nurses to see how many times a summary of NAT:PD-HF was written for patients. Data records will be collected throughout the trial to record the flow of patients from initial identification to final analysis, hospital service use data, reasons for missing data from NAT:PD-HF and outcome measures, time taken to complete NAT:PD-HF and outcome measures, and numbers of staff attending NAT:PD-HF group meetings. Data records will also include baseline demographic information of patients and family carers. Patient demographics would include age, gender, ethnicity, marital status, educational level, employment status, NYHA class, ACCF/AHA stage, heart failure type, ejection fraction, heart failure duration, heart failure medications, presence of a device therapy or heart transplant, and comorbidities. Family carer demographics would include age, gender, ethnicity, marital status, educational level, employment status, and relation to the patient.

8.3.5.3 Qualitative interviews

Patients, family carers, and staff members of heart failure teams will be interviewed to assess their experiences with the intervention and study design. The interviews will be conducted in person (in the study sites), by phone, or online depending on COVID-19 restrictions and participant preference. Although virtual interviews can be less accessible to some people, disrupted by technical issues, and impede observing participant emotions and visual cues and establishing rapport, they can still be empowering for participants as they feel in control while being interviewed in the comfort of their homes, and more convenient for those with limited mobility[413]. The interviews will be scheduled to last for about one hour, recorded, transcribed, and anonymised. Field notes will be taken to provide contextual information and capture aspects of non-verbal communication[414]. Interview topic guides will be developed including open-ended questions and probes to help guide the conversations.

- **Patient and family carer qualitative interviews:**

Qualitative semi-structured interviews will only be conducted with patients in the control group during the control and intervention periods. This will enable assessing and comparing their experiences with both the standard care (first period) and the intervention (second period). Two patients with different NYHA classes and two family carers will be purposively sampled from each of the three study sites to participate in three longitudinal interviews which would capture a range of experiences (**Table-35**). The first interview will be conducted within two weeks of study entry (the first clinic visit post-discharge), to assess participant expectations of the prospective care. The second interview will be conducted within two weeks of being delivered the intervention (13-14 weeks after the first clinic visit), to assess their experiences with the received standard care and short-term experiences with the intervention. The third interview will be conducted after 12 weeks of being delivered the intervention (24 weeks after the first clinic visit; at the end of the intervention period), to assess their long-term experiences with the intervention. Patient and family carer experiences with the trial design, recruitment process, and completing outcome measures will also be evaluated in the interviews. To minimise interviewing burden on patients and families, interview schedules will be made flexible to accommodate their needs and preferences.

Bereavement interviews will be conducted with family carers of patients who die during the study period if they agree to continue in the study. The interviews will start with building rapport, offering condolences, and informing the family carers of their right to stop the interview if they experience discomfort or distress. The aim of these interviews is to get insight in the bereaved family carers' and patients' problems and needs in the dying phase, their experiences with care provision and bereavement support, and how the NAT:PD-HF-based intervention facilitated or impeded care provision. One item in the *caregiver wellbeing* section of NAT:PD-HF asks if the family carer experiences grief over the impending or recent death of the patient that is interfering with their wellbeing or functioning. Bereaved family carers will be asked if and how the professional caregiver asked this question, how they addressed their grief, and whether this met their expectations. Questions about family carer experiences with the study design and procedures could be asked at the end of the interview if the family carer does not show any sign of discomfort or distress. If such signs become evident at any time during the interview, a distress protocol will be followed[415]. The interview will end by thanking the family carer and offering condolences again.

- **Staff qualitative interviews:**

Heart failure team members from diverse professions who are deemed to have the knowledge, experience, and willingness to provide rich information will be purposively sampled to participate in qualitative semi-structured interviews. Two staff members from each of the three study sites will be recruited to participate in three longitudinal interviews which would capture a range of experiences (**Table-35**). Staff will be interviewed after completing NAT:PD-HF for two patients and then after completing NAT:PD-HF for five patients to assess their experiences of using the tool. They will also be interviewed at the end of the intervention period (24 weeks) to look back at changes in practice and assess their experiences with the whole intervention and perceptions of the trial design, eligibility criteria, recruitment methods, and outcome measures. Demographic data will be collected at the beginning of the interviews including age, gender, place of work, profession, and years in the profession.

Table-35: Number of patients with heart failure, family carers, and heart failure team members planned to be interviewed in the feasibility study

	Number of interviewees	**Number of interviews**
Patients	6 (2 from each site)	18 (3 per patient)
Family carers	6 (2 from each site)	18 (3 per family carer)
Heart failure team members	6 (2 from each site)	18 (3 per team member)
Total	18	54

8.3.6 Data analysis

An outline of the feasibility study outcomes and data collection and analysis methods used to address each study objective is shown in **Table-36**.

Table-36: Feasibility study outcomes and methods of data collection and analysis

Feasibility study objectives	Feasibility study outcomes	Data collection methods	Data analysis methods
Primary objectives			
Evaluating the feasibility, acceptability, and safety of the intervention activities and materials*	Experiences with the intervention (contextual conditions, duration, burden, cost, and unexpected positive and adverse events), suggestions for improvement.	Interviews with staff, patients, and families	Qualitative + Quantitative
	NAT:PD-HF completion rate, time taken to complete, who among staff completed NAT:PD-HF, missing items, reasons for missing data.	Data records, NAT:PD-HF	
Evaluating the adherence and fidelity to the intervention protocol*	Experiences with delivering the intervention as intended, challenges in intervention implementation, reasons for protocol deviations.	Interviews with staff	Qualitative + Quantitative
	NAT:PD-HF completion rate, NAT:PD-HF summary inclusion rate in clinic letters, NAT:PD-HF group meetings attendance rate.	Data records, NAT:PD-HF	
Evaluating the feasibility and acceptability of a multi-centre, fast-track randomised controlled trial	Experiences with and willingness to randomisation, risk of contamination in the control group, acceptability of the crossover timepoint in the control group.	Interviews with staff, patients, and families	Qualitative + Quantitative
	Similarity between patients randomised to the intervention and control groups concerning demographics and baseline outcome measures.	Data records, Outcome measures	
Evaluating the appropriateness of patients' eligibility criteria	Perceptions of patients' eligibility criteria (broad or narrow).	Interviews with staff	Qualitative + Quantitative
	Patient retention rate, reasons for attrition.	Data records	
Evaluating the feasibility and acceptability of patients' recruitment procedure and materials	Experiences with recruitment process (method and materials), consent procedure, recruitment barriers, and willingness to recruit patients.	Interviews with staff, patients, and families	Qualitative + Quantitative
	Patient recruitment (consent) rate, number of recruited (consented) patients, reasons for refusal to participate, recruitment duration.	Data records	

Feasibility study objectives	Feasibility study outcomes	Data collection methods	Data analysis methods
Evaluating the acceptability of self-reported outcome measures and assessment timepoints	Experiences with completing self-reported outcome measures (appropriateness, practicality, burden, timing, frequency, and administration).	Interviews with staff, patients, and families	Qualitative + Quantitative
	Outcome measures’ completion rate, time taken to complete, missing items, reasons for missing data, outcome measures’ completion within the scheduled timeframe.	Data records, Outcome measures	
Evaluating the feasibility of collecting hospital service use data	Hospital service use data completion rate.	Data records	Quantitative
Secondary objectives			
Identifying the palliative care needs of patients and family carers and actions taken by healthcare professionals	Palliative care needs (patient wellbeing, caregiver ability to care for patient, caregiver wellbeing).	NAT:PD-HF	Quantitative
	Actions taken (directly managed, managed by other care team member, referral required).		
Providing preliminary evidence of the intervention effect on trial outcomes	Differences in study outcomes between the control and fast-track groups.	Outcome measures	Quantitative
	Longitudinal changes of study outcomes in the control and fast-track groups.	Outcome measures, NAT:PD-HF	

* Process evaluation elements.

8.3.6.1 Analytic framework

Normalisation Process Theory will provide an analytic framework for the trial parameters[250]. **Table-37** below shows how the Normalisation Process Theory constructs were used as a sensitising device to form questions about implementation processes, highlight potential problems with recruitment and data collection, and optimise trial design and study feasibility by considering the evaluation context and the impact of trial procedures on the work of all those affected by the trial: staff, patients, and family carers[250,256].

Table-37: Use of Normalisation Process Theory constructs in optimising trial parameters, adapted from Murray et al. 2010[250]

Questions	Comments
Coherence: Will the trial make sense and appear relevant to the heart failure teams, patients, and family carers?	
Is the trial easy to describe?	The trial will be described, and aims clarified, to the participating heart failure teams in the three study sites. Research nurses will discuss the study with patients and family carers and provide them with study information documents.
Is it clearly distinct from other studies?	The intervention to be tested in the trial comprises eight distinct intervention activities as identified in the Theory of Change map. It will be based on NAT:PD-HF; a tool that is not currently used in the prospective study sites.
Does it have a clear purpose for all relevant participants? **Do participants have a shared sense of its purpose?**	Heart failure teams, patients, and family carers will be informed that the study aims to explore whether providing a palliative care intervention is feasible for staff and acceptable to patients and family carers. This will be discussed with patients and family carers during recruitment and detailed in the study packs.
What benefits will the trial bring and to whom? **Are these benefits likely to be valued by potential participants?**	The benefits that the trial may bring to the heart failure teams, patients, and family carers are discussed in **section-8.3.7.4**. These likely benefits will be explained to staff, patients, and family carers to minimise gatekeeping and aid recruitment.

Will the trial fit with the overall goals and activity of the heart failure teams?	The trial and intervention were co-designed with a heart failure team in response to their needs and considering the available resources to achieve an agreed goal. Participating heart failure teams from the other sites will be assessed if they share similar goals and expectations before delivering the intervention.
Cognitive participation: Can heart failure teams, patients, and family carers see the immediate and long-term benefits of the intervention?	
Are participants likely to think the trial is a good idea? Will they see the point of the trial easily?	The goals of the trial and potential benefits and risks of participation will be explained to the heart failure teams, as well as patients and family carers during recruitment and in the provided study packs.
Will they be prepared to invest time, energy and work in it?	As the goals and likely benefits of the trial and intervention are discussed with study participants, they would feel the value of participating in such a trial. Heart failure teams will have access to additional resources and services such as palliative care needs-assessment training and peer group learning which may enhance their willingness to participate and invest in the trial.
Collective action: Is the amount of work required by the heart failure teams manageable and minimally disruptive of their existing practice?	
How will trial procedures affect the work of participants? **Will they promote or impede their work?**	Several steps will be taken to decrease the burden of study participation and enhance commitment to the study. For example, heart failure teams will not be asked to collect demographic data, administer outcome measures, or recruit patients and family carers. This would allow them to focus on delivering the intervention rather than worrying about the study procedures. In turn, patients and family carers will be asked to complete short and simple outcome measures at distant timepoints which would also decrease the burden of research.
What effect will it have on consultations?	As NAT:PD-HF will be completed during patient consultations in clinics, concerns about increased time burden will be assessed, as well as potential benefits such as triggering conversations and care plan discussions.
Will participation in the trial require extensive training for staff involved?	Training will be kept to a minimum, including a one-hour training session on NAT:PD-HF and signposting the heart failure teams to existing palliative care training courses and patient education resources.

How compatible is the trial with existing work practices? **What impact will it have on division of labour, resources, power, and responsibility between different professional groups?**	The trial and intervention were co-designed with a heart failure team considering their current practice, context, and available resources. They reckon that the intervention activities could be integrated into their daily clinics and thus the trial would not disrupt existing work practices or relationships. Similar discussions will be conducted with participating heart failure teams from the other sites.
Reflexive monitoring: Do heart failure teams, patients, and family carers provide regular feedback about the trial and intervention?	
How are participants likely to perceive the trial once it's been ongoing for a while? **Is it likely to be perceived as advantageous?**	Experiences with the trial and intervention will be addressed in qualitative interviews with the heart failure teams, patients, and family carers at different periods. Patients and family carers will also be asked about their experiences with standard care, which would provide a useful comparison between the intervention and standard care.
Will it be clear what effects the study has had?	Preliminary evidence of the intervention effect on patient and family carer outcomes will be assessed in the trial. Heart failure team members, patients, and family carers will be asked to identify unexpected positive and adverse events for the tested intervention in the qualitative interviews.
Can participants contribute feedback about study procedures? **Can the study procedures be adapted or improved based on experience?**	Heart failure teams, patients, and family carers will be asked in the qualitative interviews for their experiences with the intervention activities and materials and perceptions of study design, eligibility criteria, recruitment process, outcome measures, and assessment timepoints to refine them for the definitive trial.

8.3.6.2 Quantitative data analysis

Quantitative data at baseline and follow-up for the intervention and control groups will be entered in the latest available version of SPSS and analysed using descriptive statistics. Entered data will be rechecked to identify errors in data entry. Continuous variables will be described using means and standard deviations if normally distributed, and medians and inter-quartile ranges if not. Categorical variables will be described using frequencies and percentages. For continuous variables, the preliminary intervention effect on trial outcomes will be measured by calculating the *mean difference* between the intervention and control groups, and the *change score* between baseline and follow-up readings. For categorical variables, the preliminary intervention effect on trial outcomes will be measured by calculating the *absolute risk reduction* which is the difference in event rate between the intervention and control groups. A priori criteria to measure success in achieving specific feasibility study outcomes, and subsequently to amend the study protocol if these criteria were not met, are shown in **Table-38**. These criteria were informed by similar palliative care feasibility trials and service provider discussions in the follow-up meetings[387,407].

Table-38: A priori thresholds for specific feasibility and acceptability criteria

Feasibility study outcomes	Definition	A priori criteria
NAT:PD-HF completion rate	Percentage of patients for whom NAT:PD-HF is completed.	80%
NAT:PD-HF summary inclusion rate in clinic letters	Patients for whom a NAT:PD-HF summary is written in the clinic letter among those for whom NAT:PD-HF is completed.	70%
NAT:PD-HF group meetings attendance rate	Staff attending NAT:PD-HF group meetings among those delivering the intervention.	60%
Outcome measures completion rate	Percentage of patients for whom outcome measures are completed (also applies to family carers).	50%
Hospital service use data completion rate	Percentage of patients for whom hospital service use data are collected.	70%
Patient recruitment (consent) rate	Consented patients among those approached.	50%
Number of recruited (consented) patients	Number of recruited patients from each of the three study sites.	20
Patient retention rate at 6, 12, and 24 weeks	Patients staying in the study (not withdrawn) among those who consented.	75%

As with other palliative care interventions, high rates of attrition (loss of patients from a study) and missing data (loss of part of patient's data) are expected because of patient burden, deterioration, or death[122,234,235]. Attrition and missing data could decrease the study sample size and power to detect a difference between study groups, introduce bias where differential rates of missing data exist between study groups, and compromise external validity as data from those with the highest symptom burden are missed, leading to censoring of poor outcomes[234,236,407]. However, attrition and missing data should not be seen as indicative of poor research design[122,234]. Indeed, they will confirm recruitment of the relevant population as participants are expected to have palliative care needs and a deteriorating condition, which may make it difficult for them to complete the study or outcome measures.

Attrition and missing data will be planned for in advance, monitored, reported, and classified to describe the reasons for missingness and inform the imputation method. Steps to reduce attrition and missing data will include measuring only the *key* outcomes of the intervention, using short outcome measures, collecting outcome measures on the phone if in-person contact was not possible, and early collection of outcome measures[122,234,416]. For attrition, the classification system developed by the MORECare group will be followed: attrition due to death, attrition due to illness, and attrition at random[234]. Missing quantitative data will be assumed *missing not at random*, unless proven otherwise, as the included patients may be too ill to complete the outcome measures, which is not a random event. Although there is no agreed method for handling missing data in clinical trials[417], a statistician will be consulted to help in exploring the pattern and cause of missing data and the best imputation method[234,416].

8.3.6.3 Qualitative data analysis

The assumptions identified in the Theory of Change (see **Figure-17**), which represent the uncertainties in the intervention, were used to inform questions and probes for the interview topic guides to assess the experiences of the heart failure teams, patients, and family carers with the intervention (**Table-39**). Other questions and probes were informed by the feasibility study objectives. Transcripts of the interviews will be analysed using Braun and Clarke's approach of reflexive thematic analysis[293,294] (see **section-3.7.2.5**); aided by the latest available version of NVivo. The analysis will be a combination of inductive coding which aims to develop themes from the participants' data and deductive coding in the light of the Theory of Change assumptions.

Table-39: Interview questions and probes informed by the refined Theory of Change to assess experiences with the intervention (staff interview example)

Questions	Probes
General: What do you think about the feasibility and safety of the intervention activities and materials? What could be improved?	Duration, burden, cost, unexpected outcomes.
How did you find the NAT:PD-HF training material? Do you think the NAT:PD-HF training session provided you with the necessary skills to use NAT:PD-HF correctly?	Duration of training, delivery method, content, comprehensiveness.
How did you find the signposted list of palliative care training courses? Do you think they increased your palliative care knowledge and communication skills with patients and family carers?	Relevance, usefulness, content, comprehensiveness, time.
How did you find the signposted patient education resources (British Heart Foundation booklets, an associated website, and a list of local healthcare services)? Do you think patients were willing to read the signposted material? Do you think the material enhanced patients' understanding of heart failure, palliative care, and who to call if their condition deteriorates?	Relevance, usefulness, content, comprehensiveness.
How did you find NAT:PD-HF as a tool for identifying the palliative care needs of patients and family carers, assessing their level of concern, and informing required actions? Do you think that using NAT:PD-HF triggered palliative care conversations and care planning? Were you able to complete NAT:PD-HF as part of regular, broad medical history taking in clinics at baseline, after six months, and with change in patient functional condition?	Ease of use, content, comprehensiveness, time, willingness, relationship with patients and families.
Were you able to act on the identified primary palliative care needs of patients and family carers? Do you think you had the required materials to act on these needs?	Time, willingness, resources, skills, expertise, knowledge.
Were you able to write summaries of NAT:PD-HF in clinic letters and store them in patient medical records? What do you think about using clinic letters for writing these summaries?	Practicality, time, willingness.
Were you able to share the NAT:PD-HF summaries in clinic letters with other healthcare staff?	Practicality, information-exchange systems.
Do you think that sharing the NAT:PD-HF summaries helped to discuss patients' care plans with other healthcare staff and facilitated collaboration to address the complex palliative care needs of patients and families?	Time, willingness, trustful relationships, information-exchange systems.
How did you find the monthly group meetings to share experiences of using NAT:PD-HF in practice? Do you think they enhanced your skills and confidence in using NAT:PD-HF?	Duration of meetings, frequency of meetings, usefulness, time.

8.3.7 Ethical considerations

The study will start after obtaining ethics approval from the NHS Research Ethics Committee and Health Research Authority. The procedure of obtaining voluntary and informed consent of prospective participants was discussed in **section-8.3.4**.

8.3.7.1 Research data management

The plans for research data management will comply with the EU General Data Protection Regulation and the UK Data Protection Act 2018[344]. In-person and telephone interviews will be audio-recorded on an encrypted digital voice recorder which will be stored securely before the immediate transfer of the data to a personal password-protected laptop and encryption. The audio data will be backed up in OneDrive and then deleted permanently from the voice recorder. If online interviews are conducted, they will be video-recorded on the same laptop and the same procedures will be followed. Transcripts will be anonymised, stored on the same laptop, encrypted, and backed up in OneDrive. Hard copies of outcome measures and data records will be collected from research nurses, and NAT:PD-HF copies will be collected from heart failure teams' staff. These will be stored in a locked place and anonymised before transferring them into the laptop, encrypting, and backing up in OneDrive. The hard copies will then be destroyed.

8.3.7.2 Confidentiality and anonymity

Confidentiality of study data will be maintained by conducting the interviews in a private room or via secure online software, transcribing the interviews by a professional transcription company with a confidentiality agreement, and storing identifiable data securely. If what is said in the interviews is considered to pose a possible risk to any participant, confidentiality will be broken, and a research staff member will be informed about this. The participant will be notified about this if deemed possible. Transcripts will be anonymised and patients' names will be redacted from the returned NAT:PD-HF copies. Anonymised direct quotations from the interviews may be used in study reports and publications.

8.3.7.3 Potential risks

The feasibility study is not expected to have a considerable risk of discomfort or danger to patients and family carers. Nonetheless, unexpected outcomes and possible side effects of the study and intervention will be monitored and recorded. Death, hospitalisation, and deterioration are expected for this study population during the study. However, these would probably be unrelated to the intervention and thus do not represent a serious adverse event in palliative care trials[418]. One potential risk from the study is participant distress from answering NAT:PD-HF questions or having palliative care conversations. Participants may get distressed from reading the study information material, although this would be mitigated by not including potentially distressing terms in the study packs. Participants may also experience distress and burden while completing the outcome measures, although this would be mitigated by using validated, brief, and easy-to-complete tools that have been tested in the same population (see **section-8.3.5.1**). Participants may get tired or distressed during the qualitative interviews as they talk about their disease and care needs, which would be mitigated through asking the interview questions sensitively, focusing the talk about the trial and intervention acceptability rather than sensitive topics or illness experiences, and assessing participant capacity to continue the interview regularly.

One potential risk, related to the fast-track study design, is providing suboptimal support for patients in the control group before they receive the intervention if the intervention is found effective. However, this risk is mitigated as there is insufficient evidence of the effectiveness of NAT:PD-HF interventions (see **section-2.3.6.4**). Besides, the waiting period for the control group before they receive the intervention (12 weeks) is relatively short for the study sample as they are not near the end of life and thus are likely to still benefit from the intervention. People in the UK are used to waiting for NHS services and may not feel disadvantaged by a short wait[394,419]. Lastly, NAT:PD-HF is currently not used routinely by staff for outpatients with heart failure, who would not get the potential benefit of the tool without conducting this study.

The study is not expected to cause significant harm to the heart failure teams delivering the intervention. Still, the intervention may cause pressure on the clinics given the limited time and resources. The qualitative interviews with staff may remind them of distressing events. Staff may also feel uncomfortable sharing their ideas in the interviews as they will be recorded and held in their workplace, which would be mitigated by reassuring them that the information they provide will remain anonymous. If participants (staff, family carers, or patients) experienced significant distress during the study, a distress protocol will be used with a debriefing sheet that includes sources of support[415]. Participants will be informed that they could withdraw from the study at any time without affecting their care or rights, although their contribution to the analysis could not be withdrawn.

The study is not expected to cause significant harm to the researchers. Researchers will be encouraged to use available local counselling services for support if needed, and not to include personal phone numbers or email addresses to contact potential participants. For the in-person qualitative interviews, the main researcher will follow the Lone Worker Policy recommended by Lancaster University as the researcher will travel to interview participants alone[420]. This includes informing colleagues on the location and time of the interviews, conducting the interviews during normal work hours at prespecified agreed times, leaving the interview if signs of possible aggression appear, and checking in and out with colleagues when the interview starts and ends, respectively.

8.3.7.4 Potential benefits

Participants will be informed that they may not get direct benefits from participation in the study. Nevertheless, the intervention could contribute to meeting the palliative care needs of patients and families (desired impact). Interviewing patients and family carers may have a therapeutic benefit as they would have the opportunity to talk about their concerns which they may not be able to discuss with their family or busy healthcare professionals[421]. Patients and family carers may feel that their views are important in improving clinical practice as they contribute to the research and reflect on the received care. The intervention could also improve the palliative care knowledge, communication, and needs-assessment skills of heart failure teams as they participate in the provided and signposted training courses. They may decide to continue using NAT:PD-HF in their practice as this intervention was originally developed in response to their needs to provide a palliative care needs-assessment service for their patients.

8.4 Chapter summary

In this chapter, a protocol for a future feasibility study was outlined. The aim is to evaluate the feasibility and acceptability of the intervention and evaluation methods to inform a full definitive trial. The feasibility study will comprise a multi-centre, fast-track randomised controlled trial with embedded process evaluation. Patients with heart failure scheduled for a specialist review at cardiology or heart failure outpatient clinics two weeks after hospital discharge will be approached. Sixty patients, and their family carers if available, will be recruited from three medical centres by research nurses. Patients will initially be randomised to intervention and control groups. After 12 weeks, those in the control group will crossover into the intervention group. Quantitative and qualitative data will be collected from patients, family carers, and heart failure teams over 24 weeks per patient, including demographic characteristics, outcome measures, NAT:PD-HF data, qualitative interview data, and others. Data analysis will be informed by Normalisation Process Theory. Quantitative data will be analysed using descriptive statistics, while qualitative interviews will be informed by the refined Theory of Change and analysed using reflexive thematic analysis. In the next chapter, the findings of this research are discussed in light of the wider literature.

9 Discussion

In this study, a theory-based, complex palliative care intervention for patients with heart failure and their family carers was developed and refined with stakeholders, and a feasibility study protocol was co-designed. In this chapter, the study findings are discussed and an argument is made in relation to the research objectives and literature. The chapter starts with a reminder of the study aim and objectives and how these were addressed. Next, an overview of the main study findings is provided and the intervention development stages are outlined. Later, the study findings are compared with the literature including the intervention development process, underpinning theories, methods of Theory of Change development and analysis, Theory of Change components, secondary qualitative data analysis findings, follow-up meetings, and PPI group consultation. Subsequently, the strengths and limitations of this research are highlighted and its contribution to knowledge is presented. The chapter ends with personal reflections.

9.1 Research aim and objectives

The study aimed to develop and refine a theory-based, complex palliative care intervention for patients with heart failure and their family carers. This was prompted by the poor access of patients with heart failure to palliative care[8], and the lack of guidance on how best to integrate palliative care into standard heart failure care[63,64]. The study objectives, and how and where they were addressed in the thesis, are outlined in **Table-40**.

Table-40: Study objectives and how they were addressed

Study objectives	How they were addressed	Thesis chapters
Identify the most appropriate palliative care needs-assessment and measurement tools for patients with heart failure	A systematic mixed-studies review was conducted and published in Heart Failure Reviews journal[125].	**Chapter-2**
Develop and refine a programme theory that underpins the intervention and illustrates the mechanism of integrating palliative into standard heart failure care	Theory of Change workshops with service providers to develop a preliminary programme theory.	**Chapter-5**
	Secondary qualitative data analysis to include the voice of service users.	**Chapter-6**
	Follow-up meetings with service providers and a PPI group consultation to refine the programme theory.	**Chapter-7**
Describe the complex intervention and its key components in detail	The intervention (preliminary and refined) was systematically described using the TIDieR checklist, and its key components were illustrated in the underpinning Theory of Change (preliminary and refined).	**Chapter-5** **Chapter-7**
Describe the systematic development and refinement process of the intervention	The intervention was developed and refined following the steps recommended by the MRC framework, MORECare statement, and Bleijenberg et al.'s guidance.	**Chapter-3** **Chapter-4**
Develop a feasibility study protocol to test the acceptability and feasibility of the developed intervention and underpinning theory and inform a full definitive trial	A feasibility study protocol was co-designed in follow-up meetings with service providers and consultation with service users.	**Chapter-7** **Chapter-8**

9.2 Overview of study findings

A complex palliative care intervention for patients with heart failure and their family carers in hospital and community outpatient clinics was co-developed with stakeholders using the MRC framework, MORECare statement, and Bleijenberg et al.'s guidance[112,114,119,122]. The intervention development was underpinned by Normalisation Process Theory, guided by a qualitative methodology, and carried out in multiple steps[246,247]. Firstly, a systematic review was conducted to identify the most appropriate palliative care needs-assessment and measurement tools in patients with heart failure. Six tools were identified and compared according to their content and context of use, development, psychometrics, and clinical applications in identifying patients with palliative care needs. Despite limited evidence, NAT:PD-HF, followed by IPOS, showed superiority over other tools. While working on the review, practitioner engagement meetings and shadowing activities with service providers were conducted as further preparatory work to provide background and contextual information for the next step in the intervention development: Theory of Change group workshops. In this step, a preliminary Theory of Change underpinning the intervention was developed with stakeholders to understand its mechanism of action.

The plan after the Theory of Change workshops was to test the feasibility of the preliminary intervention, but this was impossible due to COVID-19 restrictions. Therefore, a secondary analysis of qualitative data on the experiences of patients, family carers, and professional caregivers with integrated palliative care was conducted to strengthen the intervention and include the patient and family voice, which was missing in the workshops. Four themes were generated from the analysis: Impact of heart failure, Coping and support, Recognising palliative phase, and Coordination of care. These themes were discussed in follow-up meetings with key service providers to refine the preliminary intervention and Theory of Change, and during which a feasibility study protocol was co-designed. The refinements were mainly related to the intervention activities, outcomes, settings, and study sample. Feedback on the intervention and feasibility study protocol was provided by service users in a PPI group consultation. Throughout the whole intervention development and refinement process, regular supervisory team meetings and reviewing the relevant literature helped to develop and refine the intervention and underpinning theory.

An important output of this study is the development of a novel evidence-based theoretical framework for the intervention using the participatory Theory of Change approach to explain how it is expected to work in clinical practice. Through this approach, the individual intervention components were identified and described, the anticipated changes resulting from the intervention were outlined, and an explanation of how and why these changes can be achieved was provided. This is presented graphically in a Theory of Change map that demonstrates the hypothetical causal pathway through which the intervention components interact to achieve specific long-term outcomes. The rationales or assumptions (contextual conditions) for each link in the causal pathway were identified, together with indicators to measure if the long-term outcomes have been achieved. The intervention activities and multi-level preconditions which are necessary to achieve the long-term outcomes were also identified, alongside the ultimate impact that the intervention would contribute to achieving. Ultimately, the Theory of Change informed the feasibility study protocol as it proposed questions to address the identified assumptions about how the intervention will work in practice.

9.3 Comparing study findings with the literature

9.3.1 Intervention development process and underpinning theory

Table-41 shows a comparison of the development process and underpinning theory for this intervention compared with other palliative care interventions for patients with heart failure, which were retrieved from existing reviews and a scoping search[55,59-64,422]. This intervention was developed systematically using the MRC framework, and this study includes details on the development process and adopted theories, including their role throughout the research. Such details were absent or insufficiently reported in most other palliative care interventions for patients with heart failure, with few undergoing a systematic development. Among 27 retrieved studies, 16 did not report the intervention development process or adopted theory[65,165,168,405,423-434]. This limited description makes it difficult to assess the thoroughness of the intervention components, conceptual frameworks, and mechanisms of action[124]. Conversely, good description facilitates comparisons and replication and shows transparency[114,119,122]. Examples of systematic intervention development using the MRC framework and good intervention description were demonstrated by Kane et al. and Dionne-Odom et al.[132,162,435]. Kane et al. also followed the MORECare statement, similar to this study, to develop a palliative-specific IPOS-based intervention for patients with heart failure[371]. However, they did not follow Bleijenberg et al.'s guidance which would have added more steps to further enrich the development of their intervention, including identifying the problem, examining practice and context, determining stakeholders' needs, and intervention design[119].

Clinicians and patients were involved, though to different degrees, in co-designing this intervention. Conversely, stakeholder engagement was absent or minimal in most other palliative care interventions for patients with heart failure. Co-design is key to creating a patient-centric, relevant, ethical, acceptable, feasible, effective, and implementable intervention[232,233,241,243]. Examples of thorough stakeholder engagement in designing palliative care interventions in heart failure were demonstrated in three studies where patients, family carers, and clinicians were involved throughout all stages of research to provide feedback on the intervention (nature, content, rationale, feasibility, acceptability, materials, and mode of delivery) and trial (study design, procedures, patient eligibility criteria, outcomes, and outcome measures)[435-438]. Conversely, in Kane's study, although heart failure nurses, cardiologists, and a PPI group discussed patient inclusion criteria and study participant documentation, they were not involved in developing the intervention components nor were they involved throughout all stages of research[371]. In other studies, only clinicians were involved to develop the intervention materials without input from patient groups[439-441]. Including patients in co-designing health interventions is important to ensure that the proposed intervention is acceptable, ethical, and patient-centric[119,442].

For this study, Normalisation Process Theory was used as a middle-range theory to provide an overarching theoretical framework and consider implementation issues throughout all stages of the research. It informed the choice and application of a programme theory (Theory of Change) that underpinned the intervention development. Normalisation Process Theory and Theory of Change differ from other theories and models used to inform the development of other palliative care interventions for patients with heart failure. For example, Doorenbos et al.'s intervention was based on social science and behavioural theories[352]. Such *off-the-shelf* theories focus on psychological and behavioural processes and address superficial causes of the problem, with less emphasis on implementation processes and what work should be done to integrate interventions in practice; leading to simplistic, non-context specific, and less effective interventions[443,444]. Conversely, Normalisation Process Theory and Theory of Change are implementation and programme theories, respectively, that focus on how the intervention will work in practice and interact with its context[249,270]. Research shows promising evidence of the role of these theories to strengthen all stages of the MRC framework and create feasible and implementable interventions[123,250].

Other palliative care interventions for patients with heart failure were informed by different types of theories and models. For example, Kane used a programme theory (Greenhalgh's model[143]) to illustrate how a PROM (IPOS) may identify patients' unrecognised problems; affect the clinical interaction, decision making, patient and healthcare professional behaviours, and health outcomes; and subsequently facilitate patient-centred care[371]. Drawing on this model and patient-centred care literature, Kane proposed a theoretical framework of how a PROM could facilitate patient-centred care and represented it in a linear model that connects the intervention (training heart failure nurses on patient-centred care and IPOS followed by using the tool in practice), mechanism of action (change in patient and nurse behaviours and communication), and outcomes (improved patient experience and health outcomes)[371]. In another example, Bekelman et al. developed a conceptual framework, based on the theory of unpleasant symptoms[445], of how their patient-centred intervention could improve patients' health status by integrating palliative symptom-focused and psychosocial care into chronic care[446]. Their simple model shows unidirectional relationships between antecedent factors (physical, psychological, and situational factors such as age and gender), depression, symptom experience, functional status, and health-related quality of life.

Neither Kane's nor Bekelman et al.'s intervention improved the primary outcome (symptom burden and heart failure-specific health status, respectively) when evaluated in subsequent studies[162,447]. In contrast to the Theory of Change approach, neither of the models underlying these interventions provided a detailed description of how and why the intervention is expected to work. For this study, Theory of Change enabled exploring the key components of the complex intervention and the hypothetical causal pathway through which they interact to achieve a real-world impact. This understanding is important to create an effective, implementable, pragmatic, and sustainable intervention[112,114,119,122]. Theory of Change enabled explicating the core intervention activities, preconditions, contextual factors, long-term outcomes, and desired impact; most of which were missing in those models. It was also represented in a more complex model (Theory of Change map) that allowed for several causal pathways and feedback loops and showed the rationale behind each causal link in the hypothetical pathway of change.

Table-41: Comparing the intervention development process and underpinning theory with other palliative care interventions for patients with heart failure

Study*	Intervention development process	Intervention underpinning theory/model
My study	**Detailed:** **Co-designed** with stakeholders using the MRC framework, MORECare statement, and Bleijenberg et al.'s guidance.	**Detailed:** Guided by Normalisation Process Theory and Theory of Change.
Dionne-Odom et al. 2014-2020[435,448-452]	**Detailed:** **Co-designed** with clinicians, patients, and family carers using the MRC framework; Adapted from an existing cancer intervention.	**Detailed:** Guided by Wagner's chronic illness care model[453,454].
Denvir et al. 2014-2016[406,436]	**Detailed:** **Co-designed** with patient groups and healthcare professionals using the MRC framework (partially).	**No details**
Grudzen et al. 2019-2021[437,438,455]	**Detailed:** **Co-designed** with a PPI group and content experts; Informed by survey data and direct observation of study settings.	**No details**
Kane et al. 2017-2018[132,162,371]	**Detailed:** Developed using the MRC framework and MORECare statement. **Minimal co-design**	**Detailed:** Guided by a programme theory (Greenhalgh's model)[143].
Bekelman et al. 2014-2018[404,446,447]	**Detailed:** Informed by evidence on quality of life contributors, and patient and family carer palliative care needs and preferences. **No co-design**	**Detailed:** Guided by the theory of unpleasant symptoms[445], and Wilson's and Cleary's model of health-related quality of life[456].
Johnson et al. 2018[441]	**Minimal details:** Developed with clinical champions and facilitation groups through a partnership between two charities. **Minimal co-design**	**No details**

Study*	Intervention development process	Intervention underpinning theory/model
O'Connor et al. 2016[439]	**Minimal details:** Palliative care assessment tool developed from a literature review, communication with similar existing programmes, and input from cardiologists. **Minimal co-design**	**No details**
Lewin et al. 2017[440]	**Minimal details:** Patient and family education material developed by palliative care and heart failure teams. **Minimal co-design**	**No details**
Brannstrom and Boman 2013-2014[457,458]	**Minimal details:** Developed from the goals and steps in providing palliative care for patients with heart failure as recommended by the HFA/ESC guidelines[203,459]. **No co-design**	**Detailed:** Guided by the six S's model (self-image, self-determination, social relationships, symptom control, synthesis, surrender)[460].
Wong et al. 2016-2018[461-463]	**Minimal details:** Developed from principles for palliative heart failure care adapted from different guidelines[29,203]. **No co-design**	**Detailed:** Guided by the four-C's transitional care model (comprehensiveness, continuity, coordination, collaboration)[464].
Doorenbos et al. 2016[352]	**Minimal details:** Informed by a prior intervention. **No co-design**	**Brief reference:** Guided by the self-management for chronic conditions model[465], which is based on social science and behavioural theories.
Bekelman et al. 2013-2015[466,467]	**No details** **No co-design**	**Detailed:** Guided by the chronic care model[468,469].

* Details on the intervention development process and adopted theory were lacking in 16 studies (not shown here)[65,165,168,405,423-434].

9.3.2 Applications of Normalisation Process Theory

The adopted Normalisation Process Theory has been widely used as a theoretical framework for other complex healthcare interventions, including those where decision support tools, like NAT:PD-HF in this study, were integrated into clinicians' practice[250,256,260,261]. Nonetheless, in contrast to this study, most studies either applied Normalisation Process Theory in later stages (retrospectively), rather than from the intervention development stage (prospectively), or did not use all of its components (sub-constructs)[256,260,261]. Several studies explored only the perspectives of service providers, based on claims that Normalisation Process Theory focuses more on the work of those delivering, rather than receiving, the intervention[256,260,261]. Although more emphasis was placed on service providers to develop this intervention, service users' input was also included from the secondary data analysis and PPI group consultation, which helped to assess the implementation potential of the intervention and feasibility study design from a different perspective.

Normalisation Process Theory has a wide range of applications in other complex healthcare interventions, which are comparable to those in this study, where it helped to explain the factors affecting implementation processes (barriers and facilitators) and make recommendations to improve implementation[256,260,261]. Normalisation Process Theory is often used to define the interventions, explore and understand their context, and consider how the context may affect the intervention effectiveness[250]. For this study, Normalisation Process Theory triggered thinking about relevant contextual issues (assumptions) through defining the stakeholders affected by the intervention, discussing their concerns, and co-designing the intervention to address these concerns[250]. Normalisation Process Theory is also used to analyse the proposed interventions through operationalising its constructs and components to develop questions about prospective implementation processes[250,260]. For this study, the Normalisation Process Theory components, represented in the toolkit, provided a checklist to inform the Theory of Change workshops and shape discussions with service providers.

Normalisation Process Theory is commonly used as a theoretical framework to analyse qualitative interview data, despite concerns that some data may fall outside the predetermined Normalisation Process Theory constructs[260,261]. This issue was mitigated in this study by adopting a mainly inductive approach in the secondary data analysis, though seen through the lens of the Normalisation Process Theory framework. Rather than forcing data into the theory constructs, the inductively developed themes were mapped retrospectively onto the constructs. This approach was used before in the literature[470], and it agrees with the methodological flexibility of Normalisation Process Theory[256]. Normalisation Process Theory is also used as a conceptual tool for feasibility studies and process evaluations to inform the design of trials[256,260], which mirrors the use of Normalisation Process Theory in the planned feasibility study to optimise the trial parameters.

9.3.3 Applications of Theory of Change

The adopted Theory of Change approach was used to develop complex palliative care interventions within the MRC framework in three other studies, though in different populations and settings[278-280,285,471-477]. Gilissen et al. and Lin et al. applied Theory of Change as an underlying theory for advance care planning interventions for nursing home residents in Flanders (Belgium) and for inpatients with advanced cancer and their families in Taiwan, respectively[278,280,285,473]. de Nooijer et al. adopted the same approach to design a short-term specialist palliative care service intervention for older frail people with complex needs and their family carers in primary care in Flanders[279]. Similar to this study, the use of Theory of Change enabled the identification of the intervention components and its mechanism of action and facilitated subsequent detailed intervention description[278-280,285,471-477]. It also informed the prospective evaluation of those interventions in subsequent randomised controlled trials. A comparison of the methodological components of the Theory of Change approach between this study and the other three palliative care studies is presented in **Table-42**.

Table-42: Comparing the methodological components of the Theory of Change approach with other palliative care interventions

	My study	**de Nooijer et al. 2020-2021**[279,471,472]	**Gilissen et al. 2017-2020**[278,473-475]	**Lin e al. 2019-2020**[280,285,476,477]
Intervention underpinned by Theory of Change	Palliative care needs-assessment intervention for outpatients with heart failure and their family carers	Timely short-term specialist palliative care service for older frail people with complex needs and their family carers in primary care	Advance care planning intervention for nursing home residents	Advance care planning intervention for inpatients with advanced cancer and their families
Country	UK	Belgium	Belgium	Taiwan
Methods of Theory of Change development				
Co-developed with service providers	✓	✓	✓	✓
Systematic literature review	✓	✓	✓	✓
Practitioner engagement meetings	Three meetings with service providers	**X**	**X**	**X**
Shadowing activities	Two shadowing activities with service providers	**X**	**X**	**X**
Group workshops with service providers	Three one-hour group workshops	Four half-day group workshops	Two half-day group workshops	One group workshop*
Qualitative data analysis	Secondary analysis of interview data with patients, family carers, and staff	Analysis of interview data and group discussions with patients and family carers	Contextual analysis of existing policies and national guidelines and initiatives	Analysis of interview data with patients, family carers, and staff
Follow-up meetings with service providers	Three one-hour follow-up meetings	**X**	**X**	**X**
PPI group consultation	✓	**X**	**X**	**X**
Research team meetings	✓	✓	✓	✓

	My study	**de Nooijer et al. 2020-2021**[279,471,472]	**Gilissen et al. 2017-2020**[278,473-475]	**Lin e al. 2019-2020**[280,285,476,477]
Attendees of Theory of Change workshops				
Service providers	10 multi-professional stakeholders: • 8 attending workshop-1 • 4 attending workshop-2 • 5 attending workshop-3	45 multi-professional stakeholders: • 5 attending workshop-1 • 16 attending workshop-2 • 13 attending workshop-3 • 11 attending workshop-4	21 multi-professional stakeholders: • 12 attending workshop-1 • 15 attending workshop-2	17 multi-professional stakeholders
Facilitators	2-3 facilitators	3 facilitators	2 facilitators	1 facilitator
Analysis of Theory of Change workshops				
Analysis method	Developed an own analysis approach	Directed content analysis	not clear	Developed an own analysis approach
Theoretical framework informing the analysis	Normalisation Process Theory	none	none	none

* This was a transparent expert consultation that comprised a modified nominal group technique, focus group discussion, and subsequent online consensus survey.

9.3.4 Methods of Theory of Change development

Like this study, the Theory of Change underlying the interventions in the three aforementioned palliative care studies was co-developed with service providers through group workshops, a systematic literature review, qualitative data analysis, and research team meetings[278,279,285]. Theory of Change maps were developed using the same backwards mapping approach; starting from identifying the impact and long-term outcomes of the intervention, then working backwards to identify the preconditions and intervention activities necessary to achieve them, and subsequently depicting the hypothetical pathway of change[278,279,285]. This was followed by identifying the rationales and assumptions in the causal pathway, evaluating the final draft of the map for plausibility and feasibility, and determining potential indicators to measure the achievement of the intervention outcomes[279,280,473]. In the wider health literature, Theories of Change were developed using different methods ranging from participatory approaches, such as group workshops and stakeholder interviews, to more evaluator-focused approaches, such as document reviews and programme observation[124]. However, descriptions of the Theory of Change development process and its use in the intervention design lacked details[124]. The best methods to develop an effective Theory of Change have not yet been determined.

Three one-hour Theory of Change workshops were conducted in this study, compared to a range of one to seven in the wider Theory of Change health literature[123,124]. Although the optimal number and duration of Theory of Change workshops have not yet been determined, this study workshops had a relatively short duration due to stakeholders' time constraints. Nonetheless, this was mitigated by the time spent in the preceding practitioner engagement meetings and shadowing activities, which provided background and contextual information, as well as the follow-up meetings which kept the discussions current and relevant given the additional information arising from the secondary data analysis. Service users were also consulted about this intervention, and their feedback was assessed when the preliminary proposed theory was refined. This is in contrast to the other three palliative care studies (see **Table-42**) where service users were not directly involved in developing the Theory of Change.

A systematic literature review was conducted in this and the other three palliative care studies to identify possible preconditions and intervention components in order to trigger discussion in the Theory of Change workshops[125,472,475,476]. For instance, the systematic review in this study and de Nooijer et al.'s study aimed to identify a method (tools or criteria) to identify the palliative care needs of patients[125,472]. Similarly, qualitative data analysis was conducted in all studies to trigger discussions with service providers about the identified themes[278,279,477]. For example, the qualitative interview data analysis in this study and de Nooijer et al.'s study aimed to identify ways for addressing patient and family palliative care needs and improving the provided care[279]. Throughout the process, research team meetings and reviewing relevant literature helped in building the Theory of Change map in all studies.

9.3.5 Participants in Theory of Change workshops

The number of participants in the Theory of Change workshops was smaller than that in similar palliative care studies because of participants' work and time pressure[278,279]. In the wider Theory of Change health literature, sample sizes ranged from five to 54[281,282,343]. It is not clear whether small or large numbers of participants are better for the Theory of Change workshops, though the Aspen Institute's guide to Theory of Change development recommends a maximum of eight to ten participants[267]. While a larger sample size could result in more ideas and broader discussions, some voices might not be heard and it might distract from the focus of the workshops. Conversely, the small number of participants resulted in deeper, more interactive, and more focused discussions than what would be expected if larger numbers participated. Each workshop was attended by experienced participants with diverse professional backgrounds which provided rich data and broad insight into the intervention and mitigated the small sample size issue. Importantly, all the workshops and follow-up meetings were attended by two key champions which ensured continuity and maintained the focus of the discussions.

9.3.6 Methods of Theory of Change workshop analysis

Like this study, the Theory of Change workshops in similar palliative care studies were recorded and transcribed, though for different purposes[278,279,285]. The workshops' transcripts in de Nooijer et al.'s study were analysed using directed content analysis where they were deductively coded under the Theory of Change elements (impact, long-term outcomes, preconditions, and interventions), followed by inductively categorising the codes into overarching themes and subthemes which were included in a first Theory of Change map draft[279]. Conversely, and similar to Gilissen et al.'s and Lin et al.'s studies, the workshops' transcripts for this study were not formally analysed using a known analysis technique, but rather they served to maintain a record of what was discussed and extract the Theory of Change components that came out through the discussions.

Lin et al. developed their own approach to analysing their Theory of Change workshop, including collating recommendations from the nominal group discussion, presenting highly relevant recommendations in an online survey, conducting descriptive statistics to analyse survey data and identify consensus levels, incorporating recommendations with high consensus into a Theory of Change map, and conducting thematic analysis of the survey narrative comments to aid understanding[285]. In a non-palliative care study where Theory of Change was used to develop a community-based rehabilitation intervention for patients with schizophrenia, the workshops were not recorded at all[282]. In the wider Theory of Change health literature, details on how authors analysed their workshops are often lacking[124].

As the guidance to analyse Theory of Change workshops is vague, I had to develop my own analysis approach. I collated and grouped the answers from the nominal group discussion about the desired impact of the intervention; differentiated what could be an impact from what could be a long-term outcome or precondition; extracted possible intervention activities, preconditions, rationales, and assumptions from the discussions; added more components from the relevant literature; and linked them in Theory of Change map drafts. Throughout the process, I was guided by the Normalisation Process

Theory constructs in contrast to the other palliative care studies which lacked a guiding theoretical or analytic framework to inform the analysis[278,279,285]. Whether it is necessary to record and formally analyse the Theory of Change workshops, and how best to analyse them, have not yet been determined.

9.3.7 Theory of Change components

The Theory of Change for this intervention was described using a narrative summary and represented graphically in a Theory of Change map that outlined the desired impact, long-term outcomes, preconditions, assumptions, rationales, intervention activities, and causal pathway of change. Indicators to achieve key outcomes in the map (outcome measures) were agreed upon with stakeholders in the follow-up meetings. In the wider health literature, most Theories of Change were described with either a summary or diagram, with a few details in both cases[124]. Assumptions and indicators were mostly lacking despite being core components of Theory of Change[268]. The identified Theory of Change components for this intervention share similarities to those identified in Gilissen et al.'s, de Nooijer et al.'s, and Lin et al.'s studies[278,279,285] (**Table-43**). This reflects an understanding of the ultimate goals, requirements, and contextual conditions of palliative care interventions despite different research focus and settings.

Table-43: Comparing the Theory of Change components with other palliative care interventions

	My study	**de Nooijer et al. 2020-2021**[279,471,472]	**Gilissen et al. 2017-2020**[278,473-475]	**Lin e al. 2019-2020**[280,285,476,477]
Impact	• The holistic PC needs of patients and families are met in a relevant timeframe.	• Increased quality of life of patients and families. • Timely integration of specialised PC home services for patients and families. • Increased job satisfaction among staff.	• Improved quality of care, life, and dying of patients.	• Patients have a chance to express end-of-life care wishes. • Healthcare systems have information to plan and deliver care. • Increased concordance with preferred care.
Long-term outcomes	• Reduced patient symptom burden. • Reduced family caregiving burden. • Reduced unnecessary hospitalisations.	• Fewer patient unmet needs and symptoms. • Fewer family support needs. • Fewer unnecessary hospitalisations and longer home stay. • Increased patient wellbeing. • Increased sense of security in care. • Increased continuity of care.	• Increased correspondence between received care and current preferences. • Patients and families feel involved in future care planning and are confident that end-of-life care will correspond to their preferences.	• Decreased physical and psychological distress. • Patient autonomy honoured. • Decreased uncertainty of decision making. • Set up care plans following patient preferences.

	My study	**de Nooijer et al. 2020-2021**[279,471,472]	**Gilissen et al. 2017-2020**[278,473-475]	**Lin e al. 2019-2020**[280,285,476,477]
Preconditions	• 12 preconditions at the patient and family, staff, and organisation levels. • Focus on communication, education, and PC needs identification.	• 12 preconditions at the patient and family, staff, and organisation levels. • Focus on communication, education, and PC needs identification.	• 13 preconditions mainly at the staff level. • Focus on communication, education, and ACP.	• 7 preconditions at the patient and family, staff, and organisation levels. • Focus on communication, education, and ACP.
Indicators	• Outcome measures for hospital service use, symptom burden, caregiving burden, patient illness perception, and PC needs.	• Outcome measures for symptom burden, PC needs, wellbeing, sense of security in care, continuity of care, views on care, and family carer support needs.	• Outcome measures for staff knowledge, attitudes, self-efficacy, and practices of ACP.	• Outcome measures for patient knowledge of ACP, experience of ACP participation, patient-clinician communication, and physical and psychological distress.
Assumptions	• Resources. • Time. • Willingness (commitment). • Skills, expertise, knowledge. • Training skills acquisition. • Relationships. • Information-exchange system.	• 24/7 availability of specialised PC home services. • Specialised PC home services are free of charge. • Time for home visits and multidisciplinary meetings.	• Resources. • Private space for ACP discussions. • Willingness (commitment). • Supportive organisational culture towards ACP.	• Resources. • Readiness to engage in ACP. • Training skills acquisition. • Relationships.
Rationales	Drawn from stakeholders' experience and scientific evidence in all studies			

	My study	**de Nooijer et al. 2020-2021**[279,471,472]	**Gilissen et al. 2017-2020**[278,473-475]	**Lin e al. 2019-2020**[280,285,476,477]
Intervention activities	• NAT:PD-HF staff training. • Completing NAT:PD-HF. • Addressing PC needs. • Monthly group meetings. • Writing and sharing NAT:PD-HF summary. • Signposting staff to PC training courses and patient education resources.	• Pre-intervention activities (such as staff training and PC patient identification). • Short-term delivery of specialised PC home service. • Collaborative working. • Holistic needs-based care. • Person-centred care. • Goal-oriented care.	• Selection of ACP trainer. • Buy-in by the management. • Educating staff, patients, and families on ACP. • ACP conversations and documentation. • Multidisciplinary meetings. • Regular reflection sessions. • Formal monitoring.	• Staff training on ACP and end-of-life care concept. • Staff training on end-of-life care communication. • Educating patients and families on ACP. • End-of-life communication coaching for patients. • ACP consultations.

ACP: Advance Care Planning, PC: Palliative Care.

9.3.7.1 Impact

Service providers agreed on the desired impact of this palliative care intervention: The holistic palliative care needs of patients and families are met in a relevant timeframe. In the interventions developed by Gilissen et al. and de Nooijer et al., a common impact was: Improved quality of life of patients[278,279]. Quality of life came up as a possible impact in the Theory of Change workshops in this study during the nominal group discussion, but stakeholders thought it is a natural consequence of meeting the holistic palliative care needs of patients (the agreed impact). This agrees with various models in the literature that demonstrate the relationship between patients' health needs and quality of life[478,479], with the latter being suggested as a likely surrogate and a consequence of the former[478,480]. Of note, meeting the palliative care needs of patients and improving their quality of life are the two main goals of palliative care according to the WHO[54]. Another identified impact in de Nooijer et al.'s intervention is: Timely integration of specialised palliative home care services for patients and families[279]. Integration of palliative care also came up as a possible impact in this intervention. Although not agreed as an ultimate impact, it was depicted as a precondition in the first Theory of Change map draft.

9.3.7.2 Long-term outcomes, preconditions, and indicators

Three long-term outcomes were identified for this intervention: Reduced unnecessary hospitalisations, Reduced patient symptom burden, and Reduced family caregiving burden. These are similar to those reported in de Nooijer et al.'s and Lin et al.'s studies[279,280]. Hospitalisation, symptom burden, and caregiving burden are common consequences of heart failure[33,44,481], which should be addressed by palliative care interventions[54]. While these have also been commonly reported as the primary or secondary outcomes for other palliative care interventions in heart failure[55,59-64], the choice of such outcomes was mostly not informed by an underpinning theory or stakeholders' input. To achieve the long-term outcomes, 12 preconditions were identified at the patient and family, healthcare professional, and organisation levels with a focus on the identification of palliative care needs, communication, and education. This is comparable to the number and focus of preconditions reported in Gilissen et al.'s and de Nooijer et al.'s studies[278,279], although in the former study the intervention was mainly directed at the staff level[473]. To measure if the long-term outcomes and key preconditions have been achieved when the intervention is evaluated, indicators were identified for this and the other studies[285,471,473]. If the intervention is effective, this would identify the active ingredients; while if it failed, this would identify whether this is due to implementation failure (failure to achieve the preconditions) or theory failure (failure to achieve the long-term outcomes despite achieving the preconditions)[117].

9.3.7.3 Rationales and assumptions

The rationales for specific links in the causal pathway of change were identified from stakeholders' local experience and scientific evidence from theories and relevant literature. Where such rationales did not exist, assumptions (contextual conditions) were identified. Seven assumptions were identified; most of which were similar to the other palliative care studies including the availability of time, resources, relationships, training skills acquisition, and commitment (willingness) of all actors involved[278-280]. These assumptions reflect some of the most important barriers to palliative care identified in the literature[75,76]. Addressing such contextual barriers would enhance the delivery of and access to palliative care for patients with heart failure, and contribute to meeting their palliative care needs.

9.3.7.4 Intervention activities

The intervention will mainly be provided by heart failure teams, who will collaborate with other staff to meet the patient and family palliative care needs through referrals and sharing clinic letters. Multidisciplinary and team-based palliative interventions for patients with heart failure are preferred over single-component interventions as they have more evidence for improving patient-reported outcomes and resource utilisation[59,62]. The developed intervention comprises multiple intervention activities, reflecting the complex multi-component nature of palliative care[62]. These activities are similar to those reported in other palliative care interventions[278-280], including those for patients with heart failure[55,59,62,63]. Reviews of such interventions identified common intervention activities including palliative care needs assessment, symptom management, staff and patient education, advance care planning, goals-of-care communication, shared decision making, and care coordination[55,59,62,63,422]. While these activities are mostly covered in this intervention, a common non-adopted intervention activity is the assignment of a care coordinator, although this came out in the secondary data analysis and was suggested to service providers in the follow-up meetings before being disregarded because of the absence of staff who could fulfil this role efficiently. Nevertheless, elements of care coordination are covered in this intervention through sharing NAT:PD-HF, referral pathways, individualised care plans, joint training, and collaborating in patient care among settings[482].

One notable difference from other palliative care interventions in patients with heart failure is the adoption of NAT:PD-HF to identify the holistic palliative care needs of patients and families as it showed superiority over other tools as demonstrated in the conducted systematic review and after discussion with stakeholders in the Theory of Change workshops. This contrasts with most other studies which either used criteria developed by the authors or adopted a less psychometrically robust tool to identify palliative care needs. Although NAT:PD-HF was a key component of Janssen et al.'s intervention, the non-culturally adapted Dutch translation rather than the original tool was used[165].

A novel intervention activity for this study is the monthly group meetings among healthcare providers to reflect on and share experiences of using NAT:PD-HF in clinical practice. This was suggested by a key stakeholder in the Theory of Change workshops; to my knowledge, no other palliative care intervention for patients with heart failure adopted such meetings among staff to maximise their experiences of using a palliative care needs-assessment tool in daily practice. Another novel feature of the intervention is the use of NAT:PD-HF as a sensitising tool to initiate and structure the palliative care conversations. Although NAT:PD-HF was designed and validated as a palliative care needs-assessment tool rather than a conversation aid[164], a similar tool (IPOS) was shown to have the potential to trigger care plan discussions with patients with heart failure through identifying their holistic palliative care needs[132].

Kane et al., Janssen et al., and Thoonsen et al. developed palliative care interventions for patients with heart failure that comprised training on IPOS, Dutch NAT:PD-HF, and RADPAC, respectively; followed by using the tool in practice to assess patient and family palliative care needs[132,162,165,167-170] (see **section-2.3.6.4** and **section-2.3.6.5**). All concluded that a tool alone is inadequate for palliative care interventions and thus additional intervention activities would be needed such as training heart failure teams on palliative care, communication, and needs identification, as well as educating patients on advanced heart failure. While this intervention comprises training staff on palliative care needs identification using NAT:PD-HF, it also addresses the other recommendations by signposting staff and patients to appropriate training and education resources. Another recommendation was to include guidance towards the actions required to address the palliative care needs identified by the tools[165,371]. While the heart failure teams in this study will not be given management guidelines to address the identified needs, NAT:PD-HF in itself provides guidance to triage actions. The tool training that will be provided with specialist palliative care teams before the intervention would support the heart failure teams in deciding when to manage the needs by themselves or another team member and when to refer.

The intervention will be provided in outpatient settings, which would develop rapport between patients and healthcare professionals and facilitate goals-of-care communication. It will be delivered to those with more advanced disease, as patients who have a specialist review in outpatient clinics two weeks after their hospital discharge will be recruited. In Kane et al.'s study, the plan was to include patients with advanced heart failure (NYHA class III or IV) from heart failure nurse-led clinics in two centres[371,483]. However, the lack of an inclusive definition of advanced heart failure and the subjectivity of NYHA classification between the two centres impeded recruitment. Consequently, Kane recommended that all patients by virtue of referral to such clinics could be considered automatically eligible for inclusion, as these patients have been referred to the heart failure team for symptom support and thus would have potential unmet palliative care needs regardless of their NYHA classification or illness stability[371]. This agrees with the guidelines' recommendations to provide palliative care throughout the heart failure trajectory[15,16]. Nonetheless, most palliative care interventional studies for outpatients with heart failure included those with advanced illness[55,59,62,63]. Introducing palliative care in the early stages may be impeded by fears of causing unnecessary worry to patients and families, misperceptions that heart failure is not life-limiting, and poor palliative care communication skills[79,484]. For this study, providing the intervention to all patients attending heart failure clinics was welcomed but highly debated by stakeholders who decided ultimately to include only recently admitted patients given the limited time and resources.

9.3.8 Secondary qualitative data analysis findings

In the secondary data analysis, the voice of service users was included in developing the intervention through assessing their experiences with integrated palliative care. The analysis aimed to evaluate the perceptions of patients with heart failure, family carers, and professional caregivers on the holistic palliative care needs of patients and families in the community, the key healthcare professionals involved in addressing these needs, and how to address them. Although previous heart failure studies reported experiences with palliative care[485,486], this study explored the perspectives of different participants (patients, family carers, and professional caregivers) from multiple sites and the interviews were conducted longitudinally (three months apart) and supplemented with card photos. The longitudinal interviews enabled comparing patient-related heart failure issues and professional support over time. These were found consistent with no new professional caregivers involved over that period, which is expected as these patients were recruited from integrated palliative care initiatives where they presumably received adequate support. Exploring multiple perspectives enabled identifying different heart failure issues and care experiences among patients, family carers, and professional caregivers, while the card photos facilitated exploring good and poor communication links within the patient care network.

9.3.8.1 Participant demographics

The sample included in the secondary data analysis is similar to other studies that explored the perspectives of patients with advanced heart failure, family carers, and healthcare professionals on palliative care provision[50,485,486]. Although the number of the interviewed patients and family carers in this study is relatively small, most were interviewed twice and the interviews were supplemented with professional caregivers' perspectives. Most patients and family carers were older females, which is likely to be similar to the ones who will be recruited from outpatient clinics to participate in the prospective feasibility study; making the analysis findings relevant. As the interviews were conducted in the UK and mainly included older female patients and family carers in the community, the findings may not be transferable to inpatients, younger male patients and family carers, or in countries with different healthcare structures.

9.3.8.2 Thematic map

Four themes were generated through the analysis to address the research objectives: Impact of heart failure (Theme-1), Coping and support (Theme-2), Recognising palliative phase (Theme-3), and Coordination of care (Theme-4). Other qualitative studies that assessed patients' lived experiences of heart failure, perspectives on care needs, and experiences with palliative care provision described similar themes[485,487-489], although details on how they relate to and influence each other are mostly lacking. Low et al. suggested that poor multidisciplinary communication and care coordination (covered in Theme-4) and lack of confidence among health professionals to engage in open palliative care conversations with patients (covered in Theme-3) may affect the quality of the provided care (covered in Theme-2) and thus fail to relieve the multidimensional impact of heart failure (covered in Theme-1)[485]. Likewise, in this study, the four themes were illustrated in a thematic map that shows how heart failure impact (Theme-1) could be relieved through three co-existing interrelated factors (Themes-2,3,4). Although the thematic map suggests that these factors have the same impact, it was not possible to determine, from the data available, whether some aspects were more impactful than others. However, as the themes are related, they were discussed in the follow-up meetings with service providers to refine the intervention at the same level of detail.

9.3.8.3 Theme-1: Impact of heart failure

Theme-1 described the significant impact of heart failure on patient and family lives. Patients' physical, psychological, social, practical, and information needs are commonly identified in other studies[485,487-489]. However, spiritual needs were less evident in the interviews as these could be difficult to explore because of their complex and multidimensional nature; encompassing existential questions, values, and religion[488,490]. One prominent feature was the influence of the patient-related heart failure issues on each other. For example, breathlessness and tiredness (physical issues) made patients unable to work and go out (limitation in activities of daily living), which led to loneliness (social issue), depression (psychological issue), and early retirement (financial issue), which further exacerbated their physical symptoms. As heart failure issues are interrelated, it is important to provide a holistic assessment of patient palliative care needs[203], which would be facilitated by NAT:PD-HF for this intervention.

Heart failure had a similar impact on patients and family carers, as both experienced physical, psychological, social, financial, legal, and practical issues, and both had significant information needs. A systematic review of qualitative studies exploring family carer needs in advanced heart failure identified similar areas of support needs: psychosocial support, support with daily living, and support in navigating the healthcare system[50]. This demonstrates the importance of assessing and addressing the palliative care needs of family carers alongside patients[50], which would be facilitated by NAT:PD-HF in the prospective intervention.

9.3.8.4 Theme-2: Coping and support

Theme-2 described the coping process of patients and the professional and family support. Patients developed different coping strategies to deal with heart failure, ranging from acceptance to fighting for independence, which are similar to those reported in the literature[487,488]. Given the multidimensional impact of heart failure, patients and family carers wanted to be treated as unique individuals and provided with holistic, patient-centred care[50,489]. However, cases of inadequate professional support were described where professional caregivers failed to address patient and family carer palliative care needs. Although nurses played a role in managing these needs, it was the hospices that provided the most support, while GPs had little contribution. In other studies, heart failure nurse specialists were expected to have the appropriate skills to address patient needs, but this was hampered by the lack of training in symptom control and palliative care issues[485,486].

Lack of competence will be addressed in the prospective intervention through educating the multidisciplinary heart failure teams on palliative care needs assessment using NAT:PD-HF, and signposting them to palliative care training courses. Consequently, the heart failure teams would be more confident in addressing primary palliative care needs, while referring complex cases to specialist services. Some cases of *medical failure* were attributed by patients to forgoing curative options by healthcare professionals and shifting towards palliative care, which reflects a lack of patient understanding of heart failure and palliative care[75]. This issue would be addressed in the intervention by signposting patients to relevant educational resources.

9.3.8.5 Theme-3: Recognising palliative phase

Theme-3 described the recognition of palliative patients and initiation of palliative care conversations. In line with guideline recommendations[14-16], a needs-based approach was perceived as superior to the prognostic approach to identify palliative patients given the unpredictable trajectory of heart failure. Once the recognition occurs, patients need a holistic and individualised assessment of their care needs with the initiation of palliative care early in the illness trajectory[486]. However, introducing palliative care is complicated by the lack of skills and knowledge, confusing palliative care with end-of-life care, misperceptions of palliative care referral as a medical failure, and patient unawareness of their prognosis[486]. The biggest hurdle that emerged from the interviews was how, when, and by whom the palliative care conversations should be conducted.

While open and early conversations are advocated to help patients make practical arrangements and deal with personal affairs, some healthcare professionals are still reluctant to engage in such discussions for fear of reducing hope for patients and families and avoiding triggering anxiety and depression[485]. The interviewed professional caregivers expected GPs and community nurses to initiate the conversations, but both heart failure nurse specialists and cardiologists can also be good candidates based on their knowledge of heart failure and relationship with patients[485]. For this intervention, the heart failure team were willing for these conversations, despite initial reluctance. It was agreed that the conversations should be individualised, and the heart failure teams will be signposted to training courses, as part of the intervention, to enhance their palliative care communication skills.

9.3.8.6 Theme-4: Coordination of care

Theme-4 described the organisation of care between professional caregivers across different care settings. Poor care coordination, continuity of care, and communication between patients, family carers, and healthcare professionals are commonly cited in the heart failure literature as occurring for different reasons such as lack of information, time, and resources[50,487,488]. Consequences include inappropriate hospitalisations, inability to meet patient needs, poor care delivery, and patient dissatisfaction with health care provision[485]. For this intervention, the communication with patients and family carers would be enhanced as heart failure teams complete NAT:PD-HF in the clinics to discuss their palliative care needs. The communication between healthcare staff would also be enhanced by sharing the NAT:PD-HF summary to address the identified needs.

Care coordination between cardiology and palliative care services, and between hospital and community teams, is important, with many patients complaining of poor follow-up after hospital discharge[50,488]. The interviewed participants emphasised the importance of care coordinators, although there were different perspectives on who would be the most appropriate coordinator or whether more than one is required. In other studies, while patients were willing to have a single care coordinator, health professionals thought that this might be the role of nurses or doctors or even a collective responsibility[485,486]. Care coordination was discussed in the follow-up meetings with service providers, where it was thought to be a collective responsibility that would be facilitated through information sharing and collaborative working. For this intervention, this would be triggered by sharing the NAT:PD-HF summary with other healthcare staff as needed to collaborate in addressing patient needs.

9.3.9 Follow-up meetings with service providers and PPI group consultation

In the follow-up meetings with service providers, the findings of the secondary data analysis were discussed to refine the intervention proposed after the Theory of Change workshops. A feasibility study protocol was also co-designed after discussing the prospective trial design, target study sample, recruitment methods, data collection, intervention duration and activities, and study outcomes and outcome measures. Following these meetings, service users were invited to provide their feedback on the intervention and feasibility study protocol in a PPI group consultation. This is supported by the newest MRC-2021 guidance which recommends conducting an *evaluability assessment* before a feasibility study where researchers collaborate with stakeholders to determine whether and how the intervention can be evaluated and agree on the expected and most important outcomes of the intervention, the data that could be collected, and the evaluation design[228].

The PPI group were members of the James Lind Alliance who understand the value of research as shown by their interest in the topic and the useful thoughts they shared. This mitigated the concerns of provoking discomfort as they discussed their life-limiting illness and palliative care[491]. Involving the PPI group facilitated a shared understanding of the intervention and provided evidence for its relevance to the target population, which would result in enhanced research efficiency and quality and reduced research waste[442]. Further PPI group consultation in the planned feasibility study would lead to more relevant, readable, and understandable patient information materials[492].

The PPI group recommendations were similar to those provided by other PPI groups in similar palliative care studies on heart failure. In one study, patients and family carers endorsed the use of a delayed-intervention trial where all patients would eventually receive the intervention, similar to the fast-track design suggested for this study[436]. In another study, patients and family carers recommended an earlier palliative care intervention for patients with heart failure to include those with less severe illness[450]. This was highly debated in the PPI group consultation and the preceding follow-up meetings with service providers, where it was ultimately decided not to include patients at the very early stages of their illness to reserve resources and achieve the maximum benefit of the intervention. In Kane's study, a patient and his family carer recommended using the terms "heart failure" and "palliative care" in study participant documentation to prevent ambiguity from using euphemistic terms[371]. While this contrasts with the PPI group's perspectives in this study who preferred to use the language normally used by the clinicians, patients from one site in Kane's study were already involved in developing a poster and information leaflet on palliative care for patients with heart failure, which possibly made them more comfortable to use such terms.

9.4 Strengths and limitations

9.4.1 Intervention development

A strength of this study is the robust, thorough, and iterative approach to developing the intervention through adopting several complementary, general and palliative care-specific guiding frameworks and theories. The findings from each study phase informed the next phase, which resulted in accumulated evidence that led to the development of an evidence-based theory and intervention. The MRC framework helped to inform the research approach (qualitative methodology) and offered a structure for the systematic development of the intervention alongside Bleijenberg et al.'s guidance and MORECare statement. In turn, the use of a qualitative methodology to address the research objectives enabled exploring the key components of the intervention and understanding its mechanism of action as little research has been done on these areas[215].

One issue was the time taken in the development stage of the MRC framework, which has been reported in other palliative care studies using the same framework[493,494]. However, investment in the development stage was important to overcome the ethical and practical difficulties in palliative care research and thus develop a more feasible, effective, and implementable intervention and reduce research waste[114]. A systematic review found that although 86% of feasibility studies in palliative care research concluded that the study is feasible, only 13% indicated that the authors intended to conduct a definitive trial[386]. This suggests that more time should be spent on the development process to overcome the difficulties of conducting studies on a wide scale and integrating them into clinicians' daily practice. The thorough development of this intervention and study design is innovative and could help researchers to understand how to incorporate a programme theory in the intervention development and how to provide rationales for each intervention component. The developed method to analyse the Theory of Change workshops is also innovative and could guide researchers to analyse their workshops.

Another issue is the generic nature of the MRC framework, although this was mitigated by using the MORECare statement which provided important recommendations specific to the palliative care context[122]. In addition, following Bleijenberg et al.'s guidance enriched the development phase of the MRC framework by adding more steps to the intervention development to identify existing contextual factors and address stakeholder needs[119]. The MRC framework was also strengthened by the participatory Theory of Change approach which underpinned the intervention development, and by Normalisation Process Theory which triggered thinking about implementation issues from the outset and provided an analytic framework for the Theory of Change workshops, secondary data analysis, and feasibility study protocol.

9.4.2 Implementation and co-design

A strength of this study is the participatory approach to developing the intervention and feasibility study protocol, where stakeholders were involved throughout all stages and implementation issues were considered from the outset. Involving stakeholders is essential to design an intervention responsive to their needs[119,442]. The implementation of palliative care interventions in heart failure clinical practice is challenging[495]. This was mitigated through co-designing the intervention with service providers who initiated the discussions and asked for a service to enhance palliative care provision for their patients, exploring the perspectives of service users on the developed intervention, addressing the implementation context in advance, describing the intervention in detail, and adopting an implementation theory[114,123,228,232]. One issue is that the service providers involved in co-designing the intervention were from one site only. Besides, service users had less direct input in developing the intervention due to COVID-19 restrictions. Nevertheless, the voice of patients and family carers was included from the secondary data analysis and PPI group consultation.

9.4.3 Theory of Change

The intervention was developed using a programme theory via a Theory of Change approach which comprised integrating the best current scientific evidence from research with stakeholder views. This approach triggered thinking about the role of every intervention component in achieving the desired outcomes and the rationale behind this, which is often absent in the literature[496]. The participatory nature of the Theory of Change workshops ensured the development of a context-specific intervention and a realistic pathway of change as stakeholders were engaged in discussing the preconditions required to achieve the intended long-term outcomes in their routine practice. This means that the proposed intervention has been perceived as feasible even before testing its feasibility in a formal study. A particular strength is the comprehensive application of the Theory of Change approach. This contrasts with most other studies where fewer details were reported and essential components, such as assumptions or graphical representations, were missed; making it difficult to assess the validity of the proposed causal pathways[124].

Although the developed Theory of Change could provide a model for similar palliative care interventions, it is not necessarily generalisable to different contexts nor applicable to other countries with different healthcare systems. Still, the clear pathway of change that illustrates how the preconditions lead to outcomes would enable researchers to assess the extent to which the preconditions, rationales, and assumptions are applicable in their context and evaluate whether the intervention components are transferrable or require adaptation. It could be argued that many intervention components are applicable in other developed countries where heart failure teams provide generalist palliative care, such as identifying and acting on patient and family palliative care needs, which are core components of palliative care[54]. Other components may not be directly transferrable to other countries as NAT:PD-HF is currently only available in English, Dutch, and German[164,165,199]. The developed Theory of Change could also apply to patients with other life-limiting illnesses as the proposed intervention activities may not be limited to meeting the palliative care needs of patients with heart failure. However, this needs further research and adaptations should be made such as using another needs-assessment tool as NAT:PD-HF is heart failure-specific.

A second limitation is that patients and family carers were not directly involved in building the Theory of Change map. While the initial focus was to develop a programme theory with service providers, patients and family carers would have been included at later stages in the Theory of Change workshops if it was not the COVID-19 pandemic. In the health literature, Theories of Change were not often developed with service users, with few examples where both service users and service providers participated in Theory of Change workshops[124]. For this study, the Theory of Change components, including the long-term outcomes of the intervention, could have been different if patients and family carers participated. However, the voice of patients and family carers was included from the secondary data analysis and PPI group consultation, which aided in refining the proposed Theory of Change after the workshops. On a similar note, not all potential healthcare provider stakeholders participated in developing the Theory of Change, and thus it cannot be claimed that the theory is owned by stakeholders outside the workshops. However, those who participated in the workshops represented relevant, diverse, and key stakeholders. The limited stakeholder ownership of the developed Theory of Change is justifiable as involving all stakeholders is neither feasible nor necessary[271].

A third limitation is that the identified preconditions in the Theory of Change are mainly at the patient, family, and healthcare professional levels with less focus on the macro inter-organisational level such as the collaboration between hospitals and community services. There might also be other long-term or unintended outcomes of the intervention which had not been captured in the proposed Theory of Change. The Theory of Change approach aims to identify only the necessary preconditions for implementing the intervention, rather than all involved elements[267,269]. Identifying and evaluating all possible outcomes are not feasible nor realistic. Nonetheless, unintended outcomes will be identified in the planned feasibility study. The developed Theory of Change map could be seen as a simple representation of a complex reality[278]. However, it still provides a useful model for designing the intervention and is superior to other approaches, such as logic models and logical frameworks, which have a rigid and linear structure with a minimal illustration of the causal pathways and mechanisms of the intervention[124].

A fourth limitation is that outcome measures (indicators) were not determined for all preconditions and outcomes identified in the Theory of Change map. One reason is the risk of increased burden on the intervention providers and users if all outcomes are measured in the subsequent trial. Another reason is the lack of validated outcome measures for some of the proposed outcomes, such as the heart failure team's ability to discuss care plans and address palliative care needs. Nonetheless, questions about whether each outcome is achieved will be addressed in the post-intervention qualitative interviews with staff, patients, and family carers in the planned feasibility study, but this should be approached with caution as causal relationships are difficult to be established using only qualitative data[497]. Importantly, the outcome measures selected for the definitive trial meet the recommendations from the EAPC white paper on outcome measurement in palliative care, including using brief, straightforward, psychometrically sound, and multidimensional measures that can capture the holistic palliative care needs of patients and family carers and are relevant to the research question[498].

9.4.4 Addressing palliative care barriers

The barriers to providing palliative care for patients with heart failure, covered in **section-1.4.3**, are addressed in the proposed intervention. The uncertain illness trajectory which makes it difficult for clinicians to recognise the appropriate timing for providing palliative care would be addressed by using a needs-assessment tool (NAT:PD-HF). Regardless of the illness trajectory, this palliative care intervention will be provided to patients and their family carers based on their needs, rather than uncertain prognosis. The poor communication with patients and families and reluctance to engage in palliative care conversations would be addressed by using NAT:PD-HF to facilitate such conversations, enhancing the communication skills of the heart failure teams through signposting them to palliative care training courses, and enhancing patients' perceptions of their illness through signposting them to relevant educational resources.

The poor knowledge of patients, family carers, and healthcare professionals about palliative care would be addressed through the aforementioned training courses and education resources. Heart failure teams will be informed about the local available services in the NAT:PD-HF training session, while patients and family carers will be informed about such services through stickers attached to the patient education resources. The poor collaboration between healthcare professionals would be addressed through sharing the NAT:PD-HF summary to address the identified palliative care needs and conducting monthly group meetings to share experiences of using NAT:PD-HF in practice. Finally, the issue of limited time and resources would be mitigated by delivering the intervention only to those who have a specialist review two weeks after hospital discharge. This barrier was the most difficult to overcome through the intervention, and although the heart failure team wanted to deliver the intervention to all patients attending the clinics, this was deemed difficult given the limited resources.

9.4.5 Reporting and quality checklists

Reporting guidelines and quality checklists were used throughout the thesis to enhance the research validity, transparency, replication, and comparisons. Quality checklists were used to assess the risk of bias in studies included in the systematic review, determine the quality of the primary dataset before the secondary data analysis, and assess the quality of the reflexive thematic analysis. Reporting guidelines were used for the systematic review, reflexive thematic analysis, Theory of Change, intervention description, and feasibility study protocol. Given that detailed reporting of palliative care and other non-pharmacological interventions is often lacking, a particular strength is the use of the TIDieR checklist to describe the intervention which would facilitate translating it into practice[496]. However, one item in the checklist (Tailoring) lacks details on what should, and should not, be tailored in the intervention and how to achieve that, which is a common issue in implementation studies[499,500]. Tailoring is a practice where not all participants receive an identical intervention, which allows for flexibility and individualised care[118]. It could be argued that some intervention components, such as the use of NAT:PD-HF, are less amenable to tailoring than others as changing them would affect the intervention quality. Other intervention components could be more flexible including the individualised palliative care conversations, methods and materials to address palliative care needs, and ways to share the clinic letter with other staff.

9.5 Contribution to knowledge

This study presents novel insights into palliative care research in heart failure. It provides valuable *methodological* contributions to inform the development of future palliative care interventions for patients with life-limiting illness and their family carers. The study provided a systematic and comprehensive approach to developing complex palliative care interventions using a combination of complementary frameworks, theories, and methods. This study is the first to combine the MRC framework, MORE Care guidance, Bleijenberg et al.’s guidance, Normalisation Process Theory, and the Theory of Change approach to develop a palliative care intervention. This is also the first study that uses Theory of Change and Normalisation Process Theory to develop a palliative care intervention for patients with heart failure; neither of these was used before for that purpose. The systematic and structured Theory of Change approach that underpinned the intervention development could provide an exemplar for researchers on how to develop their programme theories and how to use them to inform the development of their interventions. The study provided a novel approach to analysing the Theory of Change workshops, where guidance is vague. The systematic review that contributed to the intervention and theory development is the first to systematically evaluate palliative care needs-assessment and measurement tools in heart failure.

A main *clinical* contribution is the development of an evidence-based programme theory (Theory of Change) comprising the desired impact of the intervention, long-term outcomes, key preconditions, contextual conditions, core intervention activities, rationales for the causal links, potential outcome measures (indicators), and pathway of change. While there is increasing evidence on the effectiveness of palliative care interventions for patients with heart failure[59-64], there is little understanding of the key intervention components and the causal pathways through which they interact to achieve their outcomes. Through using a programme theory, the study contributes to the body of knowledge by providing a better understanding of the active ingredients and mechanism of integrating palliative care into standard heart failure care. This understanding would reduce research waste, enhance the implementation potential of palliative care, and enable other researchers to replicate and build on this work to develop their interventions[123]. The study thus addresses the recommendations of the MRC framework and other guidelines to adopt a theory in developing complex interventions to investigate how and why these interventions are expected to work[114,119,122]. The developed Theory of Change could also provide a model for palliative care interventions in other contexts or different disease groups. The study answers frequent calls for detailed reporting of complex health and palliative care interventions, and their development process, by adopting the TIDieR checklist[116,118,124]. This would increase the transparency of the developed intervention, enable comparison with other interventions, allow for future replication, and enhance its implementation potential[474].

9.6 Personal reflections

9.6.1 Self-reflexivity in the Theory of Change workshops

I reflected on my experiences throughout all stages of developing the Theory of Change. In the group workshops, I developed a good relationship with two key service providers who provided enormous support to my PhD project from the beginning and attended all the practitioner engagement meetings, workshops, and follow-up meetings. These *champions* are the hospital heart failure team leader, who was the first point of contact and the intermediary between me and the team; and the lead heart failure nurse specialist, who accompanied me in the shadowing activities. This prompted me subconsciously to pay more attention to their voice when I was listening to the audio recordings of the workshops. This was also the case when I was listening to the voice of my supervisors. Counterintuitively, as I became aware of this issue, it had a positive effect as it motivated me to listen to the other voices at the same level of attention.

I had an active role following each workshop discussion as I was responsible for constructing drafts of the Theory of Change map. Although constructing the map was mainly based on the workshops' discussions, it was affected by my previous knowledge and literature review. Nonetheless, these drafts were evaluated by my supervisors and shared with the participants who constantly discussed and refined them until a preliminary theory map was validated. I was concerned that my preunderstandings and literature readings might interfere with or contradict the participants' insights. This thought mainly arose when I contrasted NAT:PD-HF with IPOS in the second workshop to let the participants decide on which tool they wanted to adopt in their practice. As my systematic review concluded that NAT:PD-HF has more evidence than IPOS for use in patients with heart failure, I hoped that participants would choose NAT:PD-HF. However, I was transparent in comparing these tools and did not trigger participants to choose NAT:PD-HF. Ultimately, the participants took their time and decided on the tool they consider more appropriate in their settings two months later in the following workshop after discussions with other staff.

9.6.2 Self-reflexivity in the secondary qualitative data analysis

The qualitative interviews were analysed using *reflexive* thematic analysis, which endorses the role of researcher values and asks researchers to reflect on the analysis process[294]. Multiple factors affected the way through which I looked at the data and developed the themes, including the Normalisation Process Theory core constructs, workshops' discussions, preliminary Theory of Change, findings of the primary study, my expectations about the research topic, and my literature readings. Before the analysis, I expected that some main concepts related to palliative care and heart failure, such as physical suffering, family burden, holistic and patient-centred care, lack of and late palliative care referral, and poor palliative care knowledge, would be key ideas that I should not miss in coding and themes development. Nevertheless, I was driven by the data when developing the themes.

When working on Theme-1 in the secondary data analysis (Impact of heart failure) that describes the problems and palliative care needs of patients with heart failure and their families, I hoped that those needs are covered by NAT:PD-HF to provide more evidence on its appropriateness to the intervention. This prompted me to look deeply at the interview transcripts to find the palliative care needs included in NAT:PD-HF. Similarly, as I worked with patients with heart failure before starting my PhD I was aware of some of their problems, mainly the physical ones, and expected to capture them in the interviews to support Theme-1. However, once I realised this, I was curious to see if other problems were not covered by the tool nor shaped by my assumptions. Ultimately, the palliative care needs discussed in Theme-1 were supported by plenty of data extracts from the interviews which demonstrated the credibility of the analysis.

9.6.3 Self-reflexivity in the follow-up meetings with service providers

In the follow-up meetings after the secondary data analysis, where I aimed to refine the intervention with service providers and co-design a feasibility study protocol, there was a debate regarding the target study sample. Service providers were keen to deliver the intervention to every patient with heart failure visiting their outpatient clinics, but they were concerned whether this was possible given the limited time and resources. Therefore, they suggested selecting patients randomly to participate in the intervention; for example, the first two entering the clinic. I knew that this approach would mean that the intervention cannot be applied routinely in their daily clinics; that is, the intervention is already not feasible. I was also concerned that it would be difficult to provide an ethical rationale for selecting patients in this way, which would decrease the likelihood of getting funding for the future feasibility study.

I started to discuss alternative options with the service providers such as including new patients or those with persistent symptoms. I also discussed a few study designs where all patients would receive the intervention without significantly burdening staff. I liked the idea of the fast-track design where half the patients receive the intervention in the first period, which would minimise the staff burden, before all patients receive the intervention in a subsequent period where staff would be more skilled. Ultimately, service providers endorsed this design and decided to include recently admitted patients as the heart failure team are committed to a specialist review two weeks after hospital discharge. The main struggle in this debate was how to balance the initial desire of stakeholders to include all patients against the practicality of doing this, and how to balance their subsequent desire to include randomly selected patients against the need for scientific rigour and ethical rationale.

While thinking about the feasibility study protocol, I faced the issue of what a feasibility study is and whether and how it differs from a pilot study. Through searching the literature, I found that the two terms are often used interchangeably and inconsistently[386,501]. While some authors consider pilot studies as part of feasibility studies, others consider them mutually exclusive[390]. Some argue that feasibility studies are usually conducted before pilot studies and have a more flexible methodology[388,501]. The NIHR provided a clear distinction between these terms; a pilot study is defined as “a smaller version of the main study used to test whether the components of the main study can all work together”, while feasibility studies are “pieces of research done before a main study in order to answer the question ‘Can this study be done?’”[391]. Ultimately, I adopted the NIHR definition for the feasibility study as I want to explore whether the intervention is feasible and acceptable to healthcare professionals, patients, and family carers in order to address the identified assumptions and uncertainties before conducting the full trial.

9.6.4 Self-reflexivity in the consultation with service users

I conducted the PPI group consultation after spending more than three years developing and refining the intervention with service providers. After such a long time, I was worried that the PPI group may have concerns about the proposed intervention and study design, which means extra work might be needed to meet their needs. I was grateful to discover at the time of the consultation that the PPI group had research experience and were aware of the practicalities and difficulties of conducting palliative care studies. I remained neutral in my discussions and allowed the group members to express their opinions freely. Ultimately, they endorsed the proposed intervention and study design, while also providing informative feedback. After the meeting, I felt relief when I recognised that three years of designing the intervention with service providers were worthwhile as it was supported and perceived acceptable by service users.

10 Conclusion

Given the poor access of patients with heart failure to palliative care and lack of guidance on palliative care integration, this study aimed to develop and refine a theory-based, complex palliative care intervention for patients with heart failure and their family carers. Following a pragmatic philosophical approach, the intervention was co-developed with stakeholders using the MRC framework, MORECare statement, and Bleijenberg et al.'s guidance; underpinned by Normalisation Process Theory and Theory of Change; and guided by a qualitative methodology. This comprehensive, systematic, and rigorous approach to developing the intervention is novel; no other palliative care intervention was developed using such a combination of complementary frameworks and theories. Multiple methods were followed to develop the intervention, starting from a systematic review to identify palliative care needs-assessment and measurement tools for patients with heart failure, through Theory of Change workshops with service providers to develop a theory of how and why the intervention may work in practice, to a secondary qualitative data analysis to include the voice of service users, and ending with follow-up meetings and PPI group consultation to refine the intervention and underlying theory and co-design a feasibility study protocol. The approach used in this study to analyse the Theory of Change workshops, where guidance is lacking, is novel.

Through the development of a Theory of Change underpinning the intervention, this study provides novel insights into the potential mechanism of integrating palliative care into standard heart failure care. If the intervention proved to be successful in achieving the postulated outcomes, it will contribute to meeting the holistic palliative care needs of patients and their families. The developed Theory of Change is represented in a model that demonstrates the intervention desired impact, long-term outcomes, preconditions, intervention activities, assumptions, and hypothetical pathway of change. Rationales for the model causal links, based on scientific and local evidence, and potential outcome measures for key outcomes (indicators) were also identified. The participatory Theory of Change approach enhanced the development stage of the MRC framework and allowed stakeholders to articulate their concerns; resulting in a contextually relevant intervention with high chances of implementation. The findings from this study contribute to the growing body of knowledge for using the Theory of Change approach for developing complex health interventions, especially in the field of palliative care.

10.1 Implications for future research

This study lays the foundation for further design and evaluation of a complex palliative care intervention for patients with heart failure in outpatient settings and their family carers to explore in more depth whether, how, and why the intervention works best in routine practice. Theory of Change development is an iterative process that continues throughout all stages of the MRC framework to modify and strengthen the proposed causal pathway[123]. The next step is to test the causal links and assumptions identified in the developed Theory of Change and evaluate the feasibility and acceptability of the intervention components for further adaptation to optimise the intervention before conducting a full trial[502]. If these assumptions are met in the feasibility study, the proposed causal links will prove to be valid; and if not met, the intervention should be adjusted to fulfil the assumptions. Subsequently, the intervention effectiveness needs to be evaluated in a definitive multi-centre fast-track randomised controlled trial with an embedded process evaluation, after which the intervention components and Theory of Change could further be refined before implementation in clinical practice.

The planned randomised controlled trial for this study will add to the evidence of the effect of palliative care for patients with heart failure[59-64]. It would be the first trial that uses the fast-track design, if proved feasible, to evaluate a palliative care intervention for these patients. It would also be the first randomised controlled trial to evaluate the effect of NAT:PD-HF on patient and family carer outcomes. Findings from this trial will help to determine whether the Theory of Change approach could lead to more effective interventions. They will also help to identify the most important components in achieving the long-term outcomes, and thus components with minimal contribution could be excluded[117]. After the trial, the intervention should be evaluated in an implementation study to assess whether it could be integrated into the routine practice of heart failure teams, whether the effects observed in the randomised trial could be seen in daily practice, and whether other longer-term outcomes that may not be observed in the trial are evident[114].

Researchers should invest considerable time in developing complex interventions, trying to identify their active components and mechanism of action and think about implementation from the outset. Researchers wishing to develop a complex healthcare intervention, not necessarily in the palliative care field, are encouraged to follow the systematic approach adopted in this study. They should consider using the MRC framework in combination with complementary guidelines and strengthening theories. Particularly, they are advised to use Normalisation Process Theory to trigger thinking about implementation processes and the Theory of Change approach to help determine how and why the interventions are expected to work in practice. This would comprise explicating the desired impact and long-term outcomes of the intervention, preconditions and intervention activities required to achieve them, underlying rationales and assumptions, and hypothetical pathway of change[124]. Researchers are thus advised to provide a detailed description of their interventions and underpinning theories, including how both were developed to assess their credibility and the thoroughness of the development process[118,124].

Researchers are advised to follow the systematic Theory of Change development process adopted in this study. Co-designing Theories of Change and complex interventions with stakeholders (service providers and users) throughout all stages of the intervention development process is recommended, as this would enable considering contextual factors and implementation issues from the outset[119]. Future studies should consider involving service users in the Theory of Change workshops. Researchers should also place more emphasis on preconditions at the macro inter-organisational level when developing their Theories of Change. Further research is needed on the best approach and methods to develop effective Theories of Change, including how to analyse the Theory of Change workshops. Guidance is needed on the optimal number and duration of the Theory of Change workshops, and the optimal number of workshop participants. These may depend on who is available in the workshops, their experience and professional diversity, and depth of discussions.

Researchers are advised to use the proposed Theory of Change for their own palliative care interventions, which may include patients with other life-limiting illnesses or different contexts. This would provide evidence for the generalisability and applicability of the developed theory to different populations and settings. Researchers may also consider evaluating the suggested intervention activities and assessing the postulated outcomes for their interventions. This would provide more evidence on the hypothetical pathway of change, which could further enhance the proposed theory. This would also decrease the use of variable outcomes in trials of palliative care interventions for patients with heart failure where no consensus exists on the most appropriate outcomes[59,62]. While many outcomes identified in the developed Theory of Change lack validated outcome measures, such as the heart failure team's ability to discuss care plans and address palliative care needs, researchers are encouraged to establish robust outcome measures to evaluate such outcomes. Using the same outcomes and outcome measures is recommended to combine the evidence from different intervention studies in a meta-analysis[59,62].

10.2 Implications for practice and policy

Research funding agencies are advised to fund intervention development research to overcome the time and resource challenges of developing complex interventions. With adequate funding, researchers will have more time to develop well-designed, effective, and implementable interventions; thus reducing research waste[114]. Developing and refining this intervention and co-designing the feasibility study protocol were time-consuming and resource-intensive. More work is still needed to conduct the feasibility study and refine the intervention before conducting a definitive trial. By the time the trial starts, the context within which the intervention had been developed may change[494]. Funding may overcome this obstacle and accelerate the completion of the remaining stages of the MRC framework.

Funding is needed to supply the necessary resources for heart failure teams to provide palliative care in practice[75]. This issue was brought centre-stage in the discussions with service providers about the study sample for whom the intervention should be delivered. Although they were keen to deliver the intervention to all patients with heart failure attending the heart failure and cardiology clinics, they were certain this would be non-practical given the limited time and resources. Given the guidelines' call to provide palliative care to all patients with a life-limiting illness from the point of diagnosis[15,16], adequate funding should be provided to tackle time and resource issues. Eventually, this funding may result in cost savings as patients provided with palliative care may have reduced hospitalisations and medical resource use[59,62-64].

Policymakers are encouraged to use the developed Theory of Change as a heuristic model to guide actions and monitor progress towards meeting the holistic palliative care needs of patients and families (desired impact). They should consider adopting the outcomes identified in the developed Theory of Change to evaluate existing programmes as they could be surrogates for that impact. Policymakers should be aware of the contextual barriers (assumptions) identified in the developed Theory of Change that may impede the delivery, effectiveness, and implementation of palliative care interventions[123]. Strategies to tackle such barriers should be developed in advance which may include educating healthcare professionals, patients, and families on palliative care; improving communication and collaboration between all parties; using standardised information-exchange systems; and addressing the limited time and resources[75,76,300].

This study adds to the recommendation of integrating multidisciplinary, team-based palliative care in the practice of heart failure teams[62]. The service providers emphasised the importance of communication between healthcare professionals, group meetings, information sharing, and joint working to meet the patient and family palliative care needs. This is evident in the developed Theory of Change where interdisciplinary collaboration is demonstrated in the identified preconditions, assumptions, and intervention activities. Heart failure teams are advised to adopt a holistic needs-based approach to palliative care. The service providers acknowledged the problems of the prognostic approach given the unpredictable trajectory of heart failure[75]. Rather, they endorsed using NAT:PD-HF to identify and triage actions to address patient and family palliative care needs. Although current palliative care guidelines and policies call for more recognition of the palliative care needs of patients with heart failure[13-16], they do not provide practical steps about how to introduce palliative care, which is where this study may help. Ultimately, if this palliative care intervention proved to be feasible and effective, as will be shown in the subsequent feasibility study and definitive trial, it would be recommended to integrate it into the daily practice of heart failure teams.

10.3 My learning and final words

As an academic instructor and clinical pharmacist with experience in identifying and addressing treatment issues for patients with heart failure and other chronic life-limiting illnesses, I recognised the importance of palliative care to relieve patient and family suffering in conjunction with active medical care. Consequently, I wanted to learn how to optimise palliative care for these people, what barriers exist to palliative care delivery, and what could be done to relieve such barriers. Equally, I planned to learn more about palliative care. I was privileged to work with the stakeholders in this study and learn from their clinical and research experiences.

My PhD journey has been a worthy and great experience during which I learned many skills and further developed my professional experience and personality. An important skill I learned is how to solve problems and make decisions when unanticipated events happen, like the COVID-19 pandemic. At the time of the pandemic, I was preparing to test the feasibility of the developed intervention in clinical practice after I managed to complete the Theory of Change workshops, but this was impossible due to restrictions on non-COVID research in the NHS. Now, I believe that the pandemic provided an opportunity to re-examine the developed intervention, look for its weaknesses, and further strengthen it through the secondary data analysis, rather than rushing to the next stage to test the feasibility of a less developed intervention. I believe that the work that I had to do resulted in a better and more rigorous study than what would have been achieved without the pandemic. The core lesson I have learnt is that the quality of the PhD work (extensive and systematic intervention development) is much more important than its quantity (rushed intervention development and feasibility testing) within the limited timeframe and resources.

Through reading patient and family stories and assessing their experiences in the secondary data analysis, I developed a deeper understanding of the impact of heart failure on patients and their families, how they cope with this illness, and how they could be supported to address their palliative care needs. This PhD taught me to move beyond optimising the medical treatment for patients with heart failure (and other life-limiting illnesses) to a more holistic, patient-centred approach that addresses the care needs of both patients and families. I learned how it is difficult to recognise the palliative phase of such patients and the importance of coordinating care among healthcare teams. Through working with the heart failure team in developing the intervention, I am now more aware of the importance of team-based work and interprofessional collaboration for the success and implementation of healthcare interventions. I believe that the gap between research and practice could be addressed efficiently through working with stakeholders who desire change and are willing to improve their daily practice based on the best available scientific evidence.

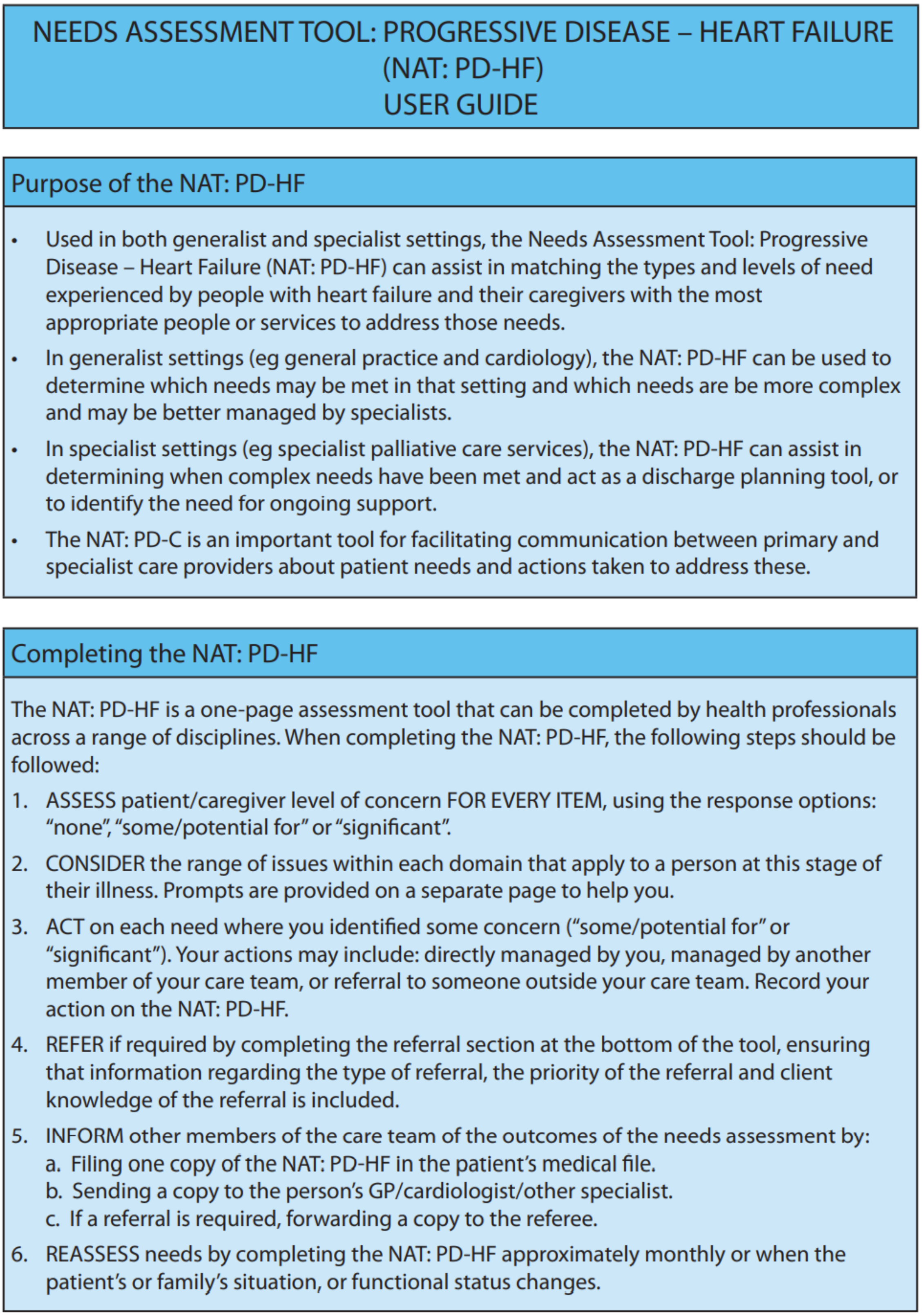
Appendices

Appendix-1: Search strategy for EMBASE (Ovid)

Keywords	Search terms	Search number
Palliative care	exp palliative therapy/ **OR** palliative nursing/ **OR** hospice/ **OR** hospice nursing/ **OR** exp terminal care/ **OR** terminal disease/ **OR** exp terminally ill patient/ **OR** "palliat*".ab,kw,ti. **OR** "hospice*".ab,kw,ti. **OR** dying.ab,kw,ti. **OR** (close adj6 (death or die* or dead)).ab,kw,ti. **OR** long term care/ **OR** ((long term or longterm) adj6 (care* or caring or ill* or disease*)).ab,kw,ti. **OR** ((end or final or late or last) adj6 (stage* or phase*)).ab,kw,ti. **OR** endstage.ab,kw,ti. **OR** (end adj6 life).ab,kw,ti. **OR** EOL.ab,kw,ti. **OR** EOLC.ab,kw,ti. **OR** (last adj6 year adj6 life).ab,kw,ti. **OR** LYOL.ab,kw,ti. **OR** living will/ **OR** (advance* adj6 (care* or caring or plan* or directive*)).ab,kw,ti. **OR** "living will*".ab,kw,ti. **OR** (terminal* adj6 (care* or caring or ill* or disease* or stage* or phase*)).ab,kw,ti. **OR** ((incurable or serious or severe or critical or advanced or progressive) adj6 (ill* or disease* or stage* or phase*)).ab,kw,ti. **OR** bereavement/ **OR** exp bereavement support/ **OR** exp grief/ **OR** treatment withdrawal/ **OR** "bereav*".ab,kw,ti. **OR** (grief or griev*).ab,kw,ti. **OR** (treat* adj6 (withhold* or withdraw*)).ab,kw,ti.	33. 1 **OR** 2 **OR** 3 **OR** 4 **OR** 5 **OR** 6 **OR** 7 **OR** 8 **OR** 9 **OR** 10 **OR** 11 **OR** 12 **OR** 13 **OR** 14 **OR** 15 **OR** 16 **OR** 17 **OR** 18 **OR** 19 **OR** 20 **OR** 21 **OR** 22 **OR** 23 **OR** 24 **OR** 25 **OR** 26 **OR** 27 **OR** 28 **OR** 29 **OR** 30 **OR** 31 **OR** 32
Heart failure	heart failure/ or cardiogenic shock/ or cardiopulmonary insufficiency/ or cardiorenal syndrome/ or exp congestive heart failure/ or exp diastolic dysfunction/ or forward heart failure/ or exp heart ventricle failure/ or exp heart ventricle overload/ or high output heart failure/ or exp systolic dysfunction/ **OR** exp congestive cardiomyopathy/ **OR** HF.ab,kw,ti. **OR** CHF.ab,kw,ti. **OR** ((heart or cardi* or myocard* or ventricular or ventricle*) adj6 (failure* or decompensat* or dysfunction* or insufficienc* or incompet* or shock*)).ab,kw,ti. **OR** paroxysmal dyspnea/ **OR** LVSD.ab,kw,ti. **OR** ((dilated or congestive) adj6 cardiomyopath*).ab,kw,ti. **OR** (cardiac output adj6 low).ab,kw,ti. **OR** heart failure.af.	44. 34 **OR** 35 **OR** 36 **OR** 37 **OR** 38 **OR** 39 **OR** 40 **OR** 41 **OR** 42 **OR** 43

Tools	clinical assessment tool/ **OR** questionnaire/ or open ended questionnaire/ or structured questionnaire/ **OR** health care survey/ **OR** exp health survey/ **OR** checklist/ **OR** exp attitude scale/ **OR** rating scale/ **OR** visual analog scale/ **OR** clinical indicator/ **OR** self report/ **OR** "tool*".ab,kw,ti. **OR** "questionnaire*".ab,kw,ti. **OR** "scor*".ab,kw,ti. **OR** "scale*".ab,kw,ti. **OR** "checklist*".ab,kw,ti. **OR** "indicator*".ab,kw,ti. **OR** "instrument*".ab,kw,ti. **OR** "measure*".ab,kw,ti. **OR** "survey*".ab,kw,ti. **OR** "profile*".ab,kw,ti. **OR** "status*".ab,kw,ti. **OR** "calculator*".ab,kw,ti. **OR** "criteria*".ab,kw,ti. **OR** "model*".ab,kw,ti. **OR** "inventor*".ab,kw,ti. **OR** (index* or indices*).ab,kw,ti. **OR** numeric rating scale/ **OR** psychological rating scale/	73. 45 **OR** 46 **OR** 47 **OR** 48 **OR** 49 **OR** 50 **OR** 51 **OR** 52 **OR** 53 **OR** 54 **OR** 55 **OR** 56 **OR** 57 **OR** 58 **OR** 59 **OR** 60 **OR** 61 **OR** 62 **OR** 63 **OR** 64 **OR** 65 **OR** 66 **OR** 67 **OR** 68 **OR** 69 **OR** 70 **OR** 71 **OR** 72
Combination		74. 33 **AND** 44 **AND** 73
Human filter	(exp animal/ or exp invertebrate/ or nonhuman/ or animal experiment/ or animal tissue/ or animal model/ or exp plant/ or exp fungus/) not (exp human/ or human tissue/)	75. 76. 74 **NOT** 75
Language limit	limit 76 to (arabic or english)	77.
Design limit	limit 77 to (editorial or letter)	78. 79. 77 **NOT** 78

Appendix-2: NAT:PD-HF tool



NEEDS ASSESSMENT TOOL: PROGRESSIVE DISEASE – HEART FAILURE
(NAT: PD-HF)
USER GUIDE

Purpose of the NAT: PD-HF

- Used in both generalist and specialist settings, the Needs Assessment Tool: Progressive Disease – Heart Failure (NAT: PD-HF) can assist in matching the types and levels of need experienced by people with heart failure and their caregivers with the most appropriate people or services to address those needs.
- In generalist settings (eg general practice and cardiology), the NAT: PD-HF can be used to determine which needs may be met in that setting and which needs are be more complex and may be better managed by specialists.
- In specialist settings (eg specialist palliative care services), the NAT: PD-HF can assist in determining when complex needs have been met and act as a discharge planning tool, or to identify the need for ongoing support.
- The NAT: PD-C is an important tool for facilitating communication between primary and specialist care providers about patient needs and actions taken to address these.

Completing the NAT: PD-HF

The NAT: PD-HF is a one-page assessment tool that can be completed by health professionals across a range of disciplines. When completing the NAT: PD-HF, the following steps should be followed:

1. ASSESS patient/caregiver level of concern FOR EVERY ITEM, using the response options: “none”, “some/potential for” or “significant”.
2. CONSIDER the range of issues within each domain that apply to a person at this stage of their illness. Prompts are provided on a separate page to help you.
3. ACT on each need where you identified some concern (“some/potential for” or “significant”). Your actions may include: directly managed by you, managed by another member of your care team, or referral to someone outside your care team. Record your action on the NAT: PD-HF.
4. REFER if required by completing the referral section at the bottom of the tool, ensuring that information regarding the type of referral, the priority of the referral and client knowledge of the referral is included.
5. INFORM other members of the care team of the outcomes of the needs assessment by:
    a. Filing one copy of the NAT: PD-HF in the patient’s medical file.
    b. Sending a copy to the person’s GP/cardiologist/other specialist.
    c. If a referral is required, forwarding a copy to the referee.
6. REASSESS needs by completing the NAT: PD-HF approximately monthly or when the patient’s or family’s situation, or functional status changes.

NEEDS ASSESSMENT TOOL : PROGRESSIVE DISEASE HEART FAILURE (NAT: PD-HF)

COMPLETE ALL SECTIONS

PATIENT NAME: ____

DATE: ______________ DIAGNOSIS: ______________________

PATIENT/ADDRESS LABEL

SECTION 1: PRIORITY REFERRAL FOR FURTHER ASSESSMENT

	Yes	No	If yellow boxes are ticked, consider assessment by SPCS
1. Does the patient have a caregiver readily available if required?		🟨	
2. Has the patient or caregiver requested a referral to a specialist palliative care service (SPCS)?	🟨		
3. Do you require assistance in managing the care of this patient and/or family?	🟨		

SECTION 2: PATIENT WELLBEING (Refer to the back page for assistance)

	Level of Concern			Action Taken		
	None	Some/ Potential	Significant	Directly managed	Managed by other care team member	Referral required
1. Is the patient experiencing unresolved physical symptoms (including problems with breathlessness, pain, fatigue, nausea, oedema, insomnia or cough)?						
2. Does the patient have problems with daily living activities?						
3. Does the patient have psychological symptoms that are interfering with wellbeing or relationships?						
4. Does the patient have concerns about how to manage his/her medication and treatment regimes?						
5. Does the patient have concerns about spiritual or existential issues?						
6. Does the patient have financial or legal concerns that are causing distress or require assistance?						
7. From the health delivery point of view, are there health beliefs, cultural or social factors involving the patient or family that are making care more complex?						

8. Does the patient require information about: ☐ The prognosis ☐ Treatment options ☐ Advance directive/resuscitation preferences ☐ Financial/legal issues
(tick any options that are relevant) ☐ Heart disease ☐ Medical/health/support services ☐ Social/emotional issues

COMMENTS: ____

SECTION 3: ABILITY OF CAREGIVER OR FAMILY TO CARE FOR PATIENT (Refer to the back page for assistance)

Who provided this information? (please tick one) ☐ Patient ☐ Caregiver ☐ Both	Level of Concern			Action Taken		
	None	Some/ Potential	Significant	Directly managed	Managed by other care team member	Referral required
1. Is the caregiver or family distressed about the patient's physical symptoms?						
2. Is the caregiver or family having difficulty providing physical care?						
3. Is the caregiver or family having difficulty coping?						
4. Is the caregiver have difficulty managing the patient's medication and treatment regimes?						
5. Does the caregiver or family have financial or legal concerns that are causing distress or require assistance?						
6. Is the family currently experiencing problems that are interfering with their functioning or inter-personal relationships, or is there a history of such problems?						

7. Does the caregiver require information: ☐ The prognosis ☐ Advance directive/resuscitation preferences ☐ Medical/health/support services ☐ Heart disease
(tick any options that are relevant) ☐ Treatment options ☐ What to do in event of patient's death ☐ Social/emotional issues ☐ Financial /legal issues

COMMENTS: ____

SECTION 4: CAREGIVER WELLBEING (Refer to the back page for assistance)

Who provided this information? (please tick one) ☐ Patient ☐ Caregiver ☐ Both	Level of Concern			Action Taken		
	None	Some/ Potential	Significant	Directly managed	Managed by other care team member	Referral required
1. Is the caregiver or family experiencing physical, practical, spiritual, existential or psychological problems that are interfering with their wellbeing or functioning?						
2. Is the caregiver or family experiencing grief over the impending or recent death of the patient that is interfering with their wellbeing or functioning?						

COMMENTS: ____

IF REFERRAL REQUIRED FOR FURTHER ASSESSMENT OR CARE, PLEASE COMPLETE THIS SECTION

1. Referral to: (Name) ______________________________
2. Referral to: (Specialty) ☐ General practitioner ☐ Social worker ☐ Psychologist ☐ Specialist palliative care service
☐ Cardiologist ☐ Other ______________
3. Priority of assessment needed: ☐ Urgent (within 24 hours) ☐ Semi-Urgent (2-7 days) ☐ Non-Urgent (next available)
4. Discussed the referral with the client. ☐ Yes ☐ No
5. Client consented to the referral. ☐ Yes ☐ No
6. Referral from: Name: ________________ Position: ____________ Signature: ____________

ISSUES TO CONSIDER WHEN RATING THE LEVEL OF CONCERN

PATIENT WELLBEING

Physical symptoms
- Does the patient present with unresolved physical symptoms such as drowsiness, fatigue, dyspnoea, vomiting/nausea, persistent cough, pain, oedema, constipation, sleep problems or loss appetite?

Activities of daily living
- Is the patient having difficulty with toileting, showering, bathing, or food preparation?
- Is there a caregiver to assist the patient?

Psychological
- Is the patient experiencing sustained lowering of mood, tearfulness, guilt or irritability, loss of pleasure or interest in usual activities?
- Is the patient experiencing feelings of apprehension, tension, anger, fearfulness or nervousness, hopelessness or a sense of isolation?
- Is the patient requesting a hastened death?

Medication and treatment
- Is the patient able to manage complex medication and treatment regimes?

Spiritual/Existential
- Is the patient feeling isolated or hopeless?
- Does the patient feel that life has no meaning or that his/her life has been wasted?
- Does the patient require assistance in finding appropriate spiritual resources or services?

Financial/Legal
- Are there financial concerns relating to loss of income or costs of treatment, travel expenses, or equipment?
- Is the family socio-economically disadvantaged?
- Are there conflicting opinions between patient and family relating to legal issues such as end-of-life care options and advance care plans?
- Is the patient or family aware of the various financial schemes available and do they need assistance in accessing these?

Health Beliefs, Social and Cultural
- Does the patient or family have beliefs or attitudes that make health care provision difficult?
- Are there any language difficulties? Does the patient or family require a translator?
- Is the family preventing information about prognosis from being disclosed to the patient?
- Does the information have to be passed on to a particular member of the family or cultural group?
- Is the patient or family feeling socially isolated?
- Does the family live more than 50km from the primary service provider?
- Is the patient of Aboriginal or Torres Strait Islander descent?
- Is the patient over 75 years of age? (NB: older patients are under-represented in SPCSs.)

Information
- Does the patient want more information about the course and prognosis of the disease and treatment options?
- Is the patient aware of the various care services available to assist them and do they need assistance in accessing these? (eg financial and legal assistance, psychological services, support groups, pastoral care.)

ABILITY OF CAREGIVER OR FAMILY TO CARE FOR PATIENT

Physical symptoms
- Are the patient's physical symptoms causing the caregiver and family distress?

Providing physical care
- Is the caregiver having difficulty coping with activities of daily living or practical issues such as equipment and transport?

Psychological
- Is the caregiver having difficulty coping with the patient's psychological symptoms?
- Is the caregiver requesting a hastened death for the patient?

Medication and treatment
- Is the caregiver having difficulty managing complex medication and treatment regimes?

Family and Relationships
- Is there any communication breakdown or conflict between patient and family over prognosis, treatment options or care giving roles?
- Is the patient particularly concerned about the impact of the illness on the caregiver or family?

Information
- Does the caregiver or family want more information about the course and prognosis of the disease and treatment?
- Is the caregiver or family aware of the care services available to assist them and do they need assistance in accessing these? (eg respite, financial and legal services, psychological services, support groups, pastoral care.)

CAREGIVER WELLBEING

Physical and psychosocial
- Is the caregiver experiencing physical symptoms eg fatigue, physical strain, blood pressure/heart problems, stress related illness, or sleep disturbances?
- Is the caregiver feeling depressed, hopeless, fearful, nervous, tense, angry, irritable or critical of others, or overwhelmed?
- Does the caregiver have spiritual/existential issues that are of concern?

Bereavement Grief (pre and post death)
- Is the caregiver or family experiencing intrusive images, severe pangs of emotion, denial of implications of loss to self and neglect of necessary adaptive activities at home or work?

Funded by the Australian Government Department of Health and Ageing and Cancer Council NSW

Appendix-3: Characteristics of the palliative care identification studies

Author, year, setting	Study design	Patient inclusion/exclusion criteria	Participants	Screened HF patients (%)
		IPOS		
Kane et al. 2017, **Kane et al. 2018** **Multi-centre; Hospital clinics; Ireland**	Parallel mixed-methods intervention feasibility study, including semi-structured interviews **Intervention:** Training HFNSs on patient-centred care and IPOS	**Inclusion:** Patients ≥ 18 years; Fluency and literacy in English; Good cognitive function; Advanced disease (NYHA class II-IV with either systolic dysfunction/HFrEF, symptoms with HFpEF, or symptoms with HFmrEF)	Patients with CHF: HFrEF, HFpEF, HFmrEF; and NYHA II-IV HF patients screened by the tool (n=25); completed the follow-up outcome measures (n=23); included in the interviews (n=18) HFNSs included in the intervention and interviews (n=4)	**Mean age:** 76 years **NYHA class:** II (32%) III (64%) IV (4%) **LVEF:** HFrEF (40%) HFmrEF/HFpEF (60%)
Roch et al. 2020 **Single centre; Hospital inpatient; Germany**	Cross-sectional	**Inclusion:** Adults; Heart failure diagnosis; Inpatients in the hospital cardiology department; Understanding German language **Exclusion:** Cognitive impairment; Substantial comprehension problems; Poor general condition	Patients with HF: NYHA II-IV HF patients screened by the tool (n=100)	**Mean age:** 78.5 years **NYHA class:** II (4%) III (65%) IV (31%) **LVEF:** ≤ 40% (40%) > 40% (58%)
		GSF-PIG		
Milnes et al. 2019 **Single centre; Hospital inpatient; Australia**	Observational cohort	**Inclusion:** Patients > 18 years; Admitted to acute hospital **Exclusion:** Paediatrics, maternity, psychiatric, day surgery	Patients with mixed diseases including CHF Patients screened by the tool (n=626); HF patients screened by the tool (n=?)	not available

Haga et al. 2012 **Single centre; Outpatient; UK (Scotland)**	Observational cohort	**Inclusion:** NYHA class III-IV; Managed by HFNSs team **Exclusion:** Patients to be discharged from HF nursing service within 6 weeks	Patients with CHF: LVD, and NYHA III-IV HF patients screened by the tool (n=138)	**Mean age:** 77 years **NYHA class:** III (74%) IIIb (21%) IV (5%) **LVD:** Mild (19%) Moderate (36%) Severe (45%)
Gardiner et al. 2013, **Ryan et al. 2013** **Multi-centre; Hospital inpatient; UK (England)**	Cross-sectional	**Inclusion:** Patients ≥ 18 years; Residents on the ward at 9.00 am on the survey day **Exclusion:** Paediatric wards, mother and baby units; Non-English speaking; Deaf patients; Non-consenting patients; Unable to consent and no one to consent on their behalf	Patients with mixed diseases including CHF Patients screened by the tool (n=514); HF patients screened by the tool (n=?)	not available
Pandini et al. 2016 **Single centre; Hospital inpatient; Italy**	Observational	**Inclusion:** Patients admitted to the medical ward from the emergency department	Patients with mixed diseases including HF (probably chronic) Patients screened by the tool (n=781); HF patients screened by the tool (n=?)	not available
RADPAC				

Thoonsen et al. 2011, Thoonsen et al. 2015, Thoonsen et al. 2019, Thoonsen et al. 2016 **Multi-centre; Primary care; Netherlands**	Cluster, two-armed randomised controlled trial, followed by a cross-sectional survey (one year after the trial) and focus group and semi-structured interviews **Intervention:** Training GPs on RADPAC and the Problems and Needs Square; coaching sessions with PC consultants; and peer group sessions **Control:** Usual patient care	**Inclusion:** Patients in general practice who died from cancer, CHF, or COPD in the past 12 months	Patients with mixed diseases including CHF **Intervention group:** Patients screened by the tool (n=216); HF patients screened by the tool (n=32) **Control group:** Patients screened by the tool (n=0) *(One year after the trial, patients were screened by the tool by untrained GPs to explore its short-term effect)* GPs randomised (I=57, C=77); included in the cross-sectional survey (I=12, C=28); included in the interviews (I=9)	not available
SPICT				
Highet et al. 2014 **Single centre; Hospital inpatient; UK (Scotland)**	Mixed-methods, prospective case-finding study	**Inclusion:** Patients with advanced kidney, liver, heart, or lung disease following an emergency admission to hospital	Patients with mixed diseases including HF Patients screened by the tool (n=?); HF patients screened by the tool (n=? *“570 patients from the cardiology unit”*)	not available
Hamano et al. 2018 **Single centre; Outpatient; Japan**	Cross-sectional	**Inclusion:** Patients ≥ 65 years	Patients with mixed diseases including HF Patients screened by the tool (n=87); HF patients screened by the tool (n=? *“5 patients with heart/vascular disease”*)	not available

Hamano et al. 2019 **Multi-centre; Outpatient; Japan**	Cross-sectional	**Inclusion:** Patients ≥ 65 years	Patients with mixed diseases including HF Patients screened by the tool (n=382); HF patients screened by the tool (n=? *“38 patients with cardiovascular disease”*)	not available
NAT:PD-HF				
Waller et al. 2013 **Single centre; Hospital inpatient/ outpatient; Australia**	Cross-sectional	**Inclusion:** HF of systolic or diastolic aetiology managed by multidisciplinary HF clinic; Patients receiving maximal therapy or documented intolerance/trial; Hospitalised for HF within the last 12 months; Good English understanding; Cognitive and emotional capacity of participating	Patients with CHF: systolic, diastolic; and NYHA I-IV HF Patients screened by the tool (n=52)	**Mean age:** 67 years **NYHA class:** I (21%) II (23%) III (50%) IV (10%) **LVEF:** < 50% (23%) > 50% (65%)
Janssen et al. 2019 **Single centre; Outpatient; Netherlands**	Mixed-methods intervention pilot, including focus group **Intervention:** Training on Dutch NAT:PD-HF	**Inclusion:** Diagnosis of CHF according to the ESC guidelines; NYHA class III-IV; Patients planned to receive a home visit by HFNS; Ability to complete written questionnaires or participate in interviews; Ability to consent **Exclusion:** Patients known to the SPC team	Patients with CHF: NYHA III-IV HF patients screened by the tool (n=23); completed the follow-up outcome measures (n=17) HFNSs included in the intervention and focus group (n=8)	**Mean age:** 84 years **NYHA class:** III (61%) IV (39%)

Campbell et al. 2015, **Campbell et al. 2018** **Single centre; Hospital inpatient; UK (Scotland)**	Observational	**Inclusion:** Patients ≥ 18 years; Admitted with acute decompensated HF; Diagnosis of HF **Exclusion:** Refusal to participate; Inability to consent or complete study assessments (cognitive/language barriers); Readmission; Geographical reasons; Isolated cor pulmonale; Acute coronary syndrome complicated by pulmonary oedema	Patients with acute on CHF: HFrEF, HFpEF; valvular heart disease; and NYHA II-IV HF patients screened by the tool (n=272)	**Mean age:** 75 years **NYHA class:** II (30%) III (52%) IV (18%) **LVEF:** ≤ 50% (67%)
NECPAL				
Gómez-Batiste et al. 2013, **Gómez-Batiste et al. 2014,** **Amblàs-Novellas et al. 2016** **Multi-centre; Primary care, hospital inpatient, social health centre, nursing homes; Spain**	Cross-sectional, population-based	**Inclusion:** Patients with advanced chronic conditions **Exclusion:** Outpatient clinics, day-care facilities, and day hospitals *(assuming patients would be identified in primary care centres)*	Patients with mixed diseases including CHF Patients screened by the tool (n=1,064); HF patients screened by the tool (n=88)	not available

de-la-Rica-Escuín et al. 2019 **Single centre; Hospital inpatient; Spain**	Cross-sectional	**Inclusion:** Patients admitted to internal medicine department; Advanced progressive chronic disease; Charlson score ≥ 3; Patient's or proxy's consent	Patients with mixed diseases including CHF Patients screened by the tool (n=142); HF patients screened by the tool (n=95)	not available
Orzechowski et al. 2019 **Single centre; Hospital inpatient; Brazil**	Cross-sectional	**Inclusion:** Patients > 35 years; Hospitalised in a cardiology service with NYHA class III-IV HF or LVEF ≤ 40% **Exclusion:** Unable to respond to tool questions and no one to respond on patient behalf	Patients with HF (probably chronic): HFrEF, and NYHA III-IV HF patients screened by the tool (n=82)	**Mean age:** 68 years
Gastelurrutia et al. 2019 **Multi-centre; Hospital clinics; Spain**	Observational	**Inclusion:** Ambulatory patients in hospital heart failure clinics	Patients with HF (probably chronic): NYHA I-IV HF patients screened by the tool (n=922)	**Mean age:** 69 years **NYHA class:** I (6%) II (74%) III (17%) IV (3%) **Mean LVEF:** 41.4%

C: Control group, CHF: Chronic Heart Failure, HF: Heart Failure, HFNS: Heart Failure Nurse Specialist, I: Intervention group, LVD: Left Ventricular Dysfunction, PC: Palliative Care, SPC: Specialist Palliative Care.

Appendix-4: Results of the tools' applications in identifying heart failure populations with palliative care needs

Author, year	Tools for identifying PC patients and needs	Findings
IPOS		
Kane et al. 2017, **Kane et al. 2018**	**Patient identification:** not reported **Needs identification:** IPOS *(version-1, patient/7-days version, self-completed by patients with help from HFNSs on request. These nurses were instructed on how to act if patients ask help to fill the tool and supervised by the primary researcher)*	**PC needs in HF patients among those assessed by IPOS (%):** Anxiety of patients and carers: 12/18 (67%); Pruritus, insomnia, immobility, leg swelling, cough *(identified by the open question)*: (?) **Intervention effect:** Short-term, slight improvement in symptom burden, quality of life, and depression, though not necessarily sustained; Worsening of caregiver burden *Statistical significance was not determined because of small sample size* **Interviews' findings:** Strengths: Themes: Identification of unmet needs; Holistic assessment; Patient empowerment Limitations: No positive effect on clinical interaction; 28% of patients did not consider the intervention to have any clinical effect; HFNSs expressed concern on the IPOS spiritual question *"Have you felt at peace?"*

Roch et al. 2020	**Patient identification:** IPOS *(German version, patient/3-days version, by reporting at least 2 tool items as overwhelming or 3 tool items as severe, self-completed by patients)* **Needs identification:** IPOS *(German version, patient/3-days version)*	**HF patients identified by IPOS for PC among those screened (%):** 56/100 (56%) **PC needs in HF patients among those assessed by IPOS (%):** Clinically relevant (moderate to overwhelming) physical symptoms: Pain: 40/100 (40%); Shortness of breath (64%); Weakness or lack of energy (62%); Nausea (12%); Vomiting (2%); Poor appetite (40%); Constipation (28%); Sore or dry mouth (68%); Drowsiness (49%); Poor mobility (67%) Other clinically relevant concerns: Patient anxiety: 56/100 (56%); Family anxiety (79%); Depression (47%); Feeling at peace (11%); Sharing feelings (42%); Information needs (22%); Practical issues (10%) **Mean IPOS scores (n=100):** Total score: 21.5/68 *(insignificant difference between NYHA II and III patients (20.9) versus NYHA IV patients (21.5))* Physical symptoms score: 13.1/40 Emotional symptoms score: 5.9/16 Communication/practical issues score: 2.5/12
GSF-PIG		
Milnes et al. 2019	**Patient identification:** GSF-PIG *(4th edition, 2011, using only the clinical disease-specific criteria, filled using medical records in hospital wards)* **Needs identification:** not reported	**HF patients identified by GSF-PIG for PC among those screened (%):** ~ 10/? (?) *This represents patients who met the GSF-HF criteria. Number of HF patients who met the other GSF disease-specific criteria, and so were also identified for PC, was not reported. Therefore, the actual number of identified HF patients might be > 10*

Haga et al. 2012	**Patient identification:** SHFM, GSF-PIG *(version-2.25, 2006, using only the clinical HF-specific criteria, filled by HFNSs who were asked about two of the GSF-HF criteria, and using the clinical HF database for the other two GSF-HF criteria)* **Needs identification:** GSF-PIG *(version-2.25, 2006, using only the clinical HF-specific criteria)*	**HF patients identified by GSF-PIG for PC among those screened (%):** 119/138 (86%) *This represents patients who met the GSF-HF criteria* **PC needs in HF patients among those assessed by GSF-PIG (%):** Difficult physical or psychological problems despite optimised therapy: 113/138 (82%); ≥ 2 hospital admissions for HF symptoms in the previous 12 months: 32/138 (24%); NYHA class III or IV symptoms: 138/138 (100%) **Characteristics and outcomes of identified patients (n=119):** Patients meeting GSF-HF criteria had spent significantly longer in HF service and hospital and had significantly more all-cause hospital admissions over the previous 12 months, compared to those not meeting the criteria. However, they did not have significantly more hospital admissions during the 12-month follow-up period
Gardiner et al. 2013, Ryan et al. 2013	**Patient identification:** GSF-PIG (*using only the clinical disease-specific criteria, filled using hospital case notes by researchers with a clinical background in medicine or nursing after undergoing training in survey methodology and data collection)* **Needs identification:** SPARC	**HF patients identified by GSF-PIG for PC among those screened (%):** ~ 38/? (?) *This represents patients who met the GSF-HF criteria. Number of HF patients who met the other GSF disease-specific criteria, and so were also identified for PC, was not reported. Therefore, the actual number of identified HF patients might be > 38* **Symptom burden in identified patients (n=38):** 61% of identified patients had significant physical burden as measured by SPARC; 39% of identified patients had significant psychological burden as measured by SPARC; Meeting the GSF-HF criteria was not a predictor of significant physical and psychological burden as measured by SPARC
Pandini et al. 2016	**Patient identification:** GSF-PIG *(4th edition, 2011, filled by a physician and nurse of the Internal Medicine ward)* **Needs identification:** not reported	**HF patients identified by GSF-PIG for PC among those screened (%):** ~ 20/? (?) *This represents cardiopulmonary patients who met the tool criteria. However, not all these patients had HF. Therefore, the actual number of identified HF patients might be < 20*
	RADPAC	

Thoonsen et al. 2011, Thoonsen et al. 2015, Thoonsen et al. 2019, Thoonsen et al. 2016	**Patient identification:** RADPAC *(filled by GPs (I) in the trial, and then filled by GPs (C) one year after the trial)* **Needs identification:** Problems and Needs Square *(proactive PC planning card)*	**HF patients identified by RADPAC for PC among those screened (%):** By GPs (I) in the trial: 2/32 (6%) By GPs (I) one year after the trial: 0/? (0%) By GPs (C) one year after the trial, shortly after being administered RADPAC: 4/? (?) *(these GPs did not identify any HF patient before being administered the RADPAC)* **Intervention effect:** Number of contacts with out-of-hours GP service, contacts with own GP, hospitalisations, and place of death were not significantly different between patients assessed by GPs (I) and patients assessed by GPs (C) *This applies to all patients "I=216, C=271"; some of whom had HF "I=32, C=52"* In post-hoc analysis; patients identified as palliative by GPs (I) had significantly more contacts with their own GP, fewer hospitalisations, and less often died in hospital compared to all other patients. However, number of contacts with out-of-hours GP service was not significantly different *This applies to all 49 identified patients; 2 of whom had HF* **Interviews' findings:** <u>Strengths</u>: Theme: Identification of palliative patients (clear indicators, integrated into some GPs' daily practice) <u>Limitations</u>: Timely recognition of HF patients who need PC was considered difficult despite using RADPAC
	SPICT	
Highet et al. 2014	**Patient identification:** SPICT *(2013, filled by senior nursing ward staff and speciality registrars)* **Needs identification:** SPICT *(2013)*	**HF patients identified by SPICT for PC among those screened (%):** ~ 16/570 (3%) *This represents patients from the cardiology unit who met the tool criteria. However, not all these patients had HF. Therefore, the actual number of identified HF patients might be < 16* **PC needs in HF patients among those assessed by SPICT (%):** *Needs were reported for mixed-disease patients, without specifying those for HF patients*

Hamano et al. 2018	**Patient identification:** SPICT-J *(Japanese version, 2015, filled by the chief researcher)* **Needs identification:** SPICT-J *(Japanese version, 2015)*	**HF patients identified by SPICT for PC among those screened (%):** ~ 3/5 (60%) *This represents heart-vascular disease patients who met the tool criteria. However, not all these patients might have HF. Therefore, the actual number of identified HF patients might be < 3* **PC needs in HF patients among those assessed by SPICT (%):** Asks for PC or treatment withdrawal: 3/3 (100%); KPS ≤ 50% and limited reversibility: 1/3 (33%); Significant weight loss or low body mass index: 1/3 (33%); Persistent troublesome symptoms: 1/3 (33%); Care dependence: 0/3 (0%); Unplanned hospital admissions: 0/3 (0%)
Hamano et al. 2019	**Patient identification:** SPICT-J *(Japanese version, 2015, filled by GPs)* **Needs identification:** SPICT-J *(Japanese version, 2015)*	**HF patients identified by SPICT for PC among those screened (%):** **~** 5/38 (13%) *This represents cardiovascular disease patients who met the tool criteria. However, not all these patients might have HF. Therefore, the actual number of identified HF patients might be < 5* **PC needs in HF patients among those assessed by SPICT (%):** NYHA class III-IV HF, or extensive, untreatable coronary artery disease with breathlessness or chest pain at rest or on minimal exertion: 4/38 (11%)
NAT:PD-HF		
Waller et al. 2013	**Patient identification:** not reported **Needs identification:** NAT:PD-HF *(filled by HF service staff (doctors and nurses) in consultation with patients)*	**PC needs in HF patients among those assessed by NAT:PD-HF (%):** Physical symptoms: (?) *most reported some concern;* Daily living activities: (?) *most reported some concern;* Psychological symptoms: (?) *most reported no concern;* Social needs: (?) *most reported no concern;* Spiritual needs: (?) *most reported no concern*

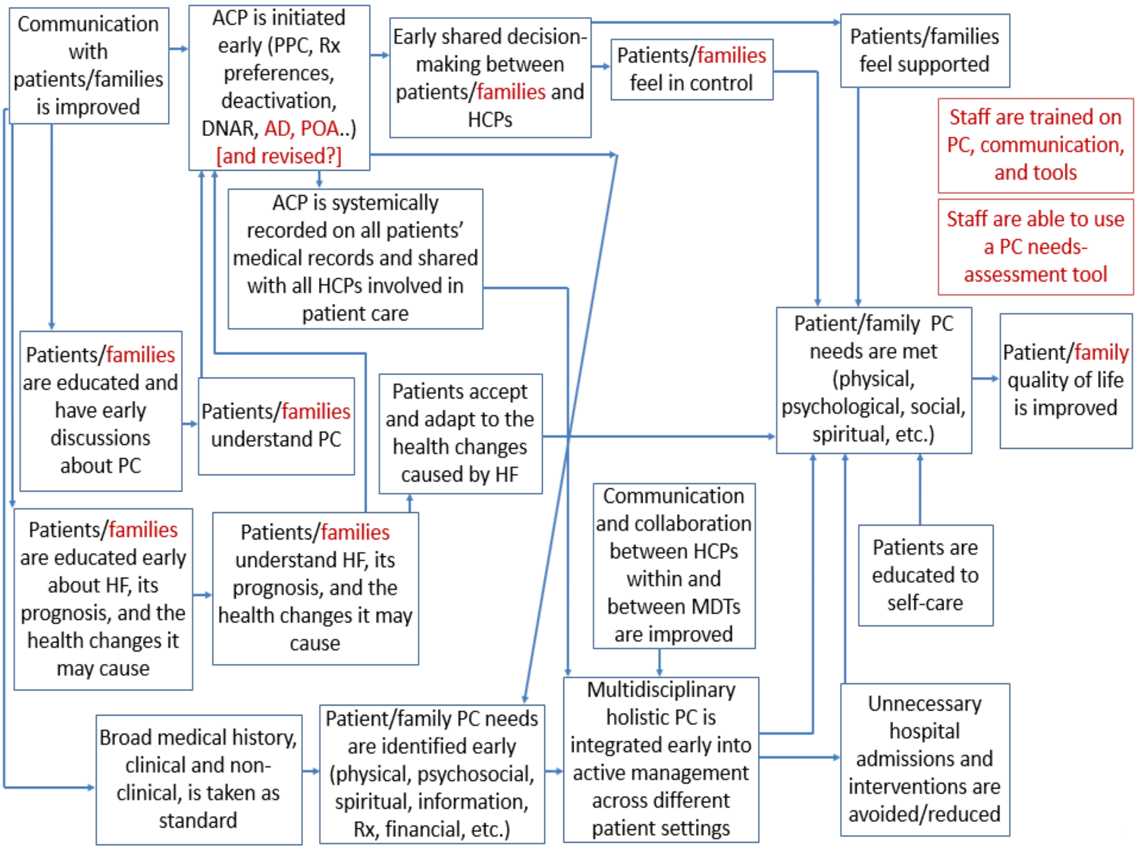
Janssen et al. 2019	**Patient identification:** NAT:PD-HF *(Dutch translation, by reporting some/potential or significant concern for any tool item, filled by HFNSs who were collaborating closely with CHF cardiologists (part of a multidisciplinary team) and trained in CHF care and motivational interviewing skills)* **Needs identification:** NAT:PD-HF *(Dutch translation)*	**HF patients identified by NAT:PD-HF for PC among those screened (%):** 23/23 (100%) **PC needs in HF patients among those assessed by NAT:PD-HF (%):** *Assessed but proportions were not reported* **Intervention effect:** No significant improvement in symptom burden, physical functioning, care dependency, and caregiver burden; Significant worsening of disease-specific health status; No effect on number of recorded advance directives, hospital admissions, and emergency room visits **Focus group findings:** <u>Strengths</u>: Paying attention to caregiver needs <u>Limitations</u>: Not helpful to discuss PC needs; Lack of questions that help to introduce and communicate about PC; Questions not fitting with patient needs; Many questions are not clear to patients; Lack of guidance towards required interventions after patient identification; Long list with several questions; Not considering to what extent patients want to discuss PC needs
Campbell et al. 2015, Campbell et al. 2018	**Patient identification:** KCCQ, SF-12, ESAS, HADS, NAT:PD-HF *(by reporting significant concern for any item in the patient wellbeing section, filled by a physician)* **Needs identification:** KCCQ, SF-12, ESAS, HADS, NAT:PD-HF	**HF patients identified by NAT:PD-HF for PC among those screened (%):** 70/272 (26%) **PC needs in HF patients among those assessed by NAT:PD-HF (%):** *Assessed but proportions were not reported* **SPC need in identified patients (n=70):** 38% of patients who met the authors' definition of "SPC need" were identified by NAT:PD-HF compared to 21% of patients who did not (significant difference); Being identified by NAT:PD-HF was an insignificant predictor of which patients need SPC according to the authors' definition *Authors defined SPC need as "persistently severe impairment of any PROM (KCCQ, SF-12, ESAS, HADS) without improvement, or severe impairment immediately preceding death"*

NECPAL		
Gómez-Batiste et al. 2013, Gómez-Batiste et al. 2014, Amblàs-Novellas et al. 2016	**Patient identification:** NECPAL *(Catalan version, filled by healthcare professionals (doctors and nurses) for the categories that require clinical judgement, and using clinical records for the quantitative variables)* **Needs identification:** NECPAL *(Catalan version)*	**HF patients identified by NECPAL for PC among those screened (%):** 80/88 (91%) *65 patients met the NECPAL-chronic heart disease criteria (not enough to be identified)* **PC needs in HF patients among those assessed by NECPAL (%):** Choice/request for PC by patient: 5/63 (8%); Choice/request for PC by family: 13/63 (21%); Need of PC by healthcare professionals: 10/63 (16%); General clinical indicators: *low level of needs (proportions were reported in detail but no space to display in this table)* **Other findings:** 98% of heart disease patients with a negative answer to the surprise question were identified for PC by NECPAL
de-la-Rica-Escuín et al. 2019	**Patient identification:** NECPAL *(version-3.0, 2016, filled by patients, caregivers, or principal investigators who were trained on using NECPAL (depending on patient condition at that time and the nature of tool items), and using patient's clinical history)* **Needs identification:** NECPAL *(version-3.0, 2016)*	**HF patients identified by NECPAL for PC among those screened (%):** > 85/95 (> 89%) *89 patients met the NECPAL-chronic heart disease criteria (not enough to be identified)* **PC needs in HF patients among those assessed by NECPAL (%):** *Needs were reported for mixed-disease patients, without specifying those for HF patients* **Other findings:** 100% of heart disease patients with a negative answer to the surprise question were identified for PC by NECPAL

Orzechowski et al. 2019	**Patient identification:** NECPAL *(Catalan version, filled by an assistant physician, patient, and/or caregiver)* **Needs identification:** NECPAL *(Catalan version)*	**HF patients identified by NECPAL for PC among those screened (%):** 45/82 (55%) **PC needs in HF patients among those assessed by NECPAL (%):** Choice/request for PC by patient/family: 30/82 (37%); Need of PC by healthcare professionals: 47/82 (57%); General clinical indicators: *low to moderate level of needs (proportions were reported in detail but no space to display in this table)*; Specific clinical indicators: *low level of needs (proportions were reported in detail but no space to display in this table)* **Other findings:** 98% of HF patients with a negative answer to the surprise question were identified for PC by NECPAL
Gastelurrutia et al. 2019	**Patient identification:** NECPAL *(Catalan version, filled by a nurse and/or physician)* **Needs identification:** NECPAL *(Catalan version)*	**HF patients identified by NECPAL for PC among those screened (%):** 297/922 (32%) **PC needs in HF patients among those assessed by NECPAL (%):** Choice/request for PC by patient/family: 4%; Need of PC by healthcare professionals: 4%; General clinical indicators: 71% (multimorbidity is the most common); HF-specific clinical indicators (≥ 2 indicators): 17% - LVEF < 30% or PAP > 60 mmHg: 19% - NYHA III/IV, severe valve disease, or inoperable coronary disease: 24% **Other findings:** 91% of HF patients with a negative answer to the surprise question were identified for PC by NECPAL

C: Control group, CHF: Chronic Heart Failure, HF: Heart Failure, HFNS: Heart Failure Nurse Specialist, I: Intervention group, KCCQ: Kansas City Cardiomyopathy Questionnaire, KPS: Karnofsky Performance Scale, PAP: Pulmonary Artery Pressure, PC: Palliative Care, SF-12: Short Form health survey-12, SHFM: Seattle Heart Failure Model, SPARC: Sheffield Profile for Assessment and Referral to Care, SPC: Specialist Palliative Care.

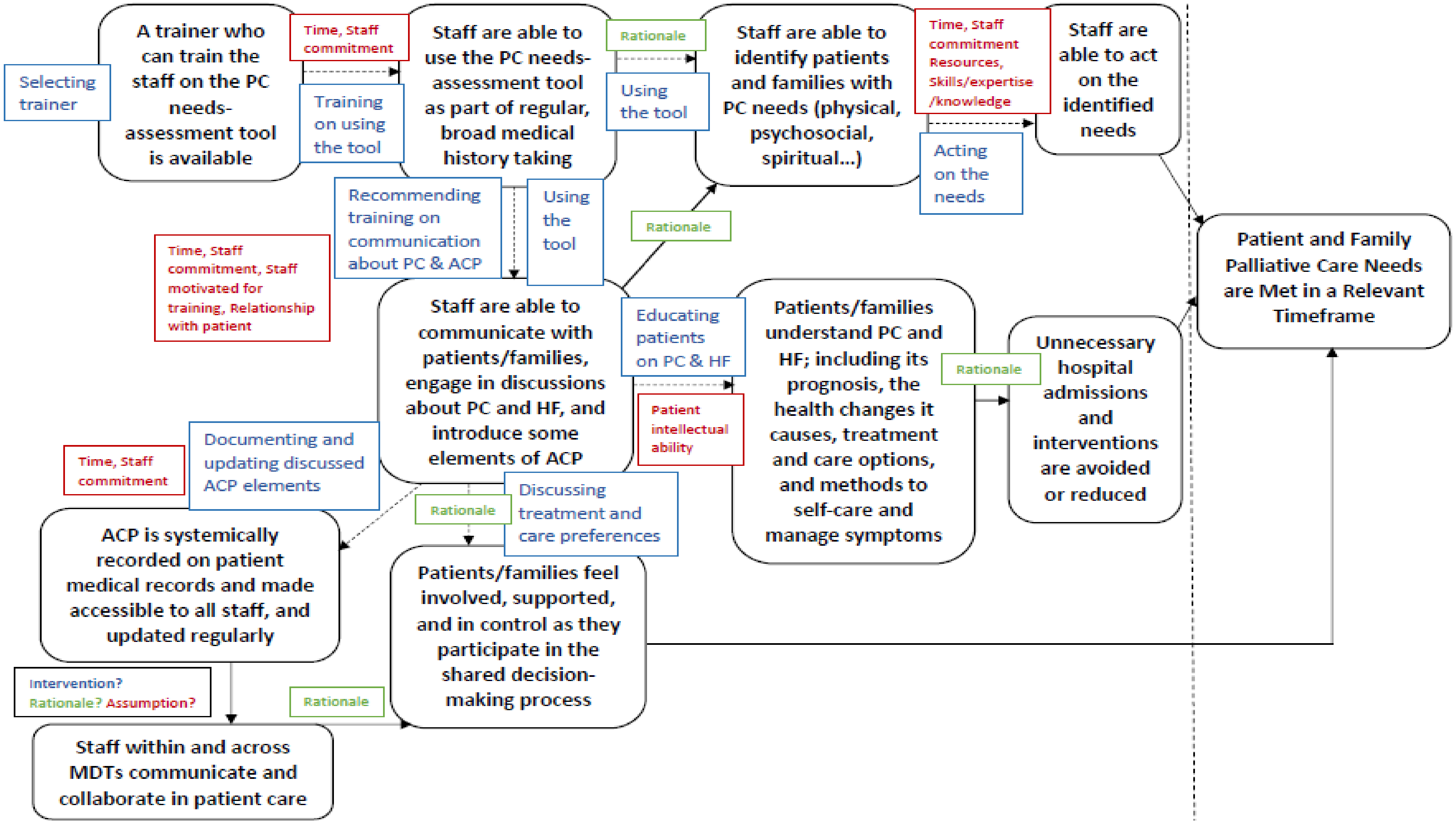
Appendix-5: First draft of the Theory of Change map



ACP: Advance Care Planning, AD: Advance Directives, DNAR: Do Not Attempt Resuscitation, HCP: Healthcare Professional, HF: Heart Failure, MDT: Multidisciplinary Team, PC: Palliative Care, POA: Power of Attorney, PPC: Preferred Place of Care, Rx: Treatment.

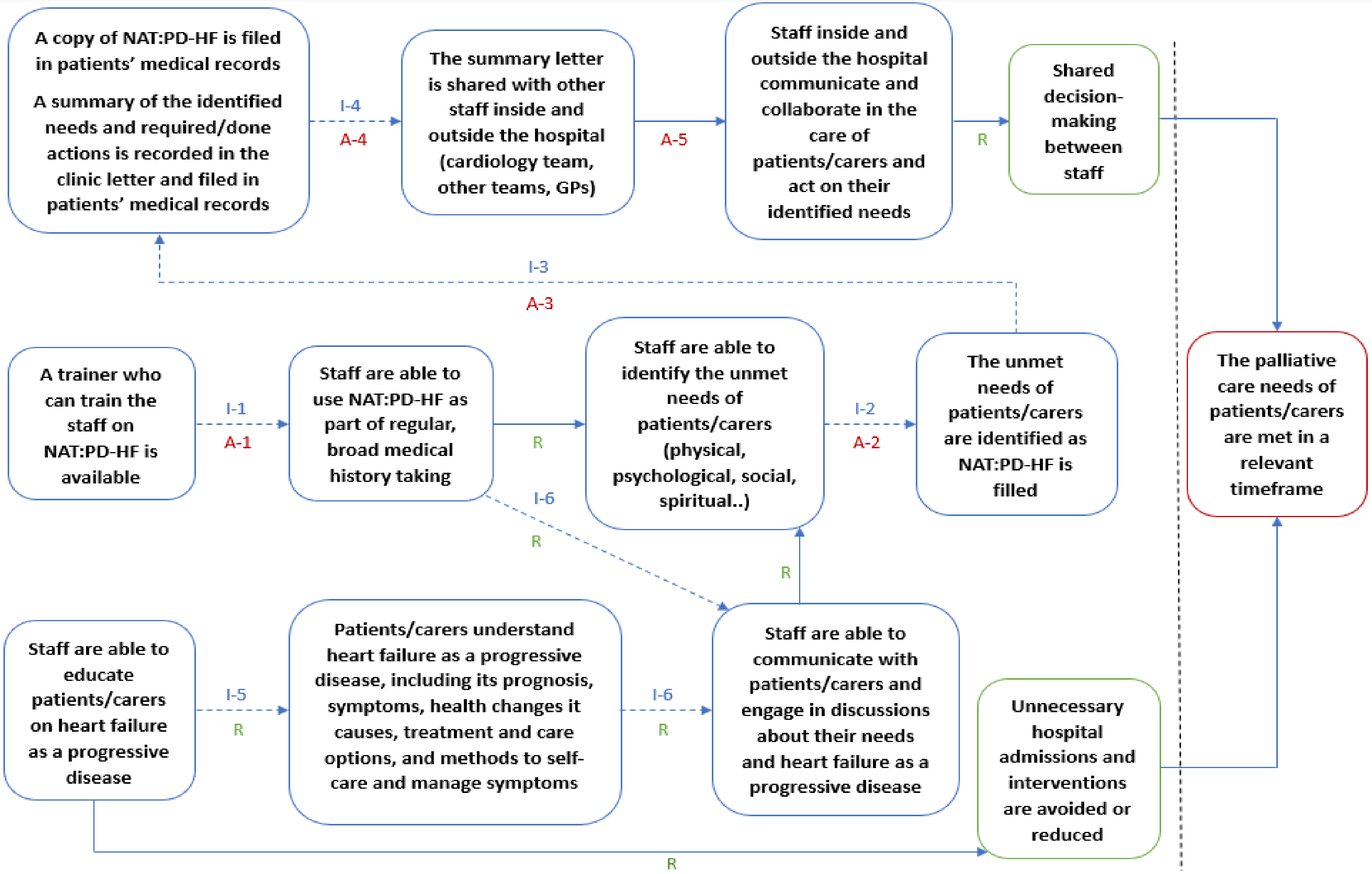
Red colour indicates suggested ideas not discussed in the workshop.

Appendix-6: Second draft of the Theory of Change map



ACP: Advance Care Planning, HF: Heart Failure, MDT: Multidisciplinary Team, PC: Palliative Care.
Black boxes: Preconditions/long-term outcomes/impact, Blue boxes: Intervention activities, Green boxes: Rationales, Red boxes: Assumptions, Dotted arrow: Intervention needed, Solid arrow: Intervention not needed.

Appendix-7: Third draft of the Theory of Change map



Key

⇢	Intervention required
→	No intervention required
I	Intervention
R	Rationale (scientific evidence or local experience)
A	Assumption

I-1	Training staff on NAT:PD-HF
I-2	Completing NAT:PD-HF
I-3	Storing NAT:PD-HF in patients' medical records
	Writing a summary of NAT:PD-HF in clinic letters and storing in patients' medical records
I-4	Sharing the summary (in the clinic letter) with other staff inside and outside the hospital
I-5	Educating patients/carers on progressive heart failure
I-6	Signposting staff to palliative care-related training (communication skills, advance care planning..)

A-1	Successful skills acquisition
A-2	Time; Motivation; Relationship with patients/carers
A-3	Time; Motivation
A-4	Time; Motivation
A-5	Time; Motivation; Resources; Skills/expertise/knowledge

Appendix-8: Sample size estimates for the feasibility study and full trial

The feasibility study will randomise 60 patients on a 1:1 basis for participation in three sites within 12 to 18 months of an enrolment period. After consultation with a statistician, and based on an estimate from service providers that 40% of patients in the control group and 20% of patients in the intervention group would be hospitalised within 12 weeks of study entry, this sample size will allow the estimation of detecting a difference in proportion of 20% of being hospitalised within 12 weeks between both treatment arms with a two-sided 95% confidence interval of width no more than 0.240 (0.105 to 0.345). The sample size calculation also accounts for an expected 25% drop-out rate.

After consultation with a statistician, we anticipate randomising 210 patients for the full study on a 1:1 basis for participation in three sites within 12 to 18 months of an enrolment period. This sample size will allow the estimation of detecting a difference in proportion of 20% of being hospitalised within 12 weeks between both treatment arms with a two-sided 95% confidence interval of width no more than 0.130 (0.143 to 0.273). The sample size calculation also accounts for a 25% drop-out rate.

Abbreviations

ACCF/AHA	American College of Cardiology Foundation/American Heart Association	InSup-C	Integrated Palliative Care in Cancer and Other Chronic Conditions
AHA/ASA	American Heart Association/American Stroke Association	IPOS	Integrated Palliative care Outcome Scale
AKPS	Australia-modified Karnofsky Performance Scale	IPQ	Illness Perception Questionnaire
CONSORT	Consolidated Standards of Reporting Trials	LVEF	Left Ventricular Ejection Fraction
COPD	Chronic Obstructive Pulmonary Disease	MORECare	Methods of Researching End of Life Care
EAPC	European Association for Palliative Care	MRC	Medical Research Council
ESAS	Edmonton Symptom Assessment System	NAT:PD-HF	Needs Assessment Tool: Progressive Disease - Heart Failure
ESAS-r	Revised Edmonton Symptom Assessment System	NECPAL	Necesidades Paliativas - Palliative Needs
ESC	European Society of Cardiology	NICE	National Institute for Health and Care Excellence
FACQ-PC	Family Appraisal of Caregiving Questionnaire for Palliative Care	NIHR	National Institute for Health Research
GP	General Practitioner	NYHA	New York Heart Association
GSF-PIG	Gold Standards Framework - Proactive Identification Guidance	PPI	Patient and Public Involvement
HADS	Hospital Anxiety and Depression Scale	PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
HFA/ESC	Heart Failure Association of the European Society of Cardiology	PROM	Patient-Reported Outcome Measure
HFmrEF	Heart Failure with mildly reduced Ejection Fraction	PROSPERO	International Prospective Register of Systematic Reviews
HFNAQ	Heart Failure Needs Assessment Questionnaire	RADPAC	Radboud Indicators for Palliative Care Needs
HFpEF	Heart Failure with preserved Ejection Fraction	SPICT	Supportive and Palliative Care Indicators Tool
HFrEF	Heart Failure with reduced Ejection Fraction	TIDieR	Template for Intervention Description and Replication
HF-CQ	Heart Failure Caregiver Questionnaire	WHO	World Health Organisation

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