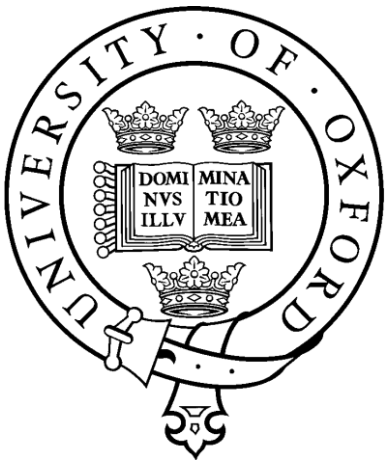
Optimising the Implementation of Advance Care Planning in Heart Failure

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ABSTRACT

Optimising the implementation of advance care planning in heart failure

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Clinicians are hesitant to talk to patients suffering from heart failure about their care preferences should they become seriously ill. Similarly, patients suffering from heart failure lack the tools to help them identify their care needs and communicate these to their healthcare professionals. This process is also known as advance care planning (ACP). Some studies show that ACP can improve the quality of life in life-threatening illnesses like heart failure. Patients expect their clinicians to initiate conversations about ACP. But as a result of clinicians' hesitance, ACP rarely takes place and patient care is affected. The overall aim of this thesis is to develop a behaviourally informed intervention targeting clinicians to engage with ACP for patients suffering from heart failure.

The different stages of the project were informed by the Medical Research Council's framework for the development and evaluation of complex interventions. The early development phase of the intervention started with an exploration of the evidence base for the impact of ACP on heart failure. The literature suggested that this led to an improved quality of life, better patient satisfaction with end-of-life care and an improved quality of communication between clinicians and patients. This was followed by a component analysis to identify interventions which had the greatest potential in changing clinicians' behaviour to engage with ACP. Patient-mediated interventions, reminders systems, educational meetings and academic detailing were among the most promising intervention categories. A subsequent literature review analysed the barriers and facilitators for ACP in heart failure leading to the design of an early model of the intervention. Findings from a clinician interview series advanced the early model and shaped the prototype of the intervention based on the Theoretical Domains Framework and Behaviour Change Techniques. The findings from a focus group study including patients and carers refined the final version of the intervention consisting of:

1. A patient-led Question Prompt List
2. A shared decision-making tool in the form of a Choices of Care Table
3. A clinician-owned ACP Reminder Sheet
4. An ACP Practice-Based Training Session

A detailed protocol for a feasibility cluster randomised controlled trial was developed to address issues surrounding the feasibility and acceptability of delivering the intervention in clinical practice. Finally, the results from this thesis informed a model for the involvement of the intervention in the clinical management of heart failure.

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STATEMENT OF CONTRIBUTIONS

This doctoral thesis is all independent and original work of which I am the sole author. My academic supervisors, Professor Bee Wee, Professor Rafael Perera, and Dr John MacArtney contributed intellectual guidance on the overall research strategy, analysis, presentation of results, and study protocol. The individuals below contributed in the following ways:

Louise Locock (LL): Associated Professor of the Health Experience Research Group (HERG), University of Oxford, advised me on the use of the Theoretical Domains Framework in Chapter Six.

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LIST OF ABBREVIATIONS

Abbreviation	Meaning
ACP	Advance care planning
APT	ACP Practice-Based Training
ARS	ACP Reminder Sheet
BCTs	Behaviour change techniques
BCTTv1	Behaviour change techniques taxonomy version 1
BCW	Behaviour change wheel
BHF	British Heart Foundation
Bsh	British Society of Heart Failure
CANHELP	Canadian Healthcare Evaluation Project
CENTRAL	Cochrane Central Register of Controlled Trials
CHF	Congestive heart failure
CI	Confidence interval
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CoC	Choices of Care Table
CONSORT	Consolidated Standards of Reporting Trials
cRCT	Cluster randomised controlled trial
CRF	Case report form
CRT	Cardiac resynchronization therapy
CTRG	Clinical trials and research governance
CTU	Clinical Trials Unit
CVD	Cardiovascular disease
DH	Department of Health
DNACPR	Do not attempt cardio-pulmonary resuscitation
DPA	Data protection act
EAPC	European Association for Palliative Care
E-lfh	E-learning for healthcare
EMBASE	Excerpta Medica Database, Elsevier
EPOC	Effective Practice Organisation of Care Group
EOL	End-of-life
EOLC	End-of-life care
GP	General Practitioner
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
GSF	Gold standard framework
HCP	Healthcare professional
HF	Heart failure
HFpEF	Heart failure with preserved ejection fraction
HFredEF	Heart failure with reduced ejection fraction
ICA	Intervention component analysis
ICD	Implantable cardioverter defibrillator
IOT	Intervention options table
IPOS	Integrated palliative care outcome scale
LVAD	Left ventricular assist device
LVD	Left ventricular dyssynchrony
MDT	Multidisciplinary team
Medline	United States National Library of Medicine Database
MeSH	Medical subject heading

MRC	Medical Research Council
NCPC	National Council for Palliative Care
NDM	Nuffield Department of Medicine
NDPCHS	Nuffield Department of Primary Care Health Sciences
NHS	National Health Service, United Kingdom
NICE	National Institute for Clinical Excellence
NIHR	National Institute of Health Research
NRES	National Research Ethics Service
NYHA	New York Heart Association Classification of heart failure
OR	Odds ratio
PaT Diagram	Part and Timing, software tool for graphic depictions of trials
PI	Principle investigator
PICO	Population/ problem, intervention, comparator, outcome
PPI	Patient and public involvement
PsychINFO	Behaviour Sciences and Mental Health Database
QPL	Question Prompt List
QOL	Quality of life
PRISMA-P	Preferred Reporting Items for Systematic Reviews and Meta-Analysis
R	Randomization
RCGP	Royal College of General Practitioners
RCP	Royal College of Physicians
RCT	Randomised controlled trial
REC	Research ethics committee
RVAD	Right ventricular assist device
RVD	Right ventricular dyssynchrony
SAE	Serious adverse event
SCOPUS	Scientific journals, books and conference proceedings database
SD	Standard deviation
SF-36	Short form quality of life scale
SMD	Standardized mean difference
SoF	Summary of findings table
SPICT	Supportive and Palliative Care Indicators Tool
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
StaRI	Standards for Reporting Implementation Studies
SW-CRT	Stepped-wedge cluster randomized controlled trial
TDF	Theoretical Domains Framework
TIDieR	Template for Intervention Description and Replication
TMG	Trial management group
UK	United Kingdom
WHO	World Health Organisation

CHAPTER ONE

Introduction

1 INTRODUCTION

1.1 HEART FAILURE

Regardless of therapeutic advances, heart failure remains an unpredictable, progressive and ultimately fatal long-term condition[1, 2]. Heart failure is now the only cardiovascular disease increasing in prevalence in the United Kingdom[3, 4]. The prevalence of heart failure is predicted to increase by 46% from 2012 to 2030 in the US[5]. In the UK, heart failure affects around one million people with 60,000 new cases annually: 1.3% of the general population and 15% of those aged over 80 years[6]. Heart failure is a leading cause of hospital admissions[7], and a substantial drain on healthcare resources[8]. Annually, there are almost 60,000 admissions with heart failure in England and Wales requiring more than 750,000 bed-days[9]. The prognosis associated with a diagnosis of heart failure is poor[10] and worse than for many cancers[11]: 38% of patients are dead within one year of diagnosis and 60% within five years[7].

1.1.1. Refractory Heart Failure

Existing therapies delay, but generally tend not to reverse disease progression[12]. Consequently, the prevalence of symptomatic heart failure despite optimal treatment, has increased, including a prolongation of the refractory or end-of-life phase of the disease[13]. Refractory heart failure is usually defined as New York Heart Association (NYHA) functional class IV or described as advanced or stage D heart failure[14]. An ageing population, a rising prevalence and new life-prolonging treatment approaches means that approximately 5% of patients suffering from heart failure have developed treatment refractory symptoms[15]. That proportion is growing[16]. One study found that around 4.5% of their study population with stage C heart failure advanced to Stage D

suggesting that over 100,000 patients would progress to end-stage heart failure in the United States annually[17]. Most patients with refractory heart failure eventually require palliative care regardless of advanced heart failure therapies like transplantation, ventricular assist device therapy or inotropic agents[18].

1.1.2 Palliative Care for Heart Failure

There was widespread recognition in the literature that patients suffering from heart failure merit support from specialist supportive and palliative care services[1-3, 19, 20]. The World Health Organisation (WHO) describes palliative care as a way to improve the quality of life of patients and families affected by a life-threatening illness[21]. Palliative care is meant to be achieved by the prevention and relief of suffering through early identification, assessment and treatment of pain, distressing symptoms and physical, psychological and spiritual problems[21]. Countries like the UK, Ireland, the US, Canada, Australia and New Zealand have developed palliative care as a medical speciality. Palliative care was initially provided for patients suffering from advanced cancer. However, over the last 50 years, this discipline has incorporated non-malignant diseases like heart failure, COPD, dementia or chronic kidney disease[7]. The WHO and the Worldwide Palliative Care Alliance estimate that the proportion of adults suffering from cardiovascular disease in need of palliative care at the end-of-life is the highest, even higher than cancer (**Figure 1**)[22].

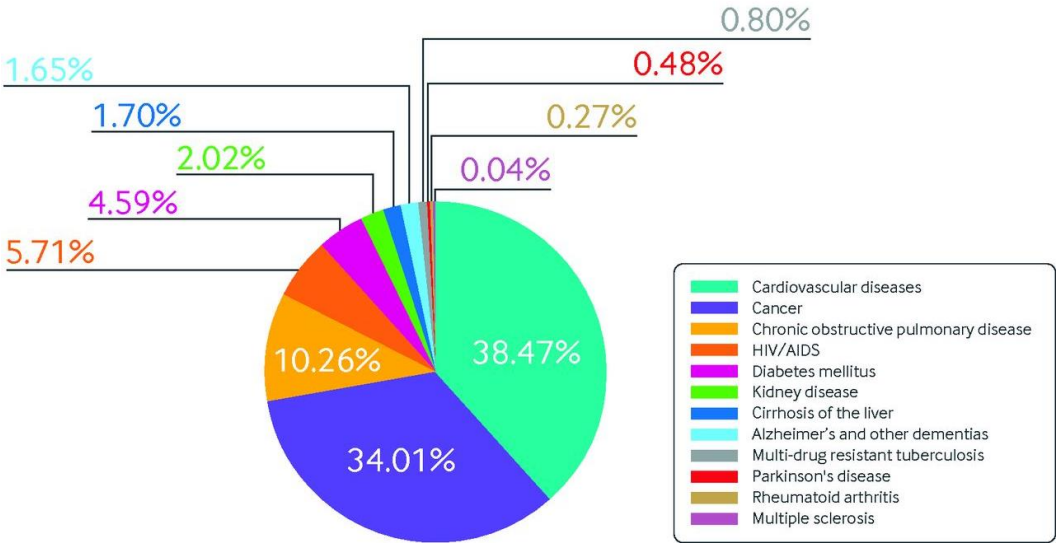


Figure 1. Distribution of adults in need of palliative care

In the UK, the National End-of-life care Framework for Heart Failure[1] recommends supportive and palliative care for patients suffering from the disease. This may include clarifying preferences for cardiopulmonary resuscitation, intubation, feeding tubes, implantable defibrillator deactivation, intensive care unit transfer, or the patient's preferred place of death or place of care. Similarly, a number of organisations and policy makers like the American Heart Association or the European Society of Cardiology support a comparable integration of palliative care as part of a comprehensive approach to treatment[23, 24].

Palliative care for heart failure is suboptimal

Despite the benefit of providing supportive and palliative care for patients suffering from heart failure[25, 26], its delivery remains suboptimal[27-30]. Only 6% of those dying from heart failure are referred to palliative care services[31]. Furthermore, only 37% of patients with end-stage heart failure were aware of a poor prognosis, only 8% of patients and 44% of family members were told by clinicians that time was short, and

36% of these patients died alone[32]. This is of great concern as these patients often experience periods of health crisis with no clear guidance when end-of-life decisions are needed[33]. While there are multiple ways to address 'suboptimal care' in heart failure by, for example, increasing the number of palliative care and heart failure nurses or palliative care beds, these measures cannot bridge a significant gap in the service provision - enabling proactive personalised care by knowing the patient's preferences *ahead* of any crises or acute deterioration. To be better prepared in the event of a health crisis, conversations[34] about care choices and future care planning early in the disease process are recommended[35]. Advance Care Planning (ACP) is known to facilitate these conversations[36, 37].

1.1.3 Heart Failure, Healthcare Policy and ACP

While the need for palliative care for patients with refractory heart failure is acute, national and international healthcare policy makers recommend the use of advance care planning and supportive care for *any* class and stage of heart failure[1, 2, 23]. Due to the unpredictable disease trajectory and high rate of complications associated with heart failure, policy makers commend initiating supportive and palliative care including advance care planning *early* in the course of the disease to be better prepared in the event of a health crisis[34, 35].

The British Heart Foundation supported Hospice UK in their document on "Heart Failure and Hospice Care" stating that "an advance care plan established *early* in someone's illness, could be crucial in guiding decisions about their place of care, levels of intervention, as their illness progresses and what matters to the patient and those close to them[2]." The National End-of-life care in Heart Failure framework encourages a timely use of advance care planning in heart failure and warns against

using it too late in the disease process[1]. The Canadian Heart and Stroke Foundation recommends that "planning for the life with heart failure and the discussion about what the future may bring, should begin "*at the time of diagnosis*, determined by the patients current health status and preferences[38]." The Scientific Statement of the American Heart Association on decision making in advanced heart failure recommends that advance care planning should be a routine part of the annual heart failure review for *any* class of heart failure and take place *before* the occurrence of a health crisis[23].

1.2 ADVANCE CARE PLANNING IN HEART FAILURE

1.2.1 Components of Advance Care Planning

Advance care planning is defined as a process of discussion between clinicians, patients, family and important others to identify the patient's preferences and aims of care if the patient may lack the competence to make such decisions in the future[36, 39]. Typically, advance care planning consists of conversations with patients and their carers at a point in time *before* they become unable to make important choices about the goals and priorities of their care[40]. This includes decisions on certain treatment options like the continuation or deactivation of an implantable cardioverter defibrillator, cardiac resynchronization therapy, the modification of drug therapies (e.g., beta blockers, angiotensin converting enzyme inhibitors, aldosterone antagonists) or whether they would like to be admitted to hospital in case of complications, the selection of a healthcare proxy or resuscitation preferences. ACP could include advance statements describing an individual's wishes about what should or not be done in case the person lost capacity[41]. While those preferences have to be taken into account as part of an overall best interest's judgement, ACP is not

legally binding[42]. Do not attempt cardiopulmonary resuscitation orders (DNACPRs) constituted one component of an ACP. However, DNACPRs alone do not represent the complexity of the ACP process[43]. National and international organizations warn against using ACP as a document driven "tick box" exercise[7, 41, 44, 45]. A number of experts emphasize the importance of considering ACP in the context of communication between healthcare professionals and patients with the aim of improving end-of-life care [46-48].

1.2.2 The Role of ACP in Heart Failure

Advance care planning is widely supported and aims to improve palliative care outcomes in heart failure by reducing suffering[21, 37, 49, 50]. Some trials suggest that ACP improves clinical outcomes like the quality of life, patients' satisfaction with end-of-life care or compliance with patients' end-of-life wishes[51, 52]. Several RCTs show that ACP could also improve the quality of care, potentially lower hospital admissions and re-admissions leading to lower healthcare costs, and lower rates of depression in surviving relatives[53-59] in heart failure. As a result of an improved engagement between clinicians and patients, ACP has the potential to increase the quality of communication between clinicians, patients and carers[21]. This in turn has the capacity to clarify expectations about the end-of-life, enables a better preparation for the last days of life and helps with the bereavement for surviving relatives[60].

What existing problems is ACP trying to solve?

The quality of life of patients suffering from heart failure can be adversely affected by unnecessary admissions to hospital, or by a focus on aggressive and unwarranted interventions such as the overuse of invasive treatment and a neglect of palliative care services[61]. Some studies indicate that ACP might reduce unnecessary hospital

admissions and unwarranted interventions and thus improve the QOL of patients[62]. A number of patients do not die at their preferred place of death, and ACP might increase the chance of dying at home or at the patient's preferred place of care [63]. Heart failure patients often experience periods of sudden deterioration in their health status with no clear guidance on treatment preferences[33]. The literature suggests that ACP could clarify patients' treatment preferences, ensure that patients' care wishes are known, respected and followed and consequently improve patient satisfaction with end-of-life care[34, 35, 51].

How might ACP address these problems?

How ACP might address these care deficits in heart failure can be described in the larger context of shared decision-making[23, 64]. Shared decision-making is commonly defined as the process of integrating both the best available evidence and patients' values and preferences in the decision-making process about their care[65]. The ethical principle of autonomy underpins shared decision-making and affirms the right of patients to select their medical therapy from a number of appropriate options[66]. In this context, advance care planning provides patients with an opportunity to clarify and articulate their care preferences about their care and facilitates an improved understanding of patients' care choices throughout the illness and at the end-of-life[36, 67]. For clinicians, it is a chance to identify and review patients' values, beliefs and goals and tailor their treatment in line with their wishes[68]. Research shows that optimal decision-making and advance care planning in heart failure require that patients' preferences have been discussed and documented in an ambulatory setting *prior* to a health crisis[23]. Clinicians should therefore take responsibility for initiating these discussions and putting into place a comprehensive plan of care consistent with patients' values and goals[69]. ACP models were developed to help heart failure

patients make informed choices, adequately plan their future care, and create reliable systems to honour these choices[46, 70]. Key to the success of ACP is a regular review and update of a patient's care preferences in the context of ongoing communication between clinicians, patients and carers[36]. But healthcare professionals find it difficult to change their behaviour and engage with advance care planning.

1.2.3 Barriers to Advance Care Planning

Despite national[1, 44, 71, 72] and international[7, 41] recommendations to implement ACP in heart failure, clinicians rarely undertake ACP conversations[47, 73, 74] in practice. In the UK, less than 8% of all eligible patients are likely to have an advance care plan[75]. A study from the US found that most patients suffering from heart failure (87.2%) did not have an advance care plan[76]. As a result, patients' quality of life and EOL Care are affected[36].A number of studies highlighted the hesitance of clinicians to talk about end-of-life issues and to initiate advance care planning[41, 77, 78]. This reticence was due to a number of barriers including the unpredictable disease trajectory of heart failure resulting in uncertain prognostication[79]. Additionally, the complexity of treatment options seemed to further discourage clinicians to actively engage patients in decision-making[50]. This inhibited the discussion about end-of-life issues[78]. Sudden deaths were common in heart failure compounding the difficulties around end-of-life conversations[38]. Simultaneously, this highlighted the importance of having such a conversation at an early stage in the course of the disease[80]. Clinicians in cardiology reported an unwillingness to discuss advance care planning citing the difficulty in prognostication and the perception of professional failure as a main barrier to effective communication[69, 81]. However, findings from research show that the majority of heart failure patients would prefer doctors to initiate these EOL conversations[69]. Most patients and carers prefer open, timely and accurate information on their

condition[82, 83]. As a result of these barriers, this dialogue rarely takes place[84]. In view of these obstacles and the increasing prevalence, symptom burden and unpredictable disease trajectory for patients living with heart failure, there exists an imperative for a systematic approach to an appropriate use of ACP[33].

The deficit in the delivery of advance care planning was not only evident on a national or international level but also locally, at my place of work. Despite the acknowledged benefits of advance care planning, the vast majority of eligible patients suffering from heart failure in Oxford had no advance care plan. Generally, clinicians did not engage with advance care planning nor did they refer eligible patients for supportive or palliative care services. I became aware of this gap during my work as a clinician there. This shortcoming was recognised by local palliative care clinicians, General Practitioners, heart failure specialist nurses and cardiologists. Consequently, I was motivated to investigate the situation by identifying the causes and finding solutions for these insufficiencies.

1.3 THE EVIDENCE GAP FOR ACP AND CLINICIAN TARGETED INTERVENTIONS

Experts agree that there is no firm evidence base in the area of advance care planning and clinician targeted interventions in heart failure [1, 36, 85, 86].

First, there is a lack of evidence on the impact of advance care planning in heart failure. For example, we do not have a systematic evaluation of the evidence whether advance care planning actually improves the quality of life of patients suffering from

heart failure. The first important question is, "What is the impact of advance care planning on the quality of life of patients suffering from heart failure?"

Second, there is a lack of evidence for an explicit rationale for intervention choice, mechanism of action, and intervention effect targeting clinicians to engage with advance care planning in heart failure. No such interventions have been developed to date[23, 85, 87]. If ACP makes a difference to patients suffering from heart failure and clinicians are hesitant to engage with ACP, the second set of questions is, "What are the most effective interventions to engage clinicians with advance care planning in heart failure?" "Why are some of these interventions more effective than others?", and "What is the optimal context and timing for these interventions to engage clinicians with ACP[41, 77, 78]?"

Third, the *qualitative* evidence base for the barriers and facilitators for the implementation of ACP by *clinicians* in *heart failure* is missing. Not knowing the barriers to an intervention can confound and undermine their entire effectiveness[88].

Fourth, there is no evidence of how the intervention components of the early model fit into the realities and constraints of clinical practice.

Fifth, there is a lack of evidence about the optimal conditions under which to implement the prototype of the intervention for a broader range of key stakeholders, like patients and carers, as well as clinicians and healthcare commissioners.

Finally, there is a lack of evidence of an appropriate trial design and study protocol to assess the feasibility and acceptability of delivering the intervention in clinical practice.

1.4 KEY AIMS

Overall Aim

The overall aim of this thesis is to develop a behaviourally informed intervention targeting clinicians to engage with ACP for patients suffering from heart failure.

Key Aims

The research in this thesis addresses the evidence gap identified in section 1.3 and answers the questions posed in that section by breaking these into the following key aims. Of note, each key aim includes several research objectives which are described separately within each chapter.

- To determine whether end-of-life care that includes advance care planning results in improved end-of-life care outcomes for patients suffering from heart failure compared to end-of-life care that does not incorporate advance care planning (Chapter 2).

This aim addresses the evidence gap of the lack of impact of advance care planning in heart failure.

- To synthesise the evidence for interventions with the greatest potential to engage clinicians with the implementation of ACP in heart failure (Chapter 3).

This aim addresses the lack of evidence for an explicit rationale for intervention choice, mechanism of action, effect and the reporting of intervention content targeting clinicians to engage with advance care planning for patients suffering from heart failure.

- To summarise the evidence from qualitative studies investigating the barriers and facilitators to the implementation of ACP by clinicians in heart failure (Chapter 4).

This aim addresses the lack of *qualitative* evidence for the barriers and facilitators for the implementation of ACP by clinicians in heart failure.

- To strengthen the iterative process of intervention synthesis by exploring the views of clinicians on the suitability of an early model of the intervention for clinical practice (Chapter 5).

This aim addresses the lack of evidence of how the components of an early model of the intervention fit into the realities and constraints of clinical practice.

- To refine distinct intervention components and synthesise the final version of the intervention by including relevant key stakeholders (Chapter 6).

This aim addresses the lack of evidence about the optimal conditions under which to implement the intervention for a broader range of stakeholders like patients, carers and clinicians.

- To develop a CTU approved trial protocol for a feasibility cluster randomized controlled trial to assess the feasibility and acceptability of delivering the intervention (Chapter 7).

This aim addresses the lack of evidence of an appropriate trial design and protocol to assess the feasibility and acceptability of delivering the intervention in clinical practice.

1.5 OVERVIEW OF THESIS METHODOLOGIES

The following sections provide an overview and a chapter-by-chapter description of the thesis methodologies used to achieve the key aims. **Table 1** graphically depicts the thesis structure showing research methods and outputs for each step and how they relate to the different stages of the Medical Research Council (MRC) framework[89] for the development and evaluation of complex interventions. The iterative design and analysis process of the intervention was informed by the Theoretical Domains Framework (TDF)[90], the Behaviour Change Wheel (BCW)[91], the Behaviour Change Taxonomy (v1)[92], and the Template for Intervention Description and Replication (TIDieR)[93]. **Figure 2** provides an overview of the intervention synthesis process from an early model of the intervention, to the prototype and to the final version.

OVERVIEW OF THE THESIS METHODOLOGIES								
Chapter of Thesis	Chapter 1	Chapter 2	Chapter 3	Chapter 4	Chapter 5	Chapter 6	Chapter 7	Chapter 8
MRC Framework	**Development Phase**							
	Identify theory		Identify Evidence Base		Modelling Process and Outcomes			
Mixed Methods Approach		**Secondary Research**			**Primary Research**			
Research Method		**Design, Implementation and Analysis**						
	Introduction	Systematic Literature Review (1) + Meta-Analyses (1)	Intervention Component Analysis, Review (2) + Meta-Analyses (2)	Explorative Systematic Literature Review (3)	Clinician Interview Series	Focus Group Study	Trial Protocol Development	Discussion and Conclusion
Output	Overview of Thesis	Impact of ACP on Outcomes in Heart Failure	Effect sizes of Intervention Components Targeting Clinicians	Intervention Options Table and Early Model of the Intervention	Prototype of the Intervention	Final Version of the Intervention	Protocol for a Feasibility Cluster RCT	Intervention Model for Clinical Practice

Table 1. Overview of thesis methodologies

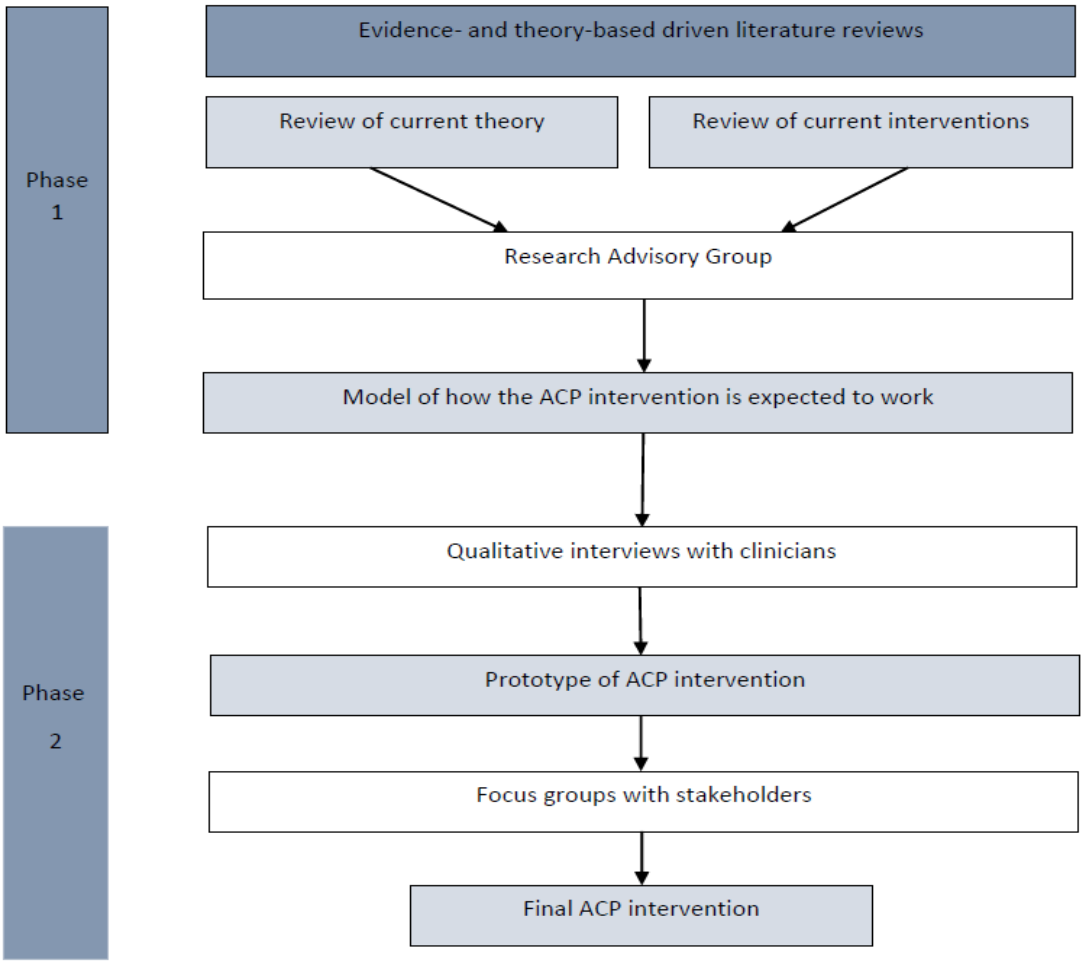


Figure 2. Iterative intervention synthesis process

1.5.1 Chapter 2. Impact of ACP on Heart Failure

The first step of the project is to determine the impact of ACP on heart failure since an objective appraisal of the entire evidence base to provide a more precise estimate of a treatment effect is missing[94, 95] . This lack of evidence includes the disease-specific effect of advance care planning on clinical outcomes like quality of life, patient satisfaction with end-of-life care and the quality of end-of-life communication. If ACP makes no positive difference to patients suffering from heart failure, there is no need to develop an intervention to optimize its implementation[96]. Consequently, Chapter 2 aims to answer the question, "What is the impact of ACP on the care of patients suffering from heart failure?"

This question is addressed by conducting a systematic review of the literature and meta-analysis which fulfils the initial requirement of the MRC framework by identifying the evidence base for the proposed intervention. The MRC process of developing and evaluating a complex intervention has several phases as illustrated in **Figure 3**. My project focusses on the MRC "Development" section which includes a) identifying the evidence base for ACP and interventions that optimise its implementation, b) identifying and developing the underlying theory and c) modelling processes and outcomes. The evidence for the effect of advance care planning on clinical outcomes for patients suffering from heart failure is summarised by the use of a meta-analysis.

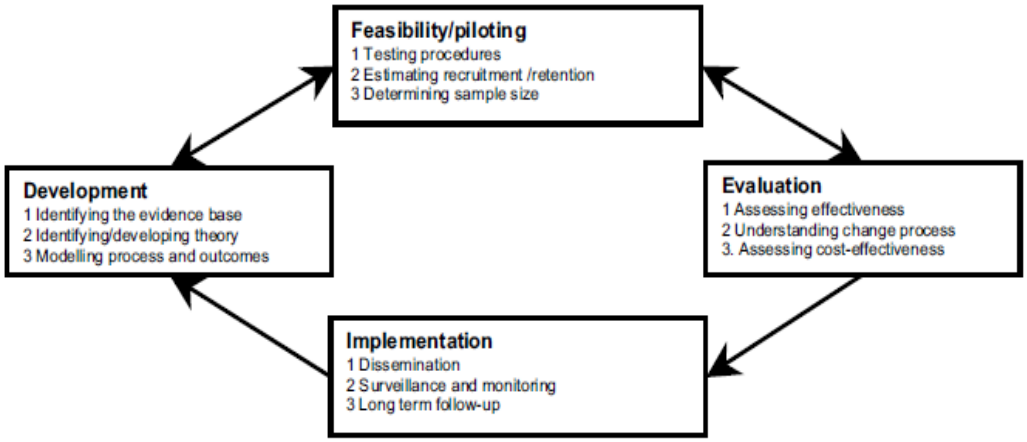


Figure 3. Elements of the MRC development and evaluation process

1.5.2 Chapter 3. Clinician Targeted Interventions

The next step is to synthesise the evidence for interventions with the greatest potential to engage clinicians with the implementation of ACP in heart failure. There are several reviews on what interventions are effective in changing *patients'* behaviour to engage with ACP [43, 97-99], but that evidence is missing for *clinicians*. Studies have shown that clinicians are reluctant to engage with ACP[41, 77, 78]. Interventions have been used in the past to change a clinician's practice pattern[100-102]. But there is no systematic evidence base for which intervention

components have the greatest potential to change clinicians' behaviour to implement ACP in heart failure, nor a clear description of their ingredients, their possible mechanism of action, timing or frequency. A second systematic literature review and meta-analysis is presented in Chapter 3, which aims to identify the most effective clinician targeted intervention components and their underlying mechanisms of action. The MRC framework, followed as part of this project, requires the use of theory to identify and understand why and how interventions work and a comprehensive reporting of their ingredients[90]. Not investigating why and how interventions work, hinders efforts to intervention design, replication and efficiency and may ultimately affect patient care[103]. These approaches include, but are not limited to, Behaviour Change Techniques (BCTs)[92], the Cochrane Effective Practice and Organisation of Care (EPOC) Group taxonomy[104], and the Template for Intervention Description and Replication (TIDieR)[103].

Effective Practice and Organisation of Care Taxonomy

The Effective Practice and Organisation of Care (EPOC)[104] Taxonomy is one recognised approach to describe and analyse interventions targeting *clinicians* in systematic reviews[105]. Identifying the categories of interventions targeting clinicians is essential in order to evaluate which of these categories might have the greatest potential in changing clinicians' behaviour[106-108]. **Appendix 1** provides a summary of definitions of the different Effective Practice and Organisation of Care intervention categories as part of the literature review reported in Chapter Three.

Behaviour Change Techniques

While Effective Practice and Organisation of Care Taxonomy is important to provide a common language, the taxonomy has some recognised limitations[106]. Mainly, Effective Practice and Organisation of Care classifications are insufficient in their level of detail to

provide an understanding of their mechanism of action required to change a clinician's behavior[109]. Behavior change techniques[90] are known to offer such an opportunity. They are defined as coordinated sets of activities designed to change specified behaviour patterns[108]. In the UK, the Department of Health used behaviour change techniques in their tobacco control strategy[110] and the National Institute of Health and Clinical Excellence (NICE) in their guidance on reducing obesity[111]. The Medical Research Council (MRC)[109], and others[112-114] affirm the importance of behaviour change techniques to advance intervention development[92]. Michie et al.[115] provide a comprehensive and coherent approach for designing and implementing these interventions[113].

Michie et al. illustrate their system of classifying intervention components in terms of a behaviour change wheel (BCW)[91]. The behaviour change wheel (**Figure 4**) consists in a structure to inform the design of interventions. The inner, green centre depicts the *conditions* required in which behaviour change can occur[116]: capability, opportunity and motivation represent this first and central layer of the wheel. They are also defined as the "COM-B model"[91] and interact to generate behaviour. Capability signifies an individual's physical and psychological ability to undertake an activity. Opportunity represents all social and physical factors outside the individual that prompts behaviour or makes it possible. Motivation includes automatic or reflective brain processes that direct an individual's behaviour[116].

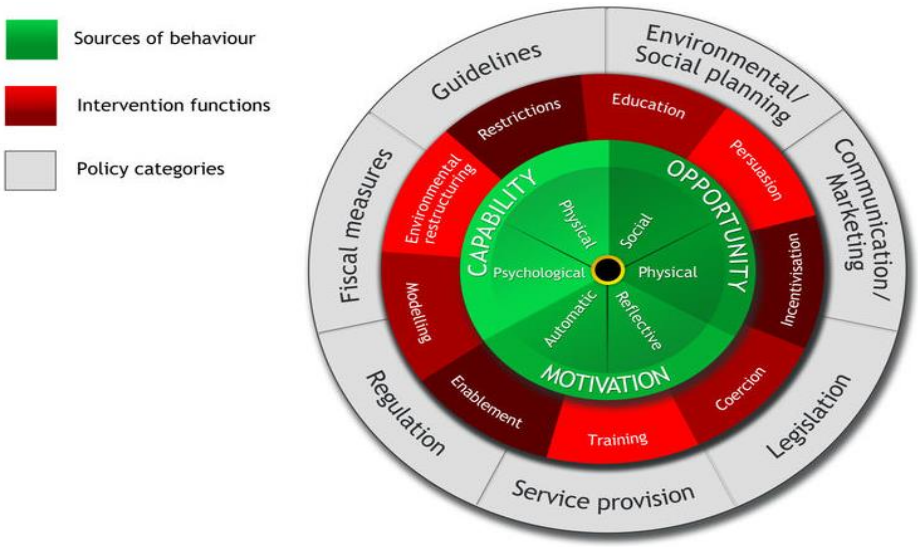


Figure 4. Behaviour Change Wheel

The second layer of the Behaviour Change Wheel consists of nine *general means* by which an intervention may change behaviour: 1. Education, 2. Persuasion, 3. Incentivisation, 4. Coercion, 5. Training, 6. Enablement, 7. Modelling, 8. Environmental restructuring, and 9. Restrictions. The nine general intervention function are informed by 93 underlying behaviour change techniques, grouped in 16 domains representing the behaviour change techniques taxonomy (**Appendix 2**), also called "BCTTv1[108]." The third and outer layer of the wheel describes the *policy* categories to support the delivery of these nine general intervention functions.

The Template for Intervention Description and Replication

Behaviour change techniques are instrumental in analysing the mechanisms of action of interventions in greater detail. However, they do not explicitly focus on other important factors of intervention delivery like timing, frequency or intensity of the intervention. Yet, these aspects are important to enhance the implementation of any proposed intervention. The authors[103] of TIDieR address this evidence gap and argue that, without a complete published description of interventions, clinicians and patients can not reliably implement interventions that are shown to be useful[103]. Furthermore, other researchers are not in a position to replicate

or build on these research findings[107]. TIDieR's use for developing and refining intervention components has been widely published[114, 117-119]. I use TIDieR for the purposes of describing and refining the intervention components identified as part of this thesis. **Appendix 3** presents a summary of the categories of TIDieR for this project. The synthesis of the quantitative evidence base for clinician-targeted interventions identifies the components with the greatest potential to engage clinicians with the implementation of advance care planning in heart failure.

1.5.3 Chapter 4. Barriers and Facilitators for ACP

The third key aim is to summarise the evidence from qualitative studies investigating the barriers and facilitators to the implementation of advance care planning by clinicians in heart failure. It is well recognised that not knowing the barriers to an intervention can confound and undermine its entire effectiveness[88]. Existing studies look at ACP, barriers to end-of-life care or heart failure. But no review has systematically evaluated the qualitative evidence base for barriers to the implementation of ACP by clinicians in heart failure. Consequently, I ask the questions, "What are the main barriers and facilitators for clinicians to implement ACP in heart failure?" I address this question with an exploratory review of the literature because that methodology and its *qualitative* synthesis of evidence has the potential to combine data from different healthcare contexts, identify research gaps and generate new evidence for the design and assessment of the intervention[120, 121]. As a result, this review identifies and synthesises thematic findings about barriers and facilitators for the implementation of ACP by clinicians. The next step is then to combine the quantitative and qualitative results of the reviews to generate the data for an early model of the intervention. This is achieved by synthesising findings using an intervention options table (IOT)[122]. This intervention options table is based on a model guided intervention synthesis approach[122] which lists the pros and cons for each possible intervention component. A research advisory group is then used to select the most

suitable intervention components for an early model of the intervention based on the information presented in the intervention options table. An early model is then identified which is further refined.

1.5.4 Chapter 5. Synthesis of the Prototype of the Intervention

The next step of the project is to strengthen the iterative process of intervention synthesis by exploring the views of clinicians on the suitability of the early model of the intervention. This is necessary to determine if that early model fits into the realities and constraints of clinical practice. One key question addressed in Chapter Five is therefore, "What do practising doctors and nurses think about the early model of the intervention and would they use it?" That question is answered using a series of clinician interviews. Qualitative methods like interviews have been used to better understand the factors influencing the implementation of interventions among clinicians[123, 124]. Furthermore, the Medical Research Council (MRC)[109], the National Institute for Clinical Excellence (NICE)[112] and others[113] assert that the interpretation of intervention effectiveness and design should not be founded solely on a theoretical evidence base but also needs to draw from practical health experience[112] to facilitate robust development and implementation. Therefore, a series of interviews focussing on the experience of clinicians with advance care planning in heart failure adequately addresses this question. The domains of the Theoretical Domains Framework (TDF)[90] are well suited as a way to explore and analyse interview findings on barriers and facilitators. The Theoretical Domains Framework domains to intervention analysis are further described in Chapter Five. Data from the interviews inform a Theoretical Domains Framework Matrix which provides a comprehensive framework to advance the early intervention model and shape the design of the prototype by linking behaviour change techniques with the

Theoretical Domains Framework domains[116, 125]. As a result, I am able to design four distinctive components which consist of:

1. A patient-led question prompt list (QPL)
2. A shared decision-making tool in the form of a Choices of Care Table (CoC)
3. A clinician-owned ACP Reminder Sheet (ARS)
4. And an ACP Practice-Based Training session (APT) to deliver the intervention

It was then important to broaden the scope of stakeholders by also including the perspectives of patients and carers to refine the prototype of the intervention.

1.5.5 Chapter 6. Final Version of the Intervention

To refine the prototype of the intervention, the scope of stakeholders needs to be made broader by also including the perspectives of patients and carers. In particular, it is relevant to understand the suitability of the intervention. Consequently, I asked the question, "What are the views of patients, carers and other key stakeholders on the suitability of the prototype of the intervention?" Focus groups were used as a methodology for intervention refinement by making the most of the communication between research participants[126]. Hence, that method provided an opportunity to tap into interpersonal communication between participants and their different or similar views on the suitability of the intervention for engaging with ACP[127, 128]. I used them in this part of my research to achieve a 360-degree perspective on the appropriateness of the Question Prompt List, Choices of Care Table, ACP Reminder Sheet and ACP Practice-Based Training. This allowed me to refine the intervention by analysing the contributions of 22 key stakeholders on the acceptability, context and mode of delivery of the intervention[129]. Additionally, I wanted to improve the reporting of the intervention for the purposes of a clinical trial and therefore will make use of TIDieR[93] as a guide. TIDieR's application for reporting intervention components for clinical trials is directly relevant to the

proposed feasibility cluster randomised controlled trial in the following chapter. Findings from the focus group study are used to define the final version of the intervention to optimise the implementation of advance care planning in heart failure. Conducting a feasibility cluster randomised controlled trial was outside the timeframe of this DPhil project, as advised by my first year (transfer) assessors. However, results from early field tests of the ACP Practice-Based Training are described in **Appendix 25**.

1.5.6 Chapter 7. Protocol for a Feasibility Cluster RCT

The key aim of the last phase of the project is to develop a CTU approved trial protocol for a feasibility cluster randomized controlled trial to assess the feasibility and acceptability of delivering the intervention. There is no firm evidence on the acceptability of behaviourally informed interventions targeting clinicians in the implementation of ACP in heart failure[96]. No complex interventions have been designed that include an evidence-based, behaviourally and theory informed approach to address the constraints of their clinical practice. A Belgian trial is planned to test an intervention to initiate ACP by GPs[130]. However, this study does not focus on patients suffering from heart failure. Additionally, the development of their intervention does not include the input from key stakeholders like patients or carers and is not underpinned by any meta-analysis or behaviour change theory. This paucity of evidence on intervention effectiveness to implement ACP in heart failure makes the proposed feasibility RCT even more relevant.

Consequently, this feasibility study asks a number of key questions including, "How feasible is it to identify, recruit and retain a sufficient proportion of NYHA Class III/IV patients to participate in the trial?" or "What is the acceptability of the intervention to clinicians and patients?" Progression criteria to a full trial are defined to address the uncertainties of the proposed feasibility study.

1.5.7 Chapter 8. Discussion and Conclusions

Chapter 8 summarises the thesis and its novel contributions to knowledge in the area of ACP, implementation research in healthcare and heart failure. The final discussion addresses the methodological strength and limitations of the thesis and gives strategic directions of how to improve and conduct advance care planning in implementation trials in healthcare. A summary table of alternative methodological approaches provides a synthesis of research objectives and methods that may guide future studies of complex implementation interventions in other life-threatening illnesses like Stroke, COPD or Dementia. Based on the quantitative and qualitative evidence from this thesis, a model of how the intervention could improve the clinical management for patients suffering from heart failure is provided.

CHAPTER TWO

The Impact of Advance Care Planning on Heart Failure

2 THE IMPACT OF ADVANCE CARE PLANNING ON HEART FAILURE

2.1 BACKGROUND

The use of advance care planning has been recommended as a means to provide better care at the end-of-life[71, 131] and improve clinical outcomes in heart failure. However, its effectiveness to achieve that aim has not been systematically evaluated[132]. Most systematic reviews on ACP have been concerned with the effect of interventions that promoted the *implementation* of ACP[97, 99, 133-139] and have focused on outcomes like the rate of ACP conversations or the completion of ACP documents. The few systematic literature reviews that have evaluated the impact of ACP on end-of-life care[43, 138, 139] have had a number of significant limitations. The studies by Brinkman-Stoppelenburg et al.[43] and Hanson et al.[138] combined qualitative and quantitative studies and did not include a meta-analysis. Therefore, more precise estimates of the impact of ACP on palliative care outcomes or heart failure were missing. Brinkman-Stoppelenburg et al.[43] only included studies solely concerned with the effects of DNCPRs while Hanson et al.[138] only contain studies from the US. We felt that completing a DNR form alone did not reflect the complexity of ACP and therefore should not have been included. The reviews by Houben et al.[139] and by Lewis et al.[140] did not focus on the effect of ACP on heart failure or distinguish between any life-threatening diseases. These reviews did not undertake a meta-analysis on important palliative care outcomes like Quality of Life (QOL) or patient satisfaction with end-of-life care. Primary outcomes reported were completion of advance directives and occurrence of end-of-life conversations. Consequently, it was important to establish in this thesis the effect of ACP on end-of-life care in heart failure using outcomes that

were important to patients like quality of life or patient satisfaction with end-of-life care[141].

2.2 AIM AND OBJECTIVES

The aim of this study was to undertake a systematic review and evaluation of RCTs to determine whether end-of-life care which included ACP resulted in improved end-of-life care outcomes for patients suffering from heart failure compared to end-of-life care which did not incorporate ACP.

The objectives were as follows:

- To determine the effect of ACP on the quality of life of patients suffering from heart failure as well as their satisfaction with end-of-life care through random effects meta-analyses
- To conduct sensitivity analyses to confirm or contest findings from the random effects meta-analyses
- To investigate causes of heterogeneity and its relation to study characteristics
- To explore characteristics of ACP interventions with high and low effect sizes

2.3 METHODS

I conducted this review in accordance with the Cochrane Handbook for Systematic Reviews of Interventions[142]. The report was based on the Preferred Reporting Items for systematic reviews and meta-analysis (PRISMA-P)[143] statement and the Cochrane Collaboration reporting items for systematic reviews and meta-analysis. The Grading of Recommendation Assessment, Development, and Evaluation (GRADE) was used to rate the quality of evidence in selected trials[144]. The description of the impact of ACP on end-of-life care outcomes was reported using CONSORT guidelines[145]. The

description of intervention content followed the Template for Intervention Description and Replication (TIDieR)[103]. The 12 item TIDieR checklist (**Appendix 3**) was an extension of the CONSORT 2010 statement (item 5)[145] and the SPIRIT 2013 statement (item 11)[146] and enabled the detailed reporting of intervention components in order to facilitate replication in a future randomised controlled trial.

2.3.1 Types of Studies

I included randomised controlled trials (RCTs) and cluster randomised controlled trials (cRCTs). Studies published as abstracts or conference presentations were only included if sufficient details were presented to allow an assessment of the methodology and an analysis of the results to be undertaken. Case series, case studies, cohort studies, narrative reviews, editorials and opinions were not included but contributed to the background information of this review. Relevant other systematic reviews were used as a source of reference. No restrictions were placed on the healthcare setting, context or healthcare professional involved. Studies had to report quantitative measures of the effect of ACP on end-of-life care outcomes.

2.3.2 Types of Participants

Patients were eligible if they suffered from heart failure, were seen in primary or secondary care, living in the community or nursing homes. I did exclude studies involving people under the age of 18 years, suffering from congenital heart disease[147] or a mental illness (e.g. schizophrenia) other than dementia[148].

2.3.3 Types of ACP Interventions

As defined in policy documents and by experts[23, 39, 42], I included all types of professional ACP interventions that provided a co-ordinated and comprehensive

approach of care for patients early, during or towards the end of a life-limiting illness. Authors had to state explicitly ACP intentions or this had to be evident in the composition of the intervention of the study. Interventions that only dealt with DNACPRs were excluded from the study because DNACPRs on their own did not represent the complexity of ACP[117].

2.3.4 Types of Outcome Measures

I followed the recommendation of the European Association for Palliative Care (EAPC) for the selection of outcome measures[149] including patient-reported outcome measures (PROMs)[150] that had been validated with heart failure patients requiring palliative care[149]. Therefore, I selected a priori as my primary outcome quality of life (QOL) and patient satisfaction with end-of-life care. As a secondary outcome, I chose the quality of end-of-life communication.

Quality of Life outcome measures had to contain key elements of what seriously ill patients and their family members considered important like trust in the treating healthcare professional, avoidance of unwanted life support, effective communication or continuity of care[151]. Palliative care specific examples of such outcomes measures are the Palliative Care Outcome Scale (POS)[152], the Edmonton Symptom Assessment Scale (ESAS)[153], the Kansas City Cardiomyopathy Questionnaire (KCCQ)[154] or the Minnesota Living with Heart Failure Questionnaire (MLHFQ)[155]. Outcomes had to be measured through instruments that had psychometric properties[156], for example, through surveys, medical records review, self-reported questionnaires or interviews. I elected three months or closest to that point in time as the most relevant follow-up period for the intervention to take effect.

2.3.5 Search Methods for Identification of Studies

Together with a specialist health science librarian (NR), I designed and conducted the literature searches. To develop a comprehensive list of search terms, I presented a table of Medical Subject Headings (MeSH) and free text words to my supervisors (BW, RP) and librarian (NR) and sought their input for additional terms. We (NR, MS) maximised specificity by combining search terms and iteratively tested the search strategies against a set of known studies from high impact journals. We (MS, NR) discussed the results of each test search to optimise the combination of MeSH terms and free text words. We used filters for searching databases like MEDLINE and EMBASE to reliably identify RCTs. The following search limits were set: 1) study design: RCTs or cRCTs, 2) limited to the English, German, French, Spanish or Chinese language. Date restrictions were not applied.

Electronic searches of studies

We searched the following data bases and records from the earliest to July 2017:

- CINAHL (Cumulative Index to Nursing and Allied Health Literature)
- Cochrane Central Register of Controlled Trials
- Cochrane Database of Systematic Reviews
- Cochrane Central Register of Controlled Trials
- Database of Abstracts of Reviews of Effects
- Embase
- ERIC
- Ovid MEDLINE(SP)
- Other Non-Indexed Citations and Ovid MEDLINE(R)
- Science Citation Index

- Social Science Citation Index & Conference Proceedings
- and PsycINFO

Publication types excluded were letters, comments, editorials, case reports and duplicates. We used a combination of controlled vocabulary (MeSH terms) and free text words. We combined the search strategy for ACP with a methodological filter to identify intervention studies[142]. An example of a MEDLINE search strategy is presented in **Appendix 4**.

2.3.6 Searching Other Resources

I checked the reference lists of 11 relevant reviews[43, 69, 97, 99, 133-139] and all potential cross references and records. I contacted authors of main trials and experts in the field who were known to conduct research for additional papers or to provide missing or unpublished study data.

2.3.7 Selection of Studies

Titles and abstracts were independently screened against inclusion criteria by two reviewers (MS, IO) using EndNote X8[157]. Disagreements were resolved by discussion or referred for arbitration to a third reviewer (RP). Full texts of screened papers were assessed for inclusion criteria and study quality. We pilot tested eligibility criteria and included a flow diagram of study selection and reasons for exclusion to conform with the PRIMSA[143] statement. We kept a list of excluded trials and documented reasons for exclusion in the 'Characteristics of Excluded Studies' in **Appendix 5**.

2.3.8 Data Extraction and Management

We pilot tested a collection form for data extraction which was then used independently by two review authors (MS, IO). We assessed the overall quality of the trials' methods by using the GRADE[158] system Version 3.6.1. A GRADE profile was created for each pooled estimate, for each outcome and for single trials comparing ACP with standard care for each end-of-life care outcome. Two authors (MS, IO) independently extracted data from papers and documented findings. **Appendix 6** gives an example of a data extraction form. As evident from the example, the collection form included an extensive set of data on study design, setting, participants including clinicians or patients, unit of randomization and analysis, intervention details according to CONSORT criteria, outcomes according to CONSORT and SPIRIT standards, limitations of the study, risk of bias, results, missing data, quality of evidence presented, and a box for any additional comments.

2.3.9 Statistical Analysis

I performed quantitative meta-analysis with RevMan 5.3.5[159] using random effects models. For individual studies with continuous data, I calculated standardized mean differences (SMDs) with 95% confidence intervals (CI) between the intervention and control group as recommend by Cochrane[142]. SMDs were appropriate in measuring effect sizes due to the reporting of continuous outcomes and the variety of existing scale instruments that were used in selected RCTs[142]. I calculated mean values and standard deviations based on the number of people involved in each intervention and control group. The effect of SMDs was interpreted as follows[160]:

- Smaller than 0.2 represented a small effect
- Between 0.2 and 0.5 was a moderate effect
- Between 0.5 and 0.8 or higher was a large effect

For ease of interpretation, we re-expressed the estimated SMD for quality of life, patient satisfaction with end-of-life care and quality of end-of-life communication as an Odds Ratio as described in the Cochrane Handbook[142].

2.3.10 Unit of Analysis Issues

Many RCTs presented outcomes for several follow-up periods. In accordance with research practice in palliative care[161], I restricted the analysis of a follow-up to a single point in time for each primary or secondary outcome. Outcome data were considered for all follow-up periods. When multiple time points were reported, I used the one closest to three months post-intervention based on the premise that it would require a reasonable length of time for ACP to take effect.

2.3.11 Dealing with Missing Data

Trial authors were contacted to request data not reported but potentially available. I reported the number of participants included in the final analysis of each study as a proportion of all participants in the study and by trial arm. Data were included only for those participants whose results were known. In view of the vast complexity of attrition rates in palliative care research, we did not adopt rigid cut-off rates for what was seen as acceptable or unacceptable. However, as a general guideline, the inclusion criteria for robust evidence of an intervention in each study arm is ideally around 70% or greater at follow-up[142].

2.3.12 Assessment of Heterogeneity

I assessed heterogeneity using the I^2 statistic which quantifies the percentage of variability in effect estimates that is due to heterogeneity rather than to chance[162]. I anticipated higher levels of heterogeneity due to different patient populations,

outcomes measured, length of follow-up periods, different compositions of ACP and healthcare settings. Thresholds for the interpretation of heterogeneity were based on Cochrane guidance[162] as follows:

- 0% to 40%: might not be important,
- 30% to 60%: may represent moderate heterogeneity,
- 50% to 90%: may represent substantial heterogeneity,
- 75% to 100%: considerable heterogeneity.

All studies included in the meta-analysis had comparable baseline characteristics between control and intervention groups.

Subgroup Analyses

Subgroup analyses were conducted for patient populations, length of follow-up and study setting. Issues surrounding heterogeneity in included studies were explored in the discussion section of this chapter (section 2.5). The characteristics of ACP interventions that resulted in either high or low effect sizes for each outcome were described in the Results section. I analysed the content, timing, frequency and context of the intervention as well as the provider involved. I have discussed common characteristics of interventions resulting in higher or lower effect sizes in the Discussion section of this chapter (section 2.5).

2.3.13 Assessing Publication Bias

I assessed publication bias by investigating the funnel plot symmetry[95] and performed Egger's Test for subgroup analysis based on study, outcome and population characteristics. The statistical level of significance was set at $p < 0.05$ for all analyses[163].

2.3.14 Risk of Bias Assessment

Two reviewers (MS, IO) independently assessed the risk of bias using the Cochrane Collaboration's tool[162] for the following risk of bias domains:

- The risk of selection bias, by considering the random sequence generation and the allocation concealment.
- The risk of performance bias, by considering the blinding of participants and personnel.
- The risk of detection bias, by considering the blinding of outcome assessments.
- The risk of attrition bias, by assessing the incomplete outcome data.
- The risk of reporting bias, by assessing selective outcome reporting.
- The risk of other bias, by assessing bias due to problems not covered in other domains.

2.3.15 Quality of Evidence

I defined the quality of evidence according to the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) Working Group[144] as (1) high (further research is unlikely to change our confidence in the estimate of effect and there are no known or suspected reporting biases: all domains are fulfilled); (2) moderate (further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate); (3) low (further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate). Again, MS and IO independently assessed the study data for each trial. To aid transparency, I explained reasons for downgrading evidence in the "Summary of findings" (Sof)[158] table for the main comparators.

Sensitivity analyses were conducted by assessing whether the effect of ACP on heart failure was sustained in studies of a low risk of bias to analyse the robustness of the pooled effect estimate.

2.4 RESULTS

2.4.1 Results of the Search

Of 5178 articles screened, we reviewed the full text of 104 studies. Fourteen studies (13 RCTs[51, 54-56, 62, 164-171], one cRCTs[172]) met all of the inclusion criteria for the quantitative analysis (see **Figure 5** for PRISMA Flow Diagram). A detailed description of each trial is provided in **Table 2.** We included 14 studies in the meta-analysis involving 2924 unique participants. We excluded 71 studies with reasons provided in **Appendix 5** "Characteristics of Excluded Studies."

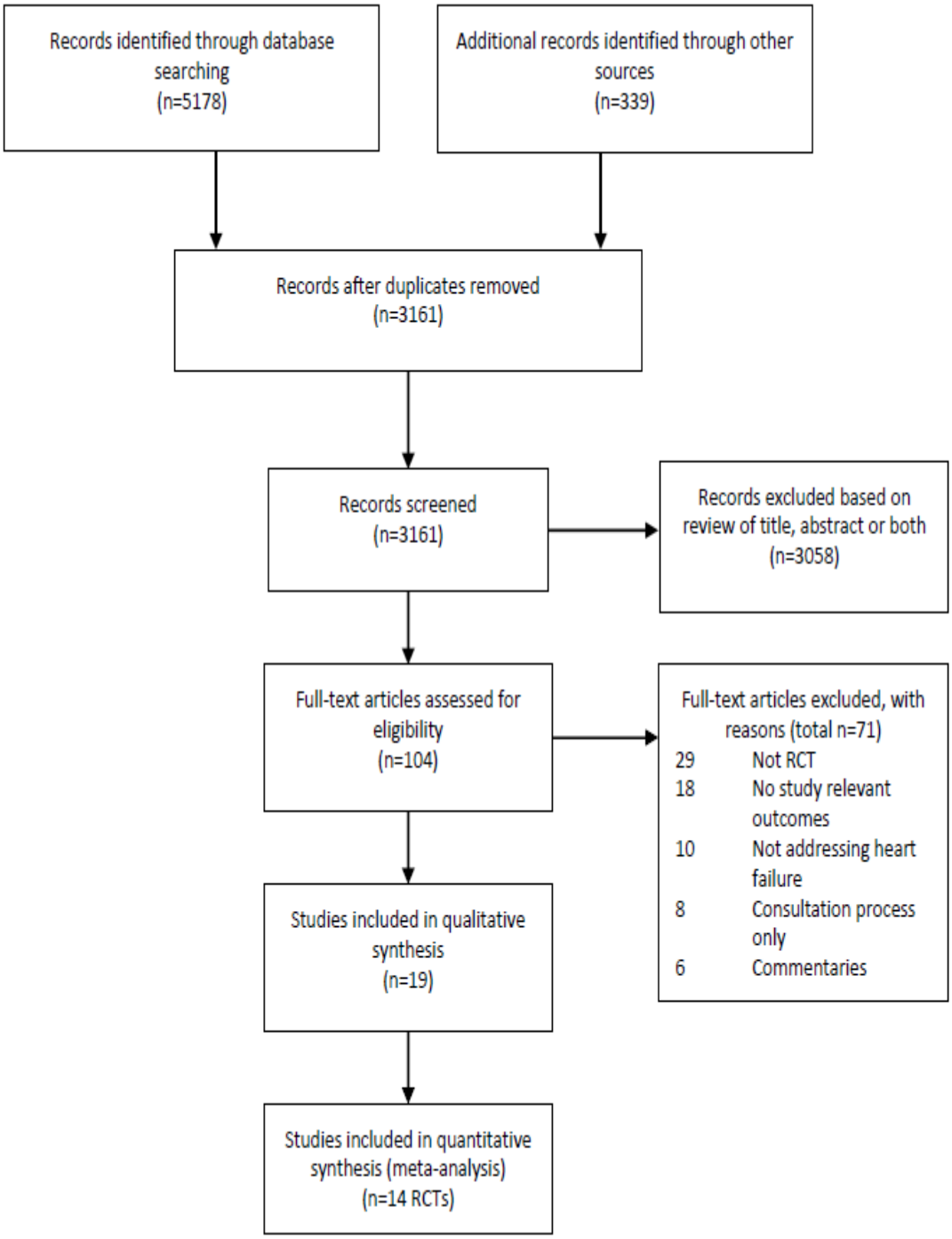


Figure 5. PRISMA flow diagram of impact of ACP on heart failure

Study (year)	Country	Setting	Speciality	Description of Healthcare Professionals (HCPs)	Description of Patients	Patients undergoing Rando-misation/ Completed	Female Patients (no/%) & Mean age (Years)	Follow-up (weeks)	Type(s) of ACP outcome(s)
Aiken[62] (2006)	USA	Community	Palliative Care	Hospice nurse and case manager	HF-NYHA III,IV and COPD	192/191	123/64 68.5	12	QOL
Au[172] (2012)	USA	Hospital	Medicine	Internal & pulmonary physicians	HF-NYHA III,IV, COPD, CRF	376/306	149/53.26 69.4	2	Quality of EOL communication
Brannstrom[54] (2014)	Sweden	Hospital	Geriatrics	Geriatricians	CHF, NYHA III-IV	72/61	21/29.1 81.9	12	QOL
Briggs[55] (2004)	USA	Hospital	Medicine	Cardiologists, renal physicians	HF-NYHA II,III, IV and CRF	27/27	11/40.74 68.7	1	Quality of EOL communication
Brumley[56] (2007)	USA	Community	Primary & Palliative Care	Primary care and palliative care clinicians	HF- NYHA III-IV, COPD, cancer	310/297	146/49 65.1	12	Patient satisfaction with EOLC
Denvir[164] (2016)	UK	Hospital	Cardiology	Cardiology staff	Patients with HF-NYHA III,IV and ACS	50/44	20/40 81.05	12	QOL
Detering[51] (2010)	Australia	Hospital	Medicine Cardiology	Internal & pulmonary physicians, cardiologists	Elderly HF patients >80 years of age	309/305	162/52.5 84.5	12	Patient satisfaction with EOLC
Doorenbos[165] (2016)	USA	Hospital	Cardiology	Cardiology staff	HF –NYHA I,II,III,IV	80/73	19/23.7 58.1	2	Quality of EOL communication
Engelhardt[166] (2006)	USA	Hospital & Community	Primary Care & Medicine	Primary and secondary care physicians	HF- NYHA III,IV, COPD, cancer	275/186	118/82.6 Not reported	12	Patient satisfaction with EOLC
Gade[167] (2008)	USA	Hospital	Medicine	Internal physicians	HF, cancer, COPD, stroke, CRF	517/512	162/59 73.3	24	Patient satisfaction with EOLC
Hopp[168] (2016)	USA	Hospital	Palliative Care	Palliative care clinician and nurse practitioner	CHF patients	85/85	41/48.2 68.1	12	QOL, Patient satisfaction with EOLC
Rogers[169] (2017)	USA	Hospital	Palliative Care Cardiology	Palliative care clinicians, cardiologists	Patients with HF-NYHA III,IV	150/ 106	71/ 47.3 71.9	12	QOL
Sidebottom[170] (2015)	USA	Hospital	Cardiology	Cardiology staff	HF patients	232/ 167	110/47.4 73.4	12	QOL
Wong[171] (2016)	Hong Kong	Hospital	Palliative Care	Palliative care physicians and nurses	Patients with HF-NYHA III,IV	84/ 84	41/ 48.8 78.3	12	QOL, Patient satisfaction with EOLC

Abbreviations: ACP**:** advance care planning; ACS: acute coronary syndrome; CHF: congestive heart failure; CRF: chronic renal failure; EOLC: end-of-life care; HCPs: healthcare professionals; HF: heart failure; NYHA: New York Heart Association; QOL: quality of life

Table 2. Characteristics of included studies

2.4.2 Sample sizes, study populations, setting and comparator

The median sample size was 209 people (range 27-517 participants). The median age of participants was 65.85 (age range 58.1-84.5 years). 40.83 % (n=1194) of the total study population were female. The unit of randomization and the unit of analysis in each trial was the patient except for the cluster RCT[172]. All trials included patients with heart failure. Most studies focused on NYHA Class III and IV patients. Two studies included NYHA Class II[55, 165] and one study NYHA Class I patients[165]. 10 of the 14 studies were conducted in the USA, one in the UK[164], one in Australia[51], one in Sweden[54], and one in Hong Kong[171]. Five studies were performed in a hospital outpatient setting, five studies in a hospital ward or hospice, two studies in primary care clinics or GP surgeries[56, 166] and one study[62] in a residential care home. Comparators were normal routine care including usual heart failure management by the cardiology staff. Typically, this included symptom control and drug management, consultations with cardiologists or heart failure specialist nurses.

2.4.3 Outcomes

Table 3 gives an overview of the outcomes assessed. Studies measured outcomes either by direct patient feedback to the research team in the form of surveys or telephone interviews, self-reporting by healthcare professionals or through post-intervention audits of computer or patient records by research staff. Quality of life was evaluated in seven studies. Five studies reported patient satisfaction with end-of-life care as an outcome. The quality of end-of-life communication was assessed in

four trials. No trial assessed clinicians' confidence in communicating End-of-life issues.

2.4.4 Excluded Studies

We excluded 71 studies. The majority of studies were excluded because they were not RCTs (n=29), did not address pre-specified outcomes (n=18), or did not include patients suffering from heart failure (n=10)[53, 58, 173-180]. For a summary of all excluded trials, please see **Appendix 5**.

2.4.5 Risk of Bias Assessment

A summary of a 'risk of bias table' is included in **Figure 6**. 9 studies reported adequate methods of random sequence generation, whilst the remaining 5 did not provide enough information to assess risk of bias and were hence judged to be at unclear risk. Adequate methods included the use of a random number generator or coin toss, whilst unclear methods were described as being 'random' in design but lacked any further definition of the method used. Allocation concealment (selection bias) was unclear in seven studies as authors did not describe methods of concealment. One study did not conceal allocations. Blinding of participants was not possible in seven trials because of the nature of the interventions. This resulted in a high risk of performance bias. Seven studies reported methods of blinding of outcome assessors (detection bias) that we judged at low risk of bias. One study[166] had a high risk of detection bias since outcome assessors were aware of the participants' allocation to the intervention group. The other remaining studies did not report any attempts to blind outcome assessors and as such were unclear for this category. Incomplete outcome data (attrition bias) was adequately addressed in all studies. Selective reporting (reporting bias) was not detected in any trial. A high risk of any

other bias was detected in two studies: the intervention group in the Brannstrom et al.[54] study was considerably older than the control group. Eight control patients in the study by Sidebottom et al.[170] received subsequently the intervention. Some intervention group patients of the same study did not receive the intervention.

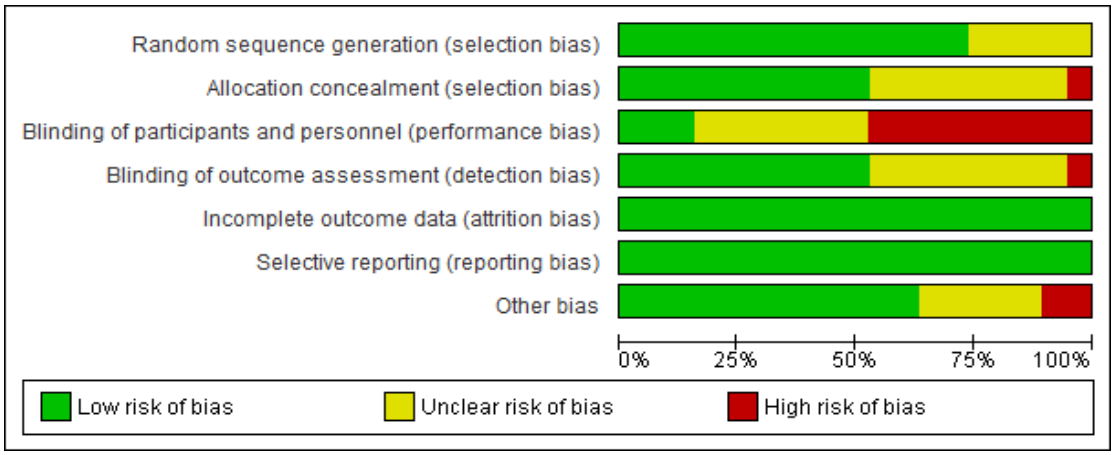


Figure 6. Risk of bias graph

2.4.6 Quality of Evidence

Table 3 provides a summary of the findings of the effects of ACP on outcomes for heart failure in end-of-life care. It shows the GRADE quality ratings for each outcome and a sensitivity analysis of studies at low risk of bias. The mean score for the overall quality of evidence across all studies was moderate after rating all GRADE criteria. This was mainly due to the fact that many participants could not be blinded to the nature of the intervention introducing a high risk of performance bias.

Effect of ACP on Heart Failure Outcomes

Patient or population: patients with heart failure
Settings: primary, secondary and residential healthcare
Intervention: advance care planning

Outcomes	Illustrative comparative risks* (95% CI) Assumed risk Control	Corresponding risk Effect of ACP on Heart Failure outcomes	No of Participants (studies)	Quality of the evidence (GRADE)	Effect (95% CI)
Quality of Life		The mean quality of life in the intervention groups was **0.38 SMD higher**	724 (7)	**Low**	**SMD 0.38** (0.09-0.66)
Patient Satisfaction with EOL Care		The mean patient satisfaction with EOL care in the intervention groups was **0.33 SMD higher**	1290 (5)	**Moderate**	**SMD 0.33** (0.10-0.57)
Quality of EOL Communication		The mean quality of EOL Communication in the intervention groups was **0.29 SMD higher**	995 (4)	**Low**	**SMD 0.29** (0.17-0.42)

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
Abbreviations
CI: Confidence Interval; **RCT:** Randomized Controlled Trial; **EOL Care:** End-of-life care; **ACP:** Advance Care Planning; **SMD**: Standardized Mean Difference;

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Table 3. Quality of evidence assessment

2.4.7 Meta-analysis on ACP and Quality of Life in Heart Failure

Quality of Life (QOL) was determined in seven studies (50%) (724 patients), of these, five were at high risk and two at low risk of bias (**Figure 7**). Five trials evaluating QOL reported statistically significant improvements related to QOL whereas two trials did not show any significant impact. Seven trials evaluating QOL at follow-up were pooled in meta-analysis. The median follow-up duration was 12 weeks. ACP was associated with a statistically significant improvement for QOL (SMD, 0.38; 95% CI [0.09 - 0.66], $p<0.009$). For ease of interpretation (see **Table 4**), we re-expressed

the estimated SMD for quality of life as an Odds Ratio (OR, 1.93; 95% CI [1.17 – 3.31]).

Heterogeneity for this outcome was significantly reduced from 71% (substantial) to 35% (might not be important) by omitting the study by Sidebottom et al. Several factors in this study may have contributed to the increase in heterogeneity: patients in the intervention group were on average 5.1 years older than patients in the control group (p=0.003). A number of patients assigned to the intervention group withdrew from the study (n=5) and did not receive the intervention. A subset of patients (n=8) in the control group received the intervention. The authors admitted that they did not achieve the originally intended sample size of 500 subjects. Additional causes for heterogeneity like patient population, length of follow-up, setting or intervention components for the other studies were explored and discussed in section 2.5 under Discussion.

I used Egger's test to analyse the funnel plot symmetry of the 7 RCTs included in the meta-analysis. There was no evidence (p=0.406) of a small study effect on publication bias (**Appendix 7**).

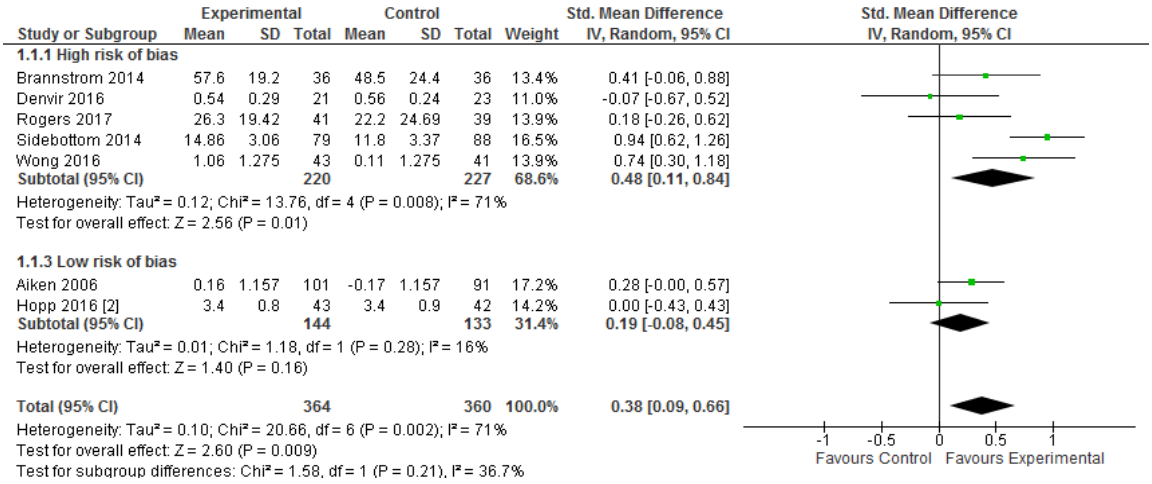


Figure 7. Association between ACP and quality of life

2.4.8 Meta-analysis on ACP and Patient Satisfaction

Patient satisfaction with end-of-life care was assessed in four studies (28.57%) reporting data on 1205 patients. One study was at high risk, one study at unclear risk of bias and two studies at low risk of bias. The median follow-up duration was 14.4 weeks. The pooled results of these studies (**Figure 8**) provide moderate quality of evidence of a statistically significant effect for ACP compared to standard care (SMD, 0.39; 95% CI [0.14-0.64]; p = 0.003). For ease of interpretation, we re-expressed the estimated SMD for patient satisfaction as an Odds Ratio (OR, 1.77; 95% CI [1.20-2.81]). An improvement in patient satisfaction with end-of-life care was reported in four studies (100%). Possible causes for heterogeneity (I^2=78%) of this subgroup were explored in subsequent sensitivity analyses. I used Egger's test[95] to analyse the funnel plot symmetry of the 4 RCTs included in the meta-analysis. There was no evidence (p=0.584) of a small study effect on publication bias (**Appendix 7**).

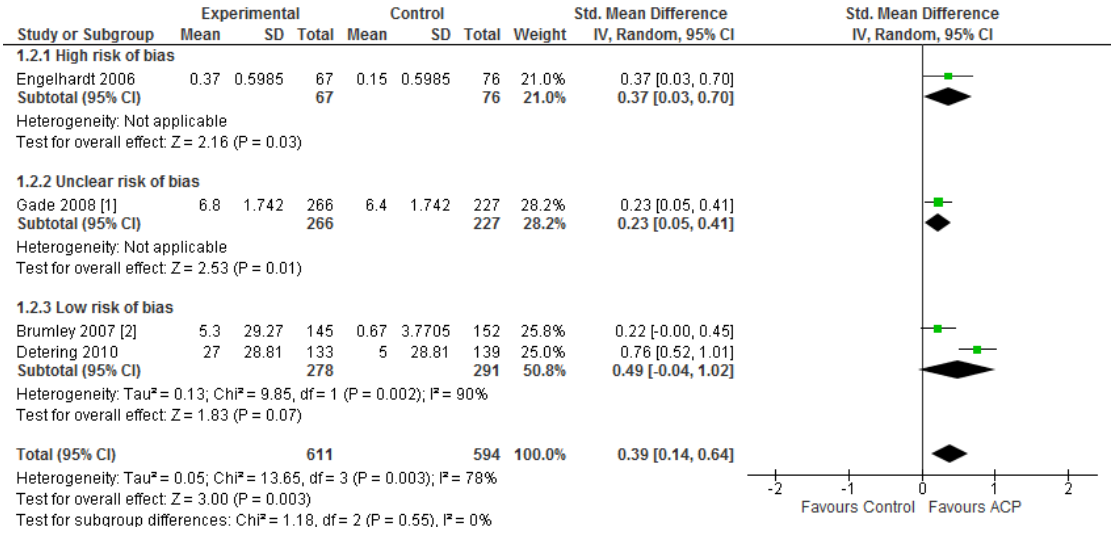


Figure 8. Association between ACP and patients' satisfaction with EOL Care

2.4.9 Meta-analysis on ACP and Quality of EOL Communication

Four studies (28.57%) measured the effect of ACP on the quality of end-of-life communication reporting data on 995 patients. Three studies were at high risk of bias and one study at unclear risk of bias. All trials evaluating quality of end-of-life communication at follow-up were pooled in meta-analysis (**Figure 9**). The median follow-up duration was 7.25 weeks. ACP was associated with statistically significant improvements for the quality of end-of-life communication (SMD, 0.29; 95% CI [0.17-0.42]; p = 0.00001). For ease of interpretation, we re-expressed the estimated SMD for the quality of end-of-life communication as an Odds Ratio (OR, 1.52; 95% CI [1.36-2.14]). All trials reported an improvement in the quality of end-of-life communication. Heterogeneity was of no significance (I^2=0%). I used Egger's test to analyse the funnel plot symmetry of the 4 RCTs included in the meta-analysis. There was no evidence (p=0.095) of a small study effect on publication bias (**Appendix 7**).

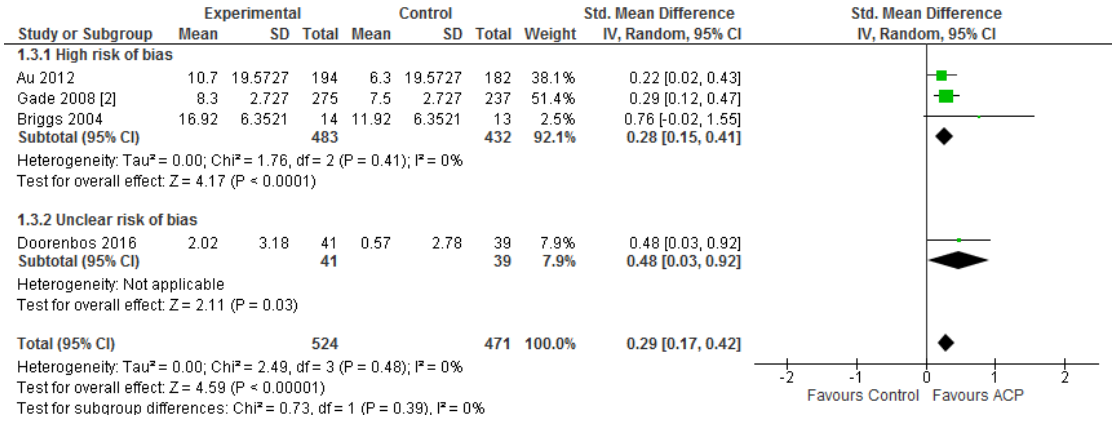


Figure 9. Association between ACP and quality of EOL communication

Table 4 re-expresses SMDs as ORs and provides a summary of estimated effect sizes of the impact of ACP in heart failure for each clinical outcome.

Outcome	SMD	LL	UL	ln(OR)	ln(OR_LL)	ln(OR_UL)	OR	LL(OR)	UL(OR)
Quality of Life	**0.38**	0.09	0.66	0.689244	0.163242	1.197108	**1.935**	1.177	3.311
Patient Satisfaction with End-of-life care	**0.33**	0.1	0.57	0.598554	0.18138	1.033866	**1.768**	1.199	2.812
Quality of End-of-life Communication	**0.29**	0.17	0.42	0.526002	0.308346	0.761796	**1.522**	1.361	2.142

Table 4. SMDs and ORs estimates of ACP in heart failure

2.4.10 Causes of Heterogeneity

To investigate possible causes of heterogeneity, several subgroup analyses were performed. I stratified outcomes for patient populations, study settings and length of follow-up periods. A summary of levels of heterogeneity for each outcome and subgroup is presented in **Table 5**. Additionally, I explored characteristics of studies that found ACP to be effective and studies that found ACP not to be effective to identify any possible explanations.

Outcome and Subgroups	Studies	Participants	Effect Size SMD, 95% CI	I^2
Quality of Life (QOL)	**7**	**724**	**0.38 [0.09-0.66]**	**71%**
Patient Population				
QOL HF Patients	6	532	0.39 [0.04-0.74]	74%
QOL HF Patients + Other Terminal Illnesses	1	192	0.28 [0.00-0.57]	n/a
Study Setting				
QOL Hospital	3	237	0.18 [-0.07-0.44]	0%
QOL Community	1	192	0.28 [0.00-0.57]	n/a
QOL Hospital and Community	3	295	0.58 [0.05-1.12]	77%
Length of Follow-up				
QOL F/u to 12 weeks	7	724	0.38 [0.09-0.66]	71%
Patient Satisfaction with EOL Care (PSEOLC)	**5**	**1290**	**0.33 [0.10-0.57]**	**75%**
Patient Population				
PSEOLC HF Patients + Other Terminal Illnesses	4	1205	0.39 [0.14-0.64]	78%
Study Setting				
PSEOLC Hospital	2	765	0.49 [-0.03-1.01]	92%
PSEOLC Community	1	297	0.22 [0.00-0.45]	n/a
PSEOLC Hospital and Community	1	143	0.37 [0.03-0.70]	n/a
Length of Follow-up				
PSEOLC F/u to 12 weeks	3	712	0.45 [0.11-0.80]	80%
PSEOLC F/u to 24 weeks	1	493	0.23 [0.05-0.41]	n/a
Quality of EOL Communication (QEOLC)	**4**	**995**	**0.29 [0.17-0.42]**	**0%**
Patient Population				
QEOLC HF Patients	1	80	0.48 [0.03-0.92]	n/a
QEOLC HF Patients + Other Terminal Illnesses	3	915	0.28 [0.15-0.41]	0%
Study Setting				
QEOLC Hospital	4	995	0.29 [0.17-0.42]	0%
Length of Follow-up				
QEOLC F/u to 4 weeks	3	483	0.33 [0.09-0.57]	20%
QEOLC F/u to 24 weeks	1	512	0.29 [0.12-0.47]	n/a

Abbreviations: **F/u:** Follow-up; **HF:** Heart Failure**; n/a:** not applicable; **PSEOLC**: Patient Satisfaction with End-of-life care; **QEOLC**: Quality of EOL Communication **QOL**: Quality of Life;

Table 5. Causes of heterogeneity

2.4.11 Subgroup Analyses by Patient Populations

Studies were stratified for each outcome by a subgroup including patients with heart failure vs a subgroup combining patients with heart failure and other terminal illnesses like cancer or COPD (**Figure 10**). Levels of heterogeneity were substantial for the subgroup heart failure patients and QOL (I^2 =74%). After excluding the study by Sidebottom et al., heterogeneity was reduced to I^2 =35%. I described possible reasons for the observed difference of effect in this study under section 2.4.7. The

patient population of heart failure and other terminally ill patients for the outcome Quality of End-of-life Communication had insignificant levels of heterogeneity (I^2=0%). Effects of ACP generally were greater in studies with heart failure patients only and less effective when heart failure patients were studied together with patients suffering from other life-limiting illnesses. The highest levels of heterogeneity were found for studies combining heart failure patients with patients suffering from other life-limiting illnesses for Patient Satisfaction with End-of-life care (I^2 =78%).

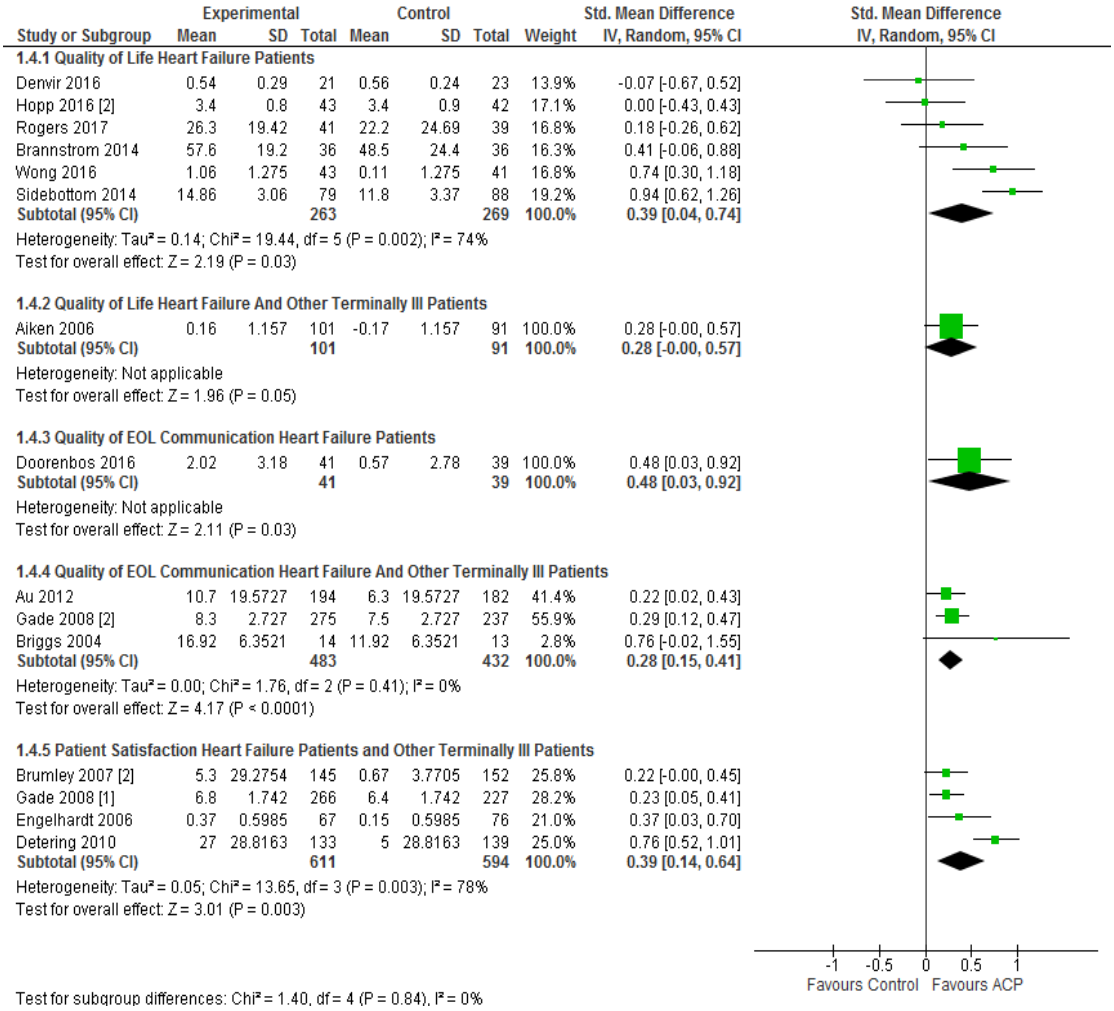


Figure 10. Subgroup analyses by patient population

2.4.12 Subgroup Analyses by Study Settings

Studies were stratified for each outcome by a subgroup including the study setting like hospital, community, and hospital and community settings. Two outcomes demonstrated no significant levels of heterogeneity for the hospital setting: Quality of Life (I^2=0%) and the Quality of End-of-life Communication in a hospital setting (I^2=0%) (**Figure 11**). Otherwise, levels of heterogeneity were substantial for the QOL in studies that involved a hospital and community setting (I^2=77%) and for Patient Satisfaction with End-of-life care in a hospital setting (I^2=92%).

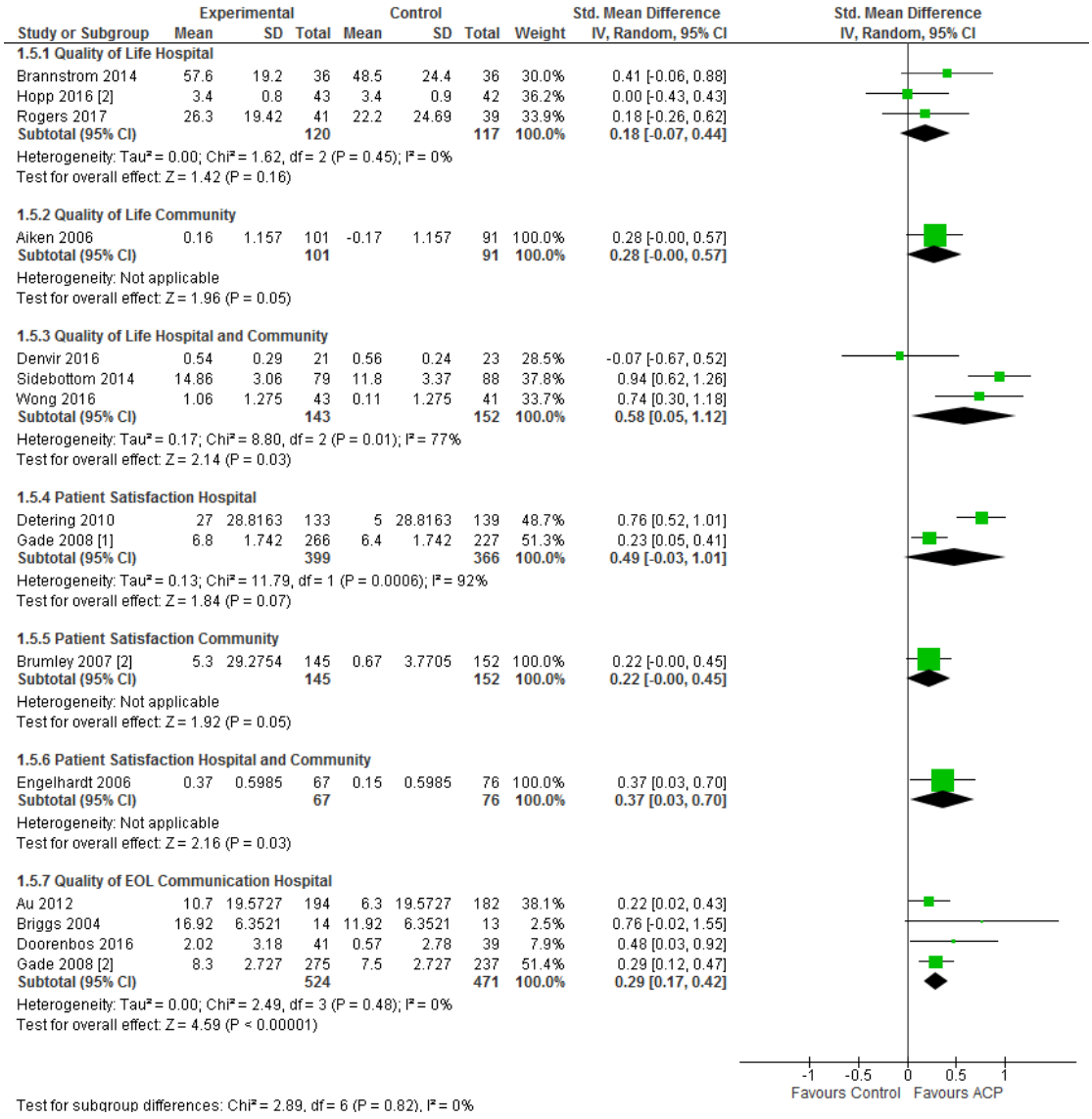


Figure 11. Subgroup analyses by study setting

2.4.13 Subgroup Analyses by Length of Follow-up

Studies were stratified according to their length of follow-up for each outcome (**Figure 12**). Follow-up periods ranged from 1-4 weeks, up to 12 weeks and up to 24 weeks. Testing for heterogeneity was difficult due to the paucity of data for each follow-up period. Levels of heterogeneity seemed lower for shorter follow-up periods (1-4 weeks) than for longer follow-up durations (up to 12 or 24 weeks). Insignificant levels of heterogeneity were found in the up to 4 weeks follow-up period for the Quality of End-of-life Communication (I^2 = 20%). The highest level of heterogeneity was identified in the up to 12 weeks follow-up period for Patient Satisfaction with End-of-life care (I^2 = 80%). Data for levels of heterogeneity for the 24 weeks follow-up period could not be generated due to the lack of comparable studies.

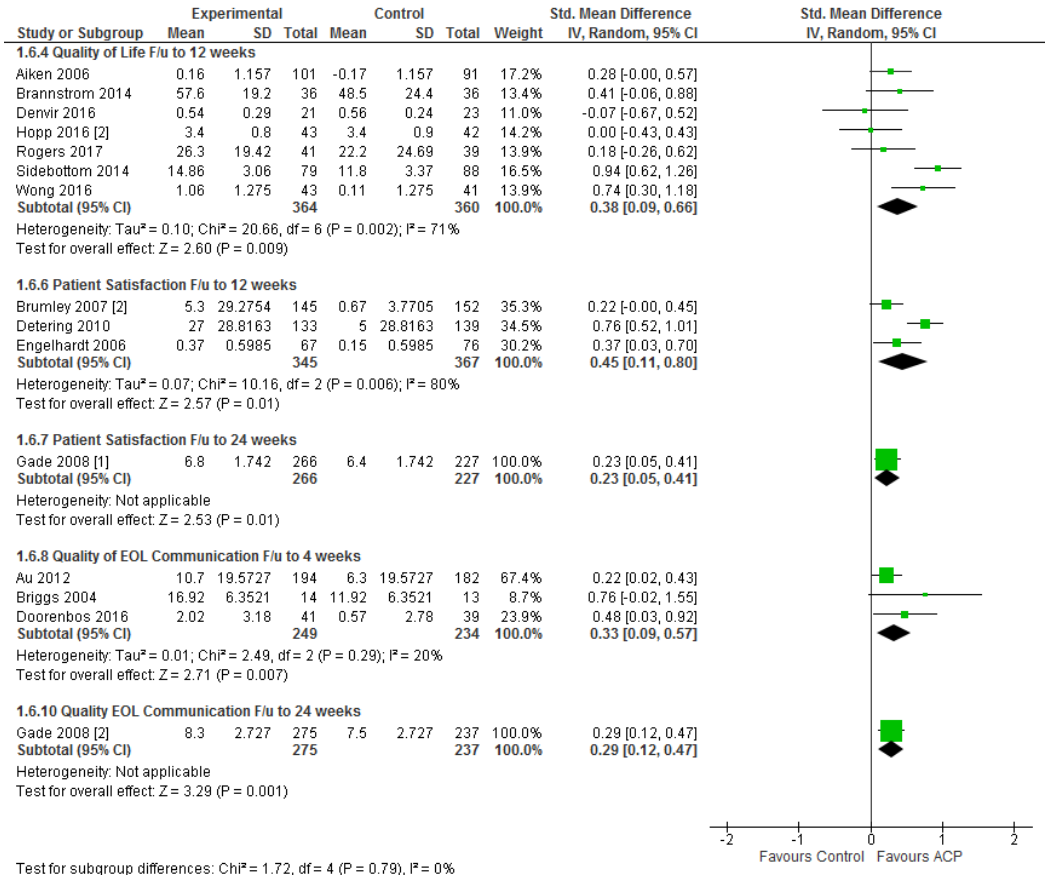


Figure 12. Subgroup analyses by length of follow-up

2.4.14 Characteristics of ACP Interventions with High and Low Effect Sizes

The following section describes characteristics of ACP interventions with the highest and lowest effect sizes by outcome. The composition, timing and follow-up of these interventions were considered and whether patients and family members were involved. Generally, ACP interventions that included multiple components, educated patients, involved family members and offered follow-up were more effective than single component interventions that did not educate patients, did not involve family members and did not offer follow-up. I have discussed the differences of these studies in more detail in the Discussion part of this chapter (section 2.5). **Table 6** summarises the characteristics of interventions with the highest and lowest effect sizes by outcomes (blue = Quality of Life [QOL]; green = Patient Satisfaction with End-of-life care [PSEOLC]; orange = Quality of End-of-life Communication [QEOLC]). Studies in grey under each outcome represent the highest effect sizes whereas studies in white show the lowest effect sizes.

Study	Outcome	Effect Size SMD [95% CI]	ACP Characteristics	ACP Timing	Education of Patient	Involvement of Family	ACP Follow-up
Sidebottom (2014)	**QOL**	0.94 [0.62-1.26]	A trained facilitator supports patients to identify their care preferences: completes an ACP health directive and a HF disease-specific care plan	At hospital admission	Yes	Yes	Yes
Wong (2016)	**QOL**	0.74 [0.30-1.18]	A complex ACP and transitional palliative care programme with interdisciplinary communication	Before hospital discharge	Yes	Yes	Yes
Hopp (2016)	**QOL**	0.00 [-0.43-0.43]	Single component ACP intervention: one meeting to complete an ACP document, no further patient support	During hospital stay	No	No	No
Denvir (2016)	**QOL**	-0.07 [-0.67-0.52]	An ACP document is discussed with patients, using a multidisciplinary approach and patient electronic records	Before hospital discharge	Unclear	Unclear	Yes
Detering (2010)	**PSEOLC**	0.76 [0.52-1.01]	A complex Respecting Patient Choices Programme including ACP, identification of patient's care preferences and surrogate decision maker	Before hospital discharge	Yes	Yes	Yes
Engelhardt (2006)	**PSEOLC**	0.37 [0.03-0.70]	A complex ACP Coordinated Care Programme: training patients to ask questions, multidisciplinary approach, increasing patient self-management	Patients were stable	Yes	Yes	Yes
Brumley (2007)	**PSEOLC**	0.22 [-0.00-0.45]	An Interdisciplinary, home-based ACP programme including patients' self-management	Patients were unwell	Unclear	Yes	Yes
Doorenboos (2016)	**QEOLC**	0.48 [0.03-0.92]	Pre-outpatient telephone call to train patients in ACP communication and identifying EOLC wishes; clinician informed of patient's wishes before visit	Hospital outpatient visit	Yes	Yes	Yes
Briggs (2004)	**QEOLC**	0.76 [-0.02-1.55]	A single ACP intervention: facilitator has a single two hour ACP meeting with patient, no interdisciplinary working and no f/u	Before elective admission to hospital	Yes	Yes	No
Abbreviations: **ACP**: Advance care planning; F/**u**: Follow-up; **HF**: Heart Failure; **PSEOLC**: Patient Satisfaction with End-of-life care; **QEOLC**: Quality of EOL Communication **QOL**: Quality of Life;							

Table 6. Characteristics of ACP interventions

2.5 DISCUSSION

2.5.1 Summary of Principal Findings

This literature review was the first systematic evaluation of the evidence base for the effect of ACP on each end-of-life care outcome in heart failure and an exploration into causes of heterogeneity. The results of the meta-analyses from 14 RCTs including 2924 participants demonstrated that ACP improved the quality of life (OR, 1.94; 95% CI [1.18 – 3.31]), patient satisfaction with end-of-life care (OR, 1.77; 95% CI [1.12-2.81]), and the quality of end-of-life communication (OR, 1.52; 95% CI [1.36-2.14]) compared to usual care.

ACP interventions that included multiple components, educated patients, involved family members and offered follow-up were more effective than single component interventions that did not educate patients, did not involve family members and did not offer follow-up. Undertaking a meta-analysis of the available data was important as it provided a measure of effect for ACP on outcomes that re relevant to patients and family members[141].

2.5.2 Exploring Heterogeneity

Substantial levels of heterogeneity are to be expected when aggregating evidence on the effect of complex interventions like ACP[181]. ACP as described in included studies consisted of multiple components and was implemented differently and in different settings[182].

The heterogeneity caused by different timings, settings or approaches to ACP seemed inherently problematic since recommendations advocate minimizing heterogeneity in

order to ensure the reliability of review findings[183]. Yet, this guidance may not always be appropriate, because an adequate consideration of complex interventions like ACP requires the integration of heterogeneous data[109]. Therefore, my challenge was to constructively explore potential causes of heterogeneity and how differences in included studies might have determined the effectiveness of ACP on outcomes.

Heterogeneity Within Each Outcome

The following sections discuss causes of the different levels of heterogeneity within each clinical outcome (quality of life, patient satisfaction with end-of-life care, quality of end-of-life communication) by focusing on studies reporting largest and smallest effects for each outcome.

Differences in Studies for Quality of Life

Sidebottom et al.[170] attributed the success of the intervention to using an ACP *trained* facilitator, educating patients in their end-of-life issues, involving a family member and offering follow-up appointments. The literature affirmed the importance of using trained facilitators, educating patients, and multiple ACP components[51, 184-187] to improve patient outcomes. Similarly, Wong et al.[171] thought that improvements in their Quality of Life outcomes were due to a comprehensive palliative care programme, multidisciplinary team working, clear referral guidelines and involvement of carers and patients alike, using trained healthcare professionals[41, 188]. This difference in effectiveness by designing ACP as a complex versus ACP as a single intervention was confirmed in the literature[189].

By contrast, Hopp et al.[168] used the design of a single component ACP intervention without any follow-up, involvement of family members or other healthcare

professionals. Additionally, their study population consisted mainly in African-Americans. Studies have shown that this patient population prefers curative rather than palliative care approaches and is less likely to engage with ACP[190, 191]. A lack of consideration of ethnic preferences, missing follow-up, the exclusion of family members and clinicians may well have contributed to the low effect of Hopp et al.'s ACP intervention. The low effect size for ACP in the study by Denvir et al.[164] was due to the study design, i.e. a feasibility RCT. The data generated in this small cohort was not intended to be sensitive or specific enough to observe a positive effect of the intervention for Quality of Life. Additionally, a high mortality rate during the follow-up period further limited the utility of their data as a trial end point.

Differences in Studies for Patient Satisfaction with EOLC

The study by Detering et al.[51] cited five factors for improving Patient Satisfaction with End-of-life care: 1. Using trained facilitators, 2. Conducting a patient-centred discussion, 3. The involvement of the family, 4. Correctly filing and communicating the ACP documentation with all parties, 5. A systematic education of doctors in communicating ACP. Likewise, the study by Engelhardt et al.[166] delivered ACP through trained care coordinators who had an institutional identity and clinical credibility. Patients could schedule extra meetings with their care coordinator if they had further questions and follow-up was provided. The importance of using trained facilitators with a clinical credibility is highlighted in the literature[192].

Lower effect sizes for Patient Satisfaction with End-of-life care were found in the study by Brumley et al.[56] While the intervention slightly improved outcomes, the authors thought that a major cause for the low effect size was the high mortality rate

of the study population before follow-up. Their results suggested that providing a multidisciplinary team early in the disease trajectory of a terminally ill home-bound patient had a small, positive effect on Patient Satisfaction with End-of-life care.

Differences in Studies for Quality of EOL Communication

Possible causes for the success of the study by Doorenboss et al.[165] corresponded with factors found in other studies of similar effect sizes: a) patients were educated by a nurse through a question prompt list before their appointment with the cardiologist, b) the nurse helped patients identifying and clarifying their care wishes, c) the clinician was trained in end-of-life communication skills and had an advanced awareness of the patient's care preferences. An additional factor may have been the comparatively short, two weeks follow-up period of the study which may have limited the long-term effect of patient-mortality on study outcomes.

Lower effect sizes for the Quality of End-of-life Communication were reported in the study by Briggs et al.[55] Possible causes for the comparatively small effect might have been similar to the factors described in the study by Hopp et al.[168]: ACP was delivered as a single intervention in the context of a two hour meeting. Interdisciplinary working and communicating the patient's end-of-life care preferences with other medical specialities was missing. While the facilitator engaged family members and was trained in delivering ACP, no follow-up was offered to the patient. Offering follow-up appointments corresponds with the nature of ACP and seems to contribute to a better patient experience[41, 193].

The timing of offering ACP as intervention in relation to the patient's disease trajectory demonstrated a similar pattern in each outcome. While most patients in the meta-analysis suffered from heart failure NYHA Class III or IV, ACP was initiated at different time points in the patient's course of disease: during an admission to hospital, after a recent hospitalization[167, 194, 195], after a deterioration in the patient's health status[56], or before a routine clinic appointment with a cardiologist[196]. These findings on the timing of ACP agree with the published literature which cites a change or deterioration in the patient's condition, a routine clinical review, or a change in a patient's personal circumstances such as moving into a care home as possible triggers for ACP[36].

Heterogeneity Within Each Subgroup

An alternative approach based on meta-analysis of subgroups was also taken to explore observed heterogeneity. The following sections discuss causes of the different levels of heterogeneity within each subgroup according to patient populations, study setting and length of follow-up.

The subgroup analyses for patient populations suggested that ACP interventions aimed at heart failure patients only might be more effective than those ACP interventions targeting patients suffering from heart failure and other terminally ill patients. This result seems plausible and included six RCTs. However, this finding should be treated with caution due to considerable levels of heterogeneity in the heart failure patient population group (I^2=74%) which was caused to some extent by the inclusion of the study by Sidebottom et al. as described in section 2.4.7. ACP interventions targeted all classes of heart failure. Patients exposed to ACP included not only those suffering from severe heart failure (NYHA Class IV) but also those

who had either no symptoms (Class I), only mild (II) or moderate (Class III) symptoms. This application of ACP to *any* stage of heart failure agreed with advice from health policy makers[1, 7, 23, 24, 197] and evidence from patient and carer feedback [69, 81, 82].

Considerable heterogeneity was found in sensitivity analyses across study settings except for the hospital setting in quality of life (SMD, 0.18, 95% CI [-0.07-0.44], I^2=0%) and the hospital setting in quality of end-of-life communication (SMD, 0.29, 95% CI [0.17-0.42], I^2=0%). These results suggest that ACP interventions might be effective for quality of life and quality of end-of-life communication in a hospital setting for patients suffering from heart failure. Data for the community setting and the hospital and community setting across other outcomes was sparse. This finding supports the call for further investigation to better understand the key factors that contribute to improved care in different clinical settings when engaging with ACP for patients suffering from heart failure.

A subgroup analyses for length of follow-up demonstrated that number of studies had short intervention periods and follow-up intervals. This may suggest uncertainty of the continuation of the effect of ACP after the intervention was withdrawn. Consequently, trials with longer follow-up periods are recommended to determine whether ACP could sustain its effect over a prolonged period of time. However, trials with longer follow-up periods may have difficulty attributing improvements in the outcomes (e.g. quality of life) to ACP alone. There will be other confounding factors, for example, through external, study-independent interventions, which will be difficult to control. Given that background, I chose a three months follow-up to

represent a pragmatic balance between sufficient time for ACP to take effect but not too long for other variables to confound the findings.

2.5.3 Comparison with Other Reviews

This review is currently the first to have analyzed the effect of ACP on end-of-life care outcomes in heart failure in a meta-analysis providing a detailed consideration of causes of observed heterogeneity. Several reviews have investigated the effectiveness of interventions to implement ACP[97, 133-137, 198]. A number of these reviews are out of date[133, 198]. Some of these reviews conflated an analysis of the impact of ACP on end-of-life care outcomes with the effect of interventions to promote the implementation of ACP in palliative care. One of the most recent reviews presented data on the efficacy of interventions to improve the implementation of ACP[139] using completion rates of advance directives and the occurrence of discussions about end-of-life as outcomes. However, data on the actual impact of ACP in end-of-life care outcomes for heart failure have not been reported.

2.5.4 Strengths and Limitations of this Review

The strength of this review and meta-analyses consists of the use of a robust search strategy, assessing the overall quality of the evidence with the GRADE system, rating risks of biases with the Cochrane risk of bias evaluation tool, statistically pooling data for each outcome and performing sensitivity analyses and exploring causes of heterogeneity. Furthermore, I used random effects models and standardized mean differences to account for variations in types of interventions across studies. However, the use of SMDs did not allow a clinical interpretation of the effect observed. Therefore, I re-expressed SMDs by transforming them to Odds Ratios. ACP improved

the Quality of Life for heart failure patients by approximately 93%, Patient Satisfaction with End-of-life care by about 76% and the Quality of End-of-life Communication by around 52%. Due to the underlying assumptions to make that conversion, the results are only an approximation. However, the clinical gain is sufficiently large to justify the effort of developing a clinician targeted intervention.

The nature of the intervention made it often impossible to blind participants to the intervention resulting in 50% of studies rated with a high risk of performance bias. Allocation concealment was unclear in 50% of studies as authors did not clearly describe methods of concealment introducing an unclear risk of selection bias. These potential sources of bias need to be considered when interpreting the reliability and statistical significance of effect sizes. The lack of blinding of participants to the ACP interventions might have accounted for overestimation of effects because of performance and detection bias. These sources of bias are a known issue in assessing complex interventions in palliative care research and remain unsolved so far.

The substantial heterogeneity in studies was mainly due to different characteristics of ACP interventions, different study populations, study settings and follow-up periods. Additionally, heart failure in itself is associated with significant co-morbidities since, by definition, the condition is a syndrome occurring as a result of other causes like hypertension, myocardial infarction, cardiomyopathy, or atrial fibrillation. Furthermore, 60% percent of heart failure patients have more than 3 co-morbidities, and only 2.5% have none[199]. Consequently, some of the RCTs included participants with other end-of-life conditions like cancer or COPD next to heart failure. These factors contributed to an increase in levels of heterogeneity.

2.6 CHAPTER SUMMARY

This review provides the evidence that ACP improves the Quality of Life (OR, 1.94; 95% CI [1.18–3.31]), Patient Satisfaction with End-of-life care (OR, 1.77; 95% CI [1.12-2.81]), and the Quality of End-of-life Communication (OR, 1.52; 95% CI [1.36-2.14]) for patients suffering from heart failure. Substantial heterogeneity existed within most subgroups mainly due to different patient populations, different study settings, length of follow-up periods and different compositions of ACP as an intervention. Based on findings from these clinical trials, factors for the successful implementation of ACP in heart failure are:

- Using multiple components as part of the ACP process and not relying on a single ACP activity
- Introducing ACP at a significant milestone in the patient's disease trajectory for example, after an unscheduled hospital admission, before hospital discharge or after a deterioration in the patient's health status
- Offering several follow-up appointments, preferably two or three meetings or points of contact (e.g. by telephone call) and over a period of time to allow for the clarification of end-of-life preferences and document ACP
- Supporting all parties involved, patients (e.g. through a question prompt list) as well as clinicians (e.g. through training) to talk about end-of-life issues
- Offering the involvement of family members or of a healthcare proxy when initiating ACP
- Working in a multidisciplinary team approach and not conducting ACP in isolation within a single specialty

This meta-analysis demonstrates that ACP is effective in improving end-of-life care outcomes for patients suffering heart failure. The clinical gain of ACP is sufficiently large to justify an effort of developing and implementing a clinician targeted intervention. However, it is known that clinicians are reluctant to initiate ACP in their daily practice. It is therefore necessary to investigate what intervention components could be effective in engaging healthcare professionals with ACP for patients who suffer from heart failure. This question is addressed in Chapter 3.

CHAPTER THREE

Clinician Targeted Interventions To Improve Advance Care Planning

3 CLINICIAN TARGETED INTERVENTIONS TO IMPROVE ACP

3.1 BACKGROUND

While the effect of interventions to optimise the implementation of advance care planning among patients and carers have been systematically evaluated in a number of reviews[97, 99, 133, 134], a rigorous assessment of the effect of interventions on *clinicians* is missing. Patients might be motivated to discuss their care preferences, engage with future care planning and explore decisions about treatment options[135, 200]. For a number of reasons, clinicians hesitate to have these conversations[69, 201]. The meta-analysis presented in Chapter Two demonstrates that advance care planning significantly improves the quality of life of patients suffering from heart failure. Therefore, it is now imperative to assess what interventions could be effective in changing clinicians' behaviour to engage with advance care planning. Until now, no interventions based on behavioural science targeting clinicians have been developed. My premise is that behavioural interventions aimed at healthcare professionals have the potential to improve the implementation of advance care planning for patients suffering from heart failure.

3.1.1 Relationships to other relevant reviews

A number of other reviews on the effects of interventions to improve the delivery of ACP have been identified[69, 97, 99, 133, 139, 202]. However, these reviews predominantly focus on interventions targeting patients in order to improve engagement with ACP but not clinicians. A precise estimate of intervention effect targeting clinicians based

on a meta-analysis of available trial data is missing. Furthermore, none of these reviews consider a detailed analysis of the different interventions according to behaviour change techniques (BCTs) in supporting clinicians in the delivery of ACP[90]. Behaviour change techniques and the Behaviour Change Techniques Taxonomy Version 1 (BCTTv1) have been used to explain intervention content and why and how their components might change clinicians' behaviour[108]. Not investigating and understanding why and how interventions might work, hinders efforts to intervention design, replication and efficiency[92] as described under section 1.3.

3.2 AIM

The aim of this chapter is to synthesise the evidence for interventions with the greatest potential to engage clinicians with the implementation of advance care planning in patients suffering from heart failure

3.3 OBJECTIVES

The objectives were:

- To determine the effectiveness of interventions targeting clinicians to engage with ACP in heart failure
- To identify which behavioural change techniques are associated with clinicians' behaviour change
- To examine which intervention components might be associated with intervention synergy and which might not
- To describe the most promising intervention components according to TIDieR and the COM-B Model

3.4 METHODS

This review follows the same approach as that described in Chapter Two including the use of the Preferred Reporting Items for systematic reviews and meta-analysis (PRISMA-P)[143] statement, the Grading of Recommendation Assessment, Development, and Evaluation (GRADE)[144]. The TIDieR[103], the Behaviour Change Techniques Taxonomy, and the Effective Practice Organisation of Care Taxonomy have been described in section 1.3.

3.4.1 Types of Studies

We included randomised controlled trials (RCTs) together with cluster randomised controlled trials (cRCTs). Studies were required to have a sufficiently detailed description of intervention components. Where this was not the case, we used the following approach:

- If the study identified that the intervention was a defined strategy, we searched online for details of the strategy and used these to classify the study components. Where insufficient details were available online, we contacted the authors directly, asking for a response by a given date.
- If the study seemed of interest but did not contain identifiable intervention components, I contacted the study authors with a template email asking them to provide any details they might have on the intervention.
- Where authors did not respond by a date specified, provided insufficient information, or where I could not find a current e-mail address, the study was excluded, with the reason for exclusion clearly identified (for example, "unclear on reminder activity").

3.4.2 Types of Participants

We included studies of clinicians who worked in either a primary, secondary care or the independent healthcare sector and looked after patients suffering from heart failure. A clinician was defined as a person whose prime function was to manage a sick person with the purpose of alleviating most effectively the total impact of the illness upon that person[203]. This included General Practitioners, cardiologists, palliative care clinicians, nurses in primary or secondary care and allied healthcare professionals like physiotherapists or occupational therapists. We excluded studies that did not mention the inclusion of patients suffering from heart failure.

3.4.3 Types of Interventions

We used the taxonomy of the Effective Practice Organisation of Care Group which defined clinician targeted interventions. Using the Taxonomy was a first important step to categorize intervention content as explained under section 1.3. There were no restrictions in terms of theory informing the intervention, the person delivering the intervention (e.g. research staff, trained clinician, social worker, counsellor, religious representative) or the healthcare setting in which the intervention was delivered (e.g., primary care, secondary care, independent or private healthcare sector or online). Interventions could be delivered using any design and by any type of media. We included interventions that promoted the implementation of any type of advance care planning like advance directives, future care plans, durable power of healthcare attorney, living wills or healthcare proxies, and interventions aimed at influencing professional practice by using patients as the agent for changing a clinician's behaviour. However, interventions that were solely aimed at changing the behaviour of patients or consumers, such as lifestyle counselling, were generally not within the

scope of this review. The exception was when professional and patient behaviour were affected by the intervention.

3.4.4 Exclusion Criteria

We excluded studies where the intervention solely targeted patients but was not intended to change clinicians' behaviour. We excluded studies that focussed exclusively on the choice of resuscitation preferences as the primary outcome measure of the intervention and did not consider the complexity of advance care planning. Conversely, we included studies which both supported the use of advance care planning and included information on resuscitation preferences. We excluded studies that did not report the components of the intervention, studies that did not explicitly include patients suffering from heart failure and studies that only dealt with the effect of the intervention on the implementation of advance care planning in paediatric but not in adult end-of-life care.

3.4.5 Types of Outcome

In contrast to the review reported in Chapter 2, the selection of outcomes for this review did not focus on any care impact the intervention might have on patients, but on whether the intervention was effective in engaging clinicians with the delivery of advance care planning. Therefore, we selected a priori as our primary outcome the completion of an advance care planning document to determine whether a clinician engaged with the process of advance care planning as a result of the intervention. ACP completion rates relate to any outcome that described data on the completion, recording or modification of any part of an ACP document. We elected the completion of an ACP document as our primary outcome because it tended to indicate

significant progress with discussing and deciding on various aspects of end-of-life care between clinicians and patients. As such, this outcome seemed further "downstream" in the pathway of care compared to the occurrence of an ACP conversation. The completion of an ACP document could, for example, include outcomes on recording end-of-life care preferences, values and choices of patients, family members or healthcare proxies. If more than one outcome follow-up was reported, we used the frequency of ACP completion rates at any time closest to three months post-intervention based on the premise that it would require a reasonable length of time for clinicians and patients to complete an ACP document after they were exposed to the intervention.

3.4.6 Search Strategy

As described in Chapter Two, together with a specialist health science librarian (NR), we designed, tested and conducted the literature searches. An example of a MEDLINE search strategy together with a list of electronic search strategy terms is included in **Appendix 8.** We searched the same bibliographic databases as described in Chapter Two. We checked the reference lists of 12 relevant reviews[43, 97-99, 133, 134, 137, 138, 198, 204, 205] and all potential cross references and records. Additionally, I contacted authors of main trials and experts in the field who are known to conduct research for additional papers or to provide missing or unpublished study data.

3.4.7 Selection of Studies, Data Extraction and Management

Three authors (MS, IO, SC) independently assessed titles and abstracts against inclusion criteria to identify potentially relevant studies using EndNote X8[157]. Those studies that were thought to be relevant were obtained as full text papers. Differences

between authors during the selection process were discussed. The opinion of a fourth author was sought (PA) where relevant. Finally, two reviewers (MS and PA) independently evaluated whether these studies should be included using the pre-specified data extraction form. I kept a list of excluded trials and documented reasons for exclusion in the 'Characteristics of Excluded Studies' (**Appendix 9)**. Data extraction and management followed the same procedures as described in Chapter Two. This included pilot testing a data collection form (**Appendix 10)** for data extraction which was then used independently by two review authors (MS, IO).

3.4.8. Intervention Coding

Two reviewers (SC, MS) independently coded interventions in each trial initially using the Effective Practice Organisation of Care Taxonomy[104]. Using the Effective Practice Organisation of Care Taxonomy as a first step helped to address the lack of precision in intervention reporting. In contrast to Michie et al.'s Behaviour Change Techniques[115], The Cochrane Effective Practice Organisation of Care Group provides a taxonomy for interventions targeting *healthcare professionals* which includes a category called "patient-mediated interventions" describing intervention components where the patient acts as the agent of change of the clinician behaviour[104]. The behaviour change taxonomy does not contain such an intervention category. By starting the intervention component analysis with the Effective Practice Organisation of Care Taxonomy, that important set of interventions was identified.

After having identified Effective Practice Organisation of Care interventions targeting clinicians, it became evident that this taxonomy provided insufficient levels of detail to describe intervention content for clinical practice[114]. Therefore, I elected Michie et

al.'s Behaviour Change Techniques Taxonomy[206] as the next step to explore whether this approach would allow for the required depth of analysis[207]. Consequently, trials were examined applying all 93 behaviour change techniques. Two reviewers (CA, MS) based their coding decisions on Michie et al.'s behaviour change techniques instructions[108] and documented the reasons for their decisions into their own coding books. Each intervention received the following score, reflecting the degree of certainty that the intervention domain was used in the trial:

- yes = 1
- unclear = 0.5
- no = 0

The 'unclear' code was applied where an intervention was not explicitly stated, but reviewers agreed that elements of the intervention description implied that it was used in the study. A score of >1.5 (max. 2.0) confirmed the use of the intervention in the trial. Discrepancies in coding were resolved by discussion. We developed a number of our own coding rules for heart failure, palliative care, and clinicians since the focus of the original Behaviour Change Techniques Taxonomy (v1) is not on heart failure. We documented the rationale of our coding decisions in a coding book (**Appendix 12).** Finally, we recorded the frequency of use of each behaviour change techniques targeting healthcare professionals and patients and conducted random effects meta-analyses to estimate the impact of the behaviour change techniques on clinicians' behaviour.

3.4.9 Statistical Analysis, Risk of Bias and Quality of Evidence Assessment

I performed quantitative meta-analysis with RevMan 5.3.5[159] using random effects models. For individual studies with dichotomous data, I calculated odds ratios (ORs) with 95% confidence intervals (CI) between the intervention and control group as recommend by Cochrane[142]. I conducted meta-analyses for the primary outcome and calculated effect sizes for each Effective Practice Organization of Care Group and behaviour change techniques intervention category.

I conducted sensitivity analyses to explore the effect of trial quality on the outcome and to investigate reasons for heterogeneity[208]. Issues surrounding heterogeneity included subgroup analyses for patient populations, trials at low risk of bias, outliers and characteristics of the most and the least effective clinician targeted interventions. These results were explored in the discussion section of this chapter (3.6).

The sample size for the included cluster RCT[196] did not need adjustment before calculating the pooled effect estimate since the intra-class coefficient had been taken into account for the cluster design. Managing units of analysis issues and missing data, assessing risk of bias and the quality of evidence followed the same procedures as described in Chapter Two.

3.5 RESULTS

Of 14175 articles screened, we reviewed the full text of 131 papers. Thirteen RCTs including one cluster RCTs representing 3709 participants met all the inclusion criteria **(Figure 13.** PRISMA Flow Diagram). Thirteen Studies[51, 62, 165-167, 170, 194-196, 209-212] were included in the qualitative analysis. We excluded 102 studies with reasons provided in the "Characteristics of Excluded Studies" (**Appendix 9**). A detailed description for each trial is included in **Table 7.** The two summary tables of the estimated effect sizes of the Effective Practice Organization of Care Taxonomy (**Table 10**) and Behaviour Change Techniques Taxonomy (**Table 11**) component analysis illustrate the difficulties in interpreting the results as the confidence intervals around the estimated effect of each category overlap.

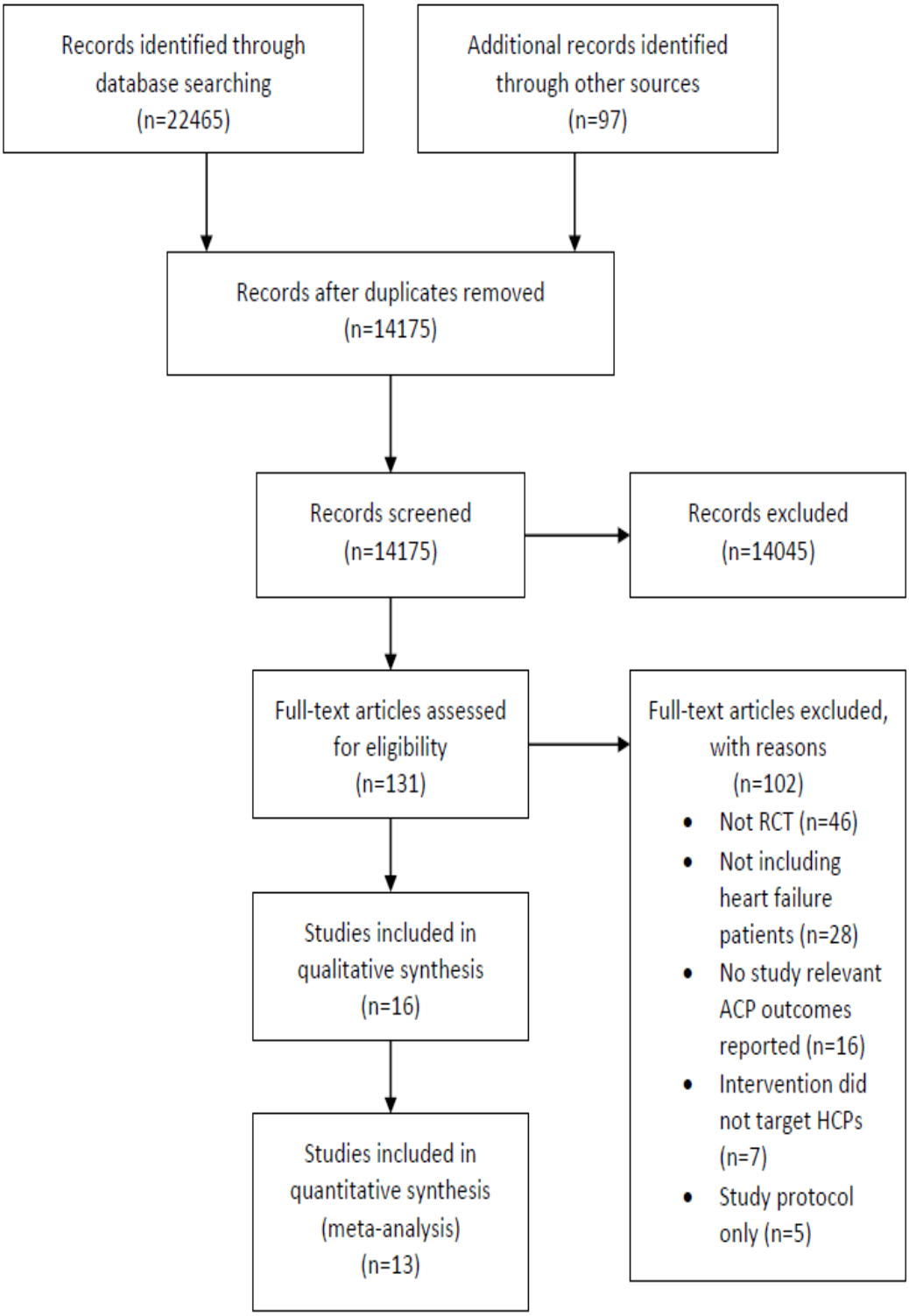


Figure 13. PRISMA flow diagram for clinician targeted interventions

Study (year)	Setting/ Country	Unit of Randomi-sation	Description of Healthcare Professionals	HCPs under-going Rando-misation & Completed (No.)	Description of Patients	Patients undergoing Rando-misation & Completed (No.)	Female Patients (no/%) & Mean age (Years)	Follow-up (weeks)	Type(s) of ACP outcome
Aiken[62] (2006)	Community, USA	Patient	Hospice nurse and case manager	N/a	CHF and COPD patients	192/191	123/64 65.5	12	ACP Doc ACP Con
Detering[51] (2010)	Hospital, Australia	Patient	Internal & pulmonary physicians, cardiologists	N/a	CHF patients >80 years of age	309/305	162/52.5 84.5	12	ACP Doc
Dexter[209] (1998)	Community, USA	Primary Care Physician	Primary Care physicians, residents, fellows and faculty	147/147	>75 years of age or > 50 years of age with terminal illness and CHF	1009/814	665/66 65.1	20	ACP Doc ACP Con
Doorenbos[165] (2016)	Hospital, USA	Patient	Cardiology staff	N/a	CHF patients	80/73	19/23.7 58.1	8	ACP Doc ACP Con
Engelhardt[166] (2006)	Hospital and community, USA	Patient	Primary and secondary care physicians	N/a	Patients with chronic HF or terminal illnesses	275/186	118/82.6 Not reported	12	ACP Doc
Gade[167] (2008)	Hospital USA	Patient	Internal physicians	N/a	Terminally ill and CHF patients	517/512	162/59 73.3	24	ACP Doc
Heffner[210] (2001)	Hospital, USA	Patients	Cardio-vascular healthcare professionals	N/a	Cardio-vascular rehabilitation patients	415/284	77/27.1 65.3	24	ACP Doc ACP Con
Heiman[196]* (2004)	Community, USA	Primary Care Clinic	Primary care faculty physicians	48/48	>70 years of age or > 50 years of age with CHF and terminal illness	1079/895	740/68.3 71.1	28	ACP Doc ACP Con
Metzger[211] (2016)	Hospital, USA	Patient	Cardiology staff	N/a	CHF patients	29/29	9/ 31.0 62.4	2	ACP Doc
Nicolasora[212] (2006)	Hospital, USA	Patient	Internal medical physicians	N/a	Patients admitted to medical ward incld. CHF	297/294	150/50.5 67.0	1	ACP Doc
Reilly[194] (1995)	Hospital, USA	Patient	Internal medical physicians	100/74	Patients from acute admissions incld. CHF	162/162	86/53 63.6	12	ACP Doc ACP Con
Rubin[195] (1994)	Hospital, USA	Patient	Patients' healthcare provider	Not reported	>65 years of age, discharged from hospital	1101/1101	517/47 Not reported	20	ACP Doc
Sidebottom[170] (2015)	Hospital, USA	Patient	Cardiology staff	N/a	CHF patients	232/ 167	110/ 7.4 73.4	12	ACP Doc
Abbreviations:	**ACP Doc:** Completion of an ACP document; **ACP Con**: Occurrence of an ACP conversation; **CHF**: congestive heart failure; * = cRCT;								

Table 7. Characteristics of included studies

3.5.1 Included Studies and Identified BCTs

While the studies examined the effects of interventions on clinician behaviour, patients were by far the most common unit of analysis to determine a change in a healthcare professional's practice. Only three studies[194, 196, 209] had clinicians as the unit of analysis.

Study Design, Size and Setting

All thirteen included studies used a randomized controlled trial design. The median sample size was 411 participants. The smallest number of participants randomized at baseline was n=29[211]. The largest sample size was n=1101[195]. The one cRCTs reported baseline cluster sizes at the practice level[196]. The median follow-up period was 14.38 weeks (range from one week to 28 weeks). Twelve of the 13 studies were conducted in the USA, and one in Australia[51]. Nine trials were performed in a hospital setting, three studies in the community[62, 196, 209] and one study involved hospital and community settings[166].

Study Participants

At the healthcare professional level, ten studies were performed with hospital physicians and three studies included primary care medical staff. Clinicians were only randomized in three trials. The remaining ten trials had patients as the unit of randomisation and analysis. The median age of patients was 68.1 years (age range between 58.1-84.5 years). 48.62 % of the total study population were female. The number of female healthcare professionals was reported only in one study[209].

Comparators to the Intervention

Comparators to the intervention were standard professional training including chronic disease management for heart failure patients. If healthcare professionals were the target of the intervention, the control group was not included in the intervention training or exposed to any form of the intervention.

Study Outcome

The completion of an ACP document was assessed in 13 RCTs. Outcomes were measured through post-intervention audits of computer or patient notes by research staff, self-reporting by the healthcare professional or direct feedback by patients to the research team in the form of surveys or telephone interviews.

Excluded Studies

We excluded most studies from the review because they were not RCTs (n=46), did not explicitly include patients suffering from heart failure (n=28), did not include study relevant ACP outcomes (n=16), did not target healthcare professionals (n=7), or reported only study protocols (n=5). For a summary of all excluded trials, please see **Appendix 9**.

Risk of Bias Assessment

Key descriptors for the risk of bias assessment of the 13 RCTs are summarised in the risk of bias graph (**Figure 14**).

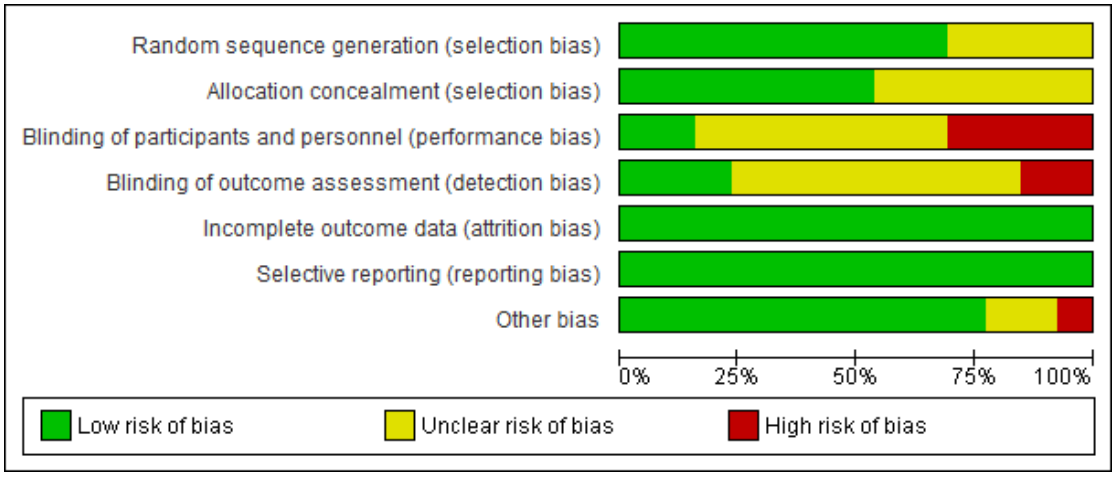


Figure 14. Risk of bias graph clinician targeted interventions

Nine studies reported adequate methods of sequence generation. Adequate methods included the use of a computer random number generator or coin toss procedures. Unclear methods were not defined or described as being 'random' in design. These remaining four trials[165, 170, 194, 195] did not provide enough information and were judged to be at unclear risk. No trial reported inadequate methods.

Seven studies reported allocation concealment in detail and were judged at low risk of bias. Allocation concealment was unclear in six included trials[165, 166, 170, 195, 202, 212] as authors did not describe methods. Some authors reported that participants were randomly and blindly allocated to control or intervention groups, but failed to describe the methods in detail. These studies were rated as at an unclear risk of bias.

Two studies reported adequate blinding of healthcare professionals[194, 196] to the intervention. Blinding of participants was not possible in a number of trials because of the nature of the methods used. Consequently, four trials[166, 167, 209, 212] had a high risk of performance bias. Seven studies were judged at unclear risk since methods were not reported in sufficient detail.

Three studies reported methods of blinding outcome assessors that we judged at low risk of bias. Outcome assessors were likely to be aware of the allocation of participants to control or intervention groups in two trials[166, 196]. The remaining eight studies did not report any attempts to blind outcome assessors and as such were unclear for this category.

Incomplete outcome data (attrition bias) and selective reporting was adequately addressed in all studies. Eight patients from the control group of Sidebottom et al.'s study received the intervention indicating issues with contamination[170].

I used Egger's test to analyse the funnel plot symmetry of the 13 RCTs included in the intervention component analysis. There was no evidence of a small study effect or publication bias for studies (n=4) including only heart failure patients (p=0.117). Studies including heart failure patients and those suffering from other terminal illnesses (n=13) demonstrated a small study effect (p=0.006) (**Appendix 11**).

Identified Behaviour Change Techniques

The number of behaviour change techniques per study ranged from 3 to 13 techniques with a median of 4.6 techniques per trial. Interventions of included studies contained multiple components and targeted a range of clinician behaviour. Seventeen behaviour change techniques targeted healthcare professionals directly while fifteen behaviour change techniques involved patients to change clinicians' behaviour. The five most commonly identified behaviour change techniques were a) instructions on how to perform the behaviour (n=9), b) prompt/ cues (n=8), c) goal setting (behaviour) (n=7), d) goal setting (outcome) (n=7), and e) information about health

consequences (n=5). **Table 8** describes the most commonly coded techniques targeting clinicians for each Behaviour Change Techniques Taxonomy category. A full coding manual with definitions can be found in **Appendix 12**.

BCT Label	BCT Domain	Definition and example of how the BCT was used
4.1 Instruction on how to perform the behaviour	4. Shaping knowledge	Advising or agreeing on how to perform the completion of an ACP. This BCT applied when healthcare professionals attended a training event like a workshop on the completion of advance care planning
1.1 Goal setting (behaviour)	1. Goals and planning	Defined as setting or agreeing on the *process* of achieving the completion of an ACP document. For example, this included the specific steps of acquiring better knowledge and skills in order to complete an ACP by undergoing training
7.1 Prompt/ cues	7. Associations	Defined as introducing an environmental or social stimulus with the purpose of completing an ACP document. This could take the form of a reminder system in patients' notes or in electronic records to prompt clinicians to complete an ACP
1.3 Goal setting (outcome)	1. Goals and planning	Described as using the content of a completed ACP document to decide whether an advance care plan was actually achieved. This could include the identification of care preferences or the appointment of a healthcare proxy
5.1 Information about health consequences	5. Natural consequences	Defined as providing HCPs with written, verbal or visual information about the health consequences of completing an ACP. This could include educating clinicians in the context of an educational programme about the pros and cons of delivering ACP
8.1 Behavioural practice/ rehearsal	8. Repetition & substitution	Prompt the practice or rehearsal of conducting ACP one or more times in the context of an educational training session (e.g. role-play)
12.1 Restructuring of the physical environment	12. Antecedents	Introduce an ACP template to the existing practice IT system to modify the current software
6.1 Demonstration of the behaviour	6. Comparison of behaviour	Provide an observable sample of an ACP discussion by demonstrating to healthcare professionals how to initiate and conduct an ACP conversation via role-play (includes 'modelling')
9.1 Credible source	9. Comparison of outcomes	Present a verbal or visual communication from a clinical champion in the field of ACP, heart failure and palliative care on the significance of advance care planning

Table 8. Definition of the most commonly coded BCTs

3.5.2 Effect of Clinician Targeted Interventions

The following **Table 9** ranks the studies according to their effect sizes and shows the behaviour change techniques coded for each trial. All studies with the highest effect sizes included behaviour change techniques that involved interventions where the patient contributed to a change in a clinician's behaviour in the delivery of ACP. Lower effect sizes were mainly found in studies that did not make use of patients to modify clinicians' behaviour in the delivery of ACP.

Study ID (n= 13) BCTs targeting clinicians to engage with ACP in heart failure	Rubin 1994	Nicolarosa 2006	Detering 2010	Heiman 2004	Aiken 2006	Metzger 2016	Sidebottom 2014	Doorenbos 2016	Dexter 1998	Engelhardt 2006	Gade 2008	Heffner 2001	Reilly 1995
1.1 Goal setting (behaviour)					■	■	■	■	■	■	■		
1.3 Goal setting (outcome)		■		■	■		■		■		■		■
1.6 Discrepancy behaviour & goal											■		
2.2 Feedback on behaviour											■		
2.7 Feedback on outcomes of behaviour											■		
3.1 Social support (unspecified)						■							
3.2 Social support (practical)											■		
4.1 Instruction on behaviour performance		■		■	■	■		■	■	■	■		■
5.1 Information about consequences				■			■			■	■		■
5.2 Salience of consequences						■	■						
5.6 Information on emotional consequences										■			
6.1 Demonstration of the behaviour							■						
7.1 Prompt/cues	■	■	■	■						■	■	■	■
8.1 Behavioural practice/ rehearsal					■			■		■			
9.1 Credible source			■			■				■	■		
12.1 Restructuring physical environment							■						
12.5 Adding objects to the environment	■												■
Study Effect Size OR [95%CI] **BCTs involving patients and carers to engage clinicians with ACP in heart failure**	61.99 [15.21 - 252.65]	18.55 [2.38 - 144.38]	14.84 [3.89 - 56.71]	5.97 [2.11 - 16.87]	5.53 [1.18 - 26.01]	4.88 [0.78 - 30.29]	2.95 [1.20 - 7.24]	2.47 [0.59 - 10.34]	2.36 [0.67 - 8.25]	2.33 [1.19 - 4.58]	1.66 [1.09 - 2.52]	1.56 [0.95 - 2.56]	1.19 [0.46 - 3.04]
1.1 Goal setting (behaviour)	■		■		■	■				■		■	
1.3 Goal setting (outcome)	■											■	■
1.4 Action planning			■										
3.1 Social support (unspecified)					■								
3.2 Social support (practical)	■		■			■							
4.1 Instruction on behaviour performance	■	■	■		■	■				■		■	■
5.1 Information about health consequences	■		■	■						■		■	■
5.6 Information about emotional consequences										■			
6.1 Demonstration of the behaviour												■	
7.1 Prompt/cues												■	■
8.1 Behavioural practice/ rehearsal		■								■		■	
9.1 Credible source										■		■	
9.2 Pros and cons		■											
12.2 Restructuring the social environment				■									
12.5 Adding objects to the environment	■	■		■									■

Table 9. Effect of patients on clinicians' ACP behaviour

Quality of Evidence

The mean score for the overall quality of evidence across all studies was moderate (**Table 10**) after rating all GRADE criteria, mainly due to a high risk of performance bias[213]. We identified four Effective Practice Organisation of Care Group intervention categories targeting healthcare professionals for the primary outcome in heart failure: patient-mediated interventions, reminders, educational meetings, and academic detailing. The "illustrative comparative risks" in the table below show the absolute risk effects of clinician targeted interventions based on different event rates for an exemplar study population. For example, based on a study population of 1000 patients, patient-mediated interventions increased clinicians' engagement with ACP from 11.5 % to 41.2%, reminder systems from 2% to 8.4%, educational meetings from 37.4% to 57.3% and academic detailing from 72.6% to 81.5% respectively.

EFFECT OF CLINICIAN TARGETED INTERVENTIONS

Population: Clinicians looking after patients suffering from heart failure. **Setting**: hospital and community**.**
Intervention: EPOC interventions targeting healthcare professionals vs Standard Professional Development.

Outcome: completion of an ACP document	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)
	Assumed risk	Corresponding risk			
	Control	**Pooled Effect on Association between Interventions and ACP documentation**			
Patient-mediated interventions	**Study population**		**OR 5.37** (2.28 to 12.62)	2644 (9)	Moderate
	115 per 1000	**412 per 1000** (229 to 622)			
	Moderate				
	114 per 1000	**409 per 1000** (227 to 619)			
Reminders	**Study population**		**OR 4.59** (1.1 to 19.17)	833 (2)	Low
	20 per 1000	**84 per 1000** (22 to 278)			
	Moderate				
	23 per 1000	**98 per 1000** (25 to 311)			
Educational meetings	**Study population**		**OR 2.25** (1.39 to 3.64)	1271 (5)	Moderate
	374 per 1000	**573 per 1000** (454 to 685)			
	Moderate				
	77 per 1000	**158 per 1000** (104 to 233)			
Academic detailing	**Study population**		**OR 1.66** (1.09 to 2.52)	512 (1)	Low
	726 per 1000	**815 per 1000** (743 to 870)			
	Moderate				
	726 per 1000	**815 per 1000** (743 to 870)			

Table 10. Intervention effect sizes according to EPOC

Effect of BCTs on the Completion of an ACP Document

Based on Michie et al.'s Behaviour Change Techniques Taxonomy (v1), we identified a total of 22 behaviour change techniques out of 93 behaviour change techniques (23.65%) (**Table 11**). Restructuring the physical environment, social support, goal setting (behaviour) and prompts/ cues demonstrated some of the highest statistically significant effect sizes. To illustrate the effect of clinician targeted behaviour change techniques, based on a study population of 1000 patients, social support increased clinicians' engagement with ACP from 13.3 % to 42.9%, prompts/ cues from 26.2% to 53.8%, or goal setting (behaviour) from 37.4% to 67.7% respectively.

EFFECT OF BEHAVIOUR CHANGE TECHNIQUES TARGETING HEALTHCARE PROFESSIONALS

Population: healthcare professionals looking after patients suffering from heart failure. **Settings:** hospital and community. **Intervention:** Behaviour Change Techniques (BCTs) targeting Healthcare Professionals

Outcome: completion of an ACP document	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)
	Assumed risk Control	Corresponding risk BCTs targeting Healthcare Professionals			
Restructuring the physical environment	**Study population**		**OR 13.03** (0.41 to 409.25)	1268 (2)	Moderate
	16 per 1000	**172 per 1000** (6 to 867)			
	Moderate				
	47 per 1000	**391 per 1000** (20 to 953)			
Social support (unspecified)	**Study population**		**OR 4.88** (0.78 to 30.29)	29 (1)	Low
	133 per 1000	**429 per 1000** (107 to 823)			
	Moderate				
	133 per 1000	**428 per 1000** (107 to 823)			
Prompts/ cues	**Study population**		**OR 3.57** (1.43 to 7.55)	2432 (7)	Moderate
	262 per 1000	**538 per 1000** (336 to 728)			
	Moderate				
	428 per 1000	**711 per 1000** (517 to 850)			
Goal setting (behaviour)	**Study population**		**OR 3.43** (1.78 to 6.62)	1349 (7)	Moderate
	374 per 1000	**672 per 1000** (515 to 798)			
	Moderate				
	91 per 1000	**256 per 1000** (151 to 399)			
Salience of consequences	**Study population**		**OR 3.25** (1.45 to 7.28)	196 (2)	Low
	97 per 1000	**259 per 1000** (135 to 439)			
	Moderate				
	112 per 1000	**291 per 1000** (155 to 479)			
Credible source	**Study population**		**OR 3.24** (1.44 to 7.29)	740 (4)	Moderate
	606 per 1000	**833 per 1000** (689 to 918)			
	Moderate				
	365 per 1000	**651 per 1000** (453 to 807)			
Demonstration of behaviour	**Study population**		**OR 2.95** (1.2 to 7.24)	167 (1)	Low
	91 per 1000	**228 per 1000** (107 to 420)			
	Moderate				
	91 per 1000	**228 per 1000** (107 to 420)			
Goal Setting (Outcome)	**Study population**		**OR 2.82** (1.6 to 4.97)	2016 (7)	Moderate
	238 per 1000	**469 per 1000** (334 to 609)			
	Moderate				

	41 per 1000	**108 per 1000** (64 to 175)			
Behavioural practice/ rehearsal	**Study population**		**OR 2.64** (1.5 to 4.67)	335 (3)	Moderate
	232 per 1000	**443 per 1000** (311 to 585)			
	Moderate				
	77 per 1000	**180 per 1000** (111 to 280)			
Information about emotional consequences	**Study population**		**OR 2.33** (1.19 to 4.58)	143 (1)	Moderate
	434 per 1000	**641 per 1000** (477 to 779)			
	Moderate				
	434 per 1000	**641 per 1000** (477 to 778)			
Instruction on behaviour performance	**Study population**		**OR 2.25** (1.49 to 3.41)	1574 (8)	Moderate
	317 per 1000	**511 per 1000** (409 to 613)			
	Moderate				
	95 per 1000	**191 per 1000** (135 to 264)			
Information about consequences	**Study population**		**OR 2.21** (1.42 to 3.46)	1511 (5)	Moderate
	349 per 1000	**543 per 1000** (433 to 650)			
	Moderate				
	114 per 1000	**221 per 1000** (154 to 308)			
Feedback on outcomes of behaviour	**Study population**		**OR 1.66** (1.09 to 2.52)	512 (1)	Low
	726 per 1000	**815 per 1000** (743 to 870)			
	Moderate				
	726 per 1000	**815 per 1000** (743 to 870)			
Discrepancy behaviour & goal	**Study population**		**OR 1.66** (1.09 to 2.52)	512 (1)	Low
	726 per 1000	**815 per 1000** (743 to 870)			
	Moderate				
	726 per 1000	**815 per 1000** (743 to 870)			
Feedback on behaviour	**Study population**		**OR 1.66** (1.09 to 2.52)	512 (1)	Low
	726 per 1000	**815 per 1000** (743 to 870)			
	Moderate				
	726 per 1000	**815 per 1000** (743 to 870)			
Adding objects to the environment	**Study population**		**OR 1.19** (0.46 to 3.04)	162 (1)	Moderate
	114 per 1000	**133 per 1000** (56 to 281)			
	Moderate				
	114 per 1000	**133 per 1000** (56 to 281)			

Table 11. Intervention effect sizes according to BCTTv1

3.5.3 Synergy of Intervention Components

Intervention synergy has been defined as the interaction of two or more components to produce a combined effect greater than the sum of their separate effects[214]. As an example of the synergistic effect of intervention components, **Figure 15** graphically depicts the interaction between behaviour change techniques in the study by Heiman et al.[196] The blue boxes indicate behaviour change techniques directed at healthcare professionals. The green boxes describe behaviour change techniques directed at patients. The triangles designate the COM-B domains[206] of motivation and capability that were enhanced as a result of the intervention. The rounded box points to the resulting behavioural change of an increased physician-patient interaction. Finally, the oval shape indicates the outcome of the behavioural change, i.e. clinicians in the intervention group completed a higher proportion of ACP documents for patients suffering from heart failure than the control participants.

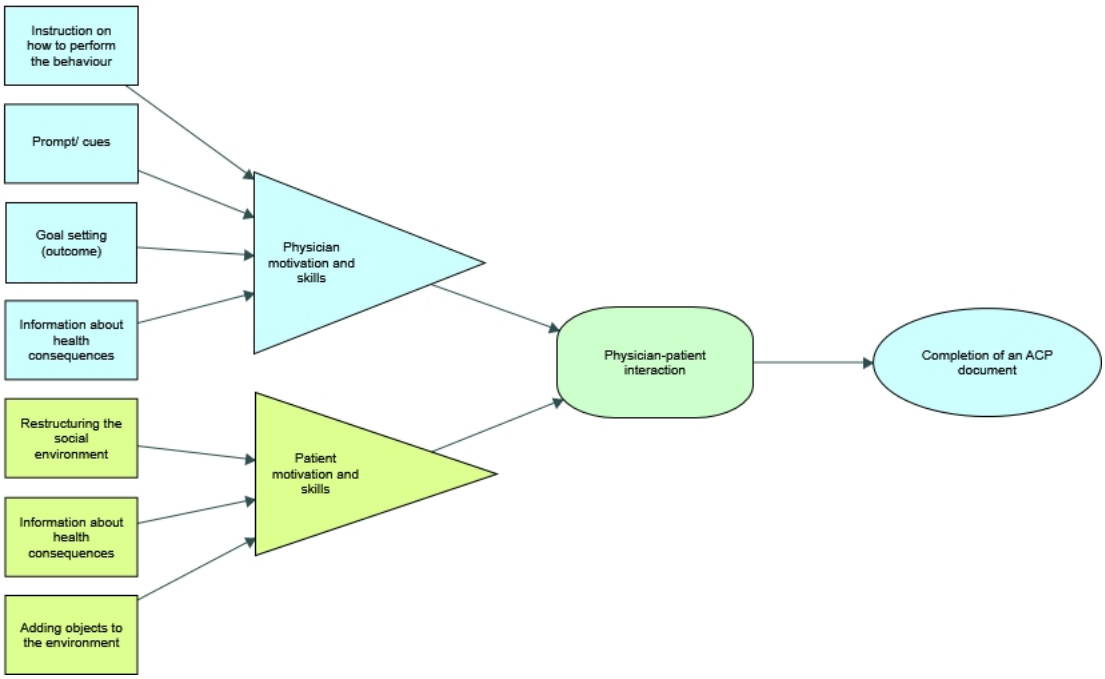


Figure 15. Synergy of intervention components

The following **Table 12** provides a summary of the content, timing and synergy of the most effective and of the least effective interventions found in the review. The column labelled ‘Synergy’ considers how intervention components might have interacted with each other to determine higher or lower effect sizes. The outcome in each of the studies was the proportion of completed ACP documents.

Study OR [95% CI]	Content of the most effective interventions Description according to EPOC and BCTTv1	Timing of the intervention	Synergy
Rubin[195] 61.99 [15.21 - 252.65]	**Physicians** received a patient visit and were prompted (prompt/cue) by the patient to talk about End-of-life issues. The provision of and completion of a durable power of attorney form (adding objects to the environment) was prompted by the patient visit. **Patients** were educated (instruction on behaviour performance, goal setting/behaviour) in how to prompt clinicians to engage with ACP and complete a durable power of attorney (goal setting/ outcome). They were offered telephone support (social support/ practical) throughout the study. Patients were sent a cover letter, an educational brochure with treatment options (information about health consequences) and a durable power of attorney form (adding objects to the environment).	Patients were educated in ACP *after a recent hospitalisation* at a time when their medical condition was stable.	Physicians responded to educated patients who had the motivation and skills to initiate discussions about their ACP preferences. Additionally, patients were given the opportunity and time to clarify their wishes before the completion of an ACP document.
Nicolasora[212] 18.55 [2.38 - 144.38]	**Physicians** were trained in using a script (instruction on behaviour performance) from which to read detailed information about ACP (goal setting/ outcome). Patients prompted (prompt/cue) clinicians to talk about ACP. **Patients** were educated (instruction on behaviour performance) in the purpose of ACP and trained how to communicate their EOLC preferences with their clinician (behavioural practice). They could reflect (pros and cons) on how the information about ACP applied to their own values.	*At the point of admission to hospital*, patients were asked by the admitting staff about their EOL wishes and the completion of an ACP document.	The *concurrent* arrangement of targeting physicians and patients resulted in an increased physician-patient dialogue, a clarification of EOL preferences and a greater proportion of completed ACPs. The training of patients and clinicians in the intervention group resulted in increased levels of motivation and skills to address ACP.
Detering[51] 14.84 [3.89-56.71]	**Physicians** received a patient visit who prompted (prompt/ cue) an ACP conversation. **Patients** received education from an ACP facilitator (credible source) using the Respecting Patient Choices model about the purpose of ACP (information about health consequences). They were educated on how to identify a surrogate decision maker (social support/ practical), and how to identify EOLC choices (goal setting/ behaviour). Typically, the facilitator met with patients and family members on three occasions before discharge to achieve an ACP (action planning).	*Before hospital discharge*, patients and family members were asked by a trained facilitator (nurse or allied health professional) whether they would like to engage with ACP.	Both, patients and facilitators, were trained in identifying and communicating End-of-life issues and ACP preferences. Patients and families were given the time and the opportunity to think about their choices leading to better shared decision making and ACP completion.
Heiman[196] 5.97 [2.11 - 16.87]	**Physicians** received computer generated reminders (prompt/cues) including an ACP template (goal setting [outcome]), training in how to use the ACP template (instruction on how to perform the behaviour), and education on the purpose of ACP (information about health consequences). **Patients** received educational brochures on ACP (information about health consequences), a set of ACP forms (adding objects to the environment). They were encouraged to ask their clinician about ACP (restructuring the social environment).	Physicians received ACP computer reminders one day prior to the patient visit. Patients received ACP education six weeks prior to their scheduled routine appointment.	Physician-patient interaction and ACP completion was increased by *simultaneously* targeting physicians and patients with reminders and training in communicating EOL/ ACP issues. The content and electronic format of the ACP reminder made it easy for the clinician to identify relevant issues that needed to be covered.

Table 12. Components of the most and least effective interventions

Study OR [95% CI]	Content of the least effective interventions Description according to EPOC and BCTTv1	Timing of the intervention	Synergy
Gade[167] 1.66 [1.09 - 2.52]	**Physicians** received support from an interdisciplinary palliative care consultative service (IPCS) in the management of HF patients. Ten individual BCTs (see Table X) were exclusively directed at healthcare professionals. **Patients** were only the passive recipients of information. While members of the IPCS team met with patients and family members on an as required basis, patients were not educated in identifying their EOLC preferences or trained in how to talk to their clinicians about ACP.	After admission to hospital, patients were approached to document their EOLC preferences.	A lack of interaction between physicians and patients was in part due to the omission of training and supporting patients to pro-actively talk to their clinicians about ACP. The comparatively small effect size of this rather costly intervention involving many clinicians was remarkable.
Heffner[210] 1.56 [0.95 - 2.56]	**Physicians** were prompted by their patients to discuss ACP. Clinicians did not receive any training or support in how to address End-of-life issues. **Patients** received only printed material on the purposes of ACP and were encouraged to talk to their clinicians about it. Patients did not receive any training in how to talk to their clinicians. Only 2% of patients in the intervention group and 12% in the control group suffered from CHF NYHA Class III and IV.	The majority of patients was at an early stage in their HF disease trajectory. The intervention was delivered in the context of a cardiovascular rehabilitation programme.	Only the minority of patients suffered from end-stage CHF. These patients might have been less motivated to talk to their clinician about ACP since the relevance seemed less obvious. Additionally, neither patients nor physicians received any training in talking about or completing an ACP.
Reilly[194] 1.19 [0.46 - 3.04]	**Physicians** received only printed material in form of a cover letter, a brochure explaining an advance directive and the New York State healthcare proxy form. No additional support was offered. **Patients** received the same printed material about advance directives. The cover letter encouraged patients to complete the form before meeting their clinician. Patients did not receive any further education, training or support in filling in the form or identifying their care preferences.	Patients who were recently discharged from hospital were sent the educational material and a healthcare proxy form.	Patients were expected to complete the form on their own before attending their next outpatient appointment with their clinician. Physicians lacked any training in engaging with ACP. A lack of support for both, physicians and patients, resulted in a low level of doctor-patient interaction and ACP completion.

Table 12. Components of the most and least effective interventions

3.5.4 Sensitivity Analyses

I undertook a number of sensitivity analyses to determine the robustness of above results[215]. Of particular interest to me was whether effect sizes would change if I restricted the analysis to trials at a low risk of bias, perform analyses with and without outliers or stratify studies restricted to only heart failure patients. My aim was to identify any consistency or inconsistency between the results of my primary analyses. If consistency of effect sizes was evident, the conclusions and credibility of my findings would be strengthened.

Sensitivity analysis for patient population

In a sensitivity analysis restricted to four RCTs[165, 170, 210, 211] including only patients suffering from heart failure (n=560) (**Figure 16**), interventions targeting healthcare professionals were associated with a statistically significant improvement of the implementation of ACP (OR 1.95, 95% CI [1.30-2.91], p<0.001). Heterogeneity was not important (I^2=0%).

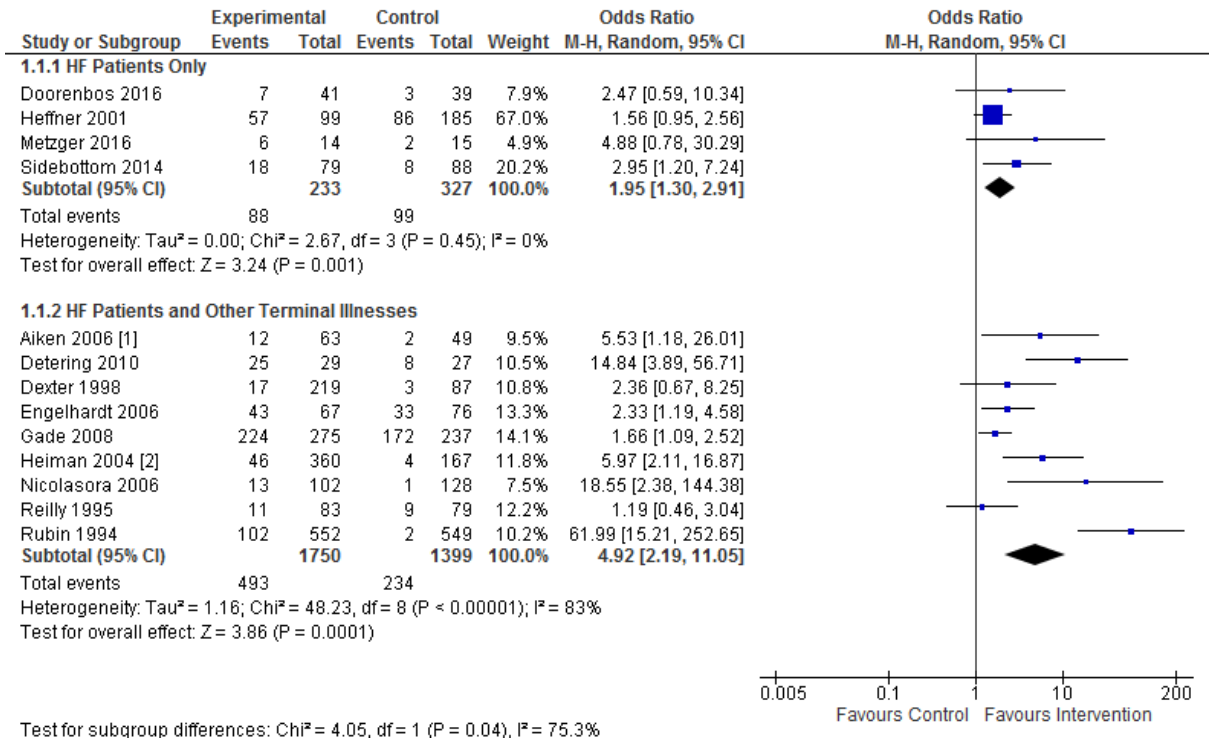


Figure 16. Sensitivity analysis for patient population

Sensitivity analysis restricted to trials at low risk of bias

In a sensitivity analysis restricted to five RCTs at low risk of bias including 643 participants (**Figure 17**), interventions targeting healthcare professionals were associated with a significant improvement in the implementation of ACP (OR 3.24, 95% CI [1.34-7.81], $p<0.01$, $I^2=69\%$). All of these studies included patients suffering from heart failure. The result from this sensitivity analysis of trials at a low risk of bias strengthened the overall conclusion that interventions are associated with a significant improvement in the implementation of ACP by healthcare professionals.

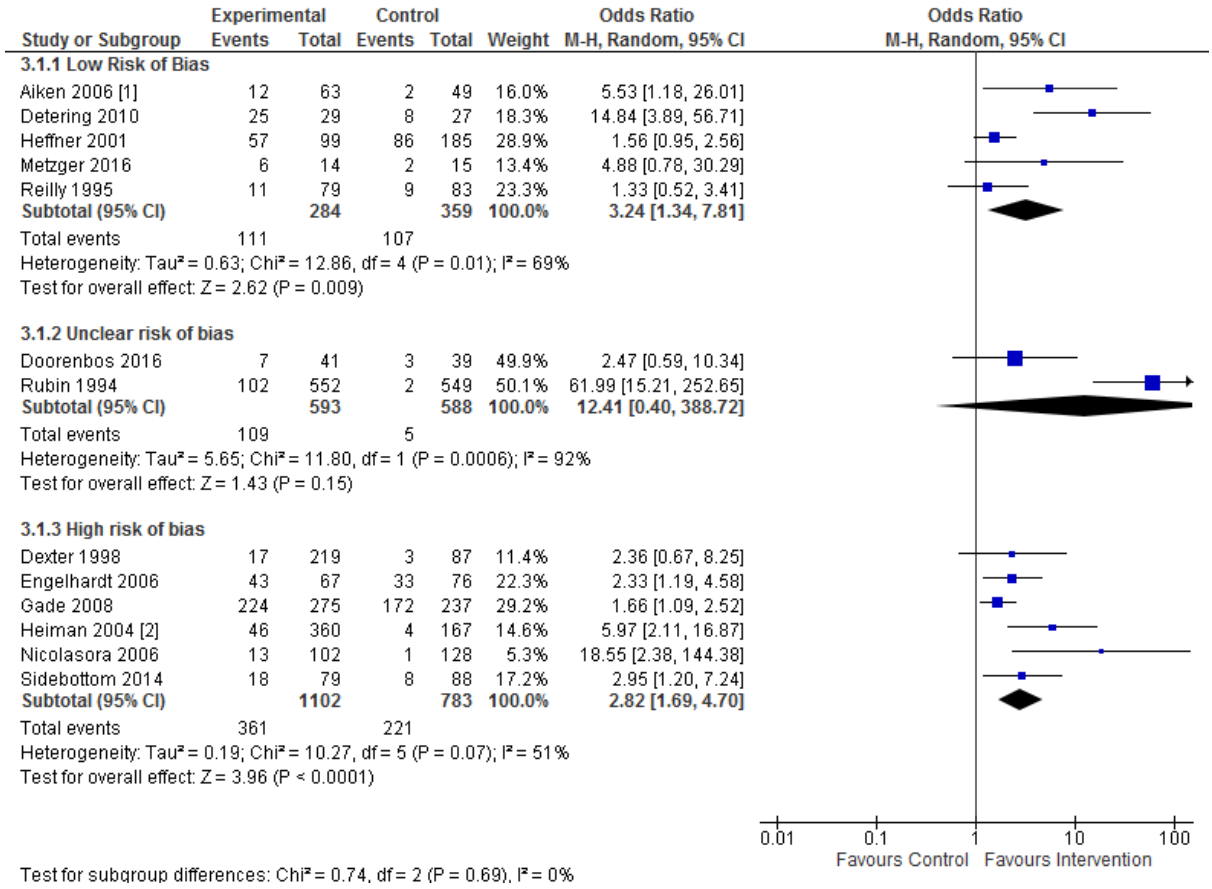


Figure 17. Sensitivity analysis of studies at low risk of bias

Sensitivity analysis excluding outliers

I excluded the three highest[51, 195, 212] and the three lowest[167, 194, 210] outliers of study effect sizes in a sensitivity analysis to determine whether this would make a significant difference to the overall effect of interventions on the implementation of ACP. Before this sensitivity analysis, the overall effect for interventions on the implementation of ACP was OR 3.81 [2.20, 6.61], $p < 0.00001$, $I^2 = 77\%$. After sensitivity analysis, the effect of interventions remained significant: OR 3.11 [2.08, 4.64], $p < 0.00001$. Importantly, heterogeneity dropped to $I^2 = 0\%$ (**Figure 18**). This result seemed to strengthen the overall accuracy of the meta-analysis.

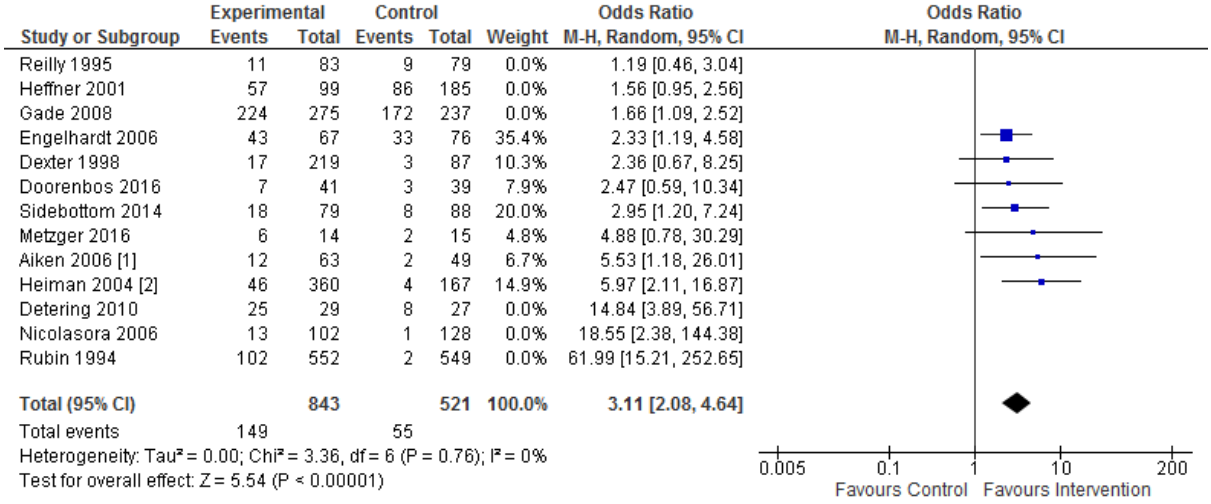


Figure 18. Sensitivity analysis of outliers

3.6 DISCUSSION

3.6.1 Summary of Principal Findings

Previously, there was no firm evidence for the effect of clinician targeted interventions to engage healthcare professionals with advance care planning in heart failure. This literature review and meta-analyses investigated 13 RCTs including 3709 participants and demonstrated that patient-mediated interventions (OR 4.75, 95% CI [2.15-10.5]), reminder

systems (OR 4.59, 95% CI [1.1-19.7]), and educational meetings (OR 2.25, 95% CI [1.39-3.64]) were the most effective intervention components. Academic detailing demonstrated only small effects (OR 1.66, 95% CI [1.09-2.52]). Results from the Behavior Change Taxonomy showed that prompts/ cues (OR 3.57, 95% CI [1.43-7.55]), goal setting (behavior) (OR 3.43, 95% CI [1.78-6.62]), salience of consequences (OR 3.25, 95% CI [1.45-7.28]), and credible source (OR 3.24, 95% CI [1.44-7.29]) resulted in the greatest changes of clinician behavior. Several sensitivity analyses including trials at low risk of bias (OR 3.24, 95% CI [1.34-7.81]) and studies restricted to only heart failure patients (OR 1.95, 95% CI [1.30-2.91]) confirmed the consistency of the results of the primary analyses.

3.6.2 Synergy of Intervention Components

The content of the most effective interventions included multiple components that *simultaneously* targeted clinicians and enabled patients to talk to their clinicians about ACP. Prompts or reminders for clinicians and patients alike plus training and education in how to communicate end-of-life issues and come to a shared decision were among the most promising techniques to optimise the implementation of ACP in heart failure.

The right timing for a clinician to engage with and deliver ACP was often associated with significant milestones in a patient's disease trajectory; for example, before patients had a scheduled appointment with their clinician[196], at the point of admission to a medical ward[212] or after a recent hospitalisation[195]. But maybe more important than the right timing were interventions that provided support for patients and family that enabled them to ask questions, clarify care preferences with their clinician and start the *process* of completing an ACP document. A lack of support of patients seemed predictably associated with lower effect sizes in the completion of ACP[167, 194]. A comparison between the studies of Rubin et

al.[195] and Reilly et al.[194] highlight that fact. Rubin et al.'s intervention might appear similar to Reilly's components. But there are two significant differences: 1) Rubin et al.'s[195] study includes telephone support for patients for the duration of the study in case patients have any questions about their healthcare proxy form. Telephone support or any other form of support for patients is missing in Reilly's intervention. 2) Patients and family members can discuss their care preferences with their clinician *before* they complete the form in Rubin's study. Reilly et al.'s intervention does not give patients the opportunity or time to discuss ACP preferences with their clinicians before the completion of the document.

3.6.3 Comparison with Other Studies

This review is the first to analyze the effect of interventions targeting healthcare professionals on the delivery of ACP in heart failure in a meta-analysis. Several reviews have investigated the effectiveness of interventions to implement ACP[97, 133, 134, 136, 137, 139, 198] but none have focused on their effect on healthcare professionals or in synthesizing the components with the greatest potential in changing clinicians' behavior. For example, the review by Houben et al.[139] only presents data on the efficacy of interventions targeting patients to improve the implementation of ACP but does not analyze which intervention components make a difference to a clinician's practice pattern.

Our results concurred with findings from a number of Cochrane reviews on the effectiveness of interventions targeting clinicians. For example, my review found that educational meetings were often combined with other interventions to maximize impact. This finding agrees with a review by Forsetlund et al.[216]. They demonstrate that training clinicians is rarely used as a stand-alone tool to improve professional practice and is nearly always combined with other techniques. A number of other Cochrane reviews[101, 209, 217] have investigated the evidence base for the effect of reminder systems and academic detailing[218]. Again, authors conclude

that these interventions appeared effective in improving clinical behavior across a number of settings preferably when combined with other interventions. Their findings largely concur with results from my meta-analysis in which reminder system were always combined with other intervention categories. The strong effect sizes for and frequency of patient-mediated interventions (e.g. shared decision-making tools or question prompt lists) in this meta-analysis is a surprise and warrants further exploration in the development of my future intervention. Published data on the effect of patient-mediated interventions to improve professional practice is sparse[219].

3.6.4 Strengths and Limitations of the Study

The strength of this review and meta-analyses consisted of the use of a robust search strategy, assessing the overall quality of the evidence with the GRADE system, rating risks of biases with the Cochrane risk of bias evaluation tool, statistically pooling data across studies, exploring intervention content and synergy, and performing sensitivity analyses. Studies restricted to only heart failure patients had insignificant levels of heterogeneity (I^2=0) by contrast with significant levels of heterogeneity (I^2=83%) in studies combining patients suffering from heart failure and patients with other terminal illnesses. The overall quality of evidence was moderate to low mainly due to a risk of performance and detection bias based on the nature of the interventions. Furthermore, confidence intervals overlapped across many intervention categories making an interpretation difficult. Of the 13 studies that were included, none were based in the UK, and questions remain whether findings necessarily translate to our national setting.

Combined Use of EPOC and BCT Taxonomies

Using the Effective Practice Organization of Care Taxonomy was an important first step towards providing a common language to describe intervention categories and attempt an

analysis of intervention effectiveness. Amongst a number of categories, the Effective Practice Organization of Care Taxonomy highlighted the importance of patient-mediated interventions, reminders and educational meetings to change clinicians' behavior. But the taxonomy risked confusing the content of the intervention with its mode of delivery or provider[107]. For example, an educational meeting is a mode of delivering an intervention. But then the intervention itself may take the form of specific communication skills on how to use shared decision-making tools. Additionally, the Effective Practice Organization of Care Taxonomy provided only a superficial level of detail in describing intervention ingredients. This made their replication very difficult. Behavior change techniques addressed that limitation and improved the description of interventions and their specific ingredients in this review[220] . While behaviour change techniques provided a greater level of detail into intervention content, overlapping confidence intervals around their effect sizes made their interpretation difficult too. Consequenlty, a consideration of the content, timing and synergy of interventions components identified those approaches which were most effective and those approaches which were least effective in engaging clinicians with advance care planning in heart failure.

3.7 CHAPTER SUMMARY

The review provided evidence from 13 published RCTs and demonstrates that clinician targeted interventions are effective in improving the implementation of ACP in heart failure. The Effective Practice Organization of Care categories of patient-mediated interventions (OR 4.75, 95% CI [2.15-10.5]), reminder systems (OR 4.59, 95% CI [1.1-19.7]), and educational meetings (OR 2.25, 95% CI [1.39-3.64]) are the most effective intervention components. Academic detailing demonstrates only small effects (OR 1.66, 95% CI [1.09-2.52]). Results

from the Behavior Change Taxonomy analysis shows that prompts/ cues (OR 3.57, 95% CI [1.43-7.55]), goal setting (behavior) (OR 3.43, 95% CI [1.78-6.62]), salience of consequences (OR 3.25, 95% CI [1.45-7.28]), and credible source (OR 3.24, 95% CI [1.44-7.29]) result in the greatest changes of clinician behavior.

Multi-component interventions that include behaviour change techniques enabling patients to discuss ACP with their physician seem to result in higher effect sizes than those interventions that did not involve patients as a modifier of clinicians' behavior. The most effective approaches appear to be interventions designed to *simultaneously* enable both, physicians and patients, to engage with ACP. The evidence suggests that the right timing for clinicians to engage with and deliver ACP is often associated with significant milestones in a patient's disease trajectory; for example, after a recent hospitalization, before a scheduled appointment with a clinician, or even at the point of admission to hospital. Based on findings from the literature review, **Table 13** summarizes some of the most promising intervention components and their mode of delivery according to TIDieR[103].

Intervention Component	Content	Timing	Provider	Format	Delivery
Patient-mediated interventions	A list with questions that clarify patients' EOL care pre-ferences, ACP treatment options, tips in talking to a clinician	When CHF patients are stable, after or before significant changes in their status of health	Research Team or Clinicians	ACP document, Question Prompt List, Shared decision-making tool for CHF	Education of patients and information provision by research team or clinicians
Education and Training	Training clinicians in how to communicate End-of-life issues and ACP to patients, case scenarios	Ongoing, as part of clinicians' CPD	Research Team or Senior clinicians	Workshop or Conference	Education, persuasive communication, model behaviour to clinicians by facilitators
Reminder systems or Prompts	Electornic or paper reminders on core aspects of ACP and CHF, links to resources on CHF and EOLC	Ongoing, as part of the professional work/ IT environment	Research Team	As part of the local IT system or the patient's paper medical records	Restructure the physical environment and provide opportunities for clinicians to engage with ACP

Table 13. Potential intervention components

Identifying and describing effective behavioral interventions in heart failure was only the first step in developing a potentially successful intervention strategy. It is well recognized in the literature that barriers to the implementation of interventions can undermine and confound their entire effectiveness[221]. Consequently, the next step was to explore and analyze the barriers and facilitators to the implementation of ACP in clinical practice[222]. This was the focus of Chapter 4.

CHAPTER FOUR

Barriers and Facilitators for ACP in Heart Failure

4 BARRIERS AND FACILITATORS FOR ACP IN HEART FAILURE

4.1 BACKGROUND

Following on from the meta-analyses of intervention effectiveness and the exploration of intervention synergy, it was now essential to identify and evaluate barriers and facilitators for the implementation of advance care planning in heart failure. If any types of interventions were meant to be successfully applied, I needed a greater understanding of the factors that either promoted or suppressed their success[223, 224]. There is an acknowledgement in the published literature that the synthesis of qualitative research could contribute to addressing queries about barriers and facilitators[225].

In general, barriers to the implementation of advance care planning could lie at an individual, organisational or national level[186]. Although most clinicians believed that patients should be told the truth, many withheld information on advance care planning to avoid the topic[50]. Prognostic uncertainty[226], time pressures[227], lack of communication skills training[228], feeling of medical failure[229], uncertainty about timing and content[81], and fear of upsetting patients had all been suggested as contributing to a reluctance to address end-of-life issues. Guidelines recommended frank conversations[112], but in practice such discussions were rare for patients with a wide range of life-limiting illnesses[75]. Healthcare professionals were waiting for cues from patients before raising end-of-life issues. As a result, advance care planning conversations rarely took place and patient care was compromised[69, 205].

To overcome these barriers, the literature identified a number of facilitators for the implementation of advance care planning by clinicians. Training clinicians in end-of-life care had the potential to address the attrition of specific palliative care skills like symptom management or difficult conversation and counselling techniques[228]. While education in end-of-life care was considered important by clinicians[230], practical experience through placements at hospices with an opportunity to share care with palliative care specialists seemed even more valued by some GPs[228]. Other factors for promoting the implementation of ACP in heart failure were the need to have sufficient time to undertake these complex discussions[231] or having specifically trained staff with an interest in end-of-life care and ACP[231]. Others suggested the use of simple decision-making tools to provide clinicians as well as patients with a structured framework for ACP conversations[186, 232].

4.1.1 Relationship to Other Relevant Reviews

While studies look at advance care planning, barriers to end-of-life care or heart failure, no review has systematically evaluated the qualitative evidence base for barriers to the implementation of ACP by *clinicians* in heart failure. To clarify the differences between my review and the reviews of other authors, the following briefly outlines the main distinctions: Lund's et al[186] systematic review investigates the barriers and facilitators to the implementation of advance care planning focussing on their workability and integration in clinical practice. However, their review does not concentrate on heart failure and only addresses to some extent the barriers facing clinicians. The review by Barclay et al.[69] investigates the literature concerning conversations between professionals and patients suffering from heart failure but does

not focus on barriers to ACP. Momen's et al.[231] narrative synthesis reviews the extent to which there is evidence that conversations with heart failure patients occur in practice and build on findings from Barclay's work. Similarly, her narrative does not focus on barriers to the implementation of ACP. Slort et al.[233] identifies barriers and facilitators for the general practitioner – patient communication in palliative care. While some of their findings are relevant to this study, the authors do not focus on heart failure or on barriers to the implementation of ACP by clinicians. De Vleminck et al.[234] does explore perceived factors hindering or facilitating GPs in engaging in advance care planning with their patients but a focus on the disease-specific barriers to heart failure is missing. A qualitative synthesis of the evidence by Smeets et al.[235] seeks to identify barriers and facilitators for optimal care in heart failure from a GP's perspective. But the study does concentrate on the clinical management aspects of heart failure rather than on changing healthcare professionals' behaviour to initiate advance care planning. Consequently, a focus on ACP is lacking. Hence, the gap in the evidence is an identification of barriers and facilitators to the implementation of ACP by healthcare professionals in heart failure.

4.2 AIM

The aim of this study was to conduct an exploratory systematic review of qualitative studies investigating the barriers and facilitators to the implementation of ACP by clinicians in heart failure.

4.3 OBJECTIVES

The objectives were as follows:

- To identify the barriers and facilitators to the implementation of ACP by healthcare professionals in heart failure
- To assess the quality and synthesise the evidence in form of an intervention options table
- To present the results of the review for discussion to the research advisory group in order to seek consensus for an early model of the intervention

4.4 METHODS

Findings from primary qualitative studies are an increasingly important source of evidence for healthcare and policy[236]. Qualitative synthesis of the evidence has the potential to combine data from different healthcare contexts, identify research gaps and generate new evidence for the design and assessment of health interventions[120, 121]. There are guidelines about how the synthesis of qualitative evidence should be performed and reported[237]. I conducted the review according to the Enhancing Transparency in Reporting the Synthesis of Qualitative Research (ENTREQ) statement[238]. This included, but was not limited to, defining the research aims and objectives, developing a review protocol, conducting data base searches, extracting data based on inclusion and exclusion criteria, assessing the methodological quality of studies and synthesising the evidence[237, 239].

4.4.1 Inclusion and Exclusion Criteria

4.4.1.1 Types of studies

We included studies that used qualitative study designs and reported original and empirical study data. Qualitative methods for data collection were focus groups, interviews, observational studies, surveys and document analysis. Data had to address barriers and facilitators for healthcare professionals to implement ACP in heart failure. Barriers and facilitators were defined as predisposing factors described by clinicians that either impede or promote their engagement with delivering ACP[229]. We included studies that reported data on barriers and facilitators for ACP in heart failure. Studies describing other terminal illnesses were excluded from the primary analysis. Editorials and narrative reviews were excluded unless they presented original study findings.

4.4.1.2 Types of participants

Participants included were all healthcare professionals like GPs, primary care nurses, palliative care consultants and nurses, cardiologists, heart failure specialist nurses, all providing EOLC for patients suffering from heart failure. Studies that solely focussed on patients without any reference to healthcare providers were excluded from the review.

4.4.1.3 Types of interventions

ACP was defined as a *process* of formal decision-making that aimed at helping patients make decisions about their future care[36]. As such ACP could provide an opportunity for clinicians to clarify a patient's care preferences in anticipation of loss of mental capacity. This could involve future treatment choices or resuscitation

options. In this way, ACP was meant to reduce uncertainty about a course of action should the clinical status of a patient deteriorate[240].

4.4.1.4 Types of outcomes and healthcare setting

We included studies that primarily described the perceptions and experiences of healthcare professionals on barriers and facilitators to the implementation of ACP in clinical practice. The healthcare setting could be primary care, nursing homes, secondary care, hospital or hospices.

4.4.2 Search Strategy and Data Sources

Studies were retrieved through systematic searches of electronic data bases, screening reference lists and contacting authors. Together with a specialist health science librarian (NR), we searched the following data sources:

- Medline,
- Embase,
- CINAHL,
- PubMed,
- Scopus,
- the British Nursing Index,
- the Cochrane Library,
- the EPOC register,
- ERIC,
- PsycINFO,
- Science Citation Index and the Grey Literature

We searched data bases from their inception until February 2017. An example of a MEDLINE search strategy is provided in **Appendix 13**. Additionally; I searched the reference lists of five reviews[69, 186, 233-235] and all potential relevant cross references and records to identify any other studies. Where required, I contacted the study authors or experts in the field for further information.

4.4.3 Data Collection and Analysis

The main purpose of this exploratory literature review was an interpretive explanation of the phenomena under investigation (the implementation of ACP) as opposed to a quantitative predictive estimate of intervention effectiveness. Therefore, I elected to use a thematic synthesis approach which drew on the methods from thematic analysis of primary sources[241] and managed these findings with the SURE framework[242]. The SURE framework (**Appendix 15**) had been validated across a number of healthcare sectors as a systematic yet flexible approach to analysing and categorising qualitative data to inform intervention development and healthcare policy[243-245].

SURE outlines five levels of analysing factors that affect the implementation of interventions in healthcare:

1. Recipients of care (e.g. patients and carers)
2. Providers of care (e.g. doctors and nurses)
3. Other stakeholders (e.g. policy makers and opinion leaders0
4. Health system constraints (e.g. financial resources)
5. Social and political constraints (e.g. legislation, political stability)

We adapted the framework by using the category that was most relevant to our review objectives: barriers and facilitators affecting *providers of care*. SURE lists the following factors affecting the implementation of interventions targeting providers:

a) Knowledge and skills
b) Attitudes re intervention/ programme acceptability, appropriateness and credibility
c) Motivation to change or adopt new behaviour

These domains were directly relevant to answering my research question about aspects that promote or impede the implementation of ACP among clinicians. In this way, the SURE framework provided a potential structure that could facilitate the synthesis of qualitative data on barriers and facilitators in a validated way. I have expanded on the strengths and limitations of using the SURE framework under "Discussion."

4.4.4 Selection of Studies

Two reviewers (SC, MS) independently assessed titles and abstracts of identified studies against inclusion criteria. Full text papers were retrieved if the content was potentially relevant to one or both authors. Two authors (MS, SC) evaluated whether these studies should be included in the review. Differences between reviewers were resolved by discussion. A list of excluded papers with reasons for their exclusion is given in **Appendix 14**.

4.4.5 Data Extraction and Management

Initially, we extracted the background information on each included study (study objectives, study design and methods, participants) and summarized these in tables. Following that, I designed a data extraction sheet that was informed by components of

the SURE framework[244] which focussed on barriers and facilitators to implementing interventions in healthcare systems. We extracted data from included studies and mapped them on to the relevant categories of the SURE framework.

4.4.6 Assessment of Risk of Bias in Included Studies

Since this review was a synthesis of qualitative studies, we did not undertake a risk of bias assessment. However, we did assess the quality of included papers.

4.4.7 Assessment of the Quality of Included Studies

Two authors (MS, SC) independently appraised the quality of included studies by using the Critical Appraisal Skills Programme (CASP) quality assessment tool[246]. CASP was used to investigate the quality of the evidence of other qualitative reviews in the past[247, 248]. We used its seven main quality criteria for assessment (**Table 14**). Each criterion was assessed with 'yes' or 'no.' If the study did not present adequate information, the rating was 'no.' This resulted in a total quality score ranging from 0 to 7 after applying equal weights. Individual studies were categorised as high quality (ratings from 6 to 7), medium quality (ratings from 4 to 5), and low quality (scores equal or lower than 3). The quality of included studies was assessed by two reviewers (MS, SC). We excluded studies of poor quality and resolved differences by discussion.

CASP Questions	Yes	No
1. Is this study qualitative research?		
2. Is the study context clearly described?		
3. Is there evidence of researcher reflexivity?		
4. Is the sampling method clearly described and appropriate for the research question?		
5. Is the method of data collection clearly described and appropriate to the research question?		
6. Is the method of analysis clearly described and appropriate to the research question?		
7. Are the claims made supported by sufficient evidence? I.e. did the data provide sufficient depth, detail and richness?		

Table 14. CASP quality criteria

4.4.8 Data Synthesis and Analysis

Findings were corroborated narratively using a thematic synthesis approach which drew on the methods from thematic analysis of primary sources, extending them to systematic reviews[248]. Thematic synthesis was one of a number of methods suggested by the Cochrane Qualitative Review Methods Group[249] where evidence was likely to be largely descriptive as opposed to highly theorised or conceptual. After reading the text of each study, we developed 'descriptive themes' followed by the generation of 'analytical themes.'[248] The generation of descriptive themes was supposed to remain close to the primary studies. The development of analytical themes went beyond the primary studies and was meant to be a stage of interpretation to identify new constructs or possible new applications to these themes[225]. Rather than develop my own framework, I opted to use the SURE framework[242] as described under 4.5.3. To advance an early model of my intervention based on the evidence of this review, I applied the analytical interpretation of themes to the development of an intervention options table as a framework for my synthesis[122].

4.4.9 Intervention Options Table

For the generation of analytical themes and how they might contribute to the advancement of an early model of my intervention, I developed an intervention options table[122]. Intervention Options Table (IOTs) were described as a means to synthesising interventions by specifying potential "best bets" among intervention components considered in systematic reviews[122]. Typically, Intervention Options Tables considered barriers and facilitators to the intervention but also included a description of the pros and cons of the potential intervention and how any issues could be addressed. There were no agreed standards for developing Intervention Options Tables. However, the authors suggested three approaches to the development of an Intervention Options Table:

1. The single-trial based choice,
2. The common component hybrid, and
3. The model-guided synthesis.

I elected the model-guided synthesis since this approach closely reflected the methodologies used in my project and involved: a) systematic reviews of the literature, b) extraction of detailed intervention descriptions, and c) the analysis of effect estimates of individual intervention components informing the selection of the most promising version of the intervention. One acknowledged limitation of the model-guided synthesis approach was the requirement for the inclusion of multiple trials providing sufficient variation and statistical power for subgroup analyses of intervention components[122]. These requirements were met by data from meta-analyses of intervention components in Chapter Three. Synthesising the findings from the exploratory literature review with findings from the meta-analyses into an

intervention options table had the potential to increase the variation of data and so strengthen the development of an early model of my intervention.

4.4.10 Early Model of the Intervention

I presented the intervention options table at a meeting of the research advisory group which consisted of a patient suffering from heart failure, a carer, a consultant in palliative medicine, a consultant heart failure specialist nurse, a GP with a special interest in cardiovascular disease, a GP with a special interest in palliative medicine and two researchers with an expertise in the design of complex interventions. The views, advice and consensus of this expert group informed the early model of the intervention by selecting the most suitable intervention components from the Intervention Options Table. The primary outcome of this review and phase of the project was the synthesis of an early model of how the intervention might work including a description of key barriers and facilitators to its implementation.

4.5 RESULTS

The literature search identified 1559 potentially eligible studies, of these, 17 papers were included in the final qualitative synthesis (**Figure 19.** PRISMA Flow Diagram).

4.5.1 Study Characteristics

Most studies (n=11) were conducted in the UK. Two studies were undertaken in Australia, one in Canada, one in Sweden, the USA and Belgium. The majority of studies (n=13) included healthcare professionals from primary care. A summary of included study characteristics is given in **Table 15**.

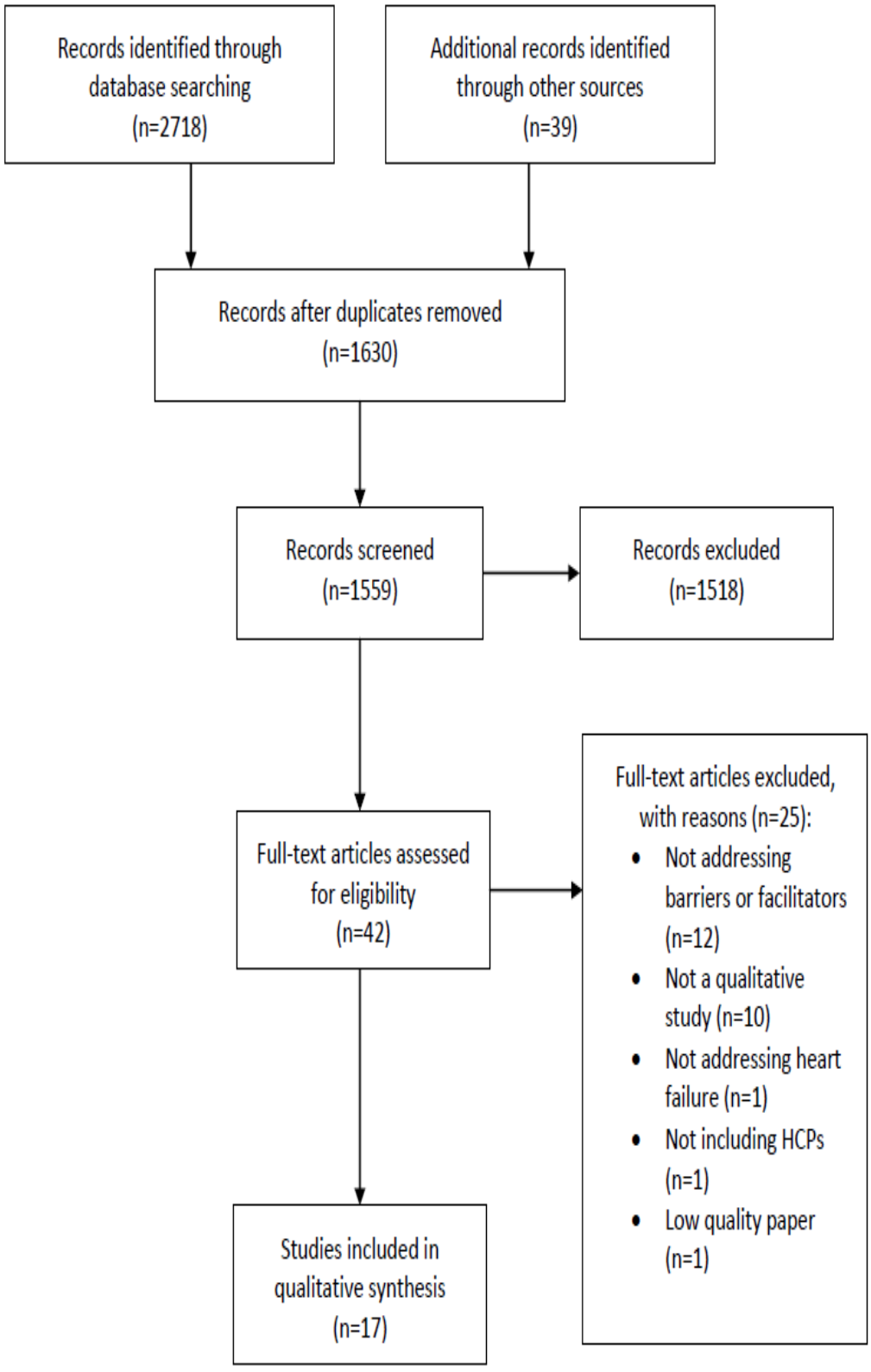


Figure 19. PRISMA flow diagram exploratory review

Study ID	Country	Relevant study objectives:	Study Design	Participants	CASP Quality assessment (Score)
Barnes (2006)[250]	UK	To explore attitudes of primary care professionals and older people toward communication of diagnosis, prognosis and symptoms in CHF	Focus groups with HCPs and interviews with patients	39 GPs, 37 nurses, 2 health visitors, 1 nursing home manager, 41 patients with CHF	High (6)
Bloomer (2013)[251]	Australia	To explore and identify the preparedness and ability of nurses to provide end-of-life care through the patient's dying phase and their families	Focus groups study with clinical nursing and management staff	12 nurses from an intensive care unit looking after cardiac and surgical patients	High (6)
Boyd (2004)[252]	UK	To identify some barriers and facilitators for clinicians to engage in ACP with patients in their last phase of life.	Interviews and focus groups with patients, carers and clinicians	16 clinicians from primary and secondary care, social and palliative care specialists	High (7)
Brooks (2017)[253]	Australia	To explore the experiences of physicians and nurses on barriers and enablers to providing EOL care	Focus group study	11 physicians and 17 nurses at an intensive care unit	High (6)
Close (2013)[254]	UK	To examine the experience of heart failure diagnosis of HCPs, nursing home staff and residents	Qualitative interviews	5 GPs, 3 HF nurses, 17 nursing home residents	High (6)
De Vleminck (2014)[234]	Belgium	To identify barriers from a GPs perspective to initiating ACP and to gain insight into any differences in barriers between cancer, CHF and dementia	Five focus groups with General Practitioners	36 General Practitioners looking after terminally ill patients	High (6)
Denvir (2014)[255]	UK	To explore the optimal content and design of a trial on EOL intervention for advanced heart disease	Community and hospital based focus groups and interviews	11 Primary and secondary care healthcare professionals	High (6)
Fuat (2003)[256]	UK	To ascertain the beliefs and decision-making practices of GPs in heart failure	Focus group study	30 GPs	Medium (5)
Glogowska (2015)[257]	UK	To explore perceptions and experiences of HCPs caring for patients suffering from HF	Qualitative interview study	24 HCPs including GPs, cardiologists, geriatricians, HF specialist nurses	High (7)
Hancock (2014)[258]	UK	To explore changes in HCPs views about the diagnosis and management of HF	Focus groups and a national survey	56 focus group participants (39 GPs, 4 cardiologists, 6 general physicians, 7 HF nurses); 514 survey responses	High (7)
Hanratty (2002)[259]	UK	To identify doctors' perceptions of the need for palliative care for heart failure and for bairiers to change	Focus groups study	34 GPs, cardiologists, geriatricians, medical and palliative care doctors	High (6)

Table 15. Characteristics of included studies

Study ID	Country	Relevant study objectives:	Study Design	Participants	CASP Quality assessment (Score)
Hayes (2015)[260]	Canada	To identify the potential challenges and opportunities to improve care for CHF in the community	Clinician interview series	28 HCPs including 5 GPs, 8 cardiologists, 8 nurses, and 4 pharmacists, 3 admin staff	High (7)
Hjelmfors (2014)[261]	Sweden	To describe nurses' perspectives on discussing End-of-life issues and prognosis with CHF patients	National survey	111 heart failure nurses	High (6)
Murray (2015)[262]	UK	To document the barriers and facilitators to palliative care in the community	European survey	Primary care HCPs from 20 European nations	High (7)
Ostertag (2008)[263]	USA	To identify concerns about EOLC amongst HCPs and members of the community	Interview and focus group study	14 primary care physicians, 19 hospice staff, 18 nursing home staff, 19 carers	Medium (5)
Selman (2007)[264]	UK	To investigate communication between staff, patients and carers on End-of-life issues for patients suffering from heart failure	Semi-structured qualitative interviews	20 patients with CHF, 11 carers, 6 palliative care clinicians and 6 cardiology clinicians	High (7)
Seymour (2010)[48]	UK	To identify factors surrounding community nurses' implementation of ACP and nurses educational needs	Six focus group discussions and three workshops	23 community nurses looking after patients affected by a terminal illness	High (7)
Abbreviations	**CHF**: congestive heart failure; **EOL**: end-of-life; **EOLC**: end-of-life care; **GP**: General Practitioner; **HCP**: healthcare professional; **HF:** heart failure;				

Table 15. Characteristics of included studies

4.5.2 Methodological Quality of Studies

Since there was no consensus on the minimum required quality CASP score for inclusion in a review, we did exclude papers on the grounds of their low methodological quality. Of the 17 papers, we rated 15 as high quality (CASP score 6-7) and two as medium quality (CASP score 4-5)[256, 263]. One study was excluded due to low quality[226]. The CASP quality ratings of the included studies are summarized in **Table 16**.

	CASP question addressed: Yes = + No = o						
Study ID	**1**	**2**	**3**	**4**	**5**	**6**	**7**
Barnes (2006)	+	+	+	+	+	o	+
Bloomer (2013)	+	+	+	+	+	+	o
Boyd (2004)	+	+	+	+	+	+	+
Brooks (2017)	+	+	+	+	+	o	+
Close (2013)	+	+	+	+	+	o	+
De Vleminck (2014)	+	+	+	+	+	+	o
Denvir (2014)	+	+	+	+	+	o	+
Fuat (2003)	+	+	+	+	o	+	o
Glogowska (2015)	+	+	+	+	+	+	+
Hancock (2014)	+	+	+	+	+	+	+
Hanratty (2002)	+	+	+	+	+	+	o
Hayes (2015)	+	+	+	+	+	+	+
Hjelmfors (2014)	+	+	+	+	o	+	+
Murray (2015)	+	+	+	+	+	+	+
Ostertag (2008)	+	+	+	+	o	o	+
Selman (2007)	+	+	+	+	+	+	+
Seymour (2010)	+	+	+	+	+	o	+

Table 16. CASP quality assessment

4.5.3 Descriptive Themes

4.5.3.1 Barriers and Facilitators

We summarised the factors reported as barriers and facilitators to the implementation of ACP by healthcare professionals in heart failure using the SURE framework **(Table 17)**. According to SURE, all barriers and facilitators at a healthcare provider level were categorised under a) knowledge and skills, b) attitudes regarding ACP's acceptability, appropriateness and credibility, and c) motivation to engage with ACP.

Factors affecting implementation of ACP	Barriers	Facilitators
Knowledge and skills	• lack of knowledge about palliative care in heart failure (e.g. the complexity of drugs, ICDs, CRTs)[234, 250-252, 256, 258, 262, 264] • lack of knowledge about the legal differences between ACP and ADtRTs[48, 234, 262, 263] • uncertainty about HF prognosis[255, 258, 259, 261, 264] • lack of EOL communication and negotiations skills[234, 261, 264] • lack of time to start and complete an ACP conversation[234, 251, 255, 257, 261] • lack of collaboration with other HCPs about the patient[253, 256] • not remembering to initiate ACP in the rush of everyday clinical practice[234, 251] • using euphemisms when talking about heart failure and the prognosis[48, 253, 258]	• being competent about palliative care in heart failure[250, 252, 258, 264] • knowing what ACP is and what it is not[48, 234, 262] • knowing the legal differences between ACP, ADRTs or living wills[48, 234, 263] • creating more time by having ACP conversations in the context of a home visit or by booking double appointments[48, 253, 258, 261] • being able to engage patients in shared decision-making and ACP[252, 253, 256, 258] • consultation with other HCPs about next steps in EOLC for the patient[256, 263] • having some sort of reminder to indicate the need to do ACP for a patient[48, 234] • being able to clarify what a patient wants to know and what a patient does not want to know[250, 264]
Attitudes regarding ACP's acceptability, appropriateness and credibility	• uncertainty about timing of ACP[48, 234, 261, 264] • emotional difficulties of having an ACP conversation[234, 258, 264] • ACP perceived as admitting defeat or as a failure to a medical treatment prerogative[253, 255] • believing that cardiologists or heart failure specialist nurses are better suited than GPs because of their expertise[234, 254, 257-259] • believing that GPs are better suited than cardiologists because they have a long-standing relationship with the patient[234, 257] • waiting for the patient to start a conversation about End-of-life issues[234, 250, 252] • concerns about the impact of ACP on the patient and the family[250, 257]	• knowing the patient and family to identify the appropriate moment to have an EOL conversation[234, 251] • knowing a patient's care preferences and values[250, 261] • being able to provide a range of treatment options appropriate to the patient's phase of illness[234, 264] • sharing information between primary and secondary healthcare teams to identify who is the appropriate HCP to have an ACP conversation and when[234, 252-257, 259, 260] • empowering patients to initiate EOL conversations with their healthcare provider[234, 250]

Table 17. Barriers and facilitators at a healthcare provider level

Factors affecting implementation of ACP	Barriers	Facilitators
Motivation to engage with ACP	• not wanting to alarm patients[48, 234, 250] • not wanting to destroy hope when initiating ACP conversations[48, 255, 261] • being afraid of talking about death and dying[48, 250, 253, 257] • fear of damaging the clinician - patient relationship[48] • fear of suggesting to patients that HCPs give up[254] on them when introducing ACP[255] • lack of human resources discourages HCPs to undertake ACP[48, 251, 258]	• being able to provide holistic end-of-life care[250, 252, 255, 260] • knowing that patients want their HCPs to be honest with them[250, 253, 257] • being able to improve the quality of life for patients and their carers when doing ACP[48, 254] • an opportunity to be open and transparent with patients and to give them a chance to prepare for the end-of-life[48, 253] • increased resources in terms of time and staff to undertake ACP and provide 'good' EOLC[251, 258]
Abbreviations: ACP: advance care planning; **ADRTs:** advance decisions to refuse treatment; **CRT:** Cardiac Resynchronization Therapy; EOL: end-of-life; **EOLC**: end-of-life care; **HCPs:** healthcare professionals; **HF**: heart failure**; ICD:** implantable cardioverter defibrillator;		

Table 17. Barriers and facilitators at a healthcare provider level

4.5.3.2 Barriers to the implementation of ACP in heart failure

We identified key barriers to the implementation of ACP by healthcare professionals in heart failure under the following categories:

- **Knowledge and skills**

One reported barrier for healthcare professionals to engage with ACP in heart failure was a lack of heart failure disease-specific knowledge[250, 256, 262, 264] which mainly affected GPs[258], primary care nurses or palliative care staff[264, 265]. This related predominantly to the complexity of available drugs or the use of implantable cardioverter defibrillator (ICDs) and cardiac resynchronization therapy (CRT)[252,258, 260]. Many times, this disease-specific barrier was aggravated by uncertainty about the prognosis of the illness which prevented ACP from taking place[50, 250, 252, 259, 261].

Furthermore, healthcare professionals described a lack of knowledge about ACP in general[48, 260], what ACP should contain or what the legal differences were between ACP and advance decisions to refuse treatment (ADRTs)[48, 263]. This in turn made communication about ACP very challenging for clinicians. A number of studies described a lack of communication- and negotiation skills[48, 228, 234, 261] in EOLC as a barrier to the implementation of ACP[253]. Euphemisms were seen as a way to avoid talking about heart failure as a diagnosis[258] as well as the terminal nature of the disease[234, 250]. However, the use of euphemisms was generally not endorsed by healthcare staff[253].

- **Attitudes regarding ACP's acceptability, appropriateness and credibility**

One attitude emerging as a barrier in implementing ACP by clinicians in heart failure was the perception that in doing so a healthcare professional would admit defeat and treatment failure[261]. This was associated with a considerable negative, emotional impact[228]. Similarly, some studies reported that clinicians saw engaging with ACP as a setback to any curative treatment effort[258, 265]. This attitude applied more to cardiologists than to primary or palliative care staff[256]. Another barrier for not undertaking ACP was a lack of collaboration between healthcare professionals. Cardiologists believed that a GP was better suited to have an ACP conversation due to a GP's long-standing relationship with the patient[259]. Conversely, some GPs thought that the cardiologist was the professional with the content expertise and therefore should start ACP[254]. There was a general lack of communication between the medical disciplines on the issue[252, 258, 265, 266]. Others reported that clinicians waited for the patient to initiate these discussions so that they were sure it was the appropriate time

to engage with ACP[48]. Underlying that lack of initiative were also fears and concerns of not wanting to upset the patient or the family[254, 261].

- **Motivation to engage with ACP**

Not wanting to cause alarm to patients or carers was a key motivational barrier for clinicians not to engage with ACP[261]. They feared that in delivering ACP, healthcare professionals would destroy hope[252]. Another study reported that their own fear of talking about death and dying was another reason for not speaking to patients about the last phase of life[260]. Some clinicians feared that starting an ACP discussion would indicate to a patient that they would give up on them and consequently damage their doctor-patient relationship[48, 265]. Another major factor that discouraged clinicians from engaging with ACP was a lack of resources[48, 252, 254, 256, 262], mainly time, qualified staff[254] and the right opportunity to address such a sensitive topic[255]. Additional barriers to motivation of healthcare professionals to carry out ACP were the competing demands of their clinical role. Workloads and stress often prevented some clinicians from undertaking ACP in heart failure[252, 258].

4.5.3.3 Facilitators to the implementation of ACP in heart failure

Studies reported a number of significant healthcare provider factors classified as facilitators to the implementation of ACP in heart failure:

- **Knowledge and skills**

Being competent in managing the complexities of palliative care in heart failure was a key factor for clinicians to engage with ACP[48, 250]. Other studies[228, 257] reported that a

robust knowledge of drug regimens and the issues surrounding the use of ICDs and CRTs boosted a clinician's confidence to start the ACP process. Healthcare professionals were also more likely to deliver ACP if they had a good understanding about what were the essential criteria of ACP[48, 250, 262]. This was especially relevant when understanding the legal differences between ACP, ADRTs or living wills[48].

Essential skills for implementing ACP were reported as being able to identify the level of a patient's need for information[250], clarifying a patient's care preferences and values[251] or being able to engage a patient in a shared decision-making process on all available treatment options[252, 253]. Study participants described that obtaining or maintaining these skills always involved some form of training[228, 252, 259]. These skills were also relevant when introducing the topic of ACP to a patient[48, 250, 262]. Starting the ACP process could happen in the context of an outpatient appointment, a routine medication review or after a hospital admission when the patient was in a stable medical condition[50, 258].

- **Attitudes regarding ACP's acceptability, appropriateness and credibility**

Studies reported a number of attitudes that appeared to promote clinicians' engagement with ACP. Some thought that ACP was easier to initiate when they knew the patient and family well[253]. The context of a long-term doctor - patient relationship was conducive for a clinician to identify the right place and time to have an EOL conversation[257, 261]. Similarly, the timing for an ACP conversation was seen as right when a patient initiated the conversation[257]. Some clinicians described a sense of relief when this occurred[46]. Starting the ACP process was perceived as being easier when primary- and secondary healthcare teams collaborated well and had reached consensus on a patient[252, 257, 260, 262].

- **Motivation to engage with ACP**

One of the key motivations for clinicians to deliver ACP was being able to provide good or holistic[252] end-of-life care. Some healthcare providers thought that ACP was able to improve the quality of life for patients and their carers[252, 263]. ACP gave clinicians the stimulus to be open and transparent[263] and created an opportunity to prepare patients for their last phase of their life[259]. Some studies described that an increase in human resources including more staff time and finances were additional motivational factors to deliver ACP[252, 258, 262]. To resolve the lack of time, some healthcare professionals started ACP in the context of a home visit[252] or by booking a double clinic appointment. Others arranged follow-up visits after the initial conversation to address any unresolved issues[48, 254].

4.5.4 Intervention Options Table

The Intervention Options Table below (**Table 18**) combined the thematic findings from the above exploratory literature review with results from the previous meta-analyses of intervention component effect sizes. Both quantitative and qualitative data were used to analyse how intervention categories could address the barriers, incorporate the facilitators and identify options for their implementation in clinical practice.

The table lists the intervention category (e.g. reminder systems) in the first column. The intervention categories were based on the previous Effective Practice Organisation of Care Taxonomy[104] as explained in Chapter One. The next column, "Intervention Components," describes the specifics of the corresponding intervention category (e.g. a computer-based reminder system, paper-based reminder system, ACP

Reminder Template) and outlines their possible benefits, limitations and options for implementation into clinical practice.

Intervention Category	Intervention Components	Benefits	Issues	Options for Implementation/ Delivery
Reminders	Computer reminder systems	Evidence shows that electronic reminders are effective in implementing ACP among clinicians	Clinicians need to be competent to identify the right moment and way of introducing an ACP conversation	Computer prompt on opening patients' records as part of electronic patient records and IT systems
	Paper medical record reminders	Evidence shows that paper reminders are effective in implementing ACP	Clinicians need to be competent to identify the right moment and way of introducing an ACP conversation	e.g. a red paper sticker on medical records.
	ACP Reminder template	Can cover all essential content of an ACP conversation	May degenerate into a tick box exercise	ACP and heart failure specific content should include the following: • Document patient's values and priorities: Quality of life, symptom control • Preferences for CPR, resuscitation, intubation, feeding tubes, implantable defibrillator deactivation, intensive care unit transfer • Preferred place of death, care, funeral arrangements • Surrogate decision maker, LPA, LW, • Re-address or reassess goals of care at next review date
	ACP as part of QOF	Financial incentive to deliver ACP	Quality of EOL care may suffer if abused as a tick box exercise	Content of the above ACP computer template may serve to 'measure' whether essential ACP criteria were discussed and documented
Educational meetings	Role-play	Effective for practising communication skills	Time investment, travel; some clinicians may be reluctant to engage with role-play	In trios: one patient, one doctor, one observer for feedback; theatre style or fish bowl approach to reduce levels of participant anxiety
	Peer support group	Good in sustaining EOL/ ACP competences; can include action learning sets	Time investment, travel	Depends on individual group arrangements: minimum once every 4 months.
	Workshop	Effective to acquire knowledge and calibrate skills with interactive exercises	Time investment: needs to be well prepared by participants to maximise effect of training	Maximal 3 – 4 hours in length; once a year for GPs and nurses with experience in routine exposure to end-of-life scenarios
	Online ACP modules	Permits flexible learning, effective for refreshing knowledge and preparing for workshop or peer group	Lack of opportunity of practising advanced communication skills	Resources from the National End-of-life care Programme (DVD/CD); from the e-learning programme in End-of-life care for All (e-ELCA) hosted by HEE; from National Council of Palliative Care (ACP Video Clips and material), from the RCGP End-of-life care Toolkit and the GMC website
	ACP communication skills training	Advanced communication skills in breaking bad news considering heart failure specific issues	Important to establish the right context for the ACP conversation: e.g. does the patient want to be alone, with family, should another clinician be present.	Ask – Tell – Ask may provide a useful framework for communicating about prognosis and goals. Should address: • The shifting balance between benefits and burdens of any treatment or test • Use phrases like "Help me to understand what is important to you."
	Conference	Good in order to get an overview and general update of EOL and ACP trends, networking, sharing knowledge	In general, not so suitable to practice essential ACP skills, time and travel required	There are many national UK conferences on palliative and EOL Care each year.

Table 18. ACP Intervention Options Table

Intervention Category	Intervention Components	Benefits	Issues	Options for Implementation/ Delivery
Patient-mediated interventions	Question prompt list (QPL)	Empowers patients with information; allows them to take initiative and ask the questions they want to have the answers for	Information in QPL needs to be written in language that is suitable to patient; QPL needs to be introduced in an appropriate way and at an appropriate time	Introduce QPL in the context of a routine visit, annual review, outpatient appt. with phrases like: "We hope for the best and plan for the worst." QPL may include decision aids presenting numerical data in more understandable ways assisting patients in clarifying their values.
	Shared decision-making tools	Enhances informed decision making, can engage patients, family members and important others in; urgent need of a palliative care treatment options table for HF	Correct timing of introducing SDM tools into the end-of-life care pathway is crucial; important to assess patient's capacity for and need for information prior to using SDM tools	SDM tools addressing palliative phase of heart failure are non-existent; findings from cancer patients show possible early introduction if communicated appropriately; needs to be evaluated specifically for heart failure patients since it has a different disease trajectory and a different perception of severity.
	Dedicated ACP appointments	Protected time to introduce and cover the topic sufficiently	Patient's readiness and need for information requires careful assessment	Commence, consolidate and conclude the initial ACP conversation over a minimal set of 2-3 appointments.
	Patient reminders to discuss ACP	An effective tool in reminding and engaging patients with ACP	The timing of patient reminders needs to be carefully evaluated by the clinician.	A patient letter should only be used after a face-to-face conversation having assessed patient's readiness and need for information
Academic detailing	Trained ACP facilitators (e.g. Social worker or nurse)	ACP facilitators are competent and confident in delivering ACP	Fragmentation of care since facilitators are not necessarily the patient's usual care giver	Trained ACP facilitators may work e.g. in hospital outpatient settings, are part of primary care clinics or employed by private medical companies
Local opinion leaders	GP with expertise in EOL Care/ ACP	Knows ACP and the constraints of GPs and nurses well, has their respect and holds therefore considerable influence	Events with local opinion leaders can be expensive and at times difficult to organise	In-house practice ACP training meetings, ACP/EOL locality events
Inter-professional education	Palliative care clinician	Experts on ACP teach GPs/nurses and can also answer case-specific questions	Time consuming, difficult to organise and maintain	E.g. ward rounds with palliative care clinicians, GPs and/ or cardiologists
Audit and feedback	Computer search of proportion of completed ACP documents and ACP conversations	Provides quantitative results on clinicians' performance and may indicate areas for improvement	May not reflect the quality of ACP conversations and may not necessarily indicate whether patient's EOL wishes were followed	Computer searches on Practice-Based IT systems
Abbreviations	**HEE:** Health Education England; **LPA**: lasting power of attorney; **LW**: living will; **SDM**: shared decision-making			

Table 18. ACP Intervention Options Table

Based on best available quantitative and qualitative evidence, the intervention options table was one way for the research advisory group to consider and select intervention components that were most appropriate to be included in an early model of my intervention[38]. Greyed-out areas of the intervention options table indicate alternative intervention components, which were not selected by the research advisory group as part of my early model. I have listed them here only to demonstrate that they were part of the original pool of options.

4.5.5 An Early Model of the Intervention

The intervention options table initiated an iterative process of intervention synthesis[257] and informed the first meeting of the research advisory group. The consensus of the research advisory group on suitable intervention components generated the early model of my intervention. Based on previous qualitative and quantitative findings, the members of the group selected the most promising intervention components and provided some input into their content and timing. The early model of the intervention consisted of the following three EPOC categories:

The ACP reminder system

An ACP reminder system could take the form of an electronic template or be based on paper. The template should include all essential ACP components for heart failure and a sample of communication phrases. ACP components should include, but were not limited to, an indication of patients' preferences for resuscitation, implantable defibrillator deactivation, intubation, feeding tubes, preferred place of death or care, or the identification of a surrogate decision maker. Additionally, the reminder sheet should contain a sample of helpful communication phrases for clinicians to start an

ACP conversation with a patient. Care should be taken not to use the ACP Reminder Sheet as a tick box exercise.

Two patient-mediated interventions

The research advisory group recommended the inclusion of two patient-mediated interventions a) a Question Prompt List for patients to initiate ACP conversations and b) a shared-decision making tool to engage clinicians and patients in discussing treatment preferences.

a) A Question Prompt List

The research advisory group recommended the use of a Question Prompt List containing questions assisting patients in clarifying their understanding of heart failure and the kind of care they would like to receive. The information of the Question Prompt List should be written in a language that is easy to understand. The content of the list should not overburden patients with information. The Question Prompt List should be introduced in an appropriate way and at an appropriate time i.e. during a routine visit, at an annual medication review, or during an outpatient appointment.

b) A shared decision-making tool

The research advisory group agreed that there was an urgent need of a palliative care shared decision-making tool for patients suffering from heart failure. The content of the tool should list different problems and complications that may occur together with heart failure and show some choices of treatment that can be offered in response. The Choices of Care Table should include but was not limited to the following complications and problems: treatment choices for lung and urine infections, choices

in the management of an implantable cardioverter defibrillator or treatment options when the symptoms of heart failure are deteriorating. The research advisory group also recommended that the introduction of the table should make it clear that patients had the freedom to change their minds on previously made treatment choices should they so desire.

An educational meeting for clinicians

The research advisory suggested including a) an interactive workshop with some form of role-play, and b) recommendations on the duration and frequency of the educational meeting. The interactive workshop should include communication skills training for clinicians to initiate and conduct an end-of-life care conversation with a patient suffering from heart failure. Role-play should be used to train essential communication skills, but the form of role-play had to be suitable and warranted further exploration in order not to cause anxiety amongst clinicians. The teaching component of the workshop should include an update on ACP and palliative care for heart failure. The duration of the training should be no longer than two to three hours otherwise clinicians might not attend given the constraints of their clinical practice. The training should ideally take place at a clinician's place of work to reach even those who otherwise might not have attended an external event.

4.6 DISCUSSION

4.6.1 Summary of Principal Findings

This review synthesised the qualitative evidence from 17 primary studies on barriers and facilitators to the implementation of ACP by clinicians in heart failure. Systematic review methods were based on recommended standards to enhance transparency and reporting for qualitative evidence[237].

Significant themes for barriers to the implementation of ACP by healthcare professionals in heart failure were:

- Lack of disease-specific knowledge about palliative care in heart failure
- Lack of skills in communicating ACP with a patient suffering from heart failure
- Lack of collaboration between healthcare professionals in order to reach consensus on when ACP is indicated
- The high emotional impact on the healthcare professional when undertaking ACP

Important themes for facilitators to help healthcare professionals engage with ACP in heart failure were:

- Being able to provide holistic end-of-life care when using ACP
- Being competent in the use of ACP and the clinical management of end-stage heart failure
- Having a trusting and long-term relationship with the patient and carers
- Being able to deliver ACP at a time and place appropriate for the patient

Based on above findings and the IOT, the research advisory group selected the following components for the early model of the intervention:

1. Training of healthcare professionals on how to deliver ACP in heart failure
2. An ACP Reminder system including a template with essential ACP criteria
3. Patient-mediated interventions consisting of a question prompt list for patients and a shared-decision making tool to engage both clinicians and patients in discussing treatment preferences

4.6.2 Comparison with Existing Literature

Several of our findings on barriers and facilitators concurred with those from other reviews: the complexity and inherent uncertainty of some aspects of end-stage heart failure management[235], skills in initiating ACP and communicating end-of-life issues[69, 265] or having sufficient resources[186] and a functioning network of collaborations between medical specialities[235] applied to our results as well. Educating and training clinicians in the delivery of ACP should help them become more skilled with the process of initiating these conversations. Being able to conduct these discussions was seen as important, since there were suggestions that supportive or palliative care for heart failure patients should be made available at all stages of the disease trajectory[267]. Having these conversations as a normal part of heart failure management was balanced by the precaution to adjust the dialogue to a patient's need for information in order to avoid a loss of hope or an increase in anxiety[231]. This applied particularly to patients who did not want to talk about end-of-life issues or engage with ACP[268]. Again, this precaution had to be considered in the context that many healthcare professionals avoided disclosing the diagnosis of heart failure or evaded answering any questions about the prognosis of the illness[78]. But the majority

of patients preferred open and honest information about their condition while maintaining a sense of hope[268]. So, the training of healthcare professionals in communicating ACP sensitively seemed even more important.

4.6.3 Strengths and Limitations

At the time of this writing, this was the first qualitative synthesis specifically addressing barriers and facilitators to the implementation of ACP by healthcare professionals in heart failure. Several of our findings concurred with other reviews. However, the global transferability of our qualitative results may be limited since the majority of included studies were based in the UK. That said, study participants came from every healthcare sector including GPs, cardiologists, palliative care clinicians and nurses from secondary, primary or community care.

The SURE framework proved to be helpful in facilitating an understanding of the barriers and facilitators to the implementation of ACP in the published literature. This approach allowed me to synthesise the findings from the thematic analysis in a systematic way according to healthcare professionals' knowledge and skills, their attitudes regarding ACP's acceptability, appropriateness and credibility and their motivation to engage with ACP. Once we achieved consensus on the barriers and facilitators in included papers, mapping these to the SURE structure was efficient and straightforward. All SURE factors of the healthcare provider level were relevant to answer my research question and to understand the barriers and facilitators to the implementation of ACP by clinicians. These barriers and facilitators informed the design of the Intervention Options Table and subsequently the early model of the intervention.

On the other hand, using the SURE framework largely centred the analysis of thematic findings on barriers and facilitators to the implementation of ACP by clinicians. This approach may have limited the diversity of qualitative data and narrowed the complexity of the phenomenon under investigation to a few pre-defined units i.e. the SURE factors affecting the implementation of the intervention by healthcare providers[269]. Consequently, there may have been a risk that other themes outside the scope of SURE were not sufficiently considered[270]. For example, the wider political or economic context of the proposed intervention received only marginal attention. Additionally, like many qualitative analysis methods, SURE consumed extra time. But overall, I thought that spending the additional time in using the SURE framework was a worthwhile investment mainly for the following reasons:

a) SURE facilitated a systematic approach to the identification and mapping of barriers and facilitators to the implementation of ACP by clinicians in heart failure.

b) Using the SURE framework synthesised findings to inform the design of the Intervention Options Table and subsequently the early model of the intervention.

The design of the Intervention Options Table was a novel outcome of this review and enabled a combination of the qualitative findings with the previous quantitative evidence base on intervention effect sizes. Consequently, the research advisory group was able to reach a consensus on the most promising intervention components to advance the development of an early model. Their selection was based on best available quantitative and qualitative evidence. The early model of the intervention included patient-mediated components in the form of a Question Prompt List and a shared decision-making tool about patient's care preferences, reminder systems and training for clinicians in how and when to engage with ACP.

Based on current findings, these intervention components may have the potential to mitigate against the high emotional impact of ACP on clinicians[254, 260]. For example, Question Prompt Lists have demonstrated the potential to empower patients to initiate end-of-life conversations with their healthcare provider[174]. If a patient would initiate the discussion about ACP in heart failure, clinicians may feel less distressed about addressing the topic by responding to a patient's question[174]. A number of studies report a small but significant increase in questions by patients about diagnosis, prognosis and treatment when a Question Prompt List has been used[174, 271, 272]. Question Prompt Lists seem to achieve that by helping patients to remember, frame and ask questions that are important to them[273, 274]. Most of these studies investigate the effect of Question Prompt Lists in a cancer setting. There are variable results for the use of Question Prompt Lists in non-cancer patients[275-277]. The evidence for the effect of Question Prompt Lists on patients suffering from heart failure is still outstanding[87].

Additionally, the qualitative and quantitative findings suggest that the components of the early model of the intervention may assist clinicians in identifying an appropriate time and place for the patient to engage with ACP[265]. For example, when a patient takes the initiative and asks a question, the clinician would have a better understanding if this was the right time for such a conversation and may feel less apprehensive of engaging with ACP[78]. Alternatively, findings from the previous intervention component analysis indicated that a change in a patient's health status, for instance, before or after a hospital admission or after an acute event, may be an appropriate time to engage with ACP[195, 196, 212]. During these milestones in a patient's illness trajectory, shared decision-making tools like a Question Prompt List or a treatment options table have been found to provide a starting point to discuss how a

patient would like to be treated if the situation should deteriorate or recur[7, 51, 174, 278, 279].

Training clinicians in how to use shared decision-making tools would be essential to facilitate ACP in heart failure[7, 279]. Studies have shown that healthcare professionals often lack disease-specific knowledge about the clinical management of advanced heart failure[256, 262] and the confidence to engage with end-of-life issues and ACP[250, 264]. The evidence suggests that key training elements should include being able to identify the level of a patient's need for information[250], clarifying a patient's care preferences and values[251] and being able to engage a patient in a conversation on all available treatment options[252, 253]. There are a number of ways to achieve these skills which may include educational meetings that use workshops, didactic teaching or role-play[62, 165, 228]. Offering training that is facilitated by local opinion leaders and experts in the field of heart failure and end-of-life care may carry greater credibility with clinicians and enhance their engagement[185, 211].

4.7 CHAPTER SUMMARY

Based on findings from the literature reviews and the Intervention Options Table, the research advisory group selected the following components for the early model of the intervention:

1. Training of healthcare professionals on how to deliver ACP in heart failure
2. An ACP Reminder system including a template with essential ACP criteria
3. Patient-mediated interventions consisting of a Question Prompt List for patients and a shared-decision making tool to engage, both clinicians and patients, in discussing treatment preferences

While the quantitative and qualitative evidence from these reviews was promising, a number of significant questions remained unanswered:

1. What did key stakeholders, such as practicing doctors and nurses, think about this early model of the intervention? Would they use it?

2. What components of the interventions needed to be improved and refined in order to meet the demands of clinical reality?

3. Had we identified all the key barriers and facilitators to the implementation of ACP in heart failure or were there more to be found in order to achieve a successful integration into clinical workflows?

These were some of the questions to be explored in the subsequent clinician interview series.

CHAPTER FIVE

Synthesis of the Intervention Prototype

5 SYNTHESIS OF THE INTERVENTION PROTOTYPE

5.1 BACKGROUND

The intervention component analysis, identifying Behaviour Change Techniques (BCT)[206] and the Intervention Options Table[122] are the first steps in following the Medical Research Council's recommendations to model the process of developing a complex intervention to optimise the implementation of ACP in heart failure[89]. However, one acknowledged limitation in the current evidence is the lack of analysis of how clinicians best engage with ACP considering the barriers and competing demands of their clinical practice when caring for patients suffering from heart failure[75, 77].

While the previous meta-analyses and the exploratory literature review provides a systematic evaluation of the quantitative and qualitative evidence base, the Medical Research Council[109] (MRC), the National Institute for Clinical Excellence (NICE)[112] and others[113] assert that the interpretation of intervention effectiveness needs to also draw from practical health experience and theory to facilitate robust development and implementation. NICE emphasizes that evidence-based results require careful scientific interpretation before their implementation into routine practice[112]. Evidence-based findings are often not applied effectively and desired health outcomes are not achieved due to a number of reasons: a) a lack of theoretical understanding of the processes and context required to change the behaviour of healthcare professionals[125], b) a lack of theoretical rationale to understand implementation interventions' target

mechanism of action[109], c) inappropriate methods used to design the intervention, or d) a lack of precise reporting of what is delivered as part of the intervention[103].

5.1.1 The Theoretical Domains Framework

Consequently, the MRC and NICE call for applying theory and qualitative methods to intervention design aiming at an increased understanding of how interventions exert their influence on clinicians' behaviour by, for example, examining how their content might relate to and interact best with a given context or mechanisms of action[92, 109, 280]. The use of theory to analyse why and how interventions might change clinicians' behaviour demonstrates some improvements in the effectiveness of implementing interventions in the past[281]. The Theoretical Domains Framework (TDF)[90] is one example of such a theory to investigate and characterise potential implementation interventions. For instance, the Theoretical Domains Framework has been used to investigate and change health professionals' behaviour in order to increase uptake of evidence when managing lower back pain[113], ordering diagnostic tests[282], transfusions[283], complying with hand hygiene guidelines[284], adherence to prescribing antibiotics[285] or cardiovascular medications[286].

The Theoretical Domains Framework is a synthesis of 33 theories of behaviour relevant to healthcare professional behaviour change[90] to identify psychological and organisational theory. Health psychology theorists in collaboration with health service researchers refined and validated the framework. Developers aim for the Theoretical Domains Framework to make psychological theory useful to researchers who may come from a variety of backgrounds and who may want to investigate a wide range of healthcare behaviour[287]. However, authors also highlight that Theoretical Domains Framework domains are not developed to link the explanatory and causal mechanism

that the individual constructs may bring from their original theory. Their main purpose is to design a pragmatic framework that enables broad exploration of health behaviour in current behaviour change theories[288]. The Theoretical Domains Framework outlines 14 possible domains consisting of 84 component constructs to explain behaviour change that could facilitate or impede successful intervention implementation[280, 287]. The domains identified are: 1) knowledge, 2) skills, 3) social/professional role and identity, 4) beliefs about capabilities, 5) optimism, 6) beliefs about consequences, 7) reinforcement, 8) intentions, 9) goals, 10) memory, attention and decision processes,11) environmental context and resources, 12) social influences, 13) emotion, 14) behavioural regulation. Since 2005, the Theoretical Domains Framework has been increasingly used in the development of complex healthcare interventions[289]. **Figure 20** shows the connection of the Theoretical Domains Framework Domains with the Capacity, Opportunity, and Motivation Behavioural (COM-B) model of the Behaviour Change Wheel (BCW). The Behaviour Change Wheel and COM-B Model have been described in detail in Chapter One. They provide a comprehensive framework to inform the design of interventions by identifying the *conditions* required in which behaviour change could occur[90, 116, 125].

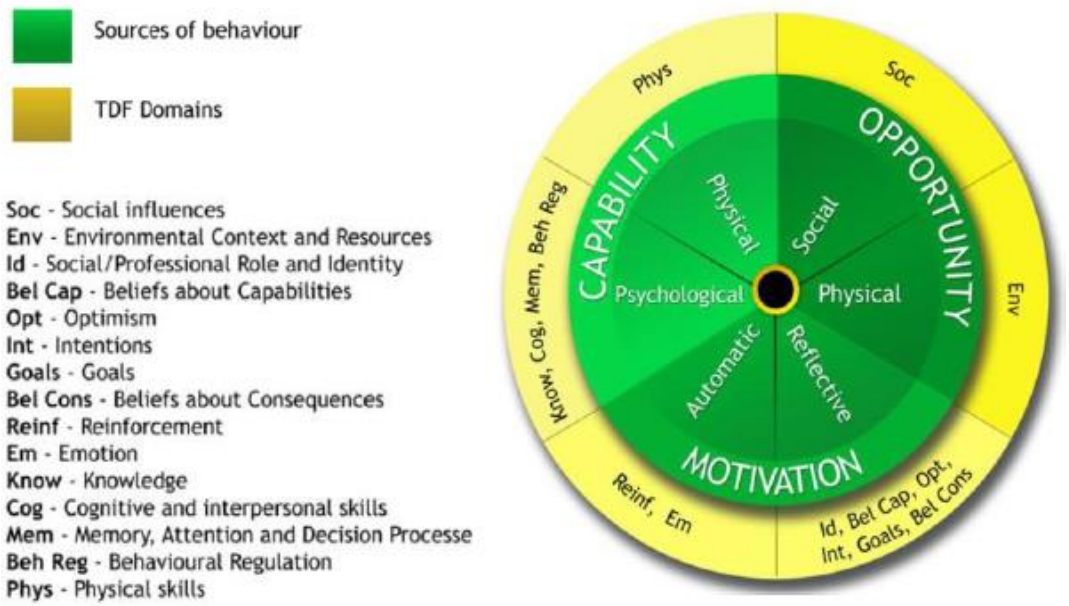


Figure 20. TDF Domains and COM-B Model

Additionally, the Theoretical Domains Framework has been particularly designed as a tool for the field of applied health research to generate or substantiate hypotheses which can be tested further in quantitative trials[287]. The Theoretical Domains Framework and its domains associate well with my aim to further explore barriers and facilitators of changing clinicians' behaviour to optimise the implementation of ACP in heart failure. Due to its pragmatic nature, I decided to use this framework to better understand factors that influence behaviour change of clinicians. Consequently, I chose to follow a recommended four-step approach to develop and select theory-informed implementation interventions[113]. **Table 19** gives an overview of how that framework was applied to the different phases of my project.

Step	Task	Application to Project
Step 1. **Identifying the problem:** Who needs to do what differently?	a. Identify the evidence practice gap b. Specify the behaviour change needed to reduce the evidence practice gap c. Specify the health professional groups whose behaviour needs changing	a. Lack of evidence on the impact of ACP in heart failure; lack of evidence for interventions changing clinicians' behaviour: addressed by syst. lit. reviews and meta-analyses (**Tables 3, 4, 9, 10, 11**) b. Healthcare professionals implementing ACP in end-of-life care and heart failure c. Healthcare professionals in primary care
Step 2. **Assessing the problem:** Using a theoretical framework, which barriers and facilitators need to be addressed?	a. From the literature and experience of the development team, select which theory(ies) or theoretical framework(s) are likely to inform the pathway of change b. Use the chosen theory(ies), or framework to identify the pathway(s) of change and the possible barriers and facilitators to that pathway c. Use qualitative and/ or quantitative methods to identify barriers and facilitators to behaviour change	a. Theoretical Domains Framework selected b. Explorative literature review identified barriers and facilitators of implementing ACP in heart failure (**Table 17**) c. Clinician interview series (n=24) exploring specific barriers and facilitators at a theoretical and practical level in end-of-life care for heart failure (**Table 21**)
Step 3. **Forming possible solutions:** Which intervention components could overcome the modifiable barriers and enhance the facilitators?	a. Use the chosen theory, or framework to identify potential behaviour change techniques to overcome the barriers and enhance the facilitators b. Identify evidence to inform the selection of potential behaviour change techniques and modes of delivery c. Identify what is likely to be feasible, locally relevant, and acceptable and combine identified components into an acceptable intervention that can be delivered	a. Used Michie's behaviour change wheel, BCT taxonomy (v1) and TDF to address barriers and facilitators (**Table 22**) b. Used quantitative and qualitative findings as well as consensus opinion from research advisory group to determine modes of delivery and selection of BCTs for the prototype of the intervention (**Table 23**) c. Used focus group study (n=22) to refine final intervention including QPL, ARS, CoC and APT. The delivery mode was a Practice-based training session (**Table 27**)
Step 4. **Evaluating the selected intervention:** How can behaviour change be measured and understood?	a. Identify mediators of change to investigate the proposed pathways of change b. Select appropriate outcome measures c. Determine feasibility of outcomes to be measured	a. Constructs theorised to be mediators of clinician behaviour change (measured by survey and interviews in a proposed cluster feasibility RCT) b. Outcomes measured at a clinician, patient and practice level c. Feasibility of outcomes to be measured as described in the trial protocol
Abbreviations	ACP: advance care planning; APT: ACP: Practice-based training; ARS: ACP Reminder Sheet; BCT: behaviour change techniques; CoC: Choices of Care Table; EOL: end-of-life; RCT: randomised controlled trial; TDF: Theoretical Domains Framework;	

Table 19. TDF application to project

5.2 AIM AND OBJECTIVES

The main aim of the interview series was to strengthen the iterative process of intervention synthesis by means of qualitative methods and intervention theory during this phase of the project.

The primary objectives were:

- To explore clinician reported experiences in using ACP in end-of-life care and heart failure

- To document their preferences and list intervention components they believe would improve efficacy as well as adherence to ACP in clinical practice.
- To use the Theoretical Domains Framework to characterise the potential theoretical mechanisms of action of implementation interventions and thus inform the design of the intervention prototype

5.3 METHODS

In order to design the prototype of the intervention, it was important to explore the views of a broad range of relevant healthcare professionals. Qualitative methods have been used to better understand and capture the factors influencing the implementation of interventions amongst clinicians[128]. Subsequently, semi-structured interviews were seen as a suitable approach to inform the prototype of the intervention. One advantage of using this method was the opportunity to generate in-depth findings based on clinicians' experience that could inform the content and mode of delivery of the intervention[290, 291]. Qualitative research seemed particularly appropriate for exploring a sensitive topic like end-of-life care and heart failure[291]. Therefore, I investigated issues relating to previously identified intervention components for which there was an evidence base and an indication that they were feasible to use. Additionally, I addressed Theoretical Domains Framework domains in the design of the interview topic guide and transcript analysis by following the above recommended four-step approach to develop and select theory-informed implementation interventions[113].

5.3.1 Inclusion and Exclusion Criteria

The qualitative interview series study involved healthcare professionals who delivered clinical services consisting of full and part-time GPs, district, practice, end-of-life care nurses as well as heart failure specialist nurses. I focused on primary care staff

because evidence suggests that GPs are considered central professionals in the management of continuous and end-of-life care[292] . Additionally, patients and carers think that GPs and other primary care staff should have a prominent role in advance care planning[293]. Secondary care doctors and private healthcare providers were excluded from the study because their approaches to heart failure treatment and ACP were significantly different compared with their primary care colleagues[294, 295]. The study was reviewed by IDREC and granted ethical approval (**R44601/RE001**). Written informed consent was given by all study participants. Research participants and their corresponding data were anonymized.

5.3.2 Recruitment

Participants were recruited from a sample of primary healthcare professionals drawn from local General Practices through research contacts in the Nuffield Department of Primary Care, professional contacts across General Practices in Oxfordshire, Buckinghamshire and Berkshire, the Thames Valley Clinical Research Network and by word of mouth. Clinicians were selected through purposive sampling using a maximum variation approach to ensure representation from men and women, a range of ages, and a range of professional backgrounds. Most primary care clinicians are expected to undertake ACP, no matter what their role, working conditions or experience. However, these factors might affect how they understand ACP. Therefore, I aimed for recruiting a wide variety of clinicians including full and part-time GPs, salaried, academic and Out-of-Hours (OoHs) GPs, community heart failure specialist nurses, practice and district nurses from urban and country practices, holding full or part-time roles. This sampling approach allowed me to capture a range of experiences including healthcare professionals with little or no experience in looking after patients suffering from heart failure. We anticipated recruiting between

25-30 participants. The final number recruited would be dependent on when data saturation was reached, a point where no new themes emerge with a high rate of duplication or recurrence of responses[296].

5.3.3 Interview Process

Clinicians were interviewed during the spring and early summer of 2016 at a place of their choice, which was usually their surgery. Interviews lasted between 35 and 60 minutes. Participants received study information (**Appendix 16**), consent and reply forms prior to the interview (**Appendix 17**). Having signed a consent form, clinicians were asked to talk about their experience with ACP and heart failure.

An interview topic guide (**Appendix 18**) was piloted and refined during the first three interviews of the study. Data from pilot testing the interview topic guide was included in the analysis. Initially, multiple questions about their experience with ACP, and barriers and facilitators to its implementation were developed. Pilot testing was performed by qualitatively testing the questions using a form of cognitive interviewing to test face validity, select the optimal question for each topic and refining the wording to produce a field-test version[297]. For example, the opening question of the first version of the topic guide asked, "What do you *think* about ACP?" Using the word "think" did not prove to be optimal since it tended to narrow participants' answers to the theory, concept or politics behind ACP. Since one of the primary objectives of the interview series was to explore clinicians' experience in using ACP, I subsequently replaced this question with "What is your *experience* with ACP?" Using the word 'experience' seemed much more suitable and prompted a natural flow of answers.

In this first, narrative section of the interview, interviewees were asked a number of open questions about ACP and heart failure. When their account came to a conclusion, the semi-structured interview topic guide was used to further explore any potentially relevant themes that were not already addressed and provided a more detailed exploration of the way clinicians understood and responded to intervention components. For example, for facilitators of implementing ACP, I asked clinicians the question "What are the factors that would help you in undertaking ACP?" This question about facilitators served as a possible starting point to explore a clinician's perspective on the usefulness of the Question Prompt List (QPL). Findings from the intervention component analysis and the exploratory literature review suggested that a Question Prompt List had the potential to facilitate ACP in clinical practice. I asked healthcare professionals if they would find it useful when a patient took the initiative of asking them questions about end-of-life issues. Following that, I would show the interviewee an early version of the Question Prompt List and receive their feedback. In this way, the feedback from participants on the Question Prompt List iteratively shaped its content and design. Not all intervention components were discussed with all participants in every interview. But every component was discussed with participants during the course of the interview series. This approach was congruent with conducting qualitative interviews, in which the investigator often focussed on one or two aspects of the research area in one interview that were important to the participant. This method ensured a more in-depth exploration of the usefulness, for example of the Question Prompt List, at the cost of superficially covering all intervention components in one interview. While not every component was discussed with every participant, all components were eventually explored to a sufficient depth.

5.3.4 Data Collection

All interviews were audio recorded, transcribed verbatim and checked for accuracy. After 24 interviews, I found that no new themes were emerging in the interviews and there was a high rate of recurrence of topics. This became evident since there were no new master coding nodes identified when analysing the interview transcripts. I used study IDs to preserve anonymity when individual participants were cited.

5.3.5 Analysis

The process of analysing interview data included four steps:

1. Thematic Analysis
2. Analysis of Intervention Ingredients
3. Analysis of Intervention Mechanism of Action
4. Deviant Case Analysis

1. Thematic Analysis

I conducted thematic analysis[298] with the aid of the qualitative data analysis package NVivo Version 11[299]. Thematic analysis is a method for identifying, analysing and reporting patterns of emergent themes within a qualitative data set. We (JM, MS) followed best published research practice[300, 301] and started our analysis by gathering excerpts from the interviews with relevance to a number of anticipated or emergent themes. We discussed the first set of interviews according to emergent themes which informed a preliminary coding framework that grew as analysis progressed. Subsequently, these codes were refined and built into wider categories with subsets. In the process of conducting interviews, we re-examined and refined our coding categories as confirming or disconfirming data was added. We regularly discussed the

emergence of new themes and coding patterns. We contrasted and compared categories of themes emerging from the data until final themes were identified to ensure their credibility and confirmability. These themes included, but were not limited to, barriers and facilitators of the implementation of ACP in heart failure.

2. Analysis of Intervention Ingredients

Based on the results of the thematic analysis and guided by the early model of the intervention, I created an outline of the likely format, provider, content and rationale of the Question Prompt List, the Choices of Care Table, the ACP Reminder Sheet, and ACP Practice-Based Training. I identified behaviour change techniques by analysing the intervention ingredients from the interview transcripts using the Behaviour Change Techniques Taxonomy (v1). All behaviour change techniques were considered when analysing the interviews. I mapped behaviour change techniques to the intervention functions of the Behaviour Change Wheel (COM-B Model) by using published guidance of the Behaviour Change Wheel Guide to Designing Interventions[206]. During this process, I was advised by a behavioural scientist (CA) who reviewed the identification and allocation of behaviour change techniques to the Behaviour Change Wheel to enhance the validation of the mapping exercise. For example, clinicians frequently said that they had a lack of skills in undertaking ACP in heart failure. So, I connected that barrier of not knowing how to conduct ACP with the behaviour change technique of "instruction on how to perform the behaviour." Similarly, clinicians were not sure about the advantages or disadvantages of delivering ACP. So, I linked that barrier to the behaviour change technique "information about health consequences" to explain the pros and cons of ACP. Following that, we connected these two behaviour change techniques with the relevant COM-B domains of psychological capability (C Ps) of knowing how to

conduct ACP in heart failure and reflexive motivation (M Re) of undertaking ACP after considering its advantages and disadvantages.

3. Analysis of Intervention Mechanism of Action

Following the identification of the specific intervention ingredients and COM-B domains, we identified their potential theoretical mechanisms of action by using the Theoretical Domains Framework. Behaviour change techniques were mapped to the Theoretical Domains Framework domains based on published guidance on which behaviour change techniques were deemed useful for influencing Theoretical Domains Framework domains[92]. For example, we connected the behaviour change techniques "instruction on how to perform the behaviour" and "information about health consequences" with the Theoretical Domains Framework domains of "Knowledge" (Kn) and "Beliefs about Health Consequences" (B con). A behavioural scientist (CA) and three senior qualitative researchers (LL, JM) including one with TDF experience (AMB) reviewed the mapping and agreed on which Theoretical Domains Framework domains the behaviour change techniques were likely to have targeted. Their consensus informed the design of the Theoretical Domains Framework Matrix (**Table 20**) and facilitated the allocation of behaviour change techniques to the components of the prototype of the intervention like the Question Prompt List or Choices of Care Table. As an extra measure of validation, I asked the research advisory group consisting of a GP with a special interest in palliative care, a patient suffering from heart failure, a cardiologist, a heart failure specialist nurse, and a consultant in palliative medicine to provide feedback on the suitability of the content and selection of the intervention prototype.

Figure 21 shows the process of how the findings from the thematic analysis informed the analyses of intervention ingredients and their mechanism of action according to behaviour change techniques, the COM-B Model and the Theoretical Domains Framework. The diagram also depicts how these hypothesised behaviour change techniques, COM-B and Theoretical Domains Framework domains shaped the Theoretical Domains Framework Matrix, which in turn informed the prototype of the Question Prompt List, the Choices of Care Table, ACP Reminder Sheet and the ACP Practice-Based Training. The advantage of analysing the content of interview transcripts in such a systematic way facilitated the identification of potentially helpful intervention components. Additionally, the process enabled a better understanding of how and why certain interventions may overcome barriers to achieve the implementation of ACP in heart failure.

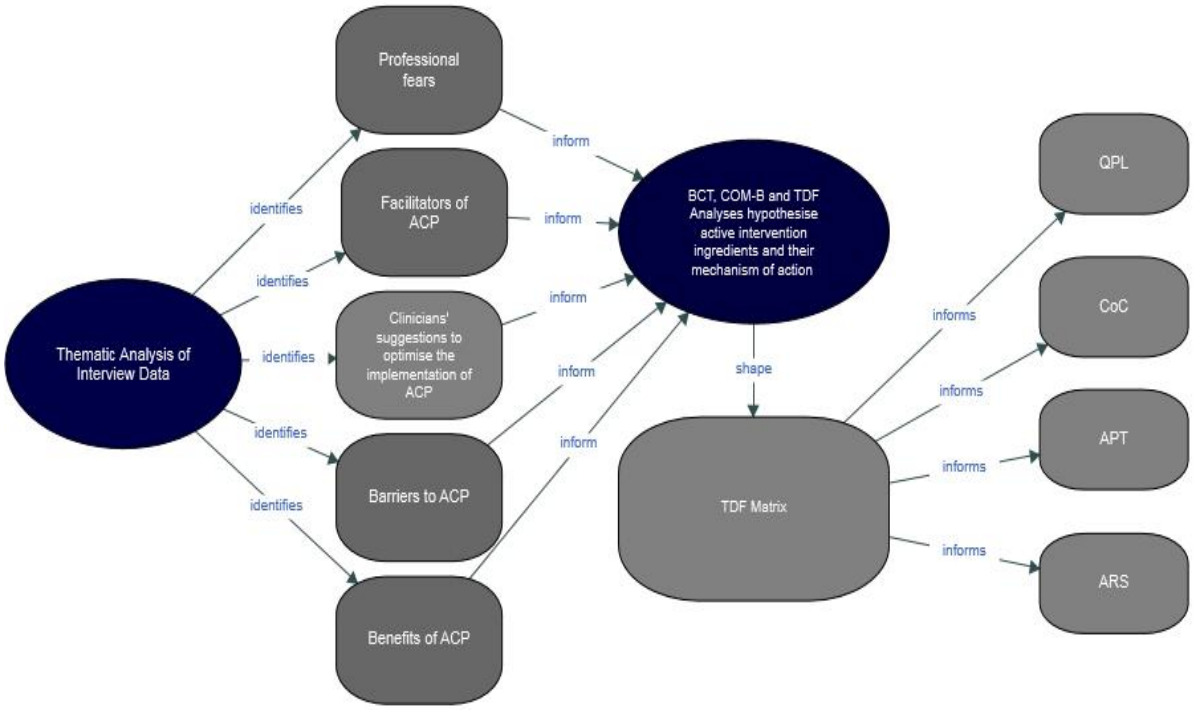


Figure 21. Analysis process for the intervention prototype

4. Deviant Case Analysis

A key aspect of rigorous qualitative research is the attention to deviant or non-conforming views. Deviant cases are considered important because they mitigate against the tendency of researchers to look for similarities in data that support their individual preferences[302]. A deviant case may be qualitative data that does not conform to the findings of the earlier analysis[303]. As such, deviant cases can create an opportunity for a more wide-ranging interpretation of the phenomenon under investigation. Therefore, deviant case analysis has the potential to explain the expected and typical as well as the unexpected and atypical[303]. I attempted to achieve that through two means:

a) Actively seeking out those interview responses that did not conform to my a priori expectation of the usefulness of ACP in heart failure or the merit of the intervention components to optimise its implementation
b) Involving a reviewer (JM) from a different, social science background to improve the potential of identifying disconfirming cases and increasing reflexivity[304].

5.4 RESULTS

5.4.1 Characteristics of Participants

A total of 24 people participated in the interviews. The majority of all interviewees (see **Table 20**) were GPs, female and of white British origin. Nearly one third of interviewees were nurses including practice nurses, heart failure specialist and district nurses. No one declined an invitation to participate.

Sample	n = 24 participants recruited
Composition of sample	17 (70.83%) GPs from Oxfordshire, Buckinghamshire and Berkshire through the NDPCHS including 9 (37.5%) full and part-time GPs, six (25.0%) salaried GPs, two (8.3%) locum and one (4.17%) OOHs GP. 7 (29.17%) nurses from Oxfordshire General Practices through the NDPCHS including two heart failure specialist nurses (8.3%).
Sex	15 (62.5%) female and nine (37.5%) male
Ethnicity	23 (95.83%) White British 1 (4.17%) Asian British
Median age	44.95 years
Age range	29-68 years

Table 20. Characteristics of interview participants

5.4.2 Thematic Findings

I explored clinicians' experience with ACP and their understanding of ACP as a process that might contribute to end-of-life care for patients suffering from heart failure. The participants were aware that I was a GP with clinical experience and specialist knowledge in palliative care, heart failure and ACP. During the first part of the interview, I therefore engaged interviewees as an interested but non-judgemental colleague to facilitate an uninterrupted and natural flow of conversation. During the subsequent semi-structured part of the interview, I used my expertise to elicit deeper reflections from healthcare professionals by, for example, referring to best practice in end-of-life care for heart failure or by discussing the competing demands of their job. The emphasis in the interviews commonly gravitated towards specific cases of patients suffering from heart failure. I used these examples to encourage GPs and nurses to think about their professional practice and how the proposed intervention components might help them to overcome barriers when delivering ACP. Initially, the thematic analysis identified five overall themes from the data to address our research objectives:

1. Benefits of ACP in Heart Failure
2. Barriers to ACP in Heart Failure
3. Fears of delivering ACP in Heart Failure
4. Facilitators of ACP in Heart Failure
5. Suggestions to optimise the implementation of ACP

Barriers, facilitators, fears and perceived benefits of ACP affected the experience of healthcare professionals which represented the foundation that informed clinicians' suggestions to optimise the implementation of ACP in heart failure. **Appendix 19** shows the entire NVivo coding tree for the interview study. Thematic analysis identified the general themes of barriers and facilitators to the implementation of ACP in heart failure. But this approach was insufficient as a framework to explain how and why interventions might exert their influence on changing clinicians' behaviour in overcoming these barriers. The Theoretical Domains Framework was designed for that purpose[90] and enabled a suitable depth of analysis.

5.4.3 Theoretical Domains Framework Findings

GPs and nurses provided in-depth information on barriers of all Theoretical Domains Framework domains. Participants suggested facilitators to the implementation of ACP on the following eleven Theoretical Domains Framework domains:

- knowledge
- skills
- social/professional role and identity
- beliefs about capabilities
- optimism
- intentions

- goals
- memory, attention and decision processes
- environmental context and resources
- social influences
- behavioural regulation.

Presented below is a detailed interview analysis of key findings for each TDF domain containing a description of barriers and facilitators:

5.4.3.1 Knowledge

The knowledge domain contained the information clinicians had about ACP in heart failure, the rationale of delivering ACP, the scientific evidence base of supporting ACP in end-of-life care and heart failure and the knowledge to have an ACP conversation and complete an ACP document. This domain explored whether these components acted as facilitators or barriers to ACP. It included the participants' understanding and perceived rationale behind using ACP in end-of-life care and for heart failure patients.

Knowledge about ACP in general and for heart failure patients in particular differed among clinicians. A number of healthcare professionals admitted that they lacked disease specific knowledge for end-stage heart failure. One GP said:

"I suppose the other thing that's tricky with heart failure in advance care planning is that you feel that you lack some specialist knowledge and that is hindering you. I ask myself, "Am I missing something? Is there something else that we could be giving to improve things?" (R6)

Conversely, one GP (R1) identified heart failure specific palliative care knowledge as a facilitator to implement ACP especially around local guidelines for prescribing, knowing how to set up a syringe driver or how to manage hypoxia in end-stage heart failure. The unpredictable disease trajectory of heart failure compared to other end-of-life conditions like cancer made it more difficult for a number of clinicians to know when to have an end-of-life care conversation with their patients. One GP said:

"*With cancer, I actually find it much easier to know that I am within a few weeks or days of someone dying because I find the disease trajectory much more predictable. And therein lies the problem with heart failure and why my ACP experience with heart failure is limited because I find it much harder to predict and getting harder."* (R5)

When asked what would facilitate to overcome these barriers, many healthcare professionals expressed the need to receive training in EOL care for heart failure to increase their knowledge base on disease-specific facts. Some participants said that training should start during undergraduate studies and continue throughout the professional career of a clinician. To make the importance of ACP memorable to trainees and establish their knowledge base about heart failure more permanently, one experienced district nurse suggested that students should be given an exercise that applies ACP to their own lives:

"*I think right at the beginning of everybody's training there needs to be stuff in there about palliative and end-of-life care and advance care planning and they start with their own advance care plan."* (R20)

The following examples summarise some key interview findings from the TDF Knowledge domain and illustrate how they informed the design of the ACP Practice-Based Training (APT) and the ACP Reminder Sheet (ARS):

- *"It's tricky with heart failure in advance care planning … you feel that you lack some specialist knowledge and that is hindering you."* (R6) This barrier was addressed by a presentation of key facts about ACP in heart failure as part of APT.
- *"I ask myself, 'Am I missing something? Is there something else that we could be giving to improve things?'"* (R6) This barrier affirmed the importance of providing a reminder template (ARS) with key criteria about ACP.
- *"Right at the beginning of everybody's training there needs to be stuff in there about palliative and end-of-life care and advance care planning."* (R20) The need for specific information about ACP in EOL Care and heart failure informed the content of APT.
- *"My ACP experience with heart failure is limited because I find it much harder to predict…"* (R5) This barrier was addressed by providing information about how and when to introduce ACP in heart failure given its unpredictable disease trajectory as part of APT.

5.4.3.2 Skills

This domain described the skills and competencies to perform ACP and the procedural ability to use shared decision-making tools in end-of-life care for heart failure. GPs and nurses provided data that they were willing to engage with delivering ACP in heart failure but felt that they were missing some specific skills to do so.

Interestingly, there was a sense of a lack of skills expressed especially among some GPs. They perceived heart failure nurse specialists as much better qualified to deal with the palliative care dimension of the disease:

"*If there is a specialist palliative care nurse or heart failure nurse in end-of-life, then expecting a GP to be better than the specialist nurse teams would be a surprise to me. If that is the presumption then it's incorrect, isn't it? I think we are definitely not any better than the specialist nurse teams."* (R4)

One nurse observed that difficulties in undertaking ACP in heart failure was not only a problem for GPs but affected every stakeholder involved including nurses, family members, patients and carers:

"*The much bigger part of the problem is that people just don't have the skills - everyone from family, staff, doctors, both don't have the competence or all the confidence to even think about these things let alone plan for how to do it.*" (R12)

In order to overcome these barriers, participants suggested having the necessary skills for undertaking ACP in heart failure. These abilities ranged from more obvious capabilities like better end-of-life communicating skills, to being able to adapt to patients' expectations, to being skilled in empowering patients to make their own decisions and design their own care plans. In terms of having better communication skills, one district nurse exclaimed in exasperation:

"*It's the language that quite often seems to be the issue in end-of-life conversations. And that's been my entire career. Doctors, some doctors just don't get it!"* (R7)

An appropriate use of language was not only about a conversation free from medical jargon, but also free from ambiguity and euphemisms. One nurse remarked (R13) that doctors had a tendency to "pussy-foot" around the severity of the disease and did not tell patients exactly what was going on. As a result, some nurses felt that they had to do the doctor's job and explain the diagnosis to patients and relatives. Being able to clearly communicate the severity of the illness and not skirting around the issue was important to many clinicians. One EOL clinical lead nurse said:

"I think unless you've seen it, you don't appreciate how different heart failure is from cancer. Being quite wishy-washy about the conversation and the diagnosis does not help. You have to let patients know that they are going to die of heart failure and be quite strict; almost firm with how you say things. I know it's really difficult to tell them that they are going to die of heart failure – but they are. You are going to have to be quite clear with them and that it's not like on the TV." (R13)

According to one district nurse, euphemisms and assumptions were an all too common part of healthcare professionals' style of conversation and advocated using plain language with patients:

"*I have found that it's better to be honest and use plain language and avoid euphemisms and avoid assuming that you are both talking about the same thing. The*

worst thing is anticipatory medication. We talk about anticipatory medication like everybody knows what that means. What are we anticipating? We need to actually say what this medication is for." (R21)

Some GPs regretted that they were not more forthright in discussing the reality of dying from heart failure with the patient and relatives:

"*I sort of regret that I wasn't more forthright with them - really - and said, "You've just to go up—and go into her room and give her a hug every day. Don't let it be that her dying has never been discussed, because you will regret it for the rest of her life"* (R14)

While most acknowledged that undertaking ACP should be part of everyone's responsibility, it was evident that the required skills came only as a result of regular practice. High levels of competence and confidence in delivering ACP were usually the result of much exposure to managing patients with terminal illnesses, years of practice, a special interest in end-of-life care or working together with other like-minded colleagues. One GP put it like this:

"*The more conversations you have with different people in different scenarios with different challenges, the more you think you've got a bank of experience to draw from. And you know what went well or what went badly."* (R4)

Adapting to patients' expectations and being able to help them to make their own end-of-life decisions were additional interpersonal skills that facilitated the delivery of ACP. One GP said:

"*In end-of-life conversations, clinicians should learn to put their professional persona away and adjust to patients' expectations. My advice to professionals is: be more genuine, drop your professional person, and be human. EOL conversations are about empathy. Respond to patients in a genuine way. Try to be on the same level as they are. Suspend your own prejudice, beliefs and preconceived ideas."* (R16)

The danger of becoming too professional and losing sight of the entirely human-to-human interaction that took place between clinicians and patients when discussing death and dying touched on some aspects of their social and professional role.

The following examples summarise some key interview findings from the TDF Skills domain and illustrate how they informed the design of APT, the QPL and the CoC:

- "*I have found that it's better to be honest and use plain language and avoid euphemisms and avoid assuming that you are both talking about the same thing."* (R21) Having better EOL communicating skills including an appropriate use of language informed the content of the role-play as part of APT.
- "*In end-of-life conversations, clinicians should learn to put their professional persona away and adjust to patients' expectations."* (R16) Gaining practice in adapting to patients' expectations informed the skill of exploring patients'

need for information as part of the role-play (APT). Being skilled in empowering patients to make their own decisions and design their own care plans informed the training in how to use the QPL and CoC.

- "*The more conversations you have with different people in different scenarios with different challenges, the more you think you've got a bank of experience to draw from.* (R4) Gaining practice in delivering ACP in different scenarios informed the content of different role-play scenarios as part of APT.

5.4.3.3 Social/ professional role and identity

This domain described the main findings of the clinicians' role and identity and their social and group norms in regards to delivering advance care planning, death and dying and training in shared decision-making tools for end-stage heart failure. Providing ACP was seen by both GPs and nurses as an important part of their role and as an important task to get right. Delivering ACP and end-of-life care significantly contributed to their job satisfaction by providing holistic primary care. One GP (R19) said:

"I think these conversations are really important to have. For me, it's the kind of human side of general practice. This is the stuff that kind of matters. For me, it's trying to provide good quality care for people; care that is holistic and care that involves their families. I mean, it's a cliché, but you only get one chance to get it right. It's also really easy for it to go wrong. …But having these conversations, I find it really satisfying."

While all GPs and nurses acknowledged that death and dying were a common experience as part of their professional role, only very rarely were they comfortable with talking about death and dying with their patients. One GP expressed it like this:

"End-of-life can be quite a taboo subject for some doctors. It's something we are a bit frightened about. That clashes with the expectation of medicine - that medicine is about curing problems, about extending life. ...Nobody is stepping back, saying, 'You are dying, and shall we plan for that so you have a good death?'" (R2)

For one GP this was due to his perception that having an EOL conversation was equal to admitting the failure of medicine and his failure in the role as a clinician:

"I think it's very difficult if your lifetime approach has been around successes and length of life. It's almost an acknowledgement of the failure of medicine, isn't it, to have that conversation." (R10)

By contrast, one GP saw dealing with death and dying just as a normal part of his role and said:

"*Talking about death and dying is not an issue to me as doctor. Never has been. It's an inevitable part of being alive. We are fooling ourselves as well as our patients if we ever think it is not."* (R23)

However, some GPs and nurses thought that addressing death and dying was not only an uncomfortable aspect of their professional role but also culturally unacceptable. Choosing the weather as a socially more comfortable topic of conversation, this taboo was described by one GP as follows:

"*I think, not having an ACP conversation, is all very British, isn't it? It's not very… it's quite an emotionally charged thing to talk about. I think people feel more comfortable talking about the weather."* (R8)

When asking participants about facilitators to overcome these barriers and have an ACP conversation, one GP replied:

"*The easiest thing of all for me is when a patient asks us a question. And there have been instances where particularly sort of older gents were saying, "Is my time up?" That clear."* (R5)

A number of healthcare professionals concurred with that view and would welcome patients taking the initiative in asking them questions. Presented with an early version of a patient-led question prompt list (QPL), one nurse thought this would help her in knowing what to talk about:

"I think that's a really good idea. I would like that. If a patient came to me in clinic and handed me the list and said, "This is the question I have for you today of this list." That would really help me." (R7)

The following examples summarise some key interview findings from the TDF Social Professional Role and Identity domain and illustrate how they informed the design of the QPL:

- *"The easiest thing of all for me is when a patient asks us a question."* (R5) This quote seemed to affirm the benefit for clinicians of patients taking the initiative and asking them questions about their care.
- *"I think that's a really good idea. I would like that. If a patient came to me in clinic and handed me the list and said, "This is the question I have for you today..."* (R7) This clinician affirmed the use of the QPL as a means of enabling patients to take the initiative in asking questions about the kind of care they would like to receive.

5.4.3.4 Beliefs about capabilities (self-efficacy)

This domain described the clinicians' beliefs about self-efficacy and control as facilitators and barriers to perform ACP in heart failure. The belief of many clinicians was that delivering ACP in heart failure was possible, necessary but difficult. The perceived belief about their capability of delivering ACP was compared by some to "grasping the nettle" (R2) or "biting the bullet" (R1). One GP described the belief in his capabilities like this:

"Discussions around advance care planning are the more difficult conversations to have. I ask myself, "Do I want to be that person that if somebody is enjoying the here and now starts talking about the end-of-life. Obviously these are the harder things to talk about, because people don't necessarily want to be thinking about it." (R6)

Most clinicians believed that the use of tools like a QPL or a Choices of Care (CoC) Table would be facilitators by increasing their capability of delivering ACP in heart failure. One GP said concerning the early model of the CoC:

"I like it, because I think these are all the discussions that we have with patients. I literally had a discussion yesterday morning with a patient who was on his way to the Emergency Multidisciplinary Unit (EMU) for IV diuretics…. So, I think it is actually quite nice having it in black and white. They can mull it over, once you've gone, rather than them just remembering parts of the conversation that you've had." (R15)

While these tools were welcomed, some clinicians cautioned not to use them rigidly by allowing the conversation to degenerate into a tick box exercise. The conversation needed to remain person-centred and tailored to the individual patient. This could be achieved by using the Question Prompt List or Choices of Care Table as an aide that informed but not dominated the natural flow of conversation between a clinicians and a patient. One nurse emphasised:

"I find it helpful if prompts ask them about who they want at their bedside in their last days. Are there specific things they want to be treated for or not be treated for? They might want to be treated for a chest infection, or they don't want to be treated for it... Be sure that it's the patient's document and it's their plan and it's not the nurse's plan. We are looking at making documentation more personalised across the district nursing team." (R20)

All participants believed that further training in ACP, training in the use of corresponding tools like the Question Prompt List or the Choices of Care Table, and in conversations skills would increase their capabilities of delivering patient-centred end-of-life care in heart failure. Relevant facilitators to enhance their capabilities were training in specific end-of-life scenarios for heart failure, addressing clinical management issues, conversation skills practiced in form of role-play, learning from

peers or role models. Clinical experts who had the necessary expert credibility and could demonstrate best practice were seen as especially useful. In order for the training to be effective and sustainable, it needed to fit into existing educational programmes of GPs and nurses. Ideally the training should take place at their local surgery. In this way, the training would also reach those professionals, who normally would not attend a palliative care event.

The following examples summarise some key interview findings from the Theoretical Domains Framework domain Beliefs and Capabilities and illustrate how they informed the design of the Choices of Care Table and Question Prompt List:

- *Are there specific things they want to be treated for or not be treated for? They might want to be treated for a chest infection, or they don't want to be treated for it."* (R20) *"I literally had a discussion yesterday morning with a patient who was on his way to the Emergency Multidisciplinary Unit (EMU) for IV diuretics…. So, I think it is actually quite nice having it in black and white."* (R15) These quotes to discuss treatment options for a chest infection and UTI informed the design of the Choices of Care Table.
- *I find it helpful if prompts ask them about who they want at their bedside in their last days."* (R20) The question about who a patient wants to be involved in their care should they become seriously ill informed the design of the QPL.

5.4.3.5 Beliefs about consequences (anticipated outcomes/attitude)

This domain described the clinicians' beliefs about the consequences of using ACP as either a barrier or a facilitator for end-of-life care in heart failure. One of the big

barriers was the belief of clinicians that delivering ACP could irrevocably damage their doctor-patient relationship: A GP said:

"*My biggest fear was getting it wrong and upsetting the person and not being able to recover that and damaging the relationship and not being able to go there again. But actually, I watched my colleague do it a few times and it went badly and she recovered it and there are ways that you can still have a rapport with somebody and still help them to have that conversation, even if you've kind of messed it up to start with. We are all human, so you don't get it right every time."* (R13)

While being aware of possible negative consequences from delivering ACP, a number of GPs and nurses pointed out that these risks could be mitigated by their trust and longstanding relationship with patients. Knowing patients well created an underpinning foundation of confidence which acted as a strong facilitator for talking about end-of-life issues. One GP contrasted the continuity of care with his patients to the more short-term nature of the patient-cardiologist relationship by saying:

"It's easier for us to have these conversations because we know our patients. We have a longitudinal relationship. We know the family. We've often got a lot of trust in the bank. And GPs on the whole are confident and competent at dealing with complex family psychosocial issues. And that's kind of what we do. So we are already a long way down the line." (R12)

The following example summarises some key interview findings from the TDF domain Beliefs about Consequences and illustrates how they informed the design of ACP Practice-Based Training:

- *"I watched my colleague do it a few times and it went badly and she recovered it and there are ways that you can still have a rapport with somebody."* (R13) This quote not only highlighted the importance of training in knowing if or when to initiate an ACP conversation but also having the opportunity to watch senior colleagues performing the ACP conversation. The theatre-style role-play as part of ACP Practice-Based Training accommodates this criterion where participants are able to observe an ACP conversation between the facilitators first before performing it themselves.

5.4.3.6 Intention, goals and optimism

These domains explored the barriers and facilitators to the intentions, motivations and goals of clinicians to practice ACP and use the Question Prompt List, Choices of Care Table and ACP Reminder Sheet for patients suffering from heart failure. It also refers to how high a priority and how strong a motivation the targeted behaviour was for participants and the potential they could see from the intervention. Many clinicians saw end-of-life care in heart failure as synonymous with providing holistic care which, in itself, represented a strong motivation to do the job. One GP said:

"I think for GPs on the whole, the thing that floats their boat, is an idea of holistic care. It is the idea of not just firefighting the moment, but actually thinking about a broader definition of health." (R21)

Being able to provide holistic care was not only a strong but a defining reason for some nurses to go to work. One district nurse explained:

"*I think end-of-life is what every district nurse goes to work for. We do like the other little bits and pieces that we do, but if they were going to take end-of-life away*

from us, I think we would all be up in arms. If they took bloods away, that's fine. Not end-of-life. For me, that's a privilege." (R24)

Many GPs and nurses perceived delivering good end-of-life care and ACP as "hugely rewarding," "satisfying" (R17) or as a "privilege" (R19). Managing the complexity of a "good death" significantly added to their job satisfaction and strengthened their motivation to deliver clinical services. One GP said:

"*ACP is time-consuming, but rewarding. I think if you end up with a good death, whatever that is, then it's something that's worth doing."* (R12)

Achieving a "good death" was also an important goal for another GP (R5). Attaining a good death took the form of dying at home surrounded by family for one of her patients:

"She had no further hospital admissions. She died peacefully at home with her family around her and that was all good." (R5)

Another goal of some GPs and nurses in delivering ACP was to prepare patients and the family for unforeseen complications of the disease and to clarify their expectations and end-of-life care preferences. One GP reached that goal by asking the patient a set of questions:

"*What is it you expect and what do you think is going on? Have you asked the consultant this and have you got a list of questions for the consultant? What do you really want? What's the balance for you around length of life versus quality of life?"* (R10)

A number of GPs and nurses perceived early versions of the Question Prompt List or Choices of Care Table as suitable tools to achieve that goal of clarifying and documenting patients' end-of-life care preferences. For example, one GP said about the contribution of the Question Prompt List:

"That list really helps the clinician to know where the patient is at, what they want, what questions they have and what is important to them. It is really helpful." (R22)

The following examples summarise some key interview findings from the TDF domain Intention, Goals and Optimism and illustrate how they informed the design of the Question Prompt List:

- *"What do you really want? What's the balance for you around length of life versus quality of life?"* (R10) This quote informed the design of a question of the Question Prompt List that clarified the balance between length of life and quality of life.
- *"This really helps the clinician to know what questions they have and what is important to them."* (R22) This quote affirmed the design of questions in the Question Prompt List to help patients identify what they wanted from their care and from their clinician.

5.4.3.7 Memory, attention and decision processes

This domain looked at memory, attention and decision processes as facilitators or barriers to implementing ACP for patients suffering from heart failure. Given that

implementing ACP is considered good practice for patients in their last phase of life, one might assume that clinicians perceived ACP as a routine procedure, a task they normally would carry out when caring for a patient with advanced disease. Many GPs and nurses supported the assumption that they were aware of the need of undertaking ACP in patients suffering from heart failure. However, one GP (R19) admitted that "*there are probably more appropriate patients out there than we are doing ACP for."* The competing demands of their job, "*the tyranny of the urgent*" (R2), the sensitive nature of the topic seemed to distract from the attention of when, how and for whom to implement ACP. One GP described the pressures of work affecting his decision-making process of implementing ACP like this:

"*I think the team work and the skill sets are there, but in the hustle and bustle and chaos and demand of the job… A lot of important things like care planning, following through or developing care plans and following through on care plans gets lost in the midst of things that just seem more urgent."* (R2)

However, GPs and nurses also described a number of existing methods that helped them in their decision-making about having ACP conversations. Their techniques ranged from identifying patients through palliative care registers, registers listing all patients who had unplanned admissions or by asking themselves "the surprise question" as one GP explained:

"*If you look at their medical history and if you look at their drug history and if you look at other features and if you look at their age and the chances of them dying in the next year. And if you ask yourself the surprise question: "Would you be surprised if this patient died in the next year?" And your answer is: "Actually, no!" You can identify a number of suitable patients."* (R6)

When asking a heart failure nurse, what would help her most in deciding whether to implement ACP for a patient or not, she replied:

"I very much believe in using templates before consultations in specific areas. But the templates don't always give you the wording to communicate well with patients. And so, that's perhaps something that could be developed. … When you are discussing a patient, a template that covers each individual patient's palliative care needs which can be completed during the meeting - that would be a useful tool." (R3)

The following examples summarise some key interview findings from the TDF domain Memory, Attention and Decision Processes and illustrate how they informed the design of the ARS:

- *"I very much believe in using templates before consultations in specific areas. But the templates don't always give you the wording to communicate well with patients. And so, that's perhaps something that could be developed."* (R3) This quote contributed to the design of a template for clinicians that included appropriate phrases to communicate ACP with patients. These quotes became part of the ARS.
- *"A template that covers each individual patient's palliative care needs which can be completed during the meeting - that would be a useful tool.* (R3) This quote indicated that part of the content of such a template should summarize the patient's palliative care needs. Ideally, a clinician should be able to complete that template during one meeting.

5.4.3.8 Social influences (norms)

This domain addressed social influences as a potential barrier or facilitator for optimising the implementation of ACP among clinicians in heart failure. One significant professional barrier for not implementing ACP in primary care was a perceived hierarchy gap between GPs and cardiologists. Published literature predominantly described a hierarchy gap between doctors and patients as a barrier for delivering ACP[38], but until now there had been a comparative paucity of qualitative data analysing barriers that exist between GPs and cardiologists.

Many GPs thought that the cardiologist was the clinical expert and should therefore be making end-of-life decisions in heart failure. GPs feared undermining the role of their secondary care colleagues by initiating an ACP conversation with a heart failure patient or by even suggesting to a cardiologist to consider such a conversation. They thought the recommendation would amount telling a cardiologist what to do. One GP described a strong sense of deference towards cardiologists as a reason for not having end-of-life conversations with heart failure patients:

"*I think the relationship could be a lot better between cardiologists and GPs. Cardiologists need more prompting to acknowledge when people have very advanced heart failure in conversations with the patient as well as in the letter to the GP. They should give the GP permission to have an end-of-life conversation. I think a lot of cardiologists would be surprised that that is the case, that GPs might feel they need permission, in a sense, to have that conversation. I think a lot of cardiologists would be surprised and think, the GPs know the patients, and they have an ongoing relationship, whereas we are just involved in this short period of time. Therefore, it's more appropriate for the GP to initiate that conversation."* (R9)

In addition to the above barrier, there was a different approach to treatment by cardiologists. Generally, GPs recognised when a curative approach to treatment had run its course and palliative measures should be considered. GPs voiced their frustration that cardiologists tended to persist with a merely interventionist approach to end-stage heart failure and by doing so, they not only evaded its palliative dimension, but denied patients the chance to talk about their end-of-life wishes. One GP said:

"I recognise that the letters from cardiologists to GPs are very much focused on we could try this tablet, and we can reduce this tablet or we can try this device; rather than any sort of written recognition that this person is very unwell now…. It's skirting around the issue isn't it? It's not really saying it directly." (R9)

In order to overcome that barrier of social deference, we explored which facilitators could overcome that obstacle. GPs and nurses saw timely inter-professional education between them and their secondary care colleagues as a significant enabler to have an ACP conversation. Ideally, the prompt to have an end-of-life conversation should come from the cardiologist or the heart failure specialist nurse since they were seen as the subject experts. One GP (R8) said:

"I would find it incredibly helpful to receive from a cardiologist or heart failure specialist nurse the information that they are happy for me to have an end-of-life conversation with a patient. …Having the sort of permission to do that would actually be really helpful, because it would make me say, "Okay, good, they think that there is not much else that can be done. She's on maximum medical therapy to help and this is about, you know, the focus is on managing symptoms and that's just so

much of an easier conversation if it feels like we are all sort of singing from the same hymn book."

Participants suggested a number of ways how cardiology could "empower" GPs to have these conversations with heart failure patients. These approaches included better networking across palliative, secondary and primary care services including community matrons. Another solution was creating a prompt for clinicians in discharge summaries, patient notes or patient passports that highlighted the importance of having an ACP conversation. A nurse suggested:

"The discharge summary can have a box which serves both as a prompt and as a means of communication between the cardiologist and the GP saying, 'Has any end-of-life conversations gone on?' Wouldn't that be good?" (R5)

The following example summarises some key interview findings from the TDF domain Social Influences and illustrate how they informed the design of the ARS:

- *"I would find it incredibly helpful to receive from a cardiologist or heart failure specialist nurse the information that they are happy for me to have an end-of-life conversations with a patient." (R8)*
- *"The discharge summary can have a box which serves both as a prompt and as a means of communication between the cardiologist and the GP…" (R5)*

  Both of these quotes informed the design of a communication prompt box between GPs and cardiologists on the suitability of having an ACP conversation as part of the ACP Reminder Sheet.

5.4.3.9 Environmental context and resources (environmental constraints)

This domain explored the availability and accessibility of resources to perform ACP and use the intervention tools as barriers or facilitators to optimise the implementation of ACP. A major theme and barrier for many GPs and nurses was the lack of sufficient opportunity, continuity of care and time to undertake ACP. One GP said:

"*I think the skills are there, but the time isn't. Responding in a timely manner or having enough time to do the complex work is very difficult."* (R1)

GPs in particular mentioned a number of reasons for having only very limited opportunities to deliver ACP in heart failure. For example, one GP explained that the OoHs system did not make much allowance to undertake ACP due to limited human resources, lack of access to IT systems and time constraints:

"The services that are available to look after it in terms of specialist services have very limited availability and limited continuity with the Out-of-Hours period. I think that's a true failing of the NHS as it is currently organised and urgently needs to be addressed." (R1)

Recently qualified GPs or salaried GPs felt that they had little experience in end-of-life care mainly due to a lack of exposure and continuity of care with relevant patients. As a result, there was a sense of a loss of ownership of these patients since they tended to be part of another colleague's list as one salaried GP explained:

"I don't feel I've got ownership of these patients. They are not on my list and they are not coming to me every time. I haven't got that relationship with them. They are somebody else's patient and they come and see me only occasionally." (R13)

Contributing to a lack of continuity of care were also national trends in General Practice where more doctors were going part-time. One GP remarked:

"One of the particular reasons why it's hard for me to manage patients in their last phase of life is because I am not in the surgery very often. Undoubtedly, it would be a lot easier if I would be in the practice every day of the week. But that is not the way General Practice is going - people are going more and more part-time." (R8)

A lack of time was indeed seen by many GPs as well as nurses as an important barrier to deliver ACP. A number of GPs thought that district and heart failure nurses were particularly well placed to have these difficult conversations since their role gave them a little bit more time. As one GP said:

"*Some GPs have only got unfortunately their ten minutes slot appointments and they have got to try and get all the information out in that time. They can be a bit brusque with too much medical terminology for the patient."* (R7)

Given these barriers to time and continuity, a number of GPs and nurses identified practical ways to address them and facilitate ACP even in the context of their busy, clinical practice. Importantly, there was a general consensus amongst participants that these conversations could not be rushed and were, by nature, time intensive as one GP said:

"You are not going to do it in ten minutes. It's going to take you two hours to do this properly. You just have to make it work. I know it's difficult." (R12)

A popular option for GPs to create more time was to have an ACP conversation in the context of a home visit as one GP described:

"*I think having two hours, one and a half to two hours after surgery to go and see this family was vital to have a successful end-of-life conversation. I see these kinds of patients after work or on the way home. It was helpful to have as much time as we needed to discuss these things. We continued with the discussion until it naturally came to an end. That is incredibly valuable."* (R4)

If going on a home visit was not feasible, GPs suggested to book double appointments or sequence appointments to initiate and conduct ACP conversations. According to one GP (R12), sequencing appointments had also the benefit of spreading the emotional burden of such a sensitive topic.

The following examples summarise some key interview findings from the TDF domain Environmental Context and Resources and illustrate how they informed the design of the APT:

- "*I think the skills are there, but the time isn't. Responding in a timely manner or having enough time to do the complex work is very difficult."* (R1) "*I think having two hours, one and a half to two hours after surgery to go and see this family was vital to have a successful end-of-life conversation. I see these kinds of patients after work or on the way home."* (R5) Teaching clinicians on how to create the time and opportunity for ACP by booking home visits, double appointments or follow-up appointments informed part of the content of APT.
- *"I don't feel I've got ownership of these patients. They are not on my list and they are not coming to me every time."* (R13) This barrier informed part of the content of APT where participants were encouraged to identify issues around

continuity of care and the most suitable medical staff in their organisation to have ACP conversations.

5.4.3.10 Emotion

This domain described stress, fear and other emotional responses (positive or negative) that could be caused by delivering ACP and using the tools acting as potential barriers or facilitators to improve the implementation of ACP. This domain might have intersected with the domain on beliefs about consequences. To avoid any confusion, I applied this domain primarily to the emotions of healthcare professional when delivering ACP.

Many GPs and nurses indicated that their own fear of death and dying may be one of the most powerful barriers why they do not engage with ACP in heart failure. One nurse described her corresponding emotions like this:

"*But what makes this conversation tricky is the fear of death, both the death of our patients and our own deaths, which I think varies subconsciously for most of us. The biomedical approach which I think still sees death as a failure, as an enemy rather than a natural part of life."* (R14)

The unpredictable nature of heart failure triggered additional fears in GPs and nurses. That fear was caused by a perceived lack of confidence and competence in managing the complexity of the disease. One GP said:

"Time is a secondary issue which is usually about fear of how to do it and fear you don't have the confidence and the competence to do it. …In cancer there tends to be a steady decline compared to heart failure. I am sure that creates a fear in us of not really knowing what will happen." (R12)

Experiencing fear when dealing with end-stage heart failure was not only confined to GPs alone but also affected specialist palliative care nurses as one district nurse described:

"I've worked with so many Macmillan nurses who have not done their job, because they've not told the patient what's going to happen or been quite honest with them, because it's been quite scary for them." (R7)

One GP offered a possible way for clinicians to manage their own emotions and fears in a more effective way by accepting the limitations of modern science and medicine and regarding death as an end point of life:

"As a professional, it can be quite difficult to start having a conversation about end-of-life care. And that's partly due to the fact that end-of-life can be quite a taboo subject for some doctors. It's something that people might be a bit frightened about. It clashes with the expectations of medicine; that medicine is about curing problems, about extending life. There is almost a disconnect from the fact of that one absolute certainty - life will come to an end. And that doesn't seem to be currently within our medical culture as a topical conversation and dialogue. People don't talk about the fact that science has its limitations and medicine has limitations…. Nobody is stepping back and saying, you are dying and shall we step back and look at how we plan for that so you can have a good death?" (R2)

The following example summarises some key interview findings from the Theoretical Domains Framework domain Emotion and illustrate how they informed the design of the ACP Practice-Based Training.

- "*But what makes this conversation tricky is the fear of death, both the death of our patients and our own deaths, which I think varies subconsciously for most of us."* (R14) That quote informed the training of clinicians in how to address the fear of death and dying with patients suffering from heart failure. Acknowledging that the topic is a difficult subject to address and how to manage expectations became part of the role-play of ACP Practice-Based Training.

5.4.3.11 Behavioural regulation

This domain explored any approach as a barrier or facilitator that was aimed at managing or changing objectively observed or measured clinicians' performance of implementing ACP in heart failure.

Some GPs perceived the monitoring of their own performance, for example, through audit and feedback as useful but warned against incentivising the delivery of ACP in heart failure:

"I think incentivising ACP as part of Quality and Outcome Framework (QOF) would be very risky. Palliative care appeared in QOF temporarily and then sort of struck off again. I was quite pleased to see it go. I think once you incentivise and organise it to that level, the risk is of that which happened – a really useful tool becomes just another tick box exercise. Healthcare professionals stopped seeing the patient. They just started seeing the form. You end up with these horror stories about people having their hydration switched off and sedation without any conversation. So then the baby gets chucked out with the bath water and ACP is gone. I would be very, very resistant really to putting ACP back into QOF. I am not against QOF…. It's been

brilliant for things like secondary prevention. But now they want to stretch it into areas where I don't think it really works. If you are trying to reduce the population risk of preventing disease, I think it has worked brilliantly." (R4)

Clinicians were conscious that their existing behaviour needed to be adapted with the proposed complex intervention. They were aware that the Question Prompt List, the Choices of Care Table and ACP Reminder Sheet could serve as prompts and reminders for their new behaviour and were likely to support a timely and sensitive delivery of ACP in heart failure. One GP said:

"I think that these tools would be excellent. Not least of all to facilitate the conversation, because it is so much easier. So that's one of the pluses of that form. You could give it to the patient in advance and they could write quite a bit on it. And that gives them the opportunity to put as much or as little and tick boxes about what they did or didn't want to discuss. That really helps the clinician to know where the patient is at. It's really helpful." (R21)

The following examples summarise some key interview findings from the TDF domain Behavioural Regulation and illustrate how they informed the design of the Question Prompt List and ACP Practice-Based Training:

- *"And that gives them the opportunity to put as much or as little and tick boxes about what they did or didn't want to discuss. That really helps the clinician to know where the patient is at. It's really helpful."* (R21) This quote indicated the usefulness of the Question Prompt List for a clinician since it gave them an idea of when a patient wanted to discuss what.
- *"A really useful tool becomes just another tick box exercise. Healthcare professionals stopped seeing the patient. They just started seeing the form."*

(R4) This remark emphasised the need for training clinicians in how to use the shared decision-making tools and to avoid the danger of using them rigidly or as a tick box exercise.

5.4.4 Deviant Findings

There appeared to be no data that refuted the overall usefulness of the Question Prompt List, the Choices of Care Table, the ACP Reminder Sheet or the training package. One explanation for that could be that interviewees were looking to please the interviewer whose intervention they were discussing. However, there were initially dissenting voices about the complexity of the design and content of the Question Prompt List and the Choices of Care Table and the type of proposed role-play. So, participants' feedback helped to refine the intervention components. For example, one GP remarked that the level of detail on an early version of the Question Prompt List (**Appendix 20**) needed to be reduced:

> *"If you have lots and lots of questions, I think it can be quite off-putting, and it won't get done."* (R20)

Another GP had a similar view on the over-complexity of an early version of the ACP Reminder Sheet (**Appendix 21**). The first page of the tool was too densely populated with information. A visual checklist with essential ACP criteria as part of the ACP Reminder Sheet was perceived as a useful tool to facilitate self-monitoring of performance. However, such a monitoring tool should be straightforward:

"You can't document to the tenth degree the kind of conversations we are having. It needs to be a few boxes that are ticked, just as a guide, almost like a check list: 'Have you discussed this, this and this with the patient." (R22)

As a method in training clinicians to deliver ACP, one GP cautioned against using the traditional form of role-play and suggested an alternative:

"So they do 'Life Box Theatre' – I think they call it - or 'Forum Theatre'. Actors will perform a play or an interview or something, a sketch. You have to tell them what to do next. They will come across a conundrum with the sketch and you have to tell them: "I want you to do it in this form or in this way." So, you are directing the show in a way. From that people learn a lot, instead of doing all the role-play yourself which everybody hates doing." (R20)

Another clinician echoed this view against traditional role-play and for being able to learn by first observing others performing ACP conversations:

"The thing about role-play is that it puts you on the spot when you have to do it with colleagues. I think it is quite a painful experience. I think doing it differently, doing it like watching a video of somebody doing it and then discussing what good phrases they have used is a bit less threatening in some ways." (R8)

In summary, findings from the Deviant Case Analysis modified the content of the ACP Training (APT), Question Prompt List (QPL) and ACP Reminder Sheet (ARS) which included:

- Using theatre style role-play instead of the traditional approach to role-play (APT)
- Reducing the number of questions of the QPL to what is essential
- Reducing the amount of information that is included in the ARS

5.4.5 Summary of Interview Findings

The following section summarises the interview findings based on study objectives:

1. Thematic analysis of clinicians' experience in ACP
2. Intervention components clinicians recommend
3. TDF analysis to specify intervention mechanism of action

5.4.5.1 Thematic analysis of clinicians' experience in ACP

The thematic analysis identified five overall themes of clinicians' experience in ACP from the data to address our research objectives:

1. Benefits of ACP in Heart Failure
2. Barriers to ACP in Heart Failure
3. Fears of delivering ACP in Heart Failure
4. Facilitators of ACP in Heart Failure
5. Suggestions to optimise the implementation of ACP

Barriers, facilitators, fears and perceived benefits of ACP affected the experience of clinicians which informed their recommendations of which intervention components might improve their engagement with advance care planning in heart failure.

5.4.5.2 Intervention components clinicians recommend

Table 21 summarises key interview findings for intervention components clinicians recommend and how they relate to the different TDF domains

TDF Domain	Key interview findings	Recommended intervention prototype component
Knowledge	• training in EOL Care and ACP for heart failure • increase clinicians' knowledge base on disease-specific facts	APT
Skills	• skills in ACP and end-of-life communication • being able to adapt to patients' expectations • skills in helping patients to make their own decisions and design their own care plans • theatre style role-play, learning from peers and clinical experts • a sustainable training programme that fits into existing practice activities	APT
Social professional role	• patients should take the initiative in asking healthcare professionals questions about heart failure and their care • a tool that helps clinicians with identifying patients end-of-life care preferences	QPL QPL and CoC
Beliefs about capabilities	• the Question Prompt List or a Choices of Care Table were seen as facilitators to increase clinicians' capability of delivering ACP in heart failure • training in ACP and tools like the QPL or the CoC to increase clinicians' capabilities of delivering patient-centred care.	QPL and CoC APT
Intention, goals, optimism	• early versions of the QPL, CoC and ARS seem suitable to clarify and document patients' end-of-life care preferences and goals • QPL, CoC, ARS and APT were seen as positive factors to support clinicians in delivering ACP	QPL, CoC and ARS
Memory, attention, decision process	• a reminder sheet should include phrases for conducting an ACP conversation, all important criteria for ACP and preferred priorities of care in heart failure, a list of contacts for all clinicians involved in the care of that patient, links to resources on ACP, end-of-life care and heart failure, a box that facilitates communication between GPs and cardiologists	ARS
Social influences	• inter-professional support and a communication prompt between primary and secondary care colleagues	APT
Environmental context and resources (environmental constraints)	• double appointments, sequence appointments or go on a home visit in order to deliver ACP in primary care	Specifies the *context* for delivering ACP
Behavioural regulation	• the QPL, CoC and ARS seem to serve as prompts and reminders for the expected behaviour and facilitate a timely and sensitive delivery of ACP in heart failure.	QPL, CoC, ARS

Table 21. Summary of interview findings for the intervention prototype

5.4.5.3 TDF analysis to specify mechanisms of action

Designing the Theoretical Domains Framework Matrix addressed Step 3. of the Theoretical Domains Framework, "Forming possible solutions." In order to design the matrix, we asked the question, "Which intervention components could overcome the modifiable barriers and enhance the facilitators?" Based on interview findings, we identified behaviour change techniques and their mechanisms of action for each intervention component and connected these with Theoretical Domains Framework domains (**Table 22**). We found all 14 domains of the Theoretical Domains Framework to be relevant for barriers and eleven domains of the 14 domains to be associated with facilitators to optimise the implementation of ACP in heart failure. Recurrent Theoretical Domains Framework domains identified either as barriers or as facilitators were knowledge, skills, social and professional role, belief about consequences, belief about capability, emotions and environmental context and resources. We extracted 21 behaviour change techniques and mapped these to the Theoretical Domains Framework domains. For example, we mapped the behaviour change techniques "instruction on how to perform the behaviour" when undertaking ACP in heart failure to the Theoretical Domains Framework domain of "Knowledge" (Kn) which represented the information clinicians had to know about ACP, the rationale of delivering ACP and the evidence base for ACP in end-of-life care. In the same way, we linked the behaviour change technique "information about health consequences" when delivering ACP with the Theoretical Domains Framework domain "Beliefs about Health Consequences" (B Con) which described the clinicians' beliefs about the consequences of delivering ACP for patients suffering from heart failure. Behaviour change techniques content related to every part of the COM-B model, particularly psychological capability and reflective motivation. One of the

Using the TDF, which barriers and facilitators need to be addressed? (Step 2)	Within which TDF and COM-B domain(s) do the barriers and facilitators operate?		Which intervention components (behaviour change techniques and mode(s) of delivery) could overcome the modifiable barriers and enhance the facilitators? (technique, mode, content) (Step 3)
	*TDF	**COM-B	
Low awareness of the significance of ACP in heart failure and a lack of disease-specific knowledge and skills about conducting ACP among clinicians	Kn Sk B Con B Ca	C Ph C Ps M Re, M Au O Ph O So	BCTs: instruction on how to perform the behaviour, information about health consequences, demonstration of behaviour, behavioural practice, credible source Mode: ACP Practice-Based Training session (APT) facilitated by senior clinicians Content: expert clinicians in heart failure and end-of-life care present information about key aspects of ACP, and demonstrate and discuss best practice of conducting an ACP conversation. Participants are given the opportunity to practice ACP in role-play
Low awareness and skills in using tools like the QPL to explore patients' care preferences and start an ACP conversation	Kn, Sk S/P Id BR Env	C Ph, C Ps O Ph M Re M Au	BCTs: instruction on how to perform the behaviour, information about health consequences, demonstration of behaviour, behavioural practice, goal setting, prompts/ cues, credible source, adding objects to the environment Mode: Practice-based training session (APT) demonstrating the use of the QPL Content: expert clinicians presents information about the use of the QPL to explore care preferences. HCPs practice key components of using the tool to perform patient-centred ACP conversations
Insufficient communication skills to explore patients' expectations on End-of-life issues and empower them to make decisions about their own care	Sk BR Env MAD	C Ps O Ph M Re M Au	BCTs: goal setting (behaviour and outcome), problem solving, instruction on how to perform the behaviour, information about health consequences, demonstration of behaviour, behavioural practice, credible source, graded task, rehearsal, feedback on behaviour Mode: APT including three patient scenarios, each with a higher degree of difficulty in communicating End-of-life issues to patients suffering from heart failure Content: expert clinicians demonstrate patient scenarios using key phrases to demonstrate options in communicating End-of-life issues and empower patients. Participants discuss and practice these during role-play in small groups with feedback from facilitators
GPs' and nurses' perceptions of causing alarm when discussing End-of-life issues or disclosing the diagnosis of heart failure to a patient	Kn, Sk B Con Em Env MAD	C Ph C Ps O Ph, O So M Re M Au	BCTs: rehearsal, feedback on behaviour, adding objects to the environment, social support (practical), instruction on how to perform the behaviour, information about health consequences, demonstration of behaviour, behavioural practice, credible source Mode: APT including the usage of the QPL and CoC Content: expert clinicians demonstrate in role-plays how to use the QPL to identify patients' need for information and how to disclose the diagnosis. They demonstrate the use of the CoC to discuss possible End-of-life issues in heart failure and corresponding care options. Participants discuss and practice the usage of these tools with feedback from peers and facilitators
Delivering ACP as part of their role is seen as uncomfortable and difficult by clinicians	S/P Id Int, Opt Goal B Con	C Ps M Re	BCTs: information about emotional consequences, instruction on how to perform the behaviour, information about health consequences, salience of consequences, credible source Mode: APT including a segment of a case-based discussion on the impact of ACP on the quality of life of patients suffering from heart failure Content: expert clinicians share from their experience how ACP can improve the quality of life of patients suffering from heart failure and add to job satisfaction by providing holistic care. Case histories are meant to highlight the contrast between the quality of life between those patients who did receive and those who did not receive ACP
Competing demands, limited time and opportunities to have an unhurried ACP conversation with a patient	Env Sk Kn	C Ps M Re O So	BCTs: restructuring the professional environment, action planning, self-monitoring of behaviour, goal setting (behaviour and outcome), problem solving, instruction on how to perform the behaviour, information about health consequences Mode: APT including a reflective exercise on how to manage ACP in the context of competing professional demands Content: expert clinicians share tips on how to integrate ACP into daily clinical routine, for example, by spacing appointments or arranging home visits. Participants are encouraged to reflect on ways that suit their professional circumstances to generate more opportunity for ACP, create an action plan that records actions and details changes to their professional behaviour
Lack of continuity of care due to part-time work, OoHs or sessional work leading to a sense of loss of ownership in looking after patients suffering from heart failure	Env B Ca BR S/P Id	C Ps M Re O So	BCTs: instruction on how to perform the behaviour, information about health consequences, problem solving, action planning, self-monitoring of behaviour Mode: APT including a reflective session for participants to generate solutions for identifying opportunities for greater exposure to implementing ACP either individually or as an organisation Content: expert clinicians provide systematic approach in the form of an action plan to identify solutions for participants who want to increase their opportunities in undertaking ACP in their current roles

Table 22. TDF Matrix

Using the TDF, which barriers and facilitators need to be addressed? (Step 2)	Within which TDF and COM-B domain(s) do the barriers and facilitators operate?		Which intervention components (behaviour change techniques and mode(s) of delivery) could overcome the modifiable barriers and enhance the facilitators? (technique, mode, content) (Step 3)
	*TDF	**COM-B	
Clinicians' beliefs about the negative and positive consequences of practising in a manner consistent with palliative care guidelines for ACP in heart failure	B Con B Ca Kn	C Ps M Re	BCT: verbal persuasion about capabilities, credible source, instruction on how to perform the behaviour, information about health consequences, salience of consequences Mode: APT including a segment of a senior clinician sharing about the negative and positive consequences of patients having and not having advance care planning in place Content: senior clinician presents persuasive message about potential harms of not having an ACP (e.g. reduced physical and mental functioning of a patient after an unnecessary hospital admission); provides an example of how a patient was appropriately managed at home without a hospital admission
Difficulties in deciding who is an appropriate patient for ACP and what kind of ACP criteria need to be addressed	MAD Kn Sk BR	C Ps C Ph O Ph M Re M Au	BCT: self-monitoring of behaviour, instruction on how to perform the behaviour, information about health consequences, goal setting (behaviour), adding objects to the environment, restructuring the professional environment, credible source Mode: APT including a segment on training about how to use the ACP Reminder Sheet (ARS) Content: expert clinicians explains the ARS which can be used either in paper form added to patient records or as an electronic template as part of IT medical records. ARS facilitates ACP and monitors which criteria have been addressed and which are still outstanding
Fear, anxiety, positive and negative effects of conducting ACP with patients suffering from heart failure	Em SI Kn B Ca	C Ps M Re O So	BCT: social support (unspecified), goal setting (behaviour), instruction on how to perform the behaviour Mode: APT including a segment of a senior clinician sharing on emotional intelligence when conducting ACP with patients and carers Content: In small peer groups, participants reflect on their own fears and concerns when conducting ACP. With support from their colleagues, they are given the opportunity to generate better individual approaches to manage their emotions
*TDF abbreviations: Kn knowledge, Sk skills, BR behavioural regulation, SI social influences, Env environmental context and resources, Reinf reinforcement, B Cap beliefs about capabilities, B Con beliefs about consequences, S/P Id social/professional role and identity, Opt optimism, Goal goals, Em emotions, MAD memory, attention and decision processes, Int Intentions **COM-B abbreviations: C Ps psychological capability, C Ph physical capability, O So social opportunity, O Ph physical opportunity, M Re reflective motivation, M Au automatic motivation			

Table 22. TDF Matrix

most common Theoretical Domains Framework domains was knowledge. This domain was usually addressed by using behaviour change techniques like 'instruction on how to perform the behaviour' or 'information about health consequences.' Another recurrent Theoretical Domains Framework domain was 'beliefs about capabilities.' This domain was frequently linked with behaviour change techniques like 'demonstration of behaviour', 'behavioural practice', 'verbal persuasion about capability', or 'credible source.'

5.5 DISCUSSION

I was able to interview 24 clinicians from a diverse range of primary healthcare professionals including GPs and nurses with no, little or significant experience in end-of-life care and heart failure. The diversity of participants, their experiences and views generated valuable data and a remarkable depth of insight to inform the prototype of the intervention. Clinician interviews proved to be a suitable method to explore how a proposed, early model of the intervention might fit into the constraints of their highly pressurised jobs. For this to happen, I was able to identify what facilitators could be strengthened and what barriers needed to be overcome. The iterative intervention synthesis process resulted in the design of the intervention prototype consisting of a question prompt list, a Choices of Care Table, an ACP Reminder Sheet, and an ACP Practice-Based Training session.

5.5.1 Strengths and Limitations

5.5.1.1 Strengths and limitations to my role as an interviewer

There were a number of limitations to my role of conducting the clinician interview series. My familiarity with ACP and end-stage heart failure has influenced the way I facilitated individual interviews[305]. Given my clinical background and subject expertise, qualitative research would define my role as someone with an "insider's perspective"[306]. My experience gave me insight into issues affecting healthcare professionals in the implementation of ACP in heart failure. Subsequently, my specific knowledge may have allowed me to generate deeper findings by questioning areas of real relevance. Conversely, others may argue, that an "outsider's perspective" on the topic of ACP in heart failure may have facilitated a greater degree

of objectivity[307]. For example, a non-clinician as an interviewer might be less invested in the clinical goals of the project. This in turn may have generated, what some may argue, more authentic knowledge[308].

Having a reflexive and open approach to the interviews helped me to negotiate between these two potential limitations. Interviewees were aware that I was a GP with a special expertise in heart failure and ACP. There was a possibility that they may have been inclined to answer my questions in a socially acceptable way[43] by, for example, affirming the significance of carrying out ACP in heart failure even if they may have had reservations about the process. Therefore, I asked open questions to allow for an uninterrupted flow of replies which gave room for answers and emergent themes that I did not expect. I also used questions that were aimed at exploring the concerns that clinicians may have had when considering advance care planning. Their anxieties and apprehensions were clearly documented particularly under the Theoretical Domains Framework domains "Emotions", "Social Influences", and "Beliefs about Consequences."

Adopting a reflexive and open approach to the interview promoted an uninterrupted flow of replies but limited a systematic discussion of each intervention component with each participant. As a result, not each component was discussed with each participant. This approach included the risk of raising an intervention component with a participant if I thought they would be more interested in it. This in turn might have excluded those participants perceived as 'less interested' in an intervention component. Those participants might have given me possibly more critical feedback. However, *all* intervention components were discussed during the interview series and

presented to individual participants. Rigidly discussing each component with each participant would not only have exhausted interviewees but also significantly restricted the emergence of new or unexpected themes. I thought this chosen approach achieved a balance by not only ensuring sufficient breadth but also adequate depth in developing each component of the prototype.

5.5.1.2 Strengths and limitations of focussing on primary care clinicians

The interview sample included only clinicians from primary care. Their views, professional backgrounds and experience with ACP and heart failure was diverse and generated meaningful insight into the development of the intervention. However, secondary care clinicians like cardiologists were excluded from the interview study. Their experience and ideas about how to best implement ACP in heart failure may differ from their primary care colleagues. Therefore, additional qualitative studies are required to assess the suitability of the current intervention before findings could translate into a secondary care context. I plan to undertake these studies in the context of a feasibility cluster RCT (see Chapter 7) which will also explore the views of secondary care clinicians on the acceptability and feasibility of the intervention.

5.5.1.3 Strengths and limitations of using the TDF

The TDF facilitated an understanding of clinical behaviour, synthesised interview findings in a systematic way, specified intervention content and possible mechanisms of action, and informed the design of the prototype of the intervention. The Theoretical Domains Framework was very useful to analyse and code interview findings by providing a suitable framework for thematic analysis consisting of 14

domains. Once consensus on the meaning of domains and constructs was achieved, the framework enabled an efficient way of identifying barriers and facilitators relevant to the design of the intervention prototype. Barriers and facilitators could be mapped to the theoretical domains[89] and used in the design of behaviour change techniques and intervention components. In this way, I followed the recommendations of the MRC framework for theoretically informed interventions[89]. Most Theoretical Domains Framework domains were useful to understanding and exploring barriers and facilitators in advance care planning for heart failure and highlighted issues at an individual clinician, primary healthcare team or organizational level. This was a necessary first step in improving the intervention and its implementation to achieve better clinical outcomes[114].

Conversely, the Theoretical Domains Framework‘s centre of analysis focusses predominantly on barriers and facilitators of implementing the intervention. One purpose of qualitative research is to characterise the range and diversity of perspectives and experiences of participants in a rich and authentic detail to gain a deeper understanding of the phenomenon under investigation[269]. The framework narrowed the complexity of the phenomenon of ACP in heart failure on pre-defined distinct units of analysis, i.e. Theoretical Domains Framework domains and corresponding behaviour change techniques which facilitated only a low level of interpretation[270]. There seemed to be a risk that other emergent themes outside its scope were not sufficiently considered[269]. Reasons for that shortcoming might be the comparatively scant capacity of the Theoretical Domains Framework of researching the wider social, cultural, political or even historical dimension of the envisaged intervention[270].

I found that Theoretical Domains Framework domains are not mutually exclusive. For example, there is an acknowledged overlap between domains "Emotions" and "Beliefs about consequences"[113]. Some related barriers and facilitators could be allocated to a number of domains. Therefore, we took some time to address a potential variation in how we (LL, AMB, JM, MS) interpreted and used the framework. Reaching consensus on how the Theoretical Domains Framework is operationalized and used is a common problem reported in the literature[285, 305, 309]. This was also due to the fact that the original validation of the framework involves predominantly participants with a good understanding of psychological theory[288]. Consequently, I followed recommendations from previous authors[113, 310] and drew from the advice of researchers (LL, AMB) with a background and experience in health psychology.

At the time of writing, this was the first study that used theory-informed approaches to strengthen the development of interventions for the implementation of advance care planning in heart failure. The themes and domains of the Theoretical Domains Framework are analysed to determine gaps in the early versions of the Question Prompt List, the Choices of Care Table, the ACP Reminder Sheet, and the ACP Practice-Based Training. The content and design of these intervention components are modified as a result. No new intervention components were added to the prototype.

5.6 CHAPTER SUMMARY

The clinician interview series provided essential data to identify key ingredients and inform the prototype of the intervention. At first, five overall themes were identified that explored the experience of GPs and nurses with ACP in heart failure:

1. Benefits of ACP in Heart Failure
2. Barriers to ACP in Heart Failure
3. Fears of delivering ACP in Heart Failure
4. Facilitators of ACP in Heart Failure
5. Suggestions to optimise the implementation of ACP

By initially using a thematic analysis approach, I was able to preserve valuable data before focussing my analysis on intervention components to overcome the barriers to engaging with ACP in heart failure. Clinicians' recommendations shaped the content and design of the prototype of:

a. the Question Prompt List,
b. the Choices of Care Table,
c. the ACP Reminder Sheet,
d. and the ACP Training session

Following that, a more detailed analysis of recommended intervention ingredients and their possible mechanism of action were facilitated by using the Theoretical Domains Framework. The resultant Theoretical Domains Framework matrix synthesised behavioural change techniques, their content and mode of delivery, and linked these with corresponding Theoretical Domains Framework domains and the Behavioural Change Wheel. 14 domains of the Theoretical Domains Framework were found to be relevant for barriers and eleven domains to be associated with facilitators to optimising the implementation of ACP in heart failure. The most common Theoretical Domains Framework domains identified either as barriers or as facilitators were knowledge, skills, social and professional role, belief about consequences, belief about capability, emotions and environmental context and resources.

As a result of the interview findings, GPs and nurses made significant contributions that advanced the content and mode of delivery of the early model of the intervention into the prototype of the Question Prompt List, the Choices of Care Table, the ACP Reminder Sheet, and the ACP Practice-Based Training. **Table 23** summarises some of the most significant findings according to TIDieR criteria:

Com-ponent	Content	Timing	Provider	Format	Delivery
QPL	Contains essential questions about EOLC and heart failure for patients to ask themselves or their clinician	When CHF patients are stable, after or before significant changes in their status of health	Clinicians or Research Team	A patient-led tool, ideally not longer than one page	Education of patients and information provision by research team or clinicians
CoC	Describes a range of treatment options from curative to palliative in case complications occur	At significiant milestones in the disease trajectory of CHF patients	Clinicians	A shared decision-making tool, ideally not longer than one page	Education of patients by their clinician; training of clinicians in using CoC by course facilitators
APT	Training in CHF ACP disease specific knowledge, how to communicate ACP, how to use shared decision making tools; case scenarios	Ongoing, as part of clinicians' continuous professional development	Senior clinicians with expertise and credibility	Practice-Based outreach, incld. role-play, lasting less than three hours	Education, persuasive communication, model behaviour to clinicians by facilitators
ARS	Contains core quality criteria of ACP in heart failure, communication tips, links to resources	Ongoing, as part of the professional work/ IT environment	Research Team	As part of paper medical records or as part of the local IT system	Restructure the physical environment and provide opportunities for clinicians to engage with ACP

Table 23. Components of the intervention prototype

In view of the above, there appeared to be no disconfirming data about the general concept of ACP in heart failure or any deviant findings about the overall usefulness of the proposed intervention. Dissonant findings from the interview series related more to the level of detail that should or should not be included in the different intervention components in order to make them useful for clinical practice. While clinicians confirmed the emotional impact that ACP conversations had on them (see TDF Domains Social/ Professional Role and Identity; Beliefs about Health Consequences and Emotion), they also affirmed that a tool like the Question Prompt List had the potential to relieve some of their fears when talking to patients about end-of-life issues. Similarly, the Choices of Care Table in the form of a shared decision-making

tool was welcomed by GPs and nurses because it provided a platform to consider all available treatment options with their patients. Given the paucity of shared decision-making tools in heart failure[87], the need for their development seemed confirmed by these interview findings.

As a result of this iterative synthesis process, I achieved the design of the prototype of the intervention. It was now important to broaden the scope of stakeholders by also seeking the perspectives of patients and carers to refine the intervention components and their context. This was the overall aim of the following focus group study.

CHAPTER SIX

The Final Version of the Intervention

6 THE FINAL VERSION OF THE INTERVENTION

6.1 BACKGROUND

After having obtained the input from healthcare professionals on the intervention during the previous interview series, I needed to investigate a broader view on the issues surrounding the intervention to optimise the implementation of advance care planning (ACP) in heart failure. To achieve a 360-degree perspective and refine intervention components, I wanted to explore the views from patients and carers, healthcare commissioners, primary and secondary care clinicians and researchers. I had particularly hoped to identify patients' and carers' opinions on the suitability of the intervention at different stages of the disease and inquire about its possible timing of application and impact based on their values and experiences[129]. There was little research evidence on patients' and carers' views of using tools like the Question Prompt List (QPL) or the Choices of Care Table (CoC) to facilitate ACP for heart failure[23]. I had hoped that findings from focus groups with patients and carers would provide useful data to best help clinicians in working together with their patients to plan for holistic end-of-life care[255]. Focus groups were seen as an appropriate approach to stimulate discussion and reflection among participants[259]. That method was also particularly valuable for debate[311] to build on insights from the previous 24 interviews, to refine the intervention components and provide an environment for topics to emerge to which participants may not have given much advanced consideration[126, 238].

6.2 AIM AND OBJECTIVES

The aim of the focus group study was to refine four distinct intervention components and synthesise the final version of the intervention by including relevant key stakeholders.

. The objectives were as follows:

- To achieve a 360-degree perspective on the suitability of the intervention by exploring the views of all key stakeholders
- To identify patients' and carers' opinions on the acceptability of the intervention components at different stages of the disease and inquire about its possible timing and impact based on their values and experiences
- To improve the completeness of intervention reporting and refine each component to allow for implementation in a clinical trial by using the Template for Intervention Description and Replication (TIDieR) as a guide

6.3 METHODS

Focus groups make the most of the communication between research participants in order to generate data[126]. Hence, that methodology provided an opportunity to tap into interpersonal communication between participants and their different or similar views on heart failure and perception on the suitability of the intervention. It was my responsibility as a group moderator to ensure that all who wanted, could voice their views[312]. One known disadvantage of focus groups was the fact that this format could silence individual voices of dissent[313]. I was therefore careful to keep patients and carers and clinicians in separate groups. Patients might have otherwise felt intimidated by GPs and nurses and held back with their views and answers[314].

Similarly, healthcare professionals may not have openly discussed their fears about the impact of ACP on their relationship with patients if they had been present[315].

6.3.1 Composition of Focus Groups

The following describes the main composition of the focus groups and their objectives:

Focus Group 1: Patients with heart failure and their carers

The patient sample was taken from our key target group: people suffering from heart failure and their carers. I have addressed the advantages and disadvantages of combining patients and carers in the discussion section of this chapter. We aimed at recruiting between five to seven patients and/or carers per group who were affected by heart failure. A participant information sheet in plain English describing the purpose of the focus group and the proposed intervention was made available to participants before the group meeting.

Focus Group 2: Healthcare professionals

Healthcare professionals (n=5-7) were sampled from local GP practices, the Cardiology Department of Oxford University Hospital Trust (OUH) and a Hospice that is part of the OUH. The aim of this group was to discuss and take forward findings from the patients' and carers' focus group(s) and to better understand how the intervention may warrant modification in order to fit more closely with the complexities and realities of their clinical practice.

Focus Group 3: Researchers, clinicians and commissioners

The aim of this third focus group was to bring together findings from preceding focus groups and discuss how these might inform the final version of the intervention. A

purposive sample of clinicians, commissioners and researchers was sampled from professional contacts in the Nuffield Department of Primary Care Health Sciences (NDPCHS).

The minimum number of meetings for each focus group depended on when theoretical saturation of themes was reached after coding and analysing transcripts[12]. We expected that this process would take a minimum of 2-3 meetings for each group. The upper limit of numbers of focus groups (maximal 4-5) depended on results from our interim analysis indicating whether a different group composition was warranted.

6.3.2 Inclusion and Exclusion Criteria

Patients who were older than 18 years of age and had the mental capacity to consent were included in the study as well as their carers who were affected by heart failure. Patients who suffered from congenital heart disease were excluded from the study because their experience of heart failure was significantly different from that of non-congenital onset of the disease. The research ethics committee thought that this patient cohort could have adversely affected the data saturation. Additionally, we did exclude participants who did not adequately understand English since the format of a focus group setting did not lend itself readily to making use of an interpreter. Moreover, this research did not involve participants who were unable to represent their own interests or were particularly susceptible to coercion, such as vulnerable individuals. We included healthcare professionals from primary, secondary and community care as well as researchers and healthcare commissioners. We did not exclude a clinician who previously was part of the interview study and wanted to

participate in a focus group. The study was reviewed by IDREC and granted ethics approval (**16/SC/0300**). Written consent was gained from all study participants.

6.3.3 Recruitment

Patients, clinicians and researchers were recruited using a purposive sampling approach aiming for maximal variation of participants. As such, we looked for patients, carers and clinicians who were willing to participate in the study, had prior knowledge or experience with heart failure and advance care planning and were able to communicate their experiences and opinions in an understandable way. Their names were chosen from a list of participants who had registered a prior interest as a response to an invitation in person or advertised through local networks. Participants came generally from GP surgeries across Thames Valley or through professional contacts through the NDPCHS. We had contacted approximately 30 participants about this study. Recruitment material as illustrated in our participant information sheet (**Appendix 22**) did not make any therapeutic promises.

6.3.4 Focus Group Process and Materials

Focus groups with patients, carers, clinicians, researchers and healthcare commissioners took place during the summer and early autumn of 2016. We met either at a GP surgery or at the NDPCHS. Participants had received study information, consent forms and reply forms prior to the meetings. Participants were made aware that I was a GP with clinical experience and specialist knowledge in palliative care, heart failure and advance care planning. During the first part of the focus group, I facilitated an uninterrupted and natural flow of exchange between group members by initially asking a set of open questions. These questions were part of a topic guide (**Appendix 23**) and were refined during the first meeting of each

focus group. Some of these questions focussed on participants' experience with ACP and heart failure. During the first segment of the meeting, I tried to interrupt as little as possible and facilitate a natural flow of communication. In a subsequent more focussed part, I used my expertise to elicit deeper reflections from participants on proposed intervention components like the QPL, CoC or ARS. The emphasis in focus groups with patients and carers commonly centred around their own experience of living with a serious illness, how they experienced interacting with medical professionals and how the QPL or CoC might help them. The discussion in focus groups with clinicians, researchers and commissioners looked to explore constraints in the delivery of clinical services, the acceptability, the right context and timing for using these tools. We used specific examples from their professional practice and how the proposed intervention components might help them to engage with ACP during their daily routine.

6.3.5 Data Collection

All focus groups were audio-recorded, fully transcribed verbatim and checked for accuracy. After five focus groups, the last being the ones with clinicians, researchers and commissioners, we felt that the data had approached saturation since no new themes emerged. Additionally, there seemed to be a high rate of recurrence of topics from previous groups[296]. Again, we used study IDs to preserve the anonymity when individuals were cited.

6.3.6 Analysis

The analysis of focus group findings consisted of three analytical steps:

1. Thematic Analysis
2. Analysis according to TIDieR
3. Deviant Case Analysis

1. Thematic Analysis

On completion of the first meeting of each focus group, audio recordings were transcribed and analysed using a thematic analysis approach. Accordingly, I reviewed and coded textual data into themes using NVivo qualitative coding and data analysis software[299]. We (JM, MS) reviewed samples of the coding to seek agreement on emerging themes. As part of the iterative process of analysis, I compiled and analysed all transcripts together to consider the emergence of any new themes after each meeting of each focus group. One aim of this interim analysis was to provide me with an indication whether the recruitment of an additional focus group with a different group composition may have been warranted. This may have highlighted the emergence of additional themes to be explored. We (JM, MS) discussed emergent themes which informed an early coding framework that grew as the analysis progressed. In the process of coding themes from focus groups, we re-examined and refined our categories as confirming and disconfirming data was added. Additionally, we reviewed findings from the interview and retrospectively analysed data if it contributed to the refinement of the intervention. Quotes from focus group participants are signified with "F", statements from interview findings are denoted with "R." This process ensured the credibility and confirmability of the data. Once we concluded the thematic analysis, we coded data according to the TIDieR categories.

Again, we (JM and MS) discussed and re-examined our coding categories. As a result, this process of analysis allowed me to shape the components of the final intervention.

2. Template for Intervention Description and Replication (TIDieR) Analysis

While thematic analysis captured a range of emergent themes[298, 316], the TIDieR approach was used to achieve the refinement of the final intervention components[317]. The 12 item TIDieR checklist, as described in Chapter One, enabled the explicit reporting of the QPL, CoC, the ACP Reminder Sheet (ARS) and the ACP Practice-Based Training Session (APT) to allow for implementation and replication in a future randomised controlled trial[103]. TIDieR addressed the design for intervention components by including intervention parameters that were not the explicit focus of the previously used Theoretical Domains Framework or Behaviour Change Techniques[113, 310]. These parameters addressed, but were not limited to, procedures, infrastructure, timing and intensity of the intervention[103]. Procedures predominantly referred to the sequence of steps to be followed to carry out the intervention. Infrastructure largely addressed the provider for the intervention and the suitable locations where the intervention was supposed to occur. Timing explored when each intervention component was best delivered to patients suffering from heart failure. Intensity denoted the duration, number and schedule of sessions to deliver the intervention to patients and healthcare professionals. **Figure 22** gives an overview of how the process of thematic analysis informed the synthesis and refinement of the final version of the QPL, CoC, APT and ARS according to the following TIDieR

criteria: 1. Rationale and Mechanism, 2. Materials, 3. Procedures, 4. Provider, 5. Modes of Delivery, 6. Timing and Intensity.

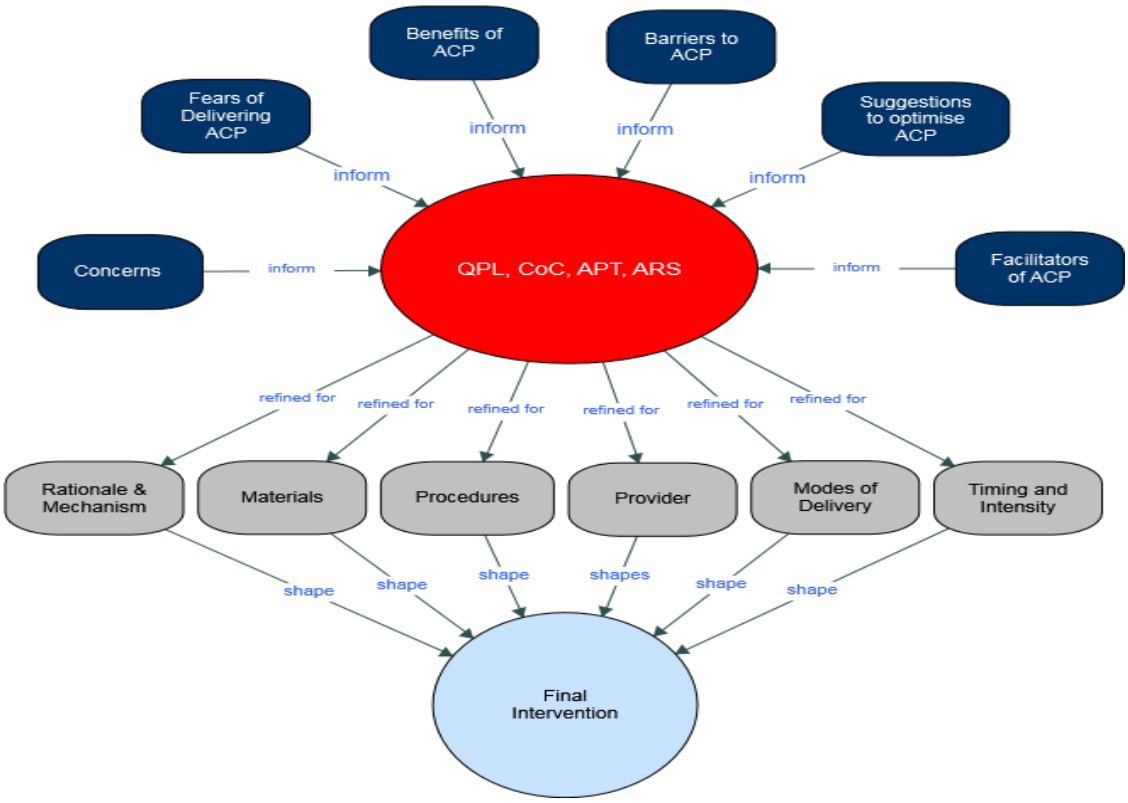


Figure 22. Analysis process of the final intervention

Appendix 24 provides an example of an individual coding structure by node according to TIDieR and a related word cloud for a clinician focus group that informed the refinement of the intervention. This chapter shows segments of each intervention component that underwent significant changes as a result of qualitative findings. The next chapter shows each intervention in its entirety. Many intervention segments largely remained unchanged because participants affirmed their design and not because I discounted their feedback.

3. Deviant Case Analysis

As with analysing interview findings, I was retrospectively looking for deviant cases in the qualitative data from the focus group study that did not conform to the findings of the overall analysis[318]. Again, I attempted to achieve that by mainly two ways:

a) Actively seeking out those focus group findings that did not conform to my expectation of the usefulness of the intervention components to optimise the implementation of ACP in heart failure

b) Involving a reviewer (JM) from a different research background to improve the potential of identifying disconfirming cases and increasing reflexivity[304].

6.4 RESULTS

A total of 22 people participated in the focus group study. The majority of all participants were patients/ carers and female (**Table 24**). Overall, five focus groups were held, each lasting between 90 and 120 minutes. Patients and carers met on two occasions. Healthcare professionals participated in two focus groups. A mixed group consisting of clinicians, researchers and commissioners took place once. No participant became unduly distressed or complained. All were able to complete the group sessions.

Sample	n = 22 participants recruited
Composition of sample	10 (45.45%) patients and carers from local General Practices and through the NDPCHS PPI Network 8 (36.36%) clinicians from Oxford University Hospital Trust and Oxfordshire General Practices 4 (18.18%) researchers and healthcare commissioners through the NDPCHS
Sex	Patients: female (n=5), male (n=5) Clinicians: female (n=5), male (n=3) Researchers and commissioners: female (n=2), male (n=2)
Ethnicity	22 (100%) White British
Median age (range)	Patients: 64.4 years (55-87 years) Clinicians: 53.25 years (44-69 years) Researchers and commissioners: 54.75 years (50-56 years)

Table 24. Characteristics of focus group participants

6.4.1 Thematic Findings

Six themes emerged from the thematic analysis which included the previous five themes from the interview series plus an additional theme named “Patient Concerns:”

1. Benefits of ACP in Heart Failure
2. Barriers to ACP in Heart Failure
3. Facilitators of ACP in Heart Failure
4. Professional fears of delivering ACP in Heart Failure
5. Suggestions to optimise the implementation of ACP in Heart Failure
6. Patient and carer concerns

6.4.2 Intervention Synthesis According to TIDieR

The following section describes how the statements from the focus group participants (F) and, where relevant, from the interviewees (R) refined each of the four intervention components:

1. The Question Prompt List (QPL)
2. The Choices of Care Table (CoC)
3. The ACP Reminder Sheet (ARS)
4. The ACP Practice-Based Training Session (APT)

6.4.3 Synthesis of the Question Prompt List

The prototype of the question prompt list was refined according to the following TIDieR criteria:

6.4.3.1 Rationale and Mechanism

While most clinicians from the interview series welcomed the idea of a QPL, it was now imperative to explore patients' and carers' views on the question prompt list. One patient explained the rationale for using the QPL:

"I would expect a doctor to make such a tool available to me because it empowers me. It gives me a chance to clarify my choices. You know where you are at, although you appreciate the doctors have a fear not to upset patients, but I would say that it is actually in the best interest of the patient." (F14)

A number of patients and carers expressed slightly different views about reasons and benefits for using the QPL including being given the permission to ask their clinician questions. One carer whose spouse was recently diagnosed with heart failure said:

"If you've got something like this, that's actually written out in front of you, at least it gives you a little perspective on what's happening and what you can actually ask, doesn't it?" (F17)

That sense of needing permission[318] to ask questions originated in part from a hierarchy gap between patients and their doctors[319]. Patients awaited the initiative of their GPs in order to have these conversations. However, if they would be given the QPL, they felt they had the right to address these issues with their HCPs.
Another patient suffering from heart failure thought that using the QPL could not only improve his communication with his GP but also with his family:

"I think, for myself, if a doctor asks me these questions, at least then I had that discussion with him. Then, it would be easier for me to talk to the family about it and also for the doctor to talk with the family." (F13)

Concurring with findings from the clinician interview series, one GP thought that one reason for using the QPL was its potential to facilitate end-of-life conversations between healthcare professionals and patients:

"This is going to bridge that conversation gap. It gives patients the permission to ask questions and empowers them and it encourages them. And I think it's a relief." (F6)

However, another GP expressed her concerns when using a tool like the QPL:

"My prime reservation is not to disrupt an important defence mechanism of patients when using these tools. Your education package will really have to address that—that's what holds me back." (F1)

Inner defence mechanisms of patients were an important aspect to be aware of when considering using tools to facilitate end-of-life conversations. One patient who was recently diagnosed with heart failure remarked:

"Like I said, I would put these questions at the back of my mind and don't take them in. As I said, I would just go day after day." (F18)

Recognising a patient's autonomy of not engaging with ACP was important to one palliative care specialist nurse:

"Non-engagement with ACP is not that a patient doesn't understand. It's that they might just be choosing to not engage with that stuff." (F7)

There was a general consensus among clinicians to respect and work with such a position. While the above patient preferred not to engage with planning his future care beyond immediate day-to-day requirements, he could see the need for someone taking a more long-term view and referred to his wife as a person who could use the QPL:

"I would get my wife to ask the doctor these questions, and tell him, 'Please tell my wife.'" (F18)

Most clinicians welcomed the idea of a patient taking the initiative to ask them questions about their future care. One GP expanded on the benefits of patients starting the conversation:

"I think any questions that might initiate or open up a discussion, particularly if it's initiated by the patient, is a good thing because then patients can decide when to do it and what to ask. For want of a better phrase, the ball is then in their court…rather than me saying, 'This is what I want to talk about.'" (R6)

6.4.3.2 Material and Procedures

The QPL contained initially over 12 questions. However, healthcare professionals suggested including only a few essential prompts about future care and heart failure. A carer supported an overall concise format of the QPL and a minimal set of questions:

"I think the overview needs to be established. And I wonder whether you may only wish to keep it to four questions." (F3)

Recommended questions should address, for example, how much a patient wanted to know about their condition, whom they wanted to have involved or not involved in their care, or questions about heart failure treatment and its prognosis. One GP said:

"Questions need to assess the patient's idea and understanding of the disease. And of course a lot of the time, people have quite unrealistic expectations and a lack of knowledge about what is actually happening to them. No one has really told them about the prognosis or even what can be done." (R12)

Based on focus group findings, we reduced the number of questions to a total of nine. As a result, the QPL became more concise but remained relevant. Participants suggested that questions should address how much patients wanted to know or did not want to know about heart failure or questions about their care preferences or quality of life. Two GPs remarked:

"Questions for patients should result in a clarification of how much they want to know, who is going to be involved in their care, and how much they want to be involved in their care." (F4)

"That comment about quality of life, that's really important. Is there a way of including that into the list so that patients can then write, what it is that is quality of life for them?" (F10)

From a clinician's point of view, the list appeared to have the potential of gently probing and identifying patients' care preferences, increase patients' as well as clinicians' engagement with end-of-life conversations and potentially improve advance care planning and shared decision-making in heart failure. **Figure 23** illustrates these interactions.

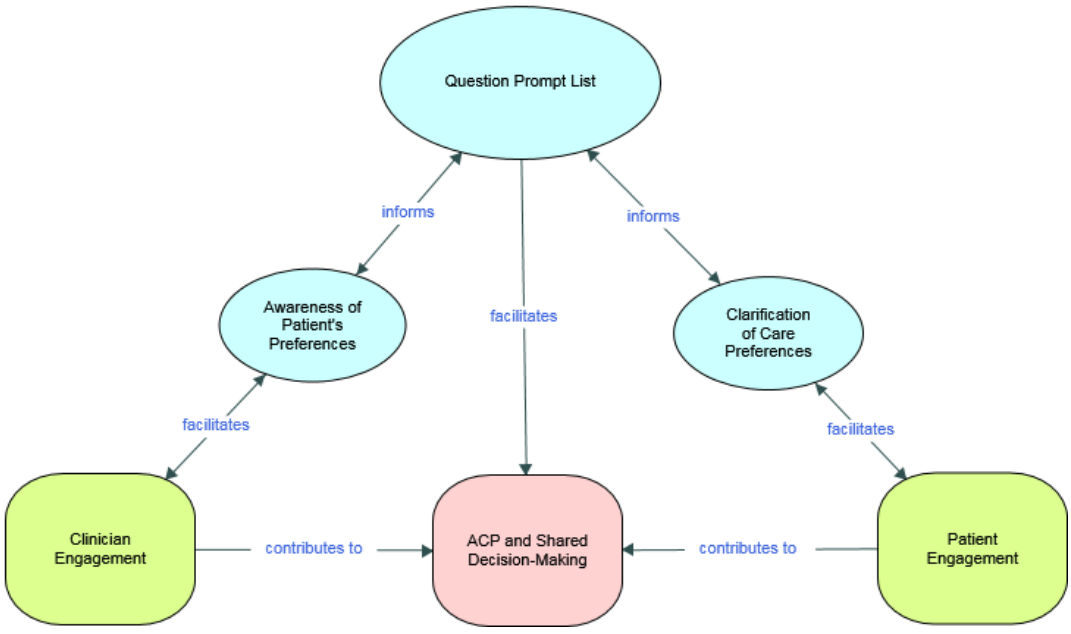


Figure 23. Effect of QPL on ACP and shared decision-making

6.4.3.3 Provider and Modes of Delivery

There was a strong expectation among patients that the QPL was made available to them by a healthcare professional. When asking a patient if he would appreciate it if his clinician gave him the tool, he answered:

"Appreciate? Appreciate is too weak a word. I would almost say, 'Expect', because it's a trusting relationship, and I expect the GP to be honest with me" (F13)

Further findings from the focus group study indicated that the most suitable healthcare professional providing discussions around end-of-life questions and heart failure might not always be the GP but the heart failure specialist nurse. Some patients and carers remarked that a GP may have considerable time constraints whereas a heart failure nurse seemed less rushed and had some expert credibility on the subject. Most focus group participants preferred the delivery of the QPL in the context of a face-to-face meeting, for example, either in the context of a routine clinical appointment or during a home visit. One carer suggested to deliver the QPL at the end of a consultation in order to stimulate her to ask questions when she meets the doctor again:

"Maybe give the QPL at the end of your time with the patient and say, "On your next visit, you need to prompt both me and yourself about discussing relevant questions from the list." (F14)

6.4.3.4 Timing and Intensity

There was a common perception from patients, carers, doctors and nurses that the QPL could and should be used early in the disease process: One patient suffering from heart failure said:

"I think it's quite good to have something like this early after they have told you. Because when you are first told it's a bit of a shock. And your mind goes sort of blank and you don't really know what to say or what to ask, to be honest. If you've got something like this, that's actually written out in front of you, at least it gives you a little perspective on what's happening and what you can actually ask, doesn't it?" (F18)

A heart failure nurse added that the timing of using the QPL depended on the patient still being able to use the list and said:

"It's best to give them this tool at a moment when they have got time to think about it and not when they are at death's door, but at a point in time when they still have the capacity." (F4)

In terms of intensity and frequency of using the QPL, participants generally suggested using the tool when and as required; for example, with the disclosure of the diagnosis, to arrange a follow-up meeting or after a change in the patient's health condition.

6.4.4 Synthesis of the Choices of Care Table

The prototype of the Choices of Care Table (CoC) was refined according to the following TIDieR criteria:

6.4.4.1 Rationale and Mechanism

From a patient's perspective, the CoC was useful for a number of reasons. For example, it allowed them to set their own agenda of how they wanted to be treated. One patient suffering from end-stage heart failure said:

"With this tool, I can set my own plan and say this is what my quality of life needs to be for me. These are the situations where I would want you to keep going. These are the situations where I wouldn't want you to keep going." (F15)

For another patient, the CoC gave him an overview over all available treatment options, and thus he felt able to control his own care. He said:

"I would like to know what the options are if the treatment is failing. This table enables me to achieve that and takes the fear away of not knowing what to do." (F16)

Another patient explained that the CoC seemed particularly useful in offering choices in the last phase of life:

"*If I had such an awful condition that gave me three months to live, that tool gives me choices. I can decide exactly what I want to do in those three months. And how I want to do it."* (F22)

Several healthcare professionals agreed with the content of the CoC because it seemed to mirror the conditions of their clinical practice. Furthermore, the tool

appeared to support them and their patients in having conversations about end-of-life issues in heart failure. One nurse said:

"*Recently, I had a patient who had heart failure and COPD and presented with a chest infection and was admitted into hospital. They managed her infection with IV antibiotics. She came home and the infection wasn't all gone. She went back into hospital for more IV antibiotics and came home. And all the while I was managing her for her heart failure. We actually ended up managing her at home mainly for her end-of-life care at that point. So she moved through all three sections of your options for treatment - from wanting to go in and have IVs to actually getting to the point of saying, 'I don't want to go into hospital any more. Just manage me at home.' And eventually we said, 'Right, actually we've reached the point of keeping her comfortable.'"* (F4)

6.4.4.2 Material and Procedure

An early version of the CoC included three different treatment options for any given complication that can occur with heart failure. Treatment options ranged from predominantly curative (red column) to palliative choices (green column).

In terms of the procedure of delivering the CoC, a number of clinicians agreed that the tool should be part of a face-to-face meeting. That meeting should be carefully planned, ideally booked in advance, and should not be rushed. One GP said:

"I would be a bit worried as to how much time I have got. You might say to the patient, 'I would really like to talk to you properly about it rather than rush this conversation. Can you book another appointment, come back and see me so that we've got time to go through it?'" (F12)

Additionally, using the CoC might not just be confined to only one meeting, but may well require a follow-up appointment. One nurse highlighted the importance of giving patients time to think through the options and not trying to complete the form during one encounter:

"*After the first meeting, they could take the table, go away and think about it. You are not putting them on the spot right then and there to have to sort of think up a care plan. But they can go away, which will give them the opportunity to think about it at home and perhaps talk about it, if they wish, with family members."* (F2)

6.4.4.3 Provider and Modes of Delivery

A number of participants agreed that the CoC should be offered to patients and carers by a healthcare professional. The clinician could be a practice nurse, GP, cardiologist or hospital nurse since the CoC seemed applicable to both a primary and secondary care context. Prior to handing out the CoC, a doctor or nurse should carefully explore what patients and carers know, want to know or don't want to know. One nurse explained:

"You need to engage the patient and the family in a conversation and double check their understanding. Even if people nod or give us the impression that they understand, sometimes they really don't. It might be that they are trying to just be polite to get out of the room as quick as they can, because they are petrified. It's really tricky." (F7)

If acceptable to a patient, one GP highlighted a possible sequence of using the CoC as a potential follow-on from the QPL:

"This tool could build on the question prompt list and be given at a time when the patient has accepted the diagnosis of heart failure." (F6)

6.4.4.4 Timing and Intensity

The timing of introducing the CoC seemed more appropriate during the later stages of the disease or after significant milestones, like hospital admissions or after a sudden deterioration in the general condition of the patient. One GP suggested:

"*I think if patients have sort of absorbed the initial shock and were given initial information about heart failure and what they have to do, then further down the road, you know, this is just when they come into phase three or four; and that's something that can be given to them."* (F10)

While it was important not introducing the CoC too early, one patient cautioned not delaying its use unnecessarily. He emphasised the introduction of the tool before the occurrence of a health crisis:

"It's got to be in there first before things fail. You have to have an opinion on yourself." (F16)

6.4.5 Synthesis of the ACP Reminder Sheet

The prototype of the ACP Reminder Sheet (ARS) was refined according to the following TIDieR criteria:

6.4.5.1 Rationale and Mechanism

Participants noted that the purpose and benefit of the ARS was mainly to remind them of all essential criteria covering ACP in heart failure, priorities of care and anticipatory management. One heart failure specialist nurse said:

"I was thinking to myself, 'Now what are the elements for advanced care planning?' I always go blank. I think, resuscitation and then I just go blank. I always need to go away and think about it and look it up again. And the ARS actually makes you think about all the aspects and all the potential situations that might arise where it's important to know what that person's view is. (F2)

One nurse commented on the sometimes negative opinions of clinicians about using lists in end-of-life care by saying:

"So this would help me, because I've got a list here. I know that people can be very scathing about lists and check lists and so on. But, I think that they are practical and helpful. And you don't have to slavishly fill in every box, do you? It's a memory prompt and it's a tool that you can use as much or as little as you like." (F2)

Picking up on the dangers of using the ARS 'slavishly,' the introduction of the tool warns against its rigid use by writing:

> *"...The ACP Criteria are only meant as prompts to guide a conversation. They are not intended to be used rigidly. The template is not expected to be filled in during one session. Typically, this takes time. Please remember that patients' care preferences vary during the course of the disease. And it is common that patients change their minds on what they want. Therefore, timely reviews of the Reminder Sheet are recommended..."*

6.4.5.2 Material and Procedures

The different ingredients of the reminder sheet were previously listed under the TDF domain "Memory, attention and decision processes." Similar to the synthesis of the prototype for the QPL and CoC, the ARS was simplified in its content and design as a result of the interview and focus group findings. For example, a GP indicated that the tool should consist of only one page which should facilitate the mapping of ACP criteria against the patient's disease trajectory:

"An ACP summary sheet should simply contain three or four things: one is, for the sake of a better word, a template with all the key criteria for advance care planning. That needs to include preferred priorities of care. Ideally, these criteria can be mapped against that patient's disease trajectory. So, I can actually see what has been discussed at what date and what is still outstanding or what needs to be revisited." (R11)

6.4.5.3 Provider, Modes of Delivery and Timing

The ARS is a clinician-owned reminder which can be used in paper form or as part of an electronic patient record. For the purposes of a proposed feasibility cluster RCT, ARS is going to be made freely available to trial participants as a hard copy. One GP (F1) suggested using the form primarily as a memory prompt as much or as little as required. However, one nurse (F2) suggested using and reviewing the ARS every time before a patient encounter primarily for two reasons: a) to refresh her memory about all ACP criteria and priorities of care and b) to provide a better consistency of care by covering all aspects of palliative care for heart failure. The later approach was supported by a palliative care nurse who was quite clear that the tool should not be used as a last resort but during the entire disease journey of a patient:

"Use the ARS not when they are at death's door but at a point in time when they can make decisions, when they have got time to think about it." (F3)

6.4.6 Synthesis of ACP Practice-Based Training Session

The prototype of the ACP Practice-Based Training Session (APT) was refined according to the following TIDieR criteria:

6.4.6.1 Rationale and Mechanism

At the beginning of the interview series, I was only certain about the general idea of delivering the intervention in the context of interactive training, since that mode of delivery was familiar, acceptable and feasible for GPs and nurses[102, 320]. Additionally, there was an evidence base from systematic reviews[102, 321] that educational training had the potential to change professional behaviour and practice.

In terms of the content of the training, there was a general consensus amongst interview and focus group participants to include case scenarios with some form of communication skills training about end-of-life issues. This took initially the form of role-play combined with some didactic teaching on how to use motivational interviewing techniques[322] or reflective questioning[323] to elicit patient care preferences. However, as more participants were invited to give their views on suitable training techniques in communicating end-of-life issues, it became apparent that role-play in front of a big group could trigger significant levels of performance anxiety[324] and might deter less confident professionals from engaging with the training. Conversely, role modelling was frequently mentioned as a facilitator that encouraged clinicians to engage with ACP. Therefore, I elected a form of role-play

that gradually involved participants in executing the desired task. Typically, this took the form of the facilitator demonstrating the desired behaviour first in front of the group. Then the trainer invites participants to reflect on what they have observed, before they are asked to practice the behaviour in small groups of their own choosing. The type of role-play is also called "Life Forum Theatre" and has the potential to reduce levels of performance anxiety in participants[325]. One nurse with an educational training portfolio commented on the idea:

"*Yes, they do a Life Forum Theatre, I think they call it. They will perform a play or an interview or something, a sketch. You have to tell them what to do next. They will come across a conundrum within the sketch and you have to tell them, 'I want you to do it in this form or this way or say it in this way. So you are directing the show in a way. People are more comfortable. From that people learn a lot. Instead of having to do role-play yourself, which everybody hates doing."* (R20)

During the process of conducting the interview series and focus group study, there were positive indications from more reticent clinicians that this type of role-play might be more engaging and less threatening than the traditional version.

6.4.6.2 Material and Procedures

Participants suggested gradually increasing the difficulty of end-of-life scenarios during the APT. This proposition matched findings from the interview study where clinicians advocated graded tasks to practice difficult cases in delivering ACP in heart failure. Subsequently, I created three settings to match these requirements. The first scenario included disclosing the diagnosis of heart failure to a patient who was not aware of the reasons for his breathlessness and leg oedema. This involved using the

QPL as a means of gently probing and exploring the patient's need for information. The second scenario described a patient suffering from NYHA Class IV who had two recent hospital admissions because of recurring chest infections. This included the CoC as a means of giving the patient an overview of the scope of treatment options ranging from curative to palliative choices. The third and most difficult scenario concerned a patient with an implantable cardioverter defibrillator. The patient's condition had deteriorated to such a degree that it was now time to explore whether to deactivate the device. A specialist palliative care nurse remarked on the content and degree of challenge in these scenarios:

"This actually makes you think about all the aspects and all the potential situations that might arise. The scenarios tease out what's important to know and what that the patient's view might be. It also gives us a chance to show patients what is available – not just when they are at death's door." (F3)

Another clinician thought that proceeding with the degree of difficulty of the training as described above "*provides a 'safe' opportunity on how to raise the subject of advance care planning."* (F2).

6.4.6.3 Provider and Modes of Delivery

Congruent with findings from the interview series, HCPs from the focus groups thought that clinicians with a background in cardiology, palliative care and medical education would have the greatest credibility to deliver the training. These findings affirmed my choice of selecting a consultant heart failure specialist nurse and a senior palliative care nurse as co-facilitators for the course.

In terms of the location, most clinicians from focus groups agreed that providing the training at a local GP surgery was the most effective way of reaching even those who would normally not attend such an event. Furthermore, this location made travelling for participants more or less unnecessary. Most surgeries had a tradition of monthly practice training events, so the APT could fit into that arrangement rather seamlessly. One GP said:

"That arrangement doesn't overload them in terms of a time commitment since it can take place as part of their monthly in-house practice training. Thinking about a long-term strategy for an area, this approach might be sustainable." (F12)

When asking patients who might be the best professionals to provide them with an end-of-life conversation, one participant answered:

"It doesn't have to be a doctor. A nurse who is trained like a Macmillan nurse could maybe do it. I think they are probably a bit better about that." (F22)

A number of heart failure nurses, district nurses and even some GPs concurred with that view. The main reason was, not that GPs lacked the skills, but that nurses seemed to have more time allocated in their role of caring for patients. Hence they might be in a more suitable position to undertake these sensitive conversations.

6.4.6.4 Timing and Intensity

In terms of the duration of the training session, most participants thought that approximately two hours was appropriate. Only one palliative care nurse had some doubts:

"Two hours is a long time. When I've done teaching at GP's surgeries, having them for 20 minutes, half an hour that's kind of like about as much as I might get them for a teaching session. An hour at a push. Two hours, I am not sure if that would fit into their diary." (F3)

I asked other participants about these time concerns. Most felt that, given the practical nature of exercising the use of the tools, two hours not only seemed a viable but a necessary duration.

When asking clinicians about the frequency with which such a course should take place, one GP said:

"If it's once a year, they would attend. I doubt they would require training more frequently." (F6)

Offering the training session to a surgery once a year seemed reasonable to most participants.

6.4.7 Deviant Findings

Focus group findings did not create any data that negated the overall usefulness of the Question Prompt List, Choices of Care Table, ACP Reminder Sheet or ACP Practice-Based Training. Generally, participants welcomed the intervention. However, participants generated discordant views that related mainly to the level and sequence of detail that should or should not be part of the different intervention components. These views contributed to the refinement of an early version of the Question Prompt

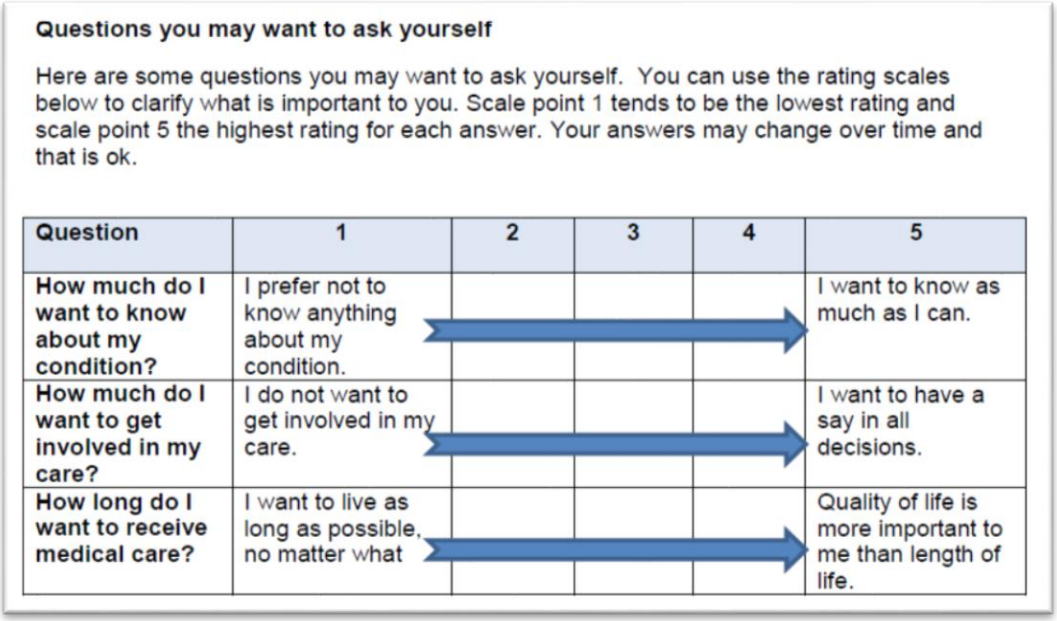
List, Choices of Care Table, ACP Reminder Sheet or ACP Practice-Based Training. The following sections consider how these deviant findings iteratively informed the development of each component resulting in the final version of the intervention. To keep this chapter concise, I have described only the main changes for each component. The next chapter shows each tool in its entirety.

The Question Prompt List

The design of the QPL was refined and changed as a result of findings from the interviews and focus groups. For example, a number of participants perceived the rating scales of the prototype of the QPL as potentially confusing. One heart failure nurse said:

"I think a lot of people find it difficult rating things, anyway. Words are almost more important. My only other thought, but this may not be practical, is the fact that you've got one to five from low to high. That may make it too complicated for patients." (F2)

Figure 24 shows a segment of an early version of the QPL including the introduction and the first set of questions with a rating scale.



Questions you may want to ask yourself

Here are some questions you may want to ask yourself. You can use the rating scales below to clarify what is important to you. Scale point 1 tends to be the lowest rating and scale point 5 the highest rating for each answer. Your answers may change over time and that is ok.

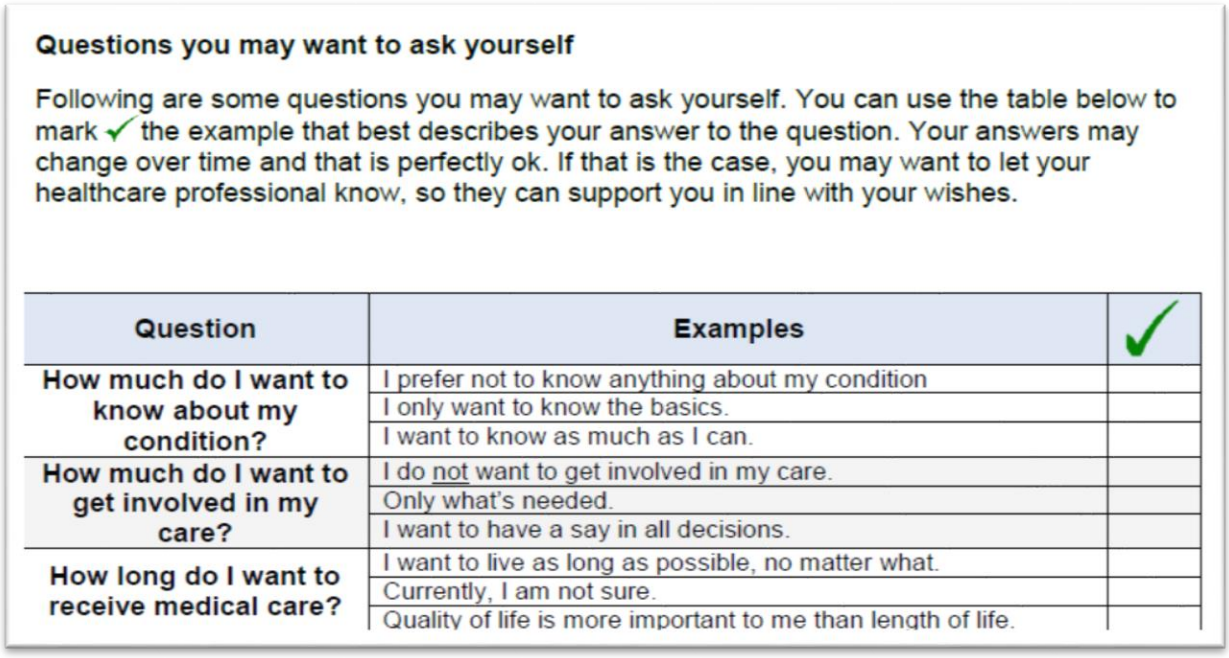
Question	1	2	3	4	5
How much do I want to know about my condition?	I prefer not to know anything about my condition.				I want to know as much as I can.
How much do I want to get involved in my care?	I do not want to get involved in my care.				I want to have a say in all decisions.
How long do I want to receive medical care?	I want to live as long as possible, no matter what				Quality of life is more important to me than length of life.

Figure 24. Segment of an early version of the QPL

The same heart failure nurse (F2) suggested using sentences that provided possible answers to the questions instead of rating scales. Patients could then indicate which sentence described most accurately their current answer. A patient supported a change in the design of the QPL from scales to words and said:

"Forgive me, I think it needs to be a verbal question that is there. A question and not just a link." (F22)

Consequently, I simplified and refined the QPL by omitting the rating scales and using a choice of three answers for each question (**Figure 25)**.



Questions you may want to ask yourself

Following are some questions you may want to ask yourself. You can use the table below to mark ✓ the example that best describes your answer to the question. Your answers may change over time and that is perfectly ok. If that is the case, you may want to let your healthcare professional know, so they can support you in line with your wishes.

Question	Examples	✓
How much do I want to know about my condition?	I prefer not to know anything about my condition	
	I only want to know the basics.	
	I want to know as much as I can.	
How much do I want to get involved in my care?	I do not want to get involved in my care.	
	Only what's needed.	
	I want to have a say in all decisions.	
How long do I want to receive medical care?	I want to live as long as possible, no matter what.	
	Currently, I am not sure.	
	Quality of life is more important to me than length of life.	

Figure 25. Segment of the final version of the QPL

Not only had the design of the QPL changed as a result of interview findings, but also part of its wording in the introduction. One example was the use of the word "delighted," which was part of the text of an early version of the QPL:

"Introduction
Some patients find it helpful to think about questions that clarify their understanding of heart failure and the kind of treatment they would like to have. Thinking about the questions below is entirely voluntary. But it can make it easier for you to make decisions about your care or to talk to people you love and those who look after your health. On your next visit, you can discuss this list with your doctor or nurse. They will be delighted to answer any questions you may have. This will enable them to support you in line with your wishes. Thank you!**"**

The choice for this word was based on initial feedback from a nurse (R9) who said:

"I think the introduction is brilliant, because of that "delighted" word, I don't think all the nurses and the doctors will be delighted. I think they are going to be petrified. But it's a brilliant word, because if people just get the sense of it's okay to

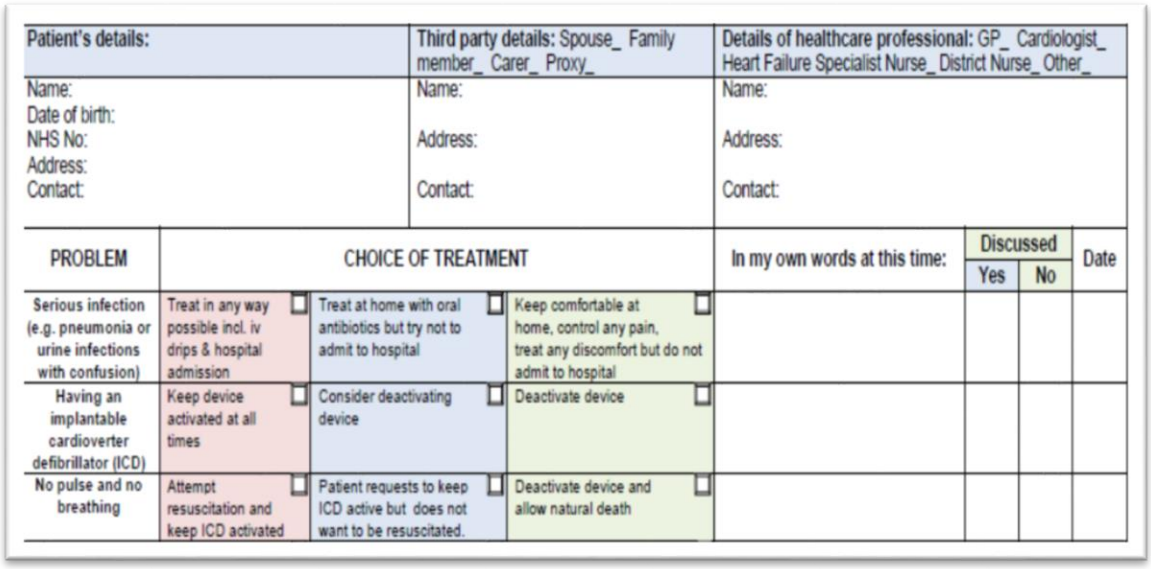
talk about this stuff, there are not many words that would beat 'delighted.' We just need to have the confidence to be delighted and not petrified."

However, subsequent clinicians expressed rather opposing views ranging from "I hate that word delighted in the introduction" (F7) to "We are not going to be delighted and they are not going to be delighted" (F3) to "Delighted? That's not how I see it. Come down a notch." (F4) So, after a number of iterations, it was replaced with the word 'glad.' The latter was acceptable to most healthcare professionals aiming to strike a fine balance between an encouragement to ask questions and the seriousness of the topic. At the end of the interview series, the relevant sentence in the introduction wrote:

> "On your next visit, you can discuss this list with your doctor or nurse. They will be glad to answer any questions you may have. This will enable them to support you in line with your wishes."

The Choices of Care Table

As a result of the clinician interview series and focus group findings, the CoC changed in some detail including its wording as well as design. Words like 'pneumonia' or 'iv infusion' were exchanged for 'lung infection' or 'drip' to only contain terms in a lay-language. **Figure 26** gives an example of an early version of the CoC.

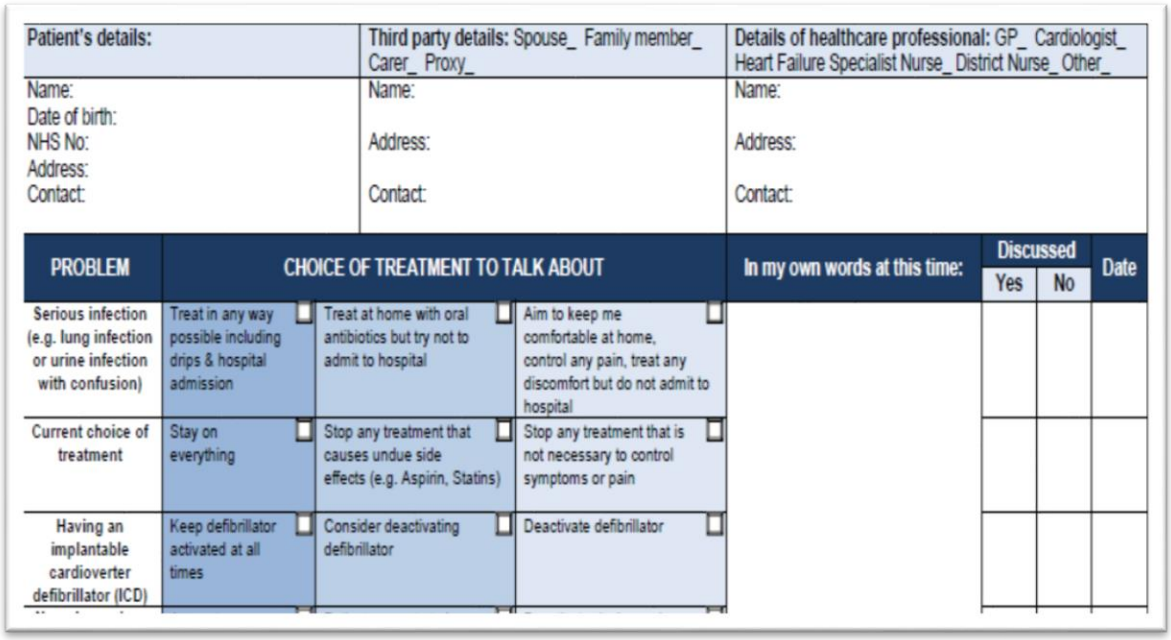


Patient's details:	Third party details: Spouse_ Family member_ Carer_ Proxy_	Details of healthcare professional: GP_ Cardiologist_ Heart Failure Specialist Nurse_ District Nurse_ Other_
Name: Date of birth: NHS No: Address: Contact:	Name: Address: Contact:	Name: Address: Contact:

PROBLEM	CHOICE OF TREATMENT			In my own words at this time:	Discussed		Date
					Yes	No	
Serious infection (e.g. pneumonia or urine infections with confusion)	☐ Treat in any way possible incl. iv drips & hospital admission	☐ Treat at home with oral antibiotics but try not to admit to hospital	☐ Keep comfortable at home, control any pain, treat any discomfort but do not admit to hospital				
Having an implantable cardioverter defibrillator (ICD)	☐ Keep device activated at all times	☐ Consider deactivating device	☐ Deactivate device				
No pulse and no breathing	☐ Attempt resuscitation and keep ICD activated	☐ Patient requests to keep ICD active but does not want to be resuscitated.	☐ Deactivate device and allow natural death				

Figure 26. Segment of an early version of the CoC

Using the colours of red, blue and green for different treatment options was perceived by a member of the research advisory group as introducing a potential risk of bias, guiding patients to the more acceptable looking green palliative care option. Shades of blue were suggested as a more neutral illustration of the different care choices. **Figure 27** shows a segment of the content of the final version of the CoC in neutral colours with patient friendly terminology.



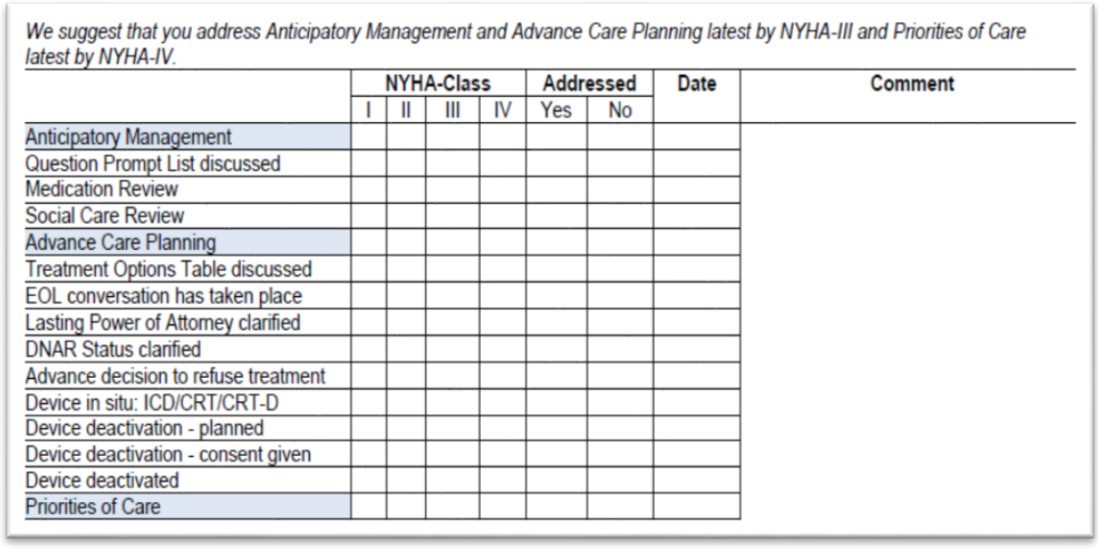
Patient's details:	Third party details: Spouse_ Family member_ Carer_ Proxy_	Details of healthcare professional: GP_ Cardiologist_ Heart Failure Specialist Nurse_ District Nurse_ Other_
Name: Date of birth: NHS No: Address: Contact:	Name: Address: Contact:	Name: Address: Contact:

PROBLEM	CHOICE OF TREATMENT TO TALK ABOUT			In my own words at this time:	Discussed		Date
					Yes	No	
Serious infection (e.g. lung infection or urine infection with confusion)	☐ Treat in any way possible including drips & hospital admission	☐ Treat at home with oral antibiotics but try not to admit to hospital	☐ Aim to keep me comfortable at home, control any pain, treat any discomfort but do not admit to hospital				
Current choice of treatment	☐ Stay on everything	☐ Stop any treatment that causes undue side effects (e.g. Aspirin, Statins)	☐ Stop any treatment that is not necessary to control symptoms or pain				
Having an implantable cardioverter defibrillator (ICD)	☐ Keep defibrillator activated at all times	☐ Consider deactivating defibrillator	☐ Deactivate defibrillator				

Figure 27. Segment of the final version of the CoC

The ACP Reminder Sheet

As part of refining the ARS, one nurse (R9) commented that the different columns for NYHA classes I-IV seemed too complex and could be abolished and merged into a single NYHA column in which to insert the current class of heart failure. **Figure 28** shows a segment of an early version of the ARS.

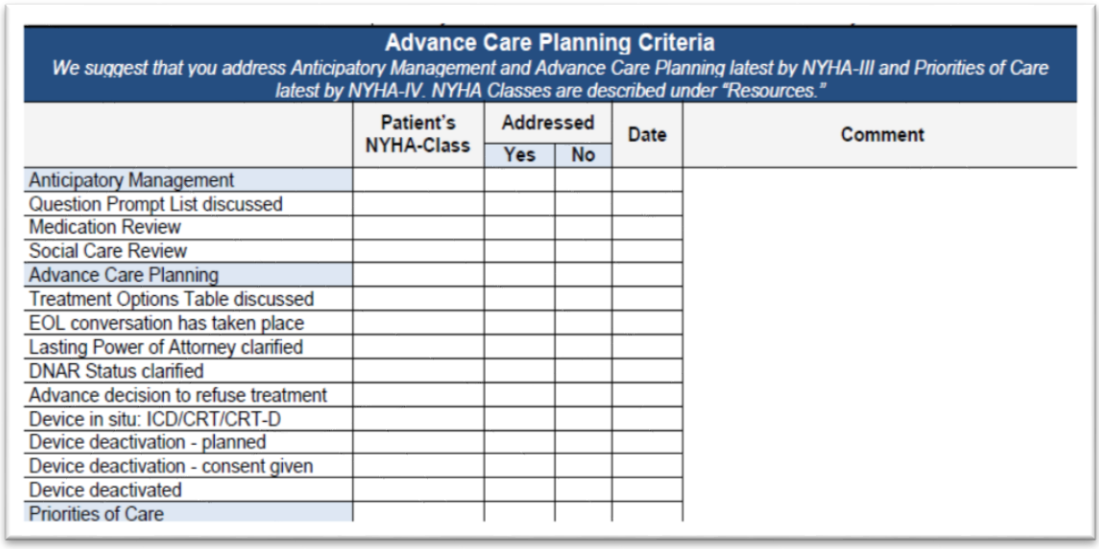


We suggest that you address Anticipatory Management and Advance Care Planning latest by NYHA-III and Priorities of Care latest by NYHA-IV.

	NYHA-Class				Addressed		Date	Comment
	I	II	III	IV	Yes	No		
Anticipatory Management								
Question Prompt List discussed								
Medication Review								
Social Care Review								
Advance Care Planning								
Treatment Options Table discussed								
EOL conversation has taken place								
Lasting Power of Attorney clarified								
DNAR Status clarified								
Advance decision to refuse treatment								
Device in situ: ICD/CRT/CRT-D								
Device deactivation - planned								
Device deactivation - consent given								
Device deactivated								
Priorities of Care								

Figure 28. Segment of an early version of the ARS

Additionally, the early version of the ARS did not contain a facility for clinicians to communicate with each other on whether to have an ACP conversation with a patient or not. That box was added as a result of suggestions from nurses and GPs during interviews and confirmed as being useful by participants of the focus group study. **Figure 29** shows a segment of the final version of the ARS.



Advance Care Planning Criteria

We suggest that you address Anticipatory Management and Advance Care Planning latest by NYHA-III and Priorities of Care latest by NYHA-IV. NYHA Classes are described under "Resources."

	Patient's NYHA-Class	Addressed		Date	Comment
		Yes	No		
Anticipatory Management					
Question Prompt List discussed					
Medication Review					
Social Care Review					
Advance Care Planning					
Treatment Options Table discussed					
EOL conversation has taken place					
Lasting Power of Attorney clarified					
DNAR Status clarified					
Advance decision to refuse treatment					
Device in situ: ICD/CRT/CRT-D					
Device deactivation - planned					
Device deactivation - consent given					
Device deactivated					
Priorities of Care					

Figure 29. Segment of the final version of the ARS

The ACP Practice-Based Training

The main difference between an early version of APT and the final version was the sequencing and use of the Case Scenarios. **Table 25** shows an early version of the intervention including a summary of the changes made as a result of the qualitative findings. Initially, one scenario just followed after the other. However, it became apparent during the focus group study, that participants would find a demonstration by a facilitator on how to perform an ACP conversation very helpful. This demonstration should take place at the beginning of the session since it had the potential to stimulate recall and reflection on how to disclose the diagnosis of heart failure and use the QPL.

Time	Topic	Changes made as a result of the qualitative findings
14:00-14:05	Welcome and Objectives	No changes made
14:05-14:20	Overview of palliative care and heart failure services	A baseline self-assessment of participants' ACP skills was included in the final version at this stage in the programme
14:20-14:30	Advance Care Planning in Heart Failure	A demonstration on how to perform an ACP conversation replaced the overview of palliative care services
14:30-14:45	Question Prompt List, Treatment Options Table, ACP Template	This item remained in the programme but came at a later stage
14:45-15:00	Coffee	Omitted given the comparatively short duration of APT
15:00-15:20	ACP conversation skills – Scenario One Objective: To initiate a general ACP conversation	Practicing Scenario One took place earlier after the demonstration on how to perform an ACP conversation
15:20-15:40	ACP conversation skills – Scenario Two Objective: To discuss ICD/ CRT deactivation	This segment of the programme remained unchanged
15:40-16:00	ACP conversation skills – Scenario Three Objective: To initiate an ACP conversation with an unsuspecting patient NYHA IV	To give participants a short break, we placed the update of palliative care services at this stage in the programme. Scenario Three followed thereafter
16:00	Close	A measurement of training effect was included in the final version

Table 25. Early version of the APT

Consequently, I placed scenario one right at the start of the training event. This scenario demonstrates how to disclose the diagnosis of heart failure to a patient, how to use the QPL and practise related skills. As a result, participants should find the subsequent teaching slots much more meaningful. **Table 26** shows the final version of the ACP Practice-Based Training Programme.

Time	Topic	Lead
14:00-14:05	Welcome and Objectives	MS, HJ, SO
14:00-14:05	Survey 1: Baseline measurement	MS
14:10-14:15	Demonstration: Competent introduction to an ACP conversation (includes QPL) – Scenario One	MS, HJ
14:15-14:30	Practice: Competent ACP introduction in trios	All participants
14:30-14:50	Introduction to evidence-based tools: Question Prompt List (QPL), Choices of Care Table (CoC), ACP Reminder Sheet (ARS)	MS
14:50-15:10	ACP conversation skills – Scenario Two Objective: To have an ACP conversation with a patient (NYHA Class IV) who had two recent admissions with pneumonia (includes CoC)	SO, HJ
15:10-15:20	Update on heart failure and palliative care services	SO, HJ
15:20-15:40	ACP conversation skills – Scenario Three Objective: To discuss ICD/ CRT deactivation (includes CoC and ARS)	HJ, SO
15:40-15:55	Plenary and Q&A	MS, SO, HJ
15:55-16:00	Survey 2: Measurement of training effect	MS
16:00	Close	
Abbreviations	**HJ:** Helen Jackson; **SO:** Stuart Oliver; **MS:** Markus Schichtel; **ICD:** implanted cardio defibrillator; **CRT:** cardiac-resynchronisation therapy	

Table 26. Final version of the APT

6.4.8 Synthesis of TIDieR Findings

Based on above findings**, Table 27** summarises how the results from interviews and focus groups refined the final version of the components of the intervention according to the Template for Intervention Description and Replication (TIDieR).

Refined intervention components	Rationale	Mode of delivery	Delivered to	Timing and Intensity
APT	To increase clinicians' confidence and competence in managing difficult end-of-life conversations with patients suffering from heart failure. To practice the use of patient-endorsed shared decision-making tools appropriate for each stage of the illness trajectory	Face-to-face for a group of healthcare professionals in primary or secondary care	Doctors, nurses and students	Generally, once a year for approx. 2 hours; as part of practice, under-graduate or post-graduate training
QPL	To sensitively disclose the diagnosis of heart failure, explore patients' care preferences and initiate an ACP conversation	Face-to-face or as a patient-led tool	Patients and healthcare professionals	Earlier during the illness trajectory or at significant milestones
CoC	To explore all available care options ranging from curative to palliative and enable shared decision-making in EOL Care	Face-to-face or as a shared decision-making tool	Patients and healthcare professionals	Later during the illness trajectory or at significant milestones
ARS	To remind clinicians of all essential criteria for anticipatory management, ACP and priorities of care. To map patients' illness trajectory against standards of care. To provide clinicians with patient-endorsed phrases to conduct EOL conversations	Clinician-owned as a hard copy or as part of electronic patient medical records	Doctors and nurses	Ongoing as part of local IT systems or paper medical records

Table 27. Final intervention synthesis according to TIDieR

6.5 DISCUSSION

The above focus group study resulted in the refinement of the final version of the intervention, which consisted of:

- The Question Prompt List (QPL)
- Choices of Care Table (CoC)
- ACP Practice-Based Training Session (APT)
- ACP Reminder Sheet (ARS)

I was able to conduct a focus group study with 22 participants from a range of stakeholders including healthcare professionals, commissioners, and patients and carers affected by heart failure. The spectrum of heart failure patients involved those

who had been diagnosed recently as well as those who suffered from the condition for many years. The range of participants, their experiences and views generated valuable data to synthesise and refine the final version of the intervention. Focus groups were a suitable method to further create insights and refine the intervention components. Parameters like procedures, timing, and intensity of the intervention were modified as a result of focus groups. The iterative synthesis process resulted in the design of the final version of the intervention consisting of the QPL, the CoC, the ARS and the Practice-based training session. No new intervention components were added to the final version.

6.5.1 Strengths and Limitations

At the time of this writing, this was the first study that used TIDieR to refine the design of interventions components for the implementation of ACP in heart failure. The domains of TIDieR were analysed to determine gaps in the prototype of the QPL, CoC, ARS and APT. Particularly, intervention parameter like procedures, timing and intensity could be refined as a result. I combined patients and their carers in focus groups primarily to take advantage of an additional perspective on the patient experience. The chance for a patient or their carer to immediately respond to a statement by the other would have been lost if I had separated them. I was also aware that combining patients with their carers might have inhibited either party to voice their opinion. On balance, I thought the advantages of including them both in a focus group were stronger than the disadvantages. As the moderator, I was aware of these potential dynamics and intended to prompt a response from a more silent person. While patients and carers represented the majority of focus group participants, their number was relatively small (n=10) and, therefore, may represent a comparatively limited range of views on the intervention.

Another limitation of the focus group study was the absence of patients from ethnic minorities. There is evidence that the engagement with ACP is lower in ethnic minorities than in white Caucasians[326]. One reason for this is that ACP in itself represents a particular approach to thinking about and planning for the last phase of life and death[327, 328]. If my intervention is to be acceptable and appropriate for all patients, carers and clinicians, participants from ethnic minorities must be included in any future feasibility work[328]. Consequently, I have considered their participation in the study protocol for the feasibility cluster RCT (Chapter 7). Similarly, other demographic factors, such as socio-economic grouping or educational attainment, could not be reasonably represented in my focus groups. This will again be a consideration for the future development of the intervention.

There were a few limitations to my role of conducting the focus group study. My familiarity with ACP and heart failure might have potentially introduced a predisposition in the way of how I facilitated the groups[305]. Since my study objective was primarily concerned with refining intervention components, there was a risk that other themes might have been overlooked by losing sight of the broader, contextual aspects[305]. Members of the focus groups were aware that I was a GP with special expertise in heart failure and ACP. Consequently, there was a possibility that they may have been inclined to answer my questions in a socially acceptable way[329].

Using TIDieR as a method of analysis for the interview and the focus group study may have been another limitation. Some argue that this approach might facilitate only a low level of interpretation[270] because of the restricted capacity of this method of

researching the wider social or historical dimension of the intervention[270]. There seemed to be a risk that other emergent themes outside its scope were not sufficiently considered[269]. To mitigate against these limitations, I used thematic analysis to ensure a more wide-ranging effort of coding. The resultant themes did not only address TIDieR domains but also resulted in valuable background information that further contributed to the design of the final intervention. For example, attitudes of GPs towards incentivising ACP in heart failure were predominantly negative. This was mainly due to the perceived risk of ACP degenerating into a tick box exercise without actually improving the quality of care. While these attitudes did not directly affect the refinement of the intervention tools according to TIDieR, this information made me aware of the potential dangers that might be associated with a future implementation of the intervention into clinical practice. For example, when drafting the opening statement for the CoC, I made sure to note that it was not to be used as a tick-box exercise, and included such warnings as part of the APT. Bringing in the TIDieR structure at a later stage of the analysis ensured that the exploration of new insights like these was not lost.

Reaching consensus on how TIDieR was operationalized seemed less complicated than applying the TDF for the previous barriers' and facilitators' analysis. This may have been due to a few factors: 1. TIDieR is not as a much a theory but a pragmatic approach to characterising intervention components, their context and mode of delivery. 2. One of the creators of TIDieR was my supervisor (RP). On one hand, this allowed for a swift clarification of any issues on how to apply the appropriate TIDieR categories to my focus group findings. His expertise may have generated deeper findings by questioning areas relevant to the TIDieR domains. Conversely, an

outsider's perspective on the intervention refinement may have facilitated a greater degree of objectivity and more authentic knowledge[307, 308].

6.5.2 Implications for Intervention Component Refinement

The following discusses the implications of the findings of the study for each component of the final version of the intervention:

6.5.2.1 The Question Prompt List

The use of question prompt lists to engage patients with end-of-life issues was acknowledged in published randomised controlled trials[174, 271, 330]. In the past, question prompt lists had been used predominantly to improve patient communication. Generally, question prompt lists were thematically ordered evidence-based lists of possible questions designed for patients and carers. A recognised effect of question prompt lists on patients was assisting them with formulating questions and encouraging a conversation with a clinician[174]. Typically, the effect of a Question Prompt List was primarily explored from a patient's perspective since they tended to be the recipient of the intervention. The fact that the qualitative methods investigated the perspective of GPs and nurses on the usefulness of the Question Prompt List was novel. This process enabled the synthesis and refinement of questions that were considered essential by patients, carers and clinicians. Consequently, I would recommend this approach for the development of question prompt lists for other life-limiting illnesses because it achieved a format and content that appeared relevant to all key stakeholders.

Clinicians reported that the Question Prompt List was not only useful for patients but allowed them to identify answers to questions that were important to patients. Since the tool was patient-led, it also indicated to a GP or a nurse when and how much information a patient wanted to be given about their condition. Knowing the right amount of information to give and knowing the correct timing to start an end-of-life conversation with a patient was obviously very important and useful for healthcare professionals. There remained a number of outstanding questions after completing the clinician interview series: "Was the prototype of the Question Prompt List acceptable from a patient and carers' point of view? And, "When was the right time to introduce the Question Prompt List to heart failure patients and their carers?" The subsequent focus group study suggested the answers: patients not only found the Question Prompt List acceptable, but some *expected* that the tool would be made available to them. Some patients and carers also noted that the Question Prompt List was especially useful in the early stages of the disease and should be provided soon after diagnosis. This seems a remarkable finding given the current paucity of tools to disclose the diagnosis of heart failure and to start an ACP conversation at the onset of the illness[331, 332].

6.5.2.2 The Choices of Care Table

The early version of the Choices of Care Table was developed as a tool underpinned by principles of shared decision-making. The concept of shared decision-making has an evidence base in published literature[23] and applies to heart failure. Its standards emphasise that healthcare professionals have a legal duty to include patients in medical decisions and fully inform them about the risks and benefits of their medical care[333]. Shared decision-making tends to include not only a clarification of a range of possible treatment options but also an identification of a patient's individual care

preferences and values[66]. Supporting clinicians in their role of facilitating shared decision-making in heart failure is one recognised aim in the literature[334]. However, no shared decision-making tools for palliative care in heart failure existed prior to this study. Given that void, GPs and nurses perceived the Choices of Care Table generally as very useful in starting an ACP conversation with their patients. The introduction paragraph of the Choices of Care Table made it clear that the tool did not describe every choice of treatment but did provide a starting point to discuss options. Clinicians were still required to exercise their professional judgement in the case of an individual's care needs. That said, healthcare professionals mentioned that the different treatment options ranging from curative to palliative treatment facilitated a sensitive discussion. The table not only provided a starting point to discuss the severity of the diagnosis, but also the risks and benefits of a preferred choice of care and reasonable alternatives. While feedback from clinicians on the prototype of the Choices of Care Table was very promising, I did not know whether patients and carers would find the tool helpful. That issue was answered by data from the focus group study. Patients and carers felt that the Choices of Care Table gave them an overview and a degree of control over available treatment options. Generally, they welcomed the tool as part of their heart failure management.

6.5.2.3 The ACP Reminder Sheet

There was an evidence base in the literature that reminder systems had the potential to improve clinician behaviour in end-of-life care and across a number of other medical specialities[217]. Reminders were defined as 'patient or encounter specific information, provided verbally, on paper or on a computer screen, which is designed or intended to prompt a health professional to recall information[104].' They had been used to prompt clinicians to perform important clinical tasks such as monitoring quality indicators for

chronic diseases like diabetes or COPD[335]. Compared to existing reminders and templates for end-of-life care, GPs and nurses commented on the usefulness of the ACP Reminder Sheet. This was mainly due to the form being concise and brief but still containing a sufficient range of criteria limiting them to what seemed clinically essential. A precise format containing all necessary information was one acknowledged reason in systematic reviews for making reminder systems effective[217].

Of particular importance to clinicians was a box to prompt communication between professionals about the need for having an ACP conversation with the patient. Additionally, a selection of phrases to start and conduct ACP conversations with patients was perceived as useful to stimulate recall and practice rehearsal prior to seeing patients. GPs and nurses found the links to resources on ACP, end-of-life care in heart failure and the New York Heart Association (NYHA) functional classification as part of the reminder sheet helpful. The reminder sheet was designed to be a clinician-owned tool. After the prototype had received very good feedback from GPs and nurses during the interview study, it was particularly important to test the selection of sample phrases with patients and carers to determine whether these were acceptable to them. Patients made no further suggestions to improve on these phrases.

6.5.2.4 The ACP Practice-Based Training Session

GPs and nurses emphasised that the mode of delivery for the intervention needed to be practical, including rehearsing sample phrases for ACP conversations so that they could develop the necessary confidence to explore patients' care preferences without alarming them. Clinicians preferred interactive training in contrast to didactic teaching. This finding is consistent with published literature[336]. Didactic teaching targets mainly knowledge barriers at the individual healthcare level but does not give

the opportunity to practice skills. By contrast, interactive education in form of workshops can target knowledge, skills and attitudes and at the individual clinician or group level[336]. In our case, the main limitation to ACP Practice-Based Training applied to release time for GPs and nurses. However, that arrangement seemed achievable for most of the participants since there was an existing and strong culture of continuous professional education in primary care[337]. It became also apparent that not all relevant healthcare professionals would be interested in attending a training event on ACP and heart failure. In order to reach those who were less likely to attend, we opted for the training to take place as part of an educational outreach to GP surgeries.

A Practice-based training session had the potential to reach even those clinicians who would not make the effort and attend an external learning event[338]. EPOC defines educational outreach or academic detailing as the "use of a trained person who meets with providers in their practice setting to provide training and information with the intent of changing the provider's practice[339]." This method may include feedback on the performance of the participants[218]. For our purposes, educational outreach also had the added advantage that facilitators generally could tailor their training to the needs and characteristics of the group they were visiting[338]. A number of studies on educational outreach typically used additional behaviour change strategies to reinforce their training aims[336] which concurred with the nature of our intervention.

Three clinicians conducted the training (HJ, SO, MS) which has potential cost implications. Two of these (HJ, SO) were expected to undertake regular medical education as part of their role description. Consequently, a fixed proportion of their

salary included time spent on training. Therefore, using these two facilitators was cost-neutral since they allocated part of their time for running the ACP Practice-Based Training. However, using a total of only two facilitators for any future session may be feasible. Lower numbers of facilitators could reduce costs without necessarily compromising the quality of the training.

While I can't present data from a randomised controlled trial, I was able to field test the ACP Practice-Based Training. In early summer 2017, I conducted ACP Practice-Based Training with 14 healthcare professionals in Oxford to generate the first quantitative and qualitative data on the effect of the training and the acceptability of the intervention components. **Appendix 25** provides the results of this field testing. Overall, outcomes from this pilot session supported the format, content, and training methods of the intervention. APT was welcomed by a range of clinicians from primary and secondary care and seemed suitable for further exploration in a clinical trial.

6.6 CHAPTER SUMMARY

In summary, the Question Prompt List, the Choices of Care Table, the ACP Reminder Sheet and the ACP Practice-Based Training Session received very favourable feedback from participants of the interview and focus group studies. As a result of the iterative intervention synthesis process, I was able to refine the Question Prompt List, the Choices of Care Table, ACP Practice-Based Training and ACP Reminder Sheet to optimise the implementation of ACP in heart failure from a patients', carers', clinicians', researchers' and healthcare commissioners' point of view. After synthesising the final version of the intervention, I had to consider a suitable trial design. The next chapter describes the rationale and protocol for the design of a

feasibility cluster randomised controlled trial to assess the acceptability and feasibility of delivering the intervention in a clinical context.

CHAPTER SEVEN

Protocol for a Feasibility Cluster Randomised Controlled Trial

7 PROTOCOL FOR A FEASIBILITY CLUSTER RCT

7.1 BACKGROUND

The previous intervention synthesis process developed and refined four intervention components based on best available quantitative and qualitative evidence and theory[207]. Such tools to help clinicians and patients identify their care preferences, plan for the future and talk about their needs are lacking in heart failure[87]. My project explored that need and developed a patient-led question prompt list (QPL), a shared decision-making (SDM) tool[7, 85] in the form of a Choices of Care Table (CoC), an ACP Reminder Sheet (ARS) for clinicians and an ACP training component targeting clinicians. Early findings from field testing in focus groups suggest that such an intervention strategy is acceptable to users and has the potential to help clinicians and patients with heart failure to identify and communicate ACP preferences. Given the lack of shared decision-making in palliative care for heart failure[23], research into the acceptability and effectiveness of this intervention is now needed and timely.

I propose a feasibility cluster randomized controlled trial (RCT) study to further investigate this complex behavioral intervention. A full, definitive RCT to show that the intervention optimizes the implementation of advance care planning would be large and expensive. Before this is justified, I need to demonstrate the feasibility and acceptability of the intervention to clinicians and patients. Conducting a feasibility cluster RCT such as that proposed in this chapter will help to inform whether a definitive cluster RCT is viable. The proposed feasibility cluster RCT will also assist

in producing a training package to deliver the intervention which could be formally evaluated for use in a variety of research settings or for health service development.

7.2 AIM AND OBJECTIVES

The aim of this phase of the research is to develop a CTU approved trial protocol for a feasibility cluster randomized controlled trial to assess the feasibility and acceptability of delivering the intervention

As recommended by the MRC framework for the development and evaluation of complex interventions[89, 109], I want to investigate and address the following objectives:

- To assess the feasibility of recruiting a sufficient proportion of primary care clusters to the intervention and control groups in the trial
- To assess the feasibility of identifying, recruiting and retaining a sufficient proportion of NYHA Class III/IV patients to participate in the trial
- To assess the acceptability of the intervention to clinicians and patients
- To evaluate the fidelity of delivering the intervention including adherence to study protocol
- To assess the feasibility of delivering the study methodologies as intended
- To evaluate the feasibility of collecting clinical outcome measures and economic analysis data
- To evaluate the level of contamination and exposure of the control group to the intervention

7.3 METHODS

7.3.1 Study Design

The trial will use a feasibility cluster RCT design with a combined qualitative component to inform the objectives of a future definitive cluster RCT. The most appropriate trial design is a simple, two-arm parallel cluster RCT. Five GP practices (three intervention clusters and two control clusters) are the units of randomization. However, data is collected from individual patients who suffer from heart failure. This trial design limits the risk of contamination between arms. Further pros and cons of the cluster randomized controlled design compared with other study design options are considered under the section "Discussion." The feasibility study will consist of a total of five primary care clusters which will be randomized to the intervention (three) and to standard care (two) so there is no bias in the selection of which practice receives the intervention. **Figure 30** shows the study flow diagram based on CONSORT guidelines for the reporting of cluster RCTs[340-343].

7.3.2 Study Duration

The total study duration for clusters is expected to last nine months. Each practice will participate in the trial for a maximum of eight months from screening to randomization, training and final follow-up. Individual clinicians and patients will participate in the study for a maximum of eight months from screening to final follow-up. **Table 28** shows a study Gantt chart with trial events and time points.

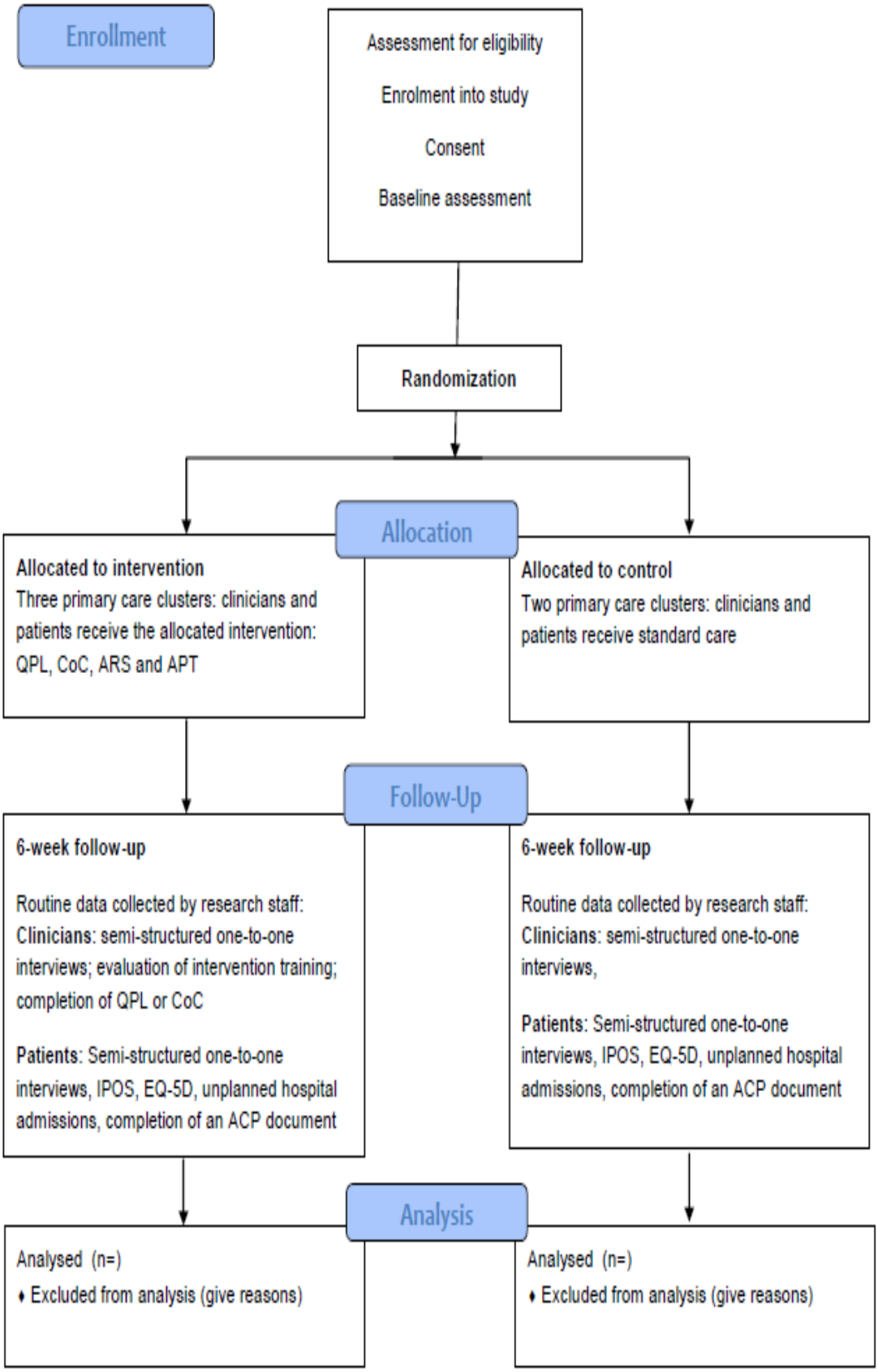


Figure 30. Study flow chart

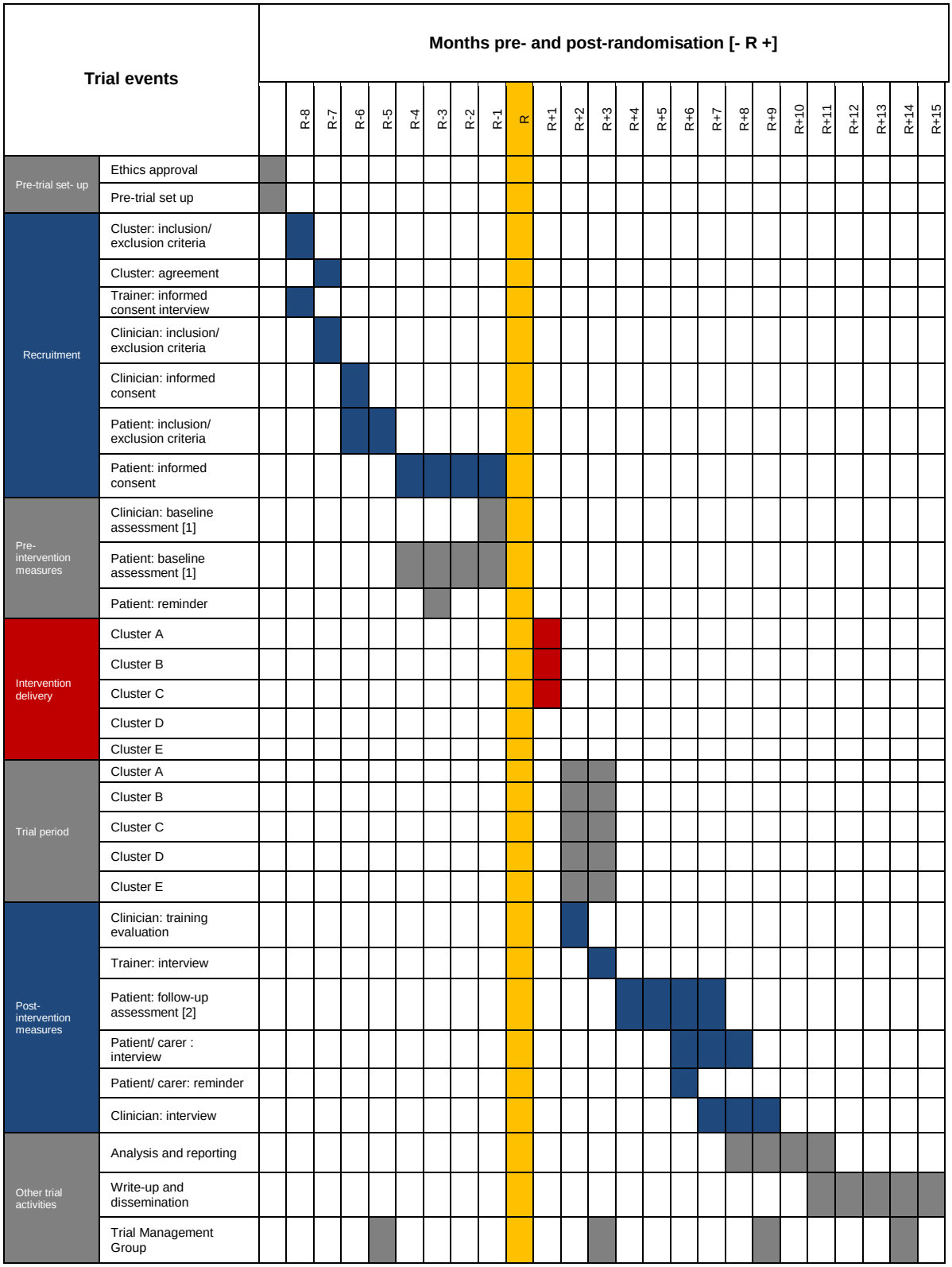


Table 28. Study Gantt Chart

Table 29 gives a summary of the study timetable as it applies to clusters and individual participants.

Study Timetable	Duration
Recruitment • Cluster recruitment, screening (1 month) • Clinician recruitment and cluster allocation to intervention (1 month) • Patient/ carer recruitment (4 months)	6 months

Pre-intervention measures
• Patient and carer screening, induction and consent:
  ○ One telephone or face-to-face screening and induction contact including:
  ▪ One baseline assessment/ survey containing IPOS, EQ-5D (45-60 minutes)
• Patient and carer screening: review of medical records on ACP conversation or documentation
• Clinician training: one ACP Practice-Based Training session (APT) for healthcare professionals on how to use intervention tools (2-2 ½ hours)
• Training evaluation: questionnaire immediately post Practice-based training session (5 minutes)
	3 months

Trial period • One patient/ carer – clinician face-to-face session (10-20 minutes) • Trainer interviews: one face-to-face session (15-30 minutes)	6 weeks
Post-intervention measures • Patient: follow-up survey including IPOS, EQ-5D (15 minutes). • Patient interview: subset of participants (n=15) one face-to-face interview or telephone session (30-45 minutes) • Clinician: follow-up survey (10 minutes) • Clinician: subset of participants (n=5) one face-to-face interview or telephone session (30-45 minutes)	3 months

Table 29. Study timetable

7.3.3 Setting and sample

The setting is primary care in England for adults suffering from heart failure in five GP practices in Thames Valley and Cambridgeshire. In this feasibility trial, primary care clusters will be stratified only on size. Therefore, the sample will be drawn from patients with heart failure attending primary healthcare. Patients will follow the care to which their surgery is randomized with matching patient information for both arms providing general information about the study, explaining that their local heart failure

services are being assessed using patient self-reported outcomes and medical record reviews.

7.3.4 Inclusion/ Exclusion criteria

Patients

Patient inclusion criteria are based on the European Society of Cardiology's CHF definition[24] and include both HFpEF and HFrEF in its definition of CHF. Patients are eligible if:

- they suffer from CHF New York Heart Association (NYHA) functional class III-IV,
- with systolic dysfunction and left ventricular ejection fraction (HFREF) of < 40% or
- heart failure symptoms and either midrange systolic function (HFmrEF) 40%-49% or
- preserved systolic function (HFpEF) > 50%.
- patients need to be older than 18 years of age with the mental capacity to consent, who are fluent and literate in English. Cognitive function will be assessed clinically by the clinicians.
- patients are excluded from the study if they suffer from a congenital heart disease or are unwilling to engage with end-of-life conversations. Patients will be excluded if they have already an ACP, are in the process of designing an ACP or where the clinician judges that they are not able to meet the demands of the study. Patients with chest pain and age < 50 years or with a severe concomitant illness (e.g. cancer) are also excluded.

Figure 31 shows the study flow diagram for an individual patient from receiving the invitation to participate until the final study assessment.

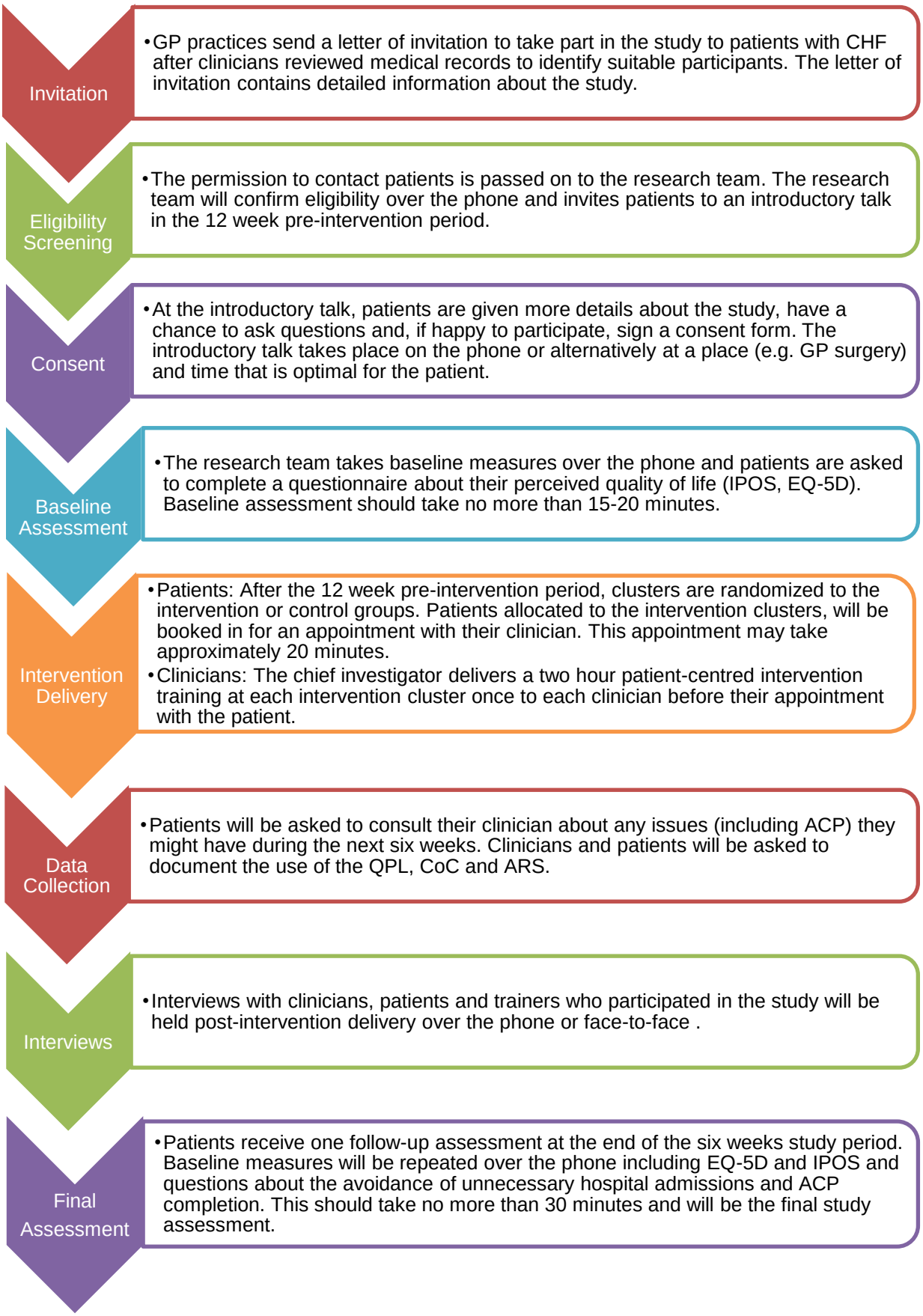


Figure 31. Study flow diagram for a participant

Healthcare Professionals

- Clinician inclusion criteria: GPs and nurses working in a primary healthcare setting delivering day-time clinical primary care services.
- Primary care inclusion criteria: urban or non-urban practices of comparable size and patient population.
- Primary care exclusion criteria: Out-of-hours services, EMU and ambulatory care units

Trainers

- Two additional clinicians have already been trained in running the training component of the intervention. These trainers are a consultant heart failure specialist nurse and a palliative care specialist nurse employed by the Oxford University Hospitals NHS Foundation Trust. Both have long-standing clinical and teaching experience in managing difficult conversations in end-of-life care for patients suffering from heart failure. Therefore, only one additional trainer is required to run APT with me. The second trainer may compensate for the absence of the other.

7.3.5 Recruitment

Cluster recruitment

We will contact relevant primary care practices explaining the study and inviting participation. The trial team may visit interested practices to provide additional information.

Patient identification and recruitment

Before randomisation of primary care practices, potentially eligible participants will be identified through the following methods:

GPs, practice nurses and district nurses will be invited to participate in the patient identification and recruitment. Patients with heart failure consulting their GP will have a read code entered into their computerised medical records or are listed on the Quality and Outcome Framework (QOF) or Gold Standard Framework (GSF) for heart failure. A member of the GP practice team will be asked to download the details of patients from these lists and read codes. A clinician, GP or nurse, will check for inclusion criteria. GPs and nurses will be able to exclude any patients they perceive as being too vulnerable to approach for involvement in research by using a dedicated exclusion code set up for the study. The GP practice team will send potential participants an invitation letter, a participant information sheet (PIS), a consent form and questionnaire. Clinicians will ask patients for permission to be contacted by the research team to discuss the study further if they so wish and identify a suitable time. After obtaining permission, clinicians will forward these details to the research team. Where patients with an identified caregiver agree, the caregiver will also be approached and consented.

Additionally, GPs and nurses will be able to identify more eligible patients during routine consultations. The GP or nurse will provide the patient with a printed invitation letter, PIS, consent form and questionnaire. The clinician will highlight that participation in the study is absolutely voluntary and suggest to the participant to ring the research team if they are interested in taking part in the study.

- **Recruitment**

All patients who agree to be contacted by the research team will be mailed a full study pack if they have not received one yet (letter of invitation, participant information leaflet, questionnaire, consent form, and a pre-paid return envelope). Participants in both arms of the trial (control and intervention arm) will be asked to give written consent to take part in a study investigating heart failure and quality of life, consisting of the baseline and follow-up questionnaire (at 6 weeks) and to allow the research team access to their medical records.

Patients interested in participating will be offered the option of telephoning the research team, blinded to practice allocation. Members of the research team will be instructed to advise patients not to disclose their allocation at the beginning of the telephone conversation. They will answer any questions and support those who need it to complete the consent form and questionnaire over the phone. Participants who consent over the phone can return the completed questionnaire and consent form to the research team in pre-paid envelopes. Clinicians will be informed of their patients' consent in the study evaluation. GP practices will be reimbursed for their time screening patient lists, participating in the intervention training and intervention delivery.

In the event that participants have missing data at baseline on the primary outcome measure, the research team will contact them by telephone to collect the missing data. At each data collection time-point (baseline and 6 weeks), non-responders will be mailed a postcard reminder 2 weeks after mailing of the initial material. At 6 weeks follow-up, non-responders will be mailed a brief data questionnaire, consisting of the

outcome measures (EQ-5D[344], IPOS[345]). Telephone collection of data will be attempted. Alternatively, we may collect data online or in the context of a face-to-face visit. Again, the research team will answer any questions and support those who need it to complete the questionnaire.

Before randomisation, intervention and control clusters will engage in two intensive periods of patient recruitment. The first recruitment period will be within three months of training clinicians in the intervention. If recruitment should be unsatisfactory, there will be a second one-month period of recruitment in each practice and clinic (intervention and control) one month after the intervention training for intervention clusters. To facilitate smooth running of the study and minimise disruption to the practices during the recruitment phase, each clinician will keep three consultation appointments per day free and will be reimbursed for doing so. Posters will be put up in waiting rooms for a few weeks before recruitment begins to inform patients about the study.

- **Recruitment of ethnic minorities**

There is some evidence that suggests that ethnic minorities are less likely to engage with ACP[326]. Low health literacy, a lack of awareness, access or knowledge about ACP or a distrust towards the health system are some one of the most commonly cited barriers to ACP[346-351] among ethnic minorities. It is therefore important to recruit a sufficient proportion of participants from ethnic minorities to explore their views on the acceptability and feasibility of the intervention and study procedures. Based on recruitment rates of ethnic minorities in published clinical studies[352-355], we aim for a proportion of ethnic minorities between 2.5-10.0% of the total study population. We

will train and ask primary care clinicians to carefully identify and reach out to ethnic minorities during the recruitment process. As part of the ACP intervention training (APT), we address some of these barriers by, for example, making clinicians aware that some ethnic minorities may have a strong preference for family-centred decision-making in ACP[346, 356]. As appropriate, we encourage healthcare professionals to involve the whole family rather than focus on the individual as favoured in Western medicine[357].

- **Recruitment homogeneity**

The categorization of CHF patients according to NYHA classes is known to be problematic[358]. This is due to a number of reasons: its lack of interrater reliability[359] and poor reproducibility[360] have been acknowledged. CHF in itself is characterized by symptom volatility[361] leading to changes in NYHA classification over a short period of time and so potentially affecting study eligibility. This fluctuation in health status applies mainly to changes from NYHA class III to NYHA class II[358]. So, restricting participation to NYHA class III/IV may exclude symptomatically stable NYHA class II patients at the time of study recruitment who may well have palliative care needs[358]. In line with palliative care research practice for heart failure and to ensure recruitment homogeneity, eligibility criteria are extended to the recruitment of patients currently classified as NYHA II who had a diagnosis of NYHA class III in the past.

7.3.6 Screening and Eligibility Assessment

Patients who are interested in taking part will call the research team on the number provided to them in their letter from their clinician. A member of the research team will discuss a potential participation with patients; will confirm eligibility based on

the inclusion and exclusion criteria over the phone. The researcher will verbally provide information as described in the PIS, answer any questions and seek informed consent. If a patient should decline participation, we will document characteristics of patients including reasons for non-participation, ethnicity, age, gender and NYHA class.

7.3.7 Baseline Assessments

Baseline assessments will be undertaken at the initial screening and consent procedures. At this point, following informed consent, a researcher will collect data from the participants over the phone in the survey form including:

- Demographic data including age, gender, ethnicity, education and NYHA class
- History of recent hospital admissions
- Quality of life according to EQ-5D[344] and IPOS[87]
- Experience of advance care planning including the occurrence of an ACP conversation or the completion of an ACP document

Data will be recorded using paper case report forms. These will then be entered into a secure electronic data base by the lead researcher.

7.3.8 Randomisation

After clusters (practices), clinicians and patients have completed the consent process and baseline measures, the research team will randomly assign clusters to receive either the intervention or the standard care via a computer generated random allocation. Selective recruitment of individuals can occur in cluster RCTs if the

people recruiting participants know the participants' allocation. In order to minimise selection bias on an individual level, randomisation of participants will take place after patient recruitment and consent procedures have been completed[362]. An independent researcher from the Clinical Trials Unit, NDPCHS, will generate the allocation for each primary care cluster. The researcher will use sequentially numbered and sealed envelopes to ensure allocation concealment until each cluster has been assigned.

7.3.9 Subsequent Appointments

Any appointments between clinicians and patients that occur after the initial baseline assessment and before the planned six-week follow-up measurement are entirely voluntary and left to the initiative of the clinician or the patient. I will capture data from any subsequent appointments at the follow-up visit.

7.3.10 Follow-up Assessment

There will be one follow-up assessment to measure intervention outcomes after a six-week intervention period. The research team will be responsible for arranging the follow-up assessment. Participants will be contacted by phone in the first instance unless an alternative contact method is requested by the participant. The research team will attempt to contact the participant at least twice by phone. If unsuccessful, we will attempt to contact patients by letter (reminder postcard) or email. The research team will also use email (or letter if preferred by participants) to remind patients of their upcoming assessment. At the 6-week follow-up assessment, we will ask patients and complete the case report form (CRF) over the phone including:

- Any documentation in changes in unplanned hospital admissions and unwarranted investigations

- Repeat the EQ-5D and IPOS as a self-reported outcome to identify any changes to patients' quality of life
- Documentation of any changes to the patients' ACP experience including the use of the Question Prompt List or the Choices of Care Table, the occurrence of an ACP conversation or the completion of an ACP document

All participants will be asked to complete a short post-intervention survey to assess aspects of the intervention (e.g. Question Prompt List or Choices of Care Table) they have received from their healthcare professional. If the participant is not willing to have a follow-up assessment over the phone and prefers a follow-up visit, we may arrange a home visit, a visit to their surgery or clinic, or a visit to the Nuffield Department of Primary Care Health Sciences at Oxford University or the Primary Care Unit at Cambridge University. .

7.4 STATISTICS AND ANALYSIS

This is a feasibility study and not powered to detect a significant effect of the intervention. The main outcome of this study is to determine the feasibility and acceptability of delivering the intervention and its proposed evaluation methodology.

7.4.1 Sample size

While a sample size is not calculated since the main outcome of interest is the feasibility and acceptability of the intervention, at least a total of 30 patients and eight clinicians are recommended to derive estimates to aid the sample size calculation for any future cluster RCT[363].

7.4.2 Cluster Size Calculation

I cautiously base my cluster size calculation[364] on a HF practice prevalence of 1%[365]. Heart failure patients are either identified with ICD codes on practice IT systems or registered on the QOF or GSF lists for heart failure. Some palliative care research in cancer suggests[366] that a 20% consent rate and a 50% attrition rate should be assumed. Therefore, the minimal cluster (practice) size would need to be of 10000 patients. Of these 10000 patients, 100 patients (1%) are likely to suffer from heart failure. We aim to recruit 20 patients suffering from heart failure (20%) per cluster and expect 10 patients (50%) to provide data at final follow-up. Assuming five clusters of equal size, this would mean a total of 50 patients at final follow-up.

7.4.3 Analysis of Progression Criteria

The primary outcome of this study is to determine the feasibility and acceptability of the intervention and its proposed evaluation methodology. Progression criteria are used in feasibility studies to inform whether it is appropriate for the study to proceed to the main trial phase or whether it is necessary or possible to modify the operational aspects of the design to promote success[367]. The following progression criteria correspond to the objectives of this feasibility trial and were reviewed and approved by the CTU (NDPCHS). They follow a traffic light assessment system[367] with the following meaning: red = stop; amber = discuss with CTU and Trial Management Group [TMG] whether sufficient changes can be made to proceed to a full trial without another feasibility assessment; green = proceed to a full trial. The thresholds for progression criteria in this feasibility study are informed by best practice in palliative care research for heart failure[87, 358, 368, 369].

The progression criteria, their method of measurement and assessment criteria are summarized in **Table 30**. For example, the progression criteria of the feasibility of recruiting a sufficient proportion of primary care clusters to the intervention or control groups, describes the thresholds of when it is appropriate for the study to proceed with a future trial or when to modify our cluster recruitment approach. Based on previous research[370], I will approach a minimum of 10 practices and from their response, I will be able to estimate practice recruitment which will inform this criterion. The criterion study recruitment and retention rates for patients specifies the proportion of participants identified, recruited and retained at each time point. Withdrawals and possible reasons for withdrawal will be reported. Based on previous studies[54, 164, 169, 368], we have defined a recruitment rate of over 0.2% of patients per cluster as a success criterion of the total number of participants to be invited to the study. If 0.1 - 0.2% of patients per cluster are recruited, we will consult the TMG to consider possible steps to increase recruitment. If < 0.1% of patients per cluster are recruited, we are aware that the chosen recruitment procedures are unlikely to be feasible for a definitive trial and will inform the TMG.

Qualitative data from interviews with patients and clinicians will generate additional findings into intervention and trial design features informing those components which can remain or, where results fall into the amber zone, changes that need to be made to improve their feasibility and acceptability.

Progression criteria[367]	Measures used	Assessment of whether criteria have been met
The feasibility of recruiting a sufficient proportion of primary care clusters to the intervention or control groups	The percentage of eligible primary care clusters recruited to the intervention and control groups ; issues re the feasibility of participation will be explored in qualitative interviews	**Green:** if ≥75% of service clusters participate in the trial = proceed[370]. **Amber**: 50-75% = the TMG will consider the feasibility of proceeding after a consideration of possible steps to increase participation of clusters. **Red**: <50% = definitive trial unlikely to be feasible.
The feasibility of recruiting a sufficient proportion of NYHA Class III/IV patients to participate in the trial	The percentage of eligible CHF patients recruited to the trial and consented at each cluster; issues re feasibility of recruitment process will be explored in qualitative interviews	**Green**: If ≥ 0.2% of patients per practice recruited = proceed[368, 371]. **Amber**: If 0.1-0.2% of patients per practice recruited = TMG will consider feasibility of proceeding after a consideration of possible steps to increase recruitment. **Red**: If < 0.1% of patients per practice = definitive trial unlikely to be feasible.
The feasibility of appropriate retention rates to six weeks follow-up	The percentage of CHF patients in the trial at the final follow-up	**Green**: Retention rate of ≥50% of consented patients = proceed given the high attrition and mortality rate in this population[369, 372]. **Amber**: If 20-60% = the TMG will consider proceeding and steps to increase retention based on available data[87]. **Red**: If < 20% = definitive trial unlikely to be feasible.
The acceptability of the intervention to participants in terms of its usability and likelihood of future use	Percentages of participants who report acceptability of the intervention components on survey questions. Issues re acceptability and usability of the intervention will be explored in qualitative interviews.	**Green**: ≥50% of clinicians and ≥50% patients found the intervention acceptable and made use of at least one of the intervention components on one occasion by the end of the study period[369] = proceed. **Amber**: 30-50% = the TMG will consider the quantitative and qualitative data and decide on whether the intervention is acceptable or could improve. **Red**: If <30% = unlikely to be acceptable in a definitive trial.
The fidelity and feasibility of delivering the intervention and study methodologies as intended	Compliance with study protocol, invite process, summary statistics for intervention fidelity measures by cluster and overall, feasibility of collecting outcome measures, response rates to interviews and surveys	**Green**: ≥90% completion of each of the questionnaires and item[368, 369] = proceed. **Amber**: 70-90% completion of each questionnaire = the TMG will consider how questionnaire completion could be improved **Green**: >70% intervention protocol adherence = proceed. **Amber**: <70% = the TMG will consider the qualitative and quantitative data and decide whether the trial methodology and the intervention were delivered as intended.
Contamination and exposure of the control group to the intervention	Percentages of participants in the control and intervention groups who report that they were exposed to the ACP intervention	**Green**: If < 20% of control participants report that they have been exposed to the ACP intervention during the study period = proceed. **Amber**: >20% contamination of control participants = the TMG will discuss how this criterion could improve in a definitive trial.
Abbreviation	**TMG**: Trial Management Group; **SDMts**: shared decision-making tools;	

Table 30. Progression criteria

7.4.4 Analysis of Clinical Outcome Measures

As described above, the primary outcome of this feasibility study is related to the study progression criteria defining the acceptability and feasibility of delivering the intervention. It is likely to be non-significant due to the limited power of this study, we want to analyze the feasibility of collecting clinical outcome measures that are important to seriously ill patients and their carers[373] and concur with recommendations from the European Association for Palliative Care on outcome measurement[149]. These outcome measures include, but are not limited to, a reduction in unplanned hospital admissions, an improvement in the quality of life[374] (QOL) as assessed by the EQ-5D and the Integrated Palliative Care Outcome Scale (IPOS).

We will use a mixed effect model[375, 376] for the analysis of the clinical outcomes (see section 7.4.4) which allows for all available data at follow-up to be included and accounts for missing data and clustering effect. In theory, this model can estimate a two-sided 95% CI to show a credible range for the true difference in clinical outcome measures like unplanned hospital admissions between intervention and control arms. The model will be adjusted for key patient-level baseline characteristics and a random effect for the GP surgeries. Baseline characteristics will be reported using summary descriptive methods for each cluster. Analyses of other clinical outcomes will be performed similarly. Due to the small sample size of this study, we will test for the normality of the data and choose a parametric and non-parametric test accordingly. Analysis will be conducted at the end of the study.

7.4.4.1 Unplanned hospital admissions

An unplanned hospital admission is defined as an admission or re-admission of a patient with an overnight stay that was not previously planned or scheduled or

elective[377, 378]. Avoiding unplanned hospital admissions is a major concern for the National Health Service[379-381] and especially relevant since heart failure is a leading cause of admissions and a substantial drain on healthcare resources[382]. This is mainly due to the high unit costs of emergency admissions compared with other forms of care and the disruption it causes to the individuals involved, elective care and inpatient waiting lists[383]. In England, there were 68 654 unplanned heart failure patient admissions in 2012/2013 with a total overall cost of around £119 million[384]. The average cost of a single, unplanned admission for heart failure was £2231 in 2010 with 12.2 days being the mean length of stay[385]. I will evaluate the cost and possible impact of the intervention on unplanned admission rates of CHF patients by survey assessment including the EQ-5D at 6-week follow-up. This data will contribute to a health economic analysis as described in Section 7.4.5.

7.4.4.2 Quality of life

- **IPOS**

The Integrated Palliative Care Outcome Scale (IPOS) can be used in clinical care to assess patients' quality of life[345]. It contains 10 items on physical symptoms, psychological, emotional and spiritual needs. The tool is a valid and reliable outcome measure with good psychometric properties for QOL in the CHF population[87]. Patients take a mean time of 6.9 min and staff 5.7 min to complete. Given the design of the study, we do not expect statistically significant effect sizes for QOL. But we will assess the suitability and acceptability of using this tool in our study and assess the impact of the intervention by survey at baseline, and at 6-week follow-up. The number of patients requiring assistance with questionnaire completion will be used as a feasibility marker.

- **EQ-5D**

Evidence supports the validity and reliability of the EQ-5D as an outcome measure within the cardiovascular area including heart failure[54, 344]. EQ-5D defines health related quality of life (HRQL) in five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/ depression. The tool imposes a minimal burden on the respondent as it is a brief, simple measure for patients to understand and to complete. The EQ-5D may be useful for future modelling of QALYs in economic evaluations of a definitive cRCT[344]. I have registered this study at the EuroQol Research Foundation's website which grants the use of the EQ-5D-5L (**ID 24459**).

7.4.5 Analysis of Intervention Components and NYHA Class

At six weeks follow-up, we will repeat baseline measures including NYHA class. We will measure the frequency of the use of the Question Prompt List, Choices of Care Table, and the completion of an ACP document or the occurrence of an ACP conversation by survey assessment. We will also ask patients whether they were offered or made use of the Question Prompt List or the Choices of Care Table or both and, if applicable, in what sequence. In this way, we will be able to capture the stage of disease in association with the likelihood of patients participating in the trial and the likelihood of patients using the intervention.

Additionally, all clinical outcomes will be measured pre-intervention delivery at baseline and at 6-week post-intervention follow-up by survey assessment. In this way, we will be able to capture the stage of disease in association with the quality of life of participating patients. While we do not expect a statistically significant effect due to

the limited power of the study, we plan to examine the direction of the effect of the intervention on unplanned hospital admissions and quality of life at six weeks by using the analysis of covariance models (ANCOVA)[386].

7.4.6 Health Economic Analysis

Patients in the intervention and control groups have access to primary and hospital-based care and thus generate costs. In addition, in the intervention group, GPs and nurses will generate additional costs due to staff time spent in training and delivering the intervention. The aim of this evaluation is to assess whether it is feasible to assess the cost-effectiveness of the intervention compared to standard care for patients with heart failure.

A simple cost-utility analysis is planned by using utility scores gathered with EQ-5D and a pool of direct costs, e.g. costs for the intervention and cost/ savings from the avoidance of unplanned hospital admissions. Our cost calculations are based on the time each clinician spends in undergoing intervention training and delivering the intervention to patients. When ACP is delivered as part of our intervention, minutes are documented and used to calculate costs for each staff category. Additionally, all our cost calculations will include estimates for the cost of unplanned hospital admissions or subsequent in-hospital care. Resource use will be costed by means of the NHS reference costs[387] and the Unit Costs of Health and Social Care guidelines[388].

In a grant proposal, we have quantified the time required for clinicians to be trained in and to administer the intervention in clinical practice. We have identified and costed the renting of premises for training and research during recruitment and costed the time for trainers and training material. In order to identify follow-up resource, we are

using questionnaires and conduct interviews with patients and clinicians including questions from the Client Service Receipt Inventory[389] to elicit information on the frequency, types and costs of resources that were incurred or prevented with ACP in heart failure. A health economist (LA) from the Nuffield Department of Primary Care has reviewed and approved this approach for a health economic analysis.

7.5 THE INTERVENTION

This intervention will be delivered at a service level rather than at a patient level. To avoid disappointment bias, we will offer to train the clinicians of the control groups in the intervention after the conclusion of the study. Then, they can deliver the intervention to patients who participated in the study if they wish to do so.

The previous analysis of what motivates and enables clinicians to deliver ACP for patients suffering from heart failure demonstrated (sections 4.5.3 and 5.4.5) that key components requiring behavioral change are: physical and social opportunity, psychological capability (including the Theoretical Domains Framework areas of knowledge, skills, and memory attention and decision processes) and Reflective Motivation (including Theoretical Domains Framework domains of Belief about capability, Optimism, Emotions, Belief about consequences; Intentions, Goals, Role and Identity and Behavioral Regulation). To target these Theoretical Domains Framework domains, the intervention consists of the Question Prompt List, the Choices of Care Table and the ACP Reminder Sheet combined with clinician training (APT). **Table 31** summarizes the main components and objectives of the intervention according to the Template for Intervention Description and Replication (TIDieR)[103].

Components	QPL	CoC	APT Training	ARS
Aim and objectives	To enable patients to clarify and communicate their ACP/ EOL care preferences	To facilitate a shared decision making process between patients and HCPs	To enable the optimal use of SDM in CHF	To remind clinicians of core ACP/ CHF criteria, resources and tips for conversations
Content	A patient-led tool consisting of questions about EOL Care and HF that patients found essential and helpful in clarifying their care preferences	A SDM tool that shows patients treatment options ranging from curative to palliative for common complications in CHF	Overview of PCC and SDM tools; Rationale for using QPL and CoC Three CHF case scenarios Practicalities of SDMs in clinical routine	Patient endorsed phrases to initiate ACP conversations, template with all essential ACP criteria, links to CHF and ACP resources, NYHA classification, GP/ cardiology e-mail prompt
Personnel	*Provider*: The CI together with a senior HFN deliver the 2-hour patient centered training at each study site once to the clinicians. The clinicians provide recruited patients with the SDMts. *Supervision*: the CI is on site when recruited patients attend the surgery and prompts the clinician to give patients the SDMts and reminds patients to make use of the tools			
Setting Schedule Duration	Patients can complete the SDMts during their appointment with their clinician or until their next review at the surgery. On arrival at the clinic, clinicians provide patients with a paper copy of the SDM tools with a clipboard and a pen			
Delivery	Only clinicians who participated in the intervention training are involved in the delivery of the QPL and CoC.			
Abbreviation	**SDM:** shared decision-making; **SDMts:** shared decision-making tools; **HCP**: healthcare professional; **CHF**: congestive heart failure; **CI**: chief investigator; **EOL**: end-of-life; **ACP** advance care planning; **HFN**: heart failure nurse; **PCC**: patient-centered care			

Table 31. TIDieR: summary of intervention components

The following sections describe the main intervention components:

7.5.1 The Question Prompt List

The Question Prompt List (QPL) is a patient-led tool in lay language that contains nine questions that patients and carers found essential to help them think about their care preferences and communicate these with their clinician (**Figure 32**).

Question Prompt List for Patients Suffering from Heart Failure

By Dr Markus Schichtel, V9, 24-08-2016

Introduction

Some patients find it helpful to think about questions that clarify their understanding of heart failure and the kind of treatment they would like to have. Thinking about the questions below is entirely voluntary. But it can make it easier for you to make decisions about your care or to talk to people you love and those who look after your health. On your next visit, you can discuss this list with your doctor or nurse. They will be glad to answer any questions you may have. This will enable them to support you in line with your wishes. Thank you!

Questions you may want to ask yourself

Following are some questions you may want to ask yourself. You can use the table below to mark ✓ the example that best describes your answer to the question. Your answers may change over time and that is perfectly ok. If that is the case, you may want to let your healthcare professional know, so they can support you in line with your wishes.

Question	Examples	✓
How much do I want to know about my condition?	I prefer not to know anything about my condition	
	I only want to know the basics.	
	I want to know as much as I can.	
How much do I want to get involved in my care?	I do not want to get involved in my care.	
	Only what's needed.	
	I want to have a say in all decisions.	
How long do I want to receive medical care?	I want to live as long as possible, no matter what.	
	Currently, I am not sure.	
	Quality of life is more important to me than length of life.	
How involved do I want my loved ones to be?	I do not want my loved ones to know anything about my health.	
	Only what's necessary	
	I am comfortable with my loved ones to know everything about my health.	

Who do I want to be involved In my care?	Who do I not want to be involved in my care?
What is most important to me about my care?	**Any other thoughts I may have:**

Questions you may want to ask your healthcare professional

Here are some questions about heart failure you may want to ask your healthcare professional about. Your doctor or nurse will be happy to answer any of these. The table gives you also the chance to mark ✓ how important that question is to you. This will help your doctor or nurse to spend more time on giving you an answer.

Question	Not important	Important	Very important	Any other questions I may have:
What is heart failure?				
What is the treatment for heart failure?				
How serious is heart failure?				
Where can I get more support? (e.g. benefits)				
What can I do if I become very ill?				

Additional Help

Here are some places you can get more help or information from. If you don't have internet access, your doctor or nurse will be pleased to assist you.

About	Organisation	Web Link
Heart Failure	Patient UK	http://patient.info/health/heart-failure-leaflet
	British Heart Foundation (BHF)	https://www.bhf.org.uk/heart-health/conditions/heart-failure.aspx
	Heart Failure Matters	http://www.heartfailurematters.org/en_GB
	HealthTalkOnline	http://www.healthtalk.org/peoples-experiences/heart-disease/
Planning for Future Care	Preferred Priorities for Care	http://www.nhsiq.nhs.uk/resource-search/publications/eolc-planning-for-future-care.aspx
	Better Together (BHF)	https://www.bhf.org.uk/publications/
	Advance Care Planning	http://www.dyingmatters.org/page/

Figure 32. Question Prompt List

7.5.2 The Choices of Care Table

The Choices of Care Table (CoC) is a shared decision-making tool to support patients with heart failure in considering the pros and cons of available treatment options if they should become seriously ill. It describes common complications in end-stage heart failure and a choice of corresponding treatment options ranging from curative to palliative care approaches. **Table 32** depicts the complete Choices of Care Table.

Heart Failure – Choices of Care Table

Dr Markus Schichtel

Some patients find it helpful to know what kind of treatment is available should they become very ill. The table below lists different problems that may go together with heart failure and shows you some choices of treatment that can be offered. The choice of treatment can range from intensive treatment (red column) to care that aims to keep patients comfortable and pain free (green column). The table does not describe every choice of treatment but is a good starting point to find out more. You can use it to talk it over with your doctor or nurse. They will be glad to answer any questions you may have. You don't need to fill in the whole table, just what is important to you at this time. The table has also space to describe in your own words what you would like to happen. You may change your mind in the future and that is completely ok. If that's the case, please let your healthcare professional know, so they can support you in line with your wishes.

Date of past review:	Date of current review:	Date of next review:
Patient's details:	**Third party details:** Spouse_ Family member_ Carer_ Proxy_	**Details of healthcare professional:** GP_ Cardiologist_ Heart Failure Specialist Nurse_ District Nurse_ Other_
Name: Date of birth: NHS No: Address: Contact:	Name: Address: Contact:	Name: Address: Contact:

PROBLEM	CHOICE OF TREATMENT TO TALK ABOUT			In my own words at this time:	Discussed		Date
					Yes	No	
Serious infection (e.g. lung infection or urine infection with confusion)	☐ Treat in any way possible including drips & hospital admission	☐ Treat at home with oral antibiotics but try not to admit to hospital	☐ Aim to keep me comfortable at home, control any pain, treat any discomfort but do not admit to hospital				
Current choice of treatment	☐ Stay on everything	☐ Stop any treatment that causes undue side effects (e.g. Aspirin, Statins)	☐ Stop any treatment that is not necessary to control symptoms or pain				
Having an implantable cardioverter defibrillator (ICD)	☐ Keep defibrillator activated at all times	☐ Consider deactivating defibrillator	☐ Deactivate defibrillator				

No pulse and no breathing	Attempt resuscitation and keep ICD activated ☐	Patient requests to keep ICD active but does not want to be resuscitated. ☐	Deactivate device and allow natural death ☐				
New health problem is found, (e.g., anaemia or poor kidney function)	Fully investigate incl. invasive tests and hospital referral ☐	Investigate by GP with basic tests but do not refer to hospital or do unpleasant tests	Note the findings and keep the person comfortable at home without further tests. ☐				
Fall with fracture	Admit to hospital for treatment ☐	Avoid admission unless symptoms are not easy to control at home ☐	Aim to keep me comfortable at home, control any pain, treat any discomfort but do not admit to hospital. ☐				
Occurrence of an end-of-life complication (e.g. severe shortness of breath)	Admit to hospital for treatment even if this may not help ☐	Avoid hospital admission unless symptoms can't be controlled at home ☐	Aim to keep me comfortable at home, control any pain, treat any discomfort but do not admit to hospital. ☐				
COPD getting worse	Treat in any way possible incl. iv drips & hospital admission ☐	Treat at home with oral medication but try not to admit to hospital ☐	Aim to keep me comfortable at home, control any pain, treat any discomfort but do not admit to hospital. ☐				
Worsening heart failure due to chemotherapy	Treat in any way possible incl. iv frusemide & hospital admission ☐	Avoid admission to hospital; admission to day unit is fine. ☐	Aim to keep me comfortable at home, control any pain, treat any discomfort but do not admit to hospital. ☐				
You may write down your own problem:							

Table 32. Choices of Care Table

7.5.3 The ACP Reminder Sheet

The ACP Reminder Sheet (ARS) summarises all core components of anticipatory management, ACP and priorities of care on one page and maps their use against the heart failure illness trajectory of the patient. Next to patient endorsed sample phrases, it includes links to resources and the NYHA classification. **Table 33** illustrates the entire ARS.

Advance Care Planning (ACP) Reminder Sheet in Heart Failure
Dr Markus Schichtel V8 20122016

You can use the ACP Reminder Sheet to inform and track your care planning for each of your patients. It gives you an overview of what ACP criteria have been addressed and which are still outstanding. Included are also patient-endorsed communication tips to start and conduct an ACP conversation, links to relevant resources and the NYHA Classification of Heart Failure. The ACP Criteria are only meant as prompts to guide a conversation. They are not intended to be used rigidly. The template is not expected to be filled in during one session. Typically, this takes time. Please remember that patients' care preferences vary during the course of the disease. And it is common that patients change their minds on what they want. Therefore, timely reviews of the Reminder Sheet are recommended.

Details of Patient:	**Third Party Details:** Spouse_ Family member_ Carer_ Proxy_	**Details of Healthcare Professional:** Cardiologist_ Gerontologist_ GP_ Heart Failure Nurse_ Palliative Care Nurse_ District Nurse_ Palliative Care Doctor_
Name: Date of birth: NHS No: Address: Contact:	Name: Address: Contact:	Name: Address: Contact:

The Advance Care Planning Conversation

Possible steps in an ACP conversation:	*Patients and carers have endorsed the following phrases. They may help you to initiate or conduct an ACP conversation.*
1. Clarify what the patient knows and/ or wants to know	Please tell me about your heart failure.
	What is your biggest concern right now?
	How is your heart failure affecting your life?
2. Identify the patient's goals and preferences	If you become more ill, what is most important to you?
	Are there any aspects of your future care that you would like to avoid?
	Can you imagine a scenario where you don't want to have treatment?
	How involved do you want your loved ones to be?
3. Tailor treatments and decisions to the goals of the patient and family	How do you see the benefit of…?
	How do you see the drawback of…?
	Who is helping to look after you?
	Who would you like to make decisions on your behalf if you are not able to?
	Would you like to know what treatment is available should you become more ill?

Advance Care Planning Criteria
We suggest that you address Anticipatory Management and Advance Care Planning latest by NYHA-III and Priorities of Care latest by NYHA-IV. NYHA Classes are described under "Resources."

	Patient's NYHA-Class	**Addressed**		**Date**	**Comment**
		Yes	**No**		
Anticipatory Management					
Question Prompt List discussed					
Medication Review					
Social Care Review					
Advance Care Planning					
Treatment Options Table discussed					
EOL conversation has taken place					
Lasting Power of Attorney clarified					
DNAR Status clarified					
Advance decision to refuse treatment					
Device in situ: ICD/CRT/CRT-D					
Device deactivation - planned					
Device deactivation - consent given					
Device deactivated					
Priorities of Care					
Preferred place of care or death					
Palliative care measures only					
Care Benefits (e.g. DS 1500)					
Palliative Care Register					
Summary Care Records					
Fast Track Summary for A&E/ OOHs					

Resources

Here is a selection of resources that provide more information about heart failure, end of life care and advance care planning.

Heart Failure	British Heart Foundation (BHF)	https://www.bhf.org.uk/heart-health/conditions/heart-failure.aspx
	Heart Failure Matters	http://www.heartfailurematters.org/en_GB
	NICE	http://cks.nice.org.uk/heart-failure-chronic#
	HealthTalkOnline	http://www.healthtalk.org/peoples-experiences/heart-disease/
End of Life Care (EOL)	Preferred Priorities for Care	http://www.nhsiq.nhs.uk/resource-search/publications/eolc-planning-for-future
	Gold Standards Framework	http://www.goldstandardsframework.org.uk/home
	Better Together (BHF)	https://www.bhf.org.uk/publications/living-with-a-heart-condition/
	Patient UK	http://patient.info/doctor/Palliative-Care-of-Heart-Failure
	RCGP Matters of Life and Death	http://www.rcgp.org.uk/Clinical-and-research/Clinical-resources/
Advance Care Planning	National Council for Palliative Care	http://www.ncpc.org.uk/freedownloads
	E-learning for Healthcare	http://www.e-lfh.org.uk/programmes/end-of-life-care/
	Dying Matters	http://www.dyingmatters.org/page/advance-care-planning
	Royal College of Physicians (RCP)	https://www.rcplondon.ac.uk/guidelines-policy/advance-care-planning

NYHA Classes

Doctors usually classify patients' heart failure according to the severity of their symptoms. The New York Heart Association (NYHA) Functional Classification is the most commonly used system.

Class	**Patient Symptoms**
I	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation or dyspnoea.
II	Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnoea.
III	Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnoea.
IV	Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.
Class	**Objective Assessment**
A	No objective evidence of cardiovascular disease. No symptoms and no limitation in ordinary physical activity.
B	Objective evidence of minimal cardiovascular disease. Mild symptoms and slight limitation during ordinary activity. Comfortable at rest.
C	Objective evidence of moderately severe cardiovascular disease. Marked limitation in activity due to symptoms, even during less-than-ordinary activity. Comfortable only at rest.
D	Objective evidence of severe cardiovascular disease. Severe limitations. Experiences symptoms even while at rest.
	Examples
Class I-D	A patient with minimal or no symptoms but a large pressure gradient across the aortic valve or severe obstruction of the left main coronary artery.
Class IV-A	A patient with severe anginal syndrome but angiographically normal coronary arteries.

Timing of ACP Conversation

Healthcare Professionals		**"An ACP conversation is now useful."**			
From	To	Disagree	Agree	Date	Comment
Name: Address: Contact:	Name: Address: Contact:	☐	☐		

Table 33. The ACP Reminder Sheet

7.5.4 The ACP Practice-Based Training

The format of the ACP Practice-Based Training (APT) was presented in the previous chapter and includes teaching in using evidence-based tools (Question Prompt List, Choices of Care Table, ACP Reminder Sheet) to support difficult conversations with heart failure patients. Training sessions are based at local GP surgeries, last between 2 and 2½ hours and contain three increasingly difficult patient scenarios. Evidence-based tools and behaviour change counselling techniques are used to practice complex communication and negotiation skills. APT also includes training in brief motivational advice on how to initiate an ACP conversation. This may or may not include the usage of the Question Prompt List, Choices of Care Table, and ACP Reminder Sheet during the first or subsequent patient visit. We suggest to healthcare professionals to give brief motivational advice in the context of their first one-to-one session with a patient to provide patients with an opportunity to talk about any end-of-life issues if they so wish. The content and the mode of delivery of the advice is informed by findings from the clinician interview series and focus group study which generated phrases suggested by patients on how to start, conduct and conclude an end-of-life care conversation. These phrases have been welcomed by patients and carers and are part of the ACP Reminder Sheet.

During the training, we emphasise that clinicians are free to use any or none of these tools to discuss issues surrounding heart failure or end-of-life care. At the end of their first appointment with their patients, clinicians are encouraged to allow a few minutes to discuss any other outstanding questions from the patient. As an important component of this first appointment, we encourage healthcare professionals to identify next steps. This may include another follow-up appointment when patients may have a further opportunity to reflect on or

formalise their care preferences. That next appointment may or may not fall into the duration of the study period.

7.6 INTERVENTION FIDELITY

Participants will be asked to consent to having their initial session audio recorded to allow for fidelity testing of the advice given. The purpose of this fidelity testing is to determine:

- If the intervention has been delivered according to the intended protocol and behavioural training models. Dependent on the doctor-patient relationship, we would expect certain motivational interview techniques to occur during this session.
- If the length and content of the session is similar across all participants within each cohort.
- Identify how successful or unsuccessful certain motivational interview techniques were delivered by the clinician when comparing their audio recorded conversations with training guidelines.

7.7 EXPECTED VALUE OF THE TRIAL

If the proposed study is successful, we will have data on progression criteria:

- Recruitment of practices
- Recruitment and retention rates for patients
- Acceptability of the intervention to clinicians and patients
- Clinicians' and patients' willingness to be randomised
- Fidelity and feasibility of delivering the intervention according to intended study methodologies
- Contamination and exposure of the control group to the intervention

Data on the acceptability, feasibility, and frequency of use of four distinct intervention components:

- A patient-led Question Prompt List
- A shared decision-making tool in the form of a Choices of Care Table
- A clinician-owned ACP Reminder Template
- An ACP Practice-Based Training package

Data on the feasibility of collecting information with the following outcome measure scales:

- EQ-5D
- IPOS

A health-economic evaluation of the intervention using utility scores gathered with EQ-5D and a pool of direct costs, e.g. costs for the intervention and cost savings from the avoidance of unplanned hospital admissions.

A well-developed and formally assessed study protocol including recruitment procedures that will lay the foundation for a future definitive cluster RCT.

Data on the following outcome measures:

- A change in unplanned hospital admissions
- A change in the quality of life (using EQ-5D and IPOS)
- A change in the proportion of the use of the QPL and CoC
- A change in the proportion of the occurrence of an ACP conversation and the completion of an ACP document

7.8 QUALITATIVE INTERVIEWS

The MRC process evaluation guidance recommends the use of qualitative methods to better understand why certain components of the intervention work or do not work [Moore 2015].

Therefore, we will conduct semi-structured interviews with trial participants after the intervention. Patients and clinicians for the qualitative interviews will be purposively identified to include a broad range of characteristics relevant to the study in terms of age, gender, ethnicity, NYHA class, heart failure type (HFpEF or HFmrEF/HFrEF). Face-to-face interviews will be audio recorded, transcribed by an independent transcription company, checked for accuracy, anonymized and imported into NVIVO software to facilitate analysis.

7.8.1 Qualitative Interviews with Patients and Carers

Post-intervention semi-structured interviews with patients and carers (n=15) will follow a proposed topic guide (**Appendix 26**). Topics will cover specifics like facilitators and barriers to the completion of the Question Prompt List, Choices of Care Table, IPOS, EQ-5D by patients, the ease of engaging their healthcare professional in an ACP conversation, the occurrence or avoidance of an unplanned hospital admission as well as more general aspects about the trial. Patient and carer data will be used to inform a future definitive cluster randomised controlled trial. Interviews will last approximately between 30 and 45 minutes, will be audio-recorded, fully transcribed, will be conducted by the chief investigator and take place at a time and location convenient for the patient and carers.

7.8.2 Qualitative Interviews with Healthcare Professionals

Post-intervention semi-structured interviews with clinicians (n=5) will follow a topic guide (**Appendix 26**). Topics will cover specifics like facilitators and barriers to the completion of the Question Prompt List, Choices of Care Table, and ACP Reminder Sheet, their ease of engaging patients in ACP conversations, any issues or difficulties in implementing ACP as well as more general aspects about the trial. Data will be used to inform a future definitive trial. Interviews will last approximately between 30 and 45 minutes, will be audio-recorded,

will be fully transcribed, and will be conducted by the chief investigator. Interviews will take place at a time and location convenient for the healthcare professional.

7.8.3 Analysis of Interviews

For the analysis of qualitative interviews, we will use a thematic analysis following the TDF[90] approach with the aid of the qualitative data analysis package NVivo Version 11 (QRS International)[299]. The TDF informed the design of the intervention and has been used to investigate and change health professionals' behaviour in a number of clinical areas. The use of the framework has been extended to investigate change in patients' behaviour[390]. The framework enables a systematic analysis of barriers and facilitators that clinicians and patients may experience when using the intervention. This will add depth to the information gathered about participants' motivations, beliefs about consequences or understanding about the role of ACP in heart failure.

The reason for undertaking interviews at the end of the trial period is that interviews earlier in the intervention period may influence participants' ACP behaviour during the rest of the study. So we want to avoid this effect but still find out whether participants' behaviour in the usage of the intervention components changes over the duration of the study. For example, it may be possible that in the early stages of the trial, clinicians make more use of the QPL to start the process of having conversations about more general end-of-life issues. At a later occasion, they may use the Choices of Care Table as a follow-up tool to discuss more specific ACP treatment preferences in case of complications. Identifying a pattern of usage over time may generate helpful insights to inform recommendations for future usage of the intervention. We will explore these aspects during interviews at the end of the study.

It is unlikely that the study will be able to determine a significant effect on the rate of completed ACP documents since this is a feasibility trial. However, the trial aims to understand participants' attitudes, perceptions and intentions towards using the tools and whether this is likely to improve or reduce the implementation of ACP in heart failure. Hence, determining the potential influence of these tools on ACP documentation is important.

7.8.4 Withdrawal of Participants and Reimbursement

Each participant and their clinician have the right to withdraw from the study at any time. If a patient or clinician request to withdraw from the study, we will explain that we would like to use their data up to the point that they have withdrawn, unless they request that we do not do so. Reasons for withdrawal will be recorded in the CRF.

While we aim to minimise the travel burden on participants, patients may attend a maximum of three study visits, either at their local GP practice, their heart failure clinic or the Nuffield Department of Primary Care Health Sciences. In order to reduce the work on participants of claiming travel expenses (providing receipts, recording mileage, completing forms), the research team will offer each participant gift cards up to the value of £30, in £10 instalments over the course of the study.

7.9 DATA AND STUDY MANAGEMENT, QUALITY ASSURANCE PROCEDURES

The trial will be run in accordance with Good Clinical Practice (GCP). I have discussed the data management and quality assurance of this study with the Operational Director of the CTU from the UKCRC registered Primary Care CTU. The CTU has agreed to provide general advice and support to ensure the study follows CTU best practice and standard

operating procedures (SOPs). A study specific Data Management Plan (DMP) will be developed for the study describing in detail the procedures that will be put in place to make certain that high quality data are produced for statistical analysis. The research team will store all paper CRFs and other study data documents, including consent forms, securely at the Primary Care Department in a locked cabinet in a locked room within a restricted access building with keypad access control system. Data will be kept in accordance with the Data Protection Act of 1998 (DPA).

7.9.1 Study Management

As the chief investigator, I will be responsible for project coordination and will be the lead trial manager and data analyst. I will be supported by the Head of the Nuffield Department of Primary Healthcare Sciences who has extensive expertise in heart failure, conducting trials and developing interventions. The National Clinical Director for End-of-life care provides me with expertise palliative care and intervention development. The Cardiovascular Theme Lead and operational director of the CTU, offers input on trial design and conduct according to Standard Operating Procedures. A CTU Senior Trial Statistician will give expert advice on statistical analysis of trial findings. A Senior Qualitative Researcher from the Health Experience Research Group (HERG) will provide guidance on all qualitative aspects of the study.

7.9.2 The Trial Management Group (TMG)

The Trial Management Group (TMG) will consist of the Chief Investigator, the Co-Chief Investigator, the collaborators, two PPI members, and one member of the CTU. The TMG will be responsible for the monitoring of all aspects of the trial's conduct and progress, and will make certain that the protocol is adhered to. They will ensure that appropriate action is

taken to guarantee participants' safety and the quality of the trial itself. The TMG will meet regularly during the course of the study. Due to the low risk nature of this feasibility study, the Trial Management Group will act as the Trial Steering Committee and Data Monitoring Committee to give oversight of all matters relating to participant safety and data quality.

7.9.3 Ethical and Regulatory Considerations

The Chief Investigator will ensure that this study is conducted in accordance with the Declaration of Helsinki. The protocol, informed consent form, participant information sheet and any proposed advertising material will be submitted to an appropriate Research Ethics Committee (REC), and HRA for written approval. The co-chief investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

7.9.4 Reporting

I will submit once a year during the study, or on request, an Annual Progress Report to the REC Committee, HRA and where required to the host organisation and the Sponsor. In addition, an End-of-Study notification and final report will be submitted to the same parties.

7.10 DISCUSSION

This feasibility cluster RCT will predominantly explore the uncertainties in delivering a complex behavioural intervention to optimise the implementation of ACP in heart failure. The feasibility of the recruitment process, retention rates and the acceptability of the intervention to patients and clinicians will be evaluated. A key anticipated clinical benefit of ACP is a reduction of inappropriate hospital admissions and an improvement in the quality of life. This study will assess whether the intervention is likely to improve these outcomes.

My aim of recruiting 2.5-10% ethnic minority patients to the study was based on published literature. If retained, this proportion will equate to only one to five of ethnic minority patients across intervention and control groups. Consequently, my ability to probe for acceptability issues of the intervention components in qualitative interviews will be limited. These comparatively low numbers indicate why it is so important to include patients from ethnic minority groups at the development stage. Since there is a known gap between intended involvement of ethnic minorities versus actual involvement in research practice[391], the proportion of ethnic minority participation at the feasibility stage will be an important consideration for informing the recruitment procedures of the definitive trial.

7.10.1 Study Design Options

I have selected a cluster RCT design mainly for the following reasons: a) the cluster RCT design versus the individual RCT minimises the contamination of the intervention which is delivered at a service level rather than an individual level, b) the cluster RCT design versus the stepped-wedge cluster RCT design (SW-CRT) has a shorter total intervention period and consequently reduces the risk of confounding through high patient mortality rates which are characteristic for end-stage heart failure populations. Additionally, the risk of selection bias and allocation bias are reduced in the cluster RCT design compared to a non-randomised pre-post intervention study. The advantage of an observational study design would be useful in assessing the extent to which primary care clinicians would be willing to implement the intervention. Given the number of primary care clusters invited to be randomised to the control and intervention groups (n=10), this assessment can also be made in the context of a randomised controlled design. An advantage of the randomised design for the feasibility study is to assess the willingness of clusters to be randomised to the intervention or control group plus an indication of the degree of contamination between clusters. This assessment appears to be important in view of planning a future definitive cluster randomised controlled

trial. **Table 34** summarises other study design options together with their advantages and disadvantages.

Design option	Pros	Cons
Cluster RCT (cRCT)	Minimises contamination, shorter study duration than SW-CRT hence less risk of confounding through high patient mortality rates	Higher numbers of patients and higher costs than for individual RCT because more study sites are involved
Stepped-wedge Cluster RCT (SW-CRT)	Economic design since all participants receive the intervention in the end; able to 'double' the amount of intervention clusters and investigate outcomes at no extra cost	Design may consume too much time for a feasibility study given the outcomes of interest; study design may exacerbate confounding through high CHF patient mortality rates
Individually randomised RCT	Less expensive than a cRCT or SW-CRT; likely to be done in less time than a cRCT and SW-CRT	Study design is inappropriate for an intervention that is delivered at a service level rather than individual participant level; carries a high risk of contamination
Parallel mixed method, pre-post intervention design	Pragmatic approach for a feasibility study	High risk of allocation and selection bias; no opportunity to investigate ICC or cluster size
Observational study non-randomized design	Useful for explaining meaning and context of an intervention	Can't say anything about the difference between the intervention and the control arm or the degree of contamination
Cross over trial	In a controlled, randomized crossover design, imbalances due to confounding covariates are reduced	Study design not feasible because doctors exposed to the ACP intervention won't forget what they have learnt when they cross over to the control group

Table 34. Study design options

7.10.2 Hawthorne Effect

As with a number of studies of this type, there is the potential for a Hawthorne Effect to occur[392]. This phenomenon is the event in which the procedure of studying the problem becomes an intervention in itself. In my study, informing patients or carers that the trial is about ACP might encourage communication with the healthcare professional and undermine the efficacy of my intervention. A Hawthorne Effect was noted in a study to improve the communication between clinicians and patients with end-stage heart failure on defibrillator management[393]. Their consent form and the consent process became an intervention in itself

but was not a generalizable approach to change practice. In order to minimise the risk of a Hawthorne Effect occurring, the following measures are considered: I will not put the words ACP in the study flyer, patient information leaflet or consent form. ACP as part of the material might otherwise prompt patients to ask their clinician or the research team about ACP and undermine best clinical care. For these reasons, the study title on patient and carer material is "A Study of Aspects of Care in Patients with Heart Failure." Survey instruments like IPOS ask patients and carers about aspects of the care they have received. So referring to the study in this way accurately describes the project. Furthermore, we will not use language in consent forms with potentially upsetting words such as "death" or "dying." This cautious approach has been used by others[394].

7.10.3 The PaT Diagram

In order to better replicate complex interventions in palliative care for life-threatening illnesses, the quality of their reporting needs to improve[59, 210, 395, 396]. A detailed description of the content of the intervention, its procedures and context is required[397]. This might be achieved by depicting complex interventions in randomised trials in the form of a "Part and Timing" (PaT) diagram[398]. A PaT diagram standardises the construction process for clinical intervention trials and ensures that every step is covered.

Figure 33 shows a PaT diagram for the proposed feasibility trial and clarifies the basic structure of each trial arm. Cluster A and B receive the intervention while Cluster C and D represent the control groups. The legend (**Figure 34**) following the diagram explains the meaning of each trial component and activity.

Timeline [Months]	Cluster A and B – Intervention	Cluster C and D - Control
R [-8]	a	a
R [-7]	b	b
R [-6]	c	c
R [-6-5]	d	d
R [-4-1]	e	e
R [-4-1]	1	1
R [-3]	f	f
R [-1]	g	g
R [=0]	Randomization	
R [+1]	2 3 4 5	
R [+1]	h	
R [+3]	6	
R [+3+5]	3 4 5	Trial period
R [+4+7]	f i Measurement of outcomes	f i Measurement of outcomes
R [+6+8]	7	
R [+7+9]	8	

Figure 33. PaT Diagram

The following legend explains the meaning of each symbol of the PaT Diagram:

a	Assess surgery for eligibility
b	Assess GPs/ nurses for eligibility
c	GP/ nurses form: consent
d	Assess patients/ carers for eligibility
e	Patient form: consent
1	Patient: baseline measurement using EQ-5D and IPOS
f	GP medical records survey: measurement of frequency of ACP conversation/ documentation in medical records
g	GP questionnaire: baseline measurement: CSCQ for confidence in communicating palliative care issues prior to undergoing the ACP Training Session
2	ACP Practice-Based Training Session (APT) for heart failure. Trainers are a GP, a heart failure and/or a palliative care specialist nurse. All have teaching and training experience. Training sessions are based at local GP surgeries, last between 2 and 2 ½ hours and include three increasingly difficult patient scenarios.
3	Question Prompt List (QPL): QPL is a patient-led tool which helps patients to clarify their understanding of the kind of care they would like to receive and enables patients to ask their clinicians the questions that are important to them.
4	ACP Choices of Care Table (CoC): CoC is a shared-decision making tool to support patients to weigh the pros and cons of treatment options in advanced heart failure. Professionals can use CoC to engage patients and their families in a shared decision-making process. It describes common complications in end-stage hear failure and a choice of corresponding options of care.
5	ACP Reminder Sheet (ARS): the ARS summarises all core components of anticipatory management, ACP and priorities of care on one page and maps their use against the heart failure illness trajectory of the patient. It includes patient-endorsed sample phrases to initiate and conduct an ACP conversation, links to resources and the NYHA classification.
h	GP/ nurse survey: evaluation of Practice-based training session: CSCQ
6	Trainer interview
7	Patient/ Carer interview: acceptability and usefulness of the intervention and its components
i	Patient survey: measurement of outcomes using EQ-5D, IPOS and assessment of use of QPL and CoC
8	GP/ nurse interview: acceptability and usefulness of the intervention and its components

Figure 34. Legend PaT diagram

7.11 CHAPTER SUMMARY

This study protocol of a feasibility cluster RCT has identified and outlined the uncertainties that need to be addressed in order to generate the necessary evidence to support the development of a definitive trial. Progression criteria have been defined as conditions that inform decisions about whether it is appropriate for the study to proceed to the main trial phase or whether it is necessary or possible to modify the operational aspects of the design. The inherent difficulties with identifying, recruiting and retaining end-stage heart failure patients including those from ethnic minorities were considered. The chosen cluster RCT design appears to be the optimal strategy given the nature of the intervention to be tested and the patient population to be investigated. I discussed the key benefits of the cluster RCT design as well as its disadvantages compared with other trial design options. The execution of this feasibility study will help to clarify the potential for progression towards a definitive cluster RCT

CHAPTER EIGHT

Discussion and Conclusions

8 DISCUSSION AND CONCLUSIONS

This chapter provides a summary of the novel contributions of the thesis and contextualises key findings in the wider advance care planning in heart failure literature. A reflection on the methodologies used and their potential strengths and limitations follows including a discussion of the time efficiency of my optimisation research. Finally, a model of how the intervention might be implemented in clinical practice is considered.

8.1 NOVEL CONTRIBUTIONS OF THE THESIS

The research presented in this thesis is the first to provide a firm evidence base for the key steps of advance care planning and clinician targeted interventions in heart failure. The thesis establishes:

1. that advance care planning is effective in improving the quality of life of patients suffering from heart failure,
2. the key components that makes ACP effective in heart failure,
3. the main barriers for clinicians to engage with ACP,
4. the synthesis of an evidence-based intervention to help clinicians deliver ACP,
5. the design of a CTU approved study protocol for a feasibility cluster randomized controlled trial.

Advance care planning improves quality of life

This research is the first to provide firm evidence for the impact of ACP on the quality of life in heart failure. A meta-analysis of 14 RCTs addressed that evidence gap and demonstrated that ACP improved the quality of life of patients suffering from heart failure (OR, 1.93; 95% CI [1.17–3.31]), their satisfaction with end-of-life care (OR, 1.76; 95% CI [1.19-2.81]), and the quality of end-of-life communication (OR, 1.52; 95% CI [1.36-2.14]). The absolute

clinical gain of ACP is sufficiently large to justify developing and implementing a clinician-targeted intervention.

Components of effective ACP

This research generated the evidence to determine which components of ACP are required to improve its implementation in heart failure and improve clinical outcomes. An analysis of intervention synergy demonstrated that interventions that *simultaneously* enabled both physicians and patients to engage with ACP are among the most effective approaches to facilitate the process. This evidence indicates that the right timing for clinicians to engage with and deliver ACP is often associated with significant milestones in a patient's disease trajectory, for example, after a recent hospitalization, before a scheduled appointment with a clinician, or even at the point of admission to hospital. Using multiple components as part of the ACP process and not relying on a single ACP activity are other key mechanisms for advance care planning to improve the quality of life in heart failure. These include offering several follow-up appointments to allow for the clarification of end-of-life care preferences, the inclusion of family members in the conversation or using a multidisciplinary team approach as opposed to limiting the discussion to one single meeting, excluding family members in the decision making process or conducting ACP in isolation within a single medical speciality.

The main barriers for clinicians to engage with ACP

Chapter four presented the evidence of the most significant barriers facing clinicians to the implementation of ACP in heart failure. An exploratory literature review of 17 primary studies identified the main barriers as a lack of disease-specific knowledge about palliative care in heart failure, a lack of skills in communicating ACP with a patient suffering from heart failure, a lack of collaboration between healthcare professionals in order to reach

consensus on patient management, and the high emotional impact on clinicians when undertaking ACP.

The synthesis of an evidence-based intervention

To fill the evidence gap on what intervention components are the most effective to enable clinicians to overcome barriers and engage with ACP in heart failure, a meta-analysis of 13 randomised controlled trials was carried out. The analysis showed that patient-mediated interventions (OR, 5.37, 95% CI, [2.28-12.62]) are the most effective approaches in increasing clinicians' engagement with ACP in heart failure, followed by reminder systems (OR 4.59, 95% CI, [1.1 to 19.17]), educational meetings (OR 2.25, 95% CI, [1.39-3.64]) and academic detailing (OR 1.66, 95% CI, [1.09-2.52]).

This thesis presents for the first time evidence of the views of clinicians and patients on the suitability of a complex intervention to engage key stakeholders with ACP in heart failure. A clinician interview series (n=24) and a focus group study (n=22) with patients, carers and clinicians addressed the previously identified evidence gap by synthesising an intervention prototype and refining four novel and distinct intervention components which are:

- A patient-led question prompt list suitable for use in the early stages of the disease. The tool has potential to sensitively explore patients' care preferences, disclose the diagnosis of heart failure and prompt an ACP conversation.
- The Choices of Care Table, a shared decision making tool is potentially suitable for use later in the heart failure disease trajectory. The tool may have the capacity to explore available treatment options ranging from curative to palliative and provide a starting point for an end-of-life conversation.

- The ACP Reminder Sheet which is a clinician-owned reminder template that shows all essential criteria for ACP and provides clinicians with patient-endorsed phrases to start and conduct ACP conversations.
- The ACP Practice-Based Training which aims to increase clinicians' confidence and competence in managing difficult end-of-life conversations with patients suffering from heart failure. This component of the intervention was welcomed by clinicians as a valuable training method that did not seem to add an additional burden to their clinical workload.

Given the current lack of evidenced-based shared decision-making tools in heart failure[87], these intervention components represent a novel contribution to clinical practice and palliative care.

The design of a CTU approved study protocol

Prior to this research, there had been no evidence for a trial assessing the feasibility of delivering an evidence-based intervention to optimize the implementation of ACP in heart failure. I addressed that evidence gap by developing a detailed study protocol for a feasibility cluster randomized controlled trial. The Clinical Trials Unit of the Nuffield Department of Primary Care, University of Oxford, approved the study protocol, which identifies and outlines the uncertainties that need to be addressed in order to generate the necessary evidence to support the development of a definitive trial. Progression criteria were defined as conditions that inform decisions about whether it is appropriate for the study to proceed to the main trial. Qualitative methods to better understand why certain components of the intervention work or do not work are embedded in the study protocol.

8.1.1 The Wider ACP in Heart Failure Context

ACP is widely supported to contribute to improved patient outcomes by facilitating a better understanding of patients' care preferences throughout the illness and at the end-of-life[36, 67]. In the UK, only a minority of eligible heart failure patients are likely to have an ACP[75]. Patients are generally willing to engage with ACP but clinicians seem hesitant to initiate these conversations. As a result, ACP remains rare and patients' quality of life and care are affected[36] including sub-optimal palliative care for patients suffering from heart failure[27, 28].

While ACP is widely seen as contributing to better palliative care, until this research, there had been no systematic evaluation of the evidence base to determine whether it actually made a difference to patients suffering from heart failure. The results from my first meta-analysis address that evidence gap and suggest that ACP improves quality of life, patients' satisfaction with end-of-life care and the quality of end-of-life communication. An important limitation of these results is the large levels of heterogeneity of effect sizes observed in the analysis except when limiting the analysis to studies including only heart failure patients. Further exploration of heterogeneity suggests that this was mainly due to different patient populations, study settings, length of follow-up periods or different compositions of ACP.

Additionally, it is reported that clinicians are reluctant to initiate ACP in their clinical practice[47, 250, 399]. Without the active engagement of clinicians, patients find it difficult to undertake ACP[400]. There had been a lack of evidence for which interventions had the greatest potential to engage *clinicians* in the implementation of ACP in heart failure. A second meta-analysis, presented in Chapter 2, addressed this evidence gap and identified patient-mediated interventions[104] as one of the most promising intervention categories to change clinicians' behaviour. Other important intervention categories likely to impact on clinicians' behaviour

are reminder systems, educational meetings and academic detailing. A limitation of these findings is overlapping confidence intervals across many intervention categories making interpretation difficult. Given the synergistic effect of the intervention components, it may not appear meaningful to break them down and test them individually. However, one novel finding as a result of this approach is the discovery of the importance of patient-mediated interventions. In the analyses, patient-mediated interventions were consistently included as a component of the most effective intervention strategies. This key-finding directly informed the development of the Question Prompt List and the Choices of Care Table. Moreover, the analysis of intervention components identified other potential factors for a successful implementation of ACP in heart failure. For example, the right timing of introducing ACP at significant milestones in a patient's disease trajectory contributes to its successful implementation[36].

While many patients want to engage with ACP or participate in shared decision-making, the literature is also clear that some patients prefer to take a less active role or delegate to others[326]. This higher threshold for engaging with ACP applies especially to ethnic minorities[346, 347]. Some ethnic minorities have a strong preference for interdependent, family-centred decision making in ACP[357] or are even willing to abdicate their autonomy to loved ones[327]. Hence, a first step toward a cultural inclusive approach to ACP is to make clinicians aware of these cross-cultural considerations. As a result, I will include these aspects in any future ACP training. For example, I will ask healthcare professionals to recognize that the principles of privacy and autonomy may sometimes apply differently to ethnic minority groups. While principles of autonomy are expected in a Western cultural worldview, relatives of a patient from an ethnic minority may require access to confidential information to enable a family-centred decision making in ACP[327].

8.2 METHODOLOGICAL STRENGTHS AND LIMITATIONS

8.2.1 Strengths of Methodologies

The strength of the methodological approach lay in a step-by-step, iterative intervention synthesis process that applied the MRC's framework for developing complex interventions, the Cochrane Effective Practice Organisation of Care (EPOC), the Behaviour Change Wheel (BCW) and Behaviour Change Techniques (BCTs) for assessing intervention ingredients and mechanism of actions. The intervention options table informed the synthesis of an early model of the intervention. The Theoretical Domains Framework (TDF) facilitated an analysis into the theory behind barriers and facilitators to the prototype of the intervention. The TIDieR checklist helped to refine the final version of the intervention. The quality of studies from all three systematic literature reviews was assessed by using the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) for the quantitative synthesis and the Critical Appraisal Skills Programme (CASP) for the qualitative assessment of included studies. All meta-analyses, sub-group analyses and sensitivity analyses were conducted using Review Manager 5 (RevMan 5.3.5). Testing for publication bias, i.e. Egger's tests were conducted using the data analysis and statistical software STATA 13.1.

Adhering to the MRC framework substantially improved the development of the intervention and the overall conduct of the different phases of the research programme. The current project was defined as a 'Development Phase' by the MRC[89] which leads to the proposed feasibility Cluster RCT. The Question Prompt List, the Choices of Care Table, the ACP Reminder Sheet and ACP Practice-Based Training were developed after systematically reviewing the available literature, conducting meta-analyses of effect sizes of intervention categories, identifying theoretical frameworks to analyse the required behavioural changes to

optimise the implementation of ACP, refining the intervention components through a focus group study and evaluating the effect of delivering the intervention in the context of ACP Training Sessions. Throughout this iterative intervention synthesis process, the research advisory group made useful suggestions and ensured patients' and healthcare professionals' findings were used to advance the intervention from an early model, to the prototype, to the final version. As recommended by MRC guidance, the protocol of the feasibility trial demonstrates that the proposed study will investigate many of the uncertainties that need to be addressed before conducting a definitive trial.

The Theoretical Domains Framework (TDF) in conjunction with the Behavioural Change Wheel (BCW) associated well with my aim to investigate these barriers and facilitators[91, 401]. The Theoretical Domains Framework and the Behavioural Change Wheel facilitated a much better understanding of the factors relating to capability, opportunity and motivation that affected behaviour change in clinicians. However, the framework constricted the complexity of the phenomenon of ACP in heart failure to pre-defined distinct units of analysis, i.e. Theoretical Domains Framework domains and corresponding behaviour change techniques. There was a risk that other emergent themes outside its scope might not be sufficiently taken into account. To ensure a more wide-ranging effort of generating themes, I elected to initially use a thematic analysis approach which addressed these issues. I was able to develop a Theoretical Domains Framework matrix which linked intervention components (behaviour change techniques and mode(s) of delivery) with their barriers and facilitators to optimise the implementation of ACP in heart failure. The matrix formed the foundation for the prototype of the intervention.

The refinement of intervention content and application followed the Template for Intervention Description and Replication (TIDieR)[103]. The domains of TIDieR were analysed to determine gaps in the prototype of the Question Prompt List, Choices of Care Table, the ACP Reminder Sheet and the ACP Practice-Based Training Session. The use of TIDieR enabled a detailed description of intervention content beyond the scope of the Theoretical Domains Framework matrix[117, 402]. Particularly, intervention parameters like the acceptability of the intervention to patients and carers, procedures of how to implement the intervention, and its timing and intensity could be advanced. This iterative intervention synthesis process resulted in the design of the final version of the Question Prompt List, the Choices of Care Table, ACP Reminder Sheet and ACP Practice-Based Training. Now, other scientists or policy makers are in a position to replicate and build on these research findings[114, 119]. Given the inclusion of the views of key stakeholders including patients, carers, healthcare professionals from primary, secondary, hospice and community care, the use of TIDieR in the development of the intervention is considered to be a strength.

8.2.2 Limitations of Methodologies

One limitation of systematic literature reviews is that they provide an overview of what has already been published but do not inform on unpublished interventions that might be potentially effective. To minimise the risk of not being aware of unpublished but relevant intervention components, I regularly communicated with experts in the field of intervention design, palliative care for heart failure, ACP and shared decision-making. The Theoretical Domains Framework, behaviour change techniques, the Effective Practice Organisation of Care and the TIDieR approaches to the analysis and design of the intervention each had their individual limitations as described in the previous chapters. However, by triangulating these

methods, I was able to address their individual blind spots by generating data that complemented the analysis and the design of the intervention.

One limitation of the process of intervention development may have been the role of the research advisory group (RAG). Members of RAG were instrumental in the design of the intervention and decided which intervention components should go forward as part of the early model or prototype of the intervention. RAG could only work with the information that I gave them based on the findings from the systematic literature reviews and qualitative studies. This may have limited the consideration of other intervention options. Conversely, RAG was informed by best available quantitative and qualitative evidence. Additionally, RAG members had considerable clinical, research or personal experience to inform the selection of the most promising intervention components for professional practice or for use as a patient. The composition of RAG included all main stakeholders (patient, carer, cardiologist, GP, consultant in palliative medicine, researcher, healthcare commissioner) to ensure a diverse input from a broad spectrum of end users.

8.2.3 Alternative Research Methodologies

The following section describes some alternative research methodologies I could have used in order to enhance the intervention synthesis process.

The *first key research aim* of this thesis was to determine whether end-of-life care which included ACP resulted in improved EOL care outcomes in heart failure compared to EOL care which did not incorporate ACP. As an alternative research methodology, I might have used a *Delphi Technique*[403] to generate a broader input from the views of clinicians on the potential impact of ACP on heart failure. The Delphi Technique uses a series of questionnaires online or on paper to generate expert opinion in an anonymous way[403]. Delphi typically takes place over a number of rounds to reach consensus. While Delphi would have

given me the consensus opinion of clinicians on the potential impact of ACP in heart failure, the method has significant disadvantages, for example, the Delphi exercise does not generate a quantitative assessment of the effect size of ACP on clinical outcomes as achieved by a meta-analysis. So, I would not have known whether implementing ACP would make a sufficiently large clinical difference to the quality of life of heart failure patients. Consequently, that lack of quantitative evidence would have made it very difficult to justify the development of an intervention to optimise the implementation of ACP.

The *second key research aim* was to synthesise the evidence for interventions with the greatest potential to engage clinicians with the implementation of ACP in heart failure. As an alternative, I could have run a series of *co-design groups*[404] to gain feedback on the suitability of potential intervention components to engage clinicians. Co-design groups are a qualitative method of investigation and has been used for intervention development[405] to improve head and neck cancer services in the UK[406]. Patients and clinicians share their respective experiences and identify improvement criteria. I could have used this approach to identify the intervention components with the greatest potential by using the perspectives of clinicians and patients. However, the disadvantages of using co-design groups compared to my second systematic review and meta-analysis would have been a lack of a quantitative estimate of effect sizes of intervention components targeting clinicians. This would have made it difficult to justify a selection of the most promising components from a quantitative perspective. Furthermore, co-design groups tend to combine patients and clinicians in one group. This approach might have inhibited either party to voice their opinion. On balance, I think that a second meta-analysis was the most appropriate step for this stage of the project.

The *third key research aim* was to summarise the evidence from qualitative studies investigating the barriers and facilitators to the implementation of ACP by clinicians in heart failure. Alternatively, I could have used an interview study with clinicians to identify barriers and facilitators for the implementation of ACP. This method would have generated some of the information I was looking for but would not have given me an overview of barriers and facilitators in published literature. Hence, the main advantage of conducting an exploratory review before undertaking the interview study was a systematic assessment of the qualitative evidence base of important primary studies. Findings from the exploratory review provided a suitable platform for the subsequent phase of the project.

The *fourth key aim* was to guide the selection of specific intervention components for an early model of the intervention. As an alternative to the model guided synthesis approach for the intervention development, I could have used the *common components hybrids* approach[122]. The advantage of the common components hybrid approach is that it can develop a composite intervention based solely on quantitative trial data and save time. However, the disadvantage of this method is that it does not investigate the mechanism of action of an intervention and is not concerned with the input of key stakeholders like patients or clinicians. By contrast, my model-guided synthesis approach allowed for the input of the Research Advisory Group consisting of patients, carers and clinicians in the selection of the most promising intervention components. This method seemed a pragmatic and robust way of combining quantitative and qualitative evidence to inform the early model of the intervention. The model-guided synthesis, which also included the subsequent interview and focus group studies, took considerably longer but enabled the essential input from a range of key stakeholders.

The *fifth key aim* was to strengthen the iterative process of intervention synthesis by exploring the views of clinicians on the suitability of an early model of the intervention for clinical practice and subsequently the prototype. As an alternative to my clinician interview series, I could have elected an ethnographic research approach[377]. Ethnography is defined as the study of social interactions, behaviours, and perceptions that occur within groups, teams, organisations and communities[407]. This approach includes observing participants in their real life setting[407]. It focuses on what people actually do in a given context rather than on what they might say they do in a more artificial setting like an interview or a focus group. As such, I may have directly observed clinicians doing ACP with their patients and recorded data in real time, rather than through recall of events as in the interview study. However, I decided not to undertake an ethnographic observational study as part of the project mainly for the following reasons: a) given that ACP is rarely done by clinicians, it would have taken an inappropriate amount of time to recruit sufficient number of clinicians and patients to organise an ethnographic study; b) an observer effect may well have resulted in clinicians positively changing their behaviour[377] by undertaking ACP with their patients; c) recording how clinicians engage with ACP is part of the proposed feasibility cluster RCT as described under intervention fidelity in Chapter 7. The timing of an ethnographic approach at the feasibility cluster RCT stage seems more meaningful since it can also examine the effect of the intervention training on clinicians.

The *sixth key research aim* of the project was to refine distinct intervention components and synthesise the final version of the intervention by including relevant key stakeholders. The focus group study included only comparatively small numbers of participants (n=22) from a white ethnic background. As an alternative method, I could have used a survey to refine the intervention components. This approach may have increased not only the number but also the

demographic range of participants especially in terms of their ethnicity. However, the opportunity to tap into the interpersonal communication *between* participants of the focus group study and their different or similar views on heart failure would have been lost when using a survey. Consequently, I thought that a focus group study had the superior dynamic to refine the intervention components.

The *seventh and final key research aim* of the thesis was to develop a CTU approved study protocol for a trial to assess the feasibility and acceptability of delivering the intervention. I have already described alternative study methodologies to the chosen feasibility cluster RCT design in the previous chapter in section 7.10.1. **Table 35** summarizes these alternative research methodologies including transferable research objectives. They may inform future research about complex interventions for other life-limiting diseases like Stroke, COPD, MND or Dementia.

8.2.4 Strengths of Intervention Development

The development of the intervention components was conducted following a systematic and rigorous iterative synthesis process. This procedure included not only healthcare professionals but also patients, carers, researchers and commissioners. Involving a wide range of key stakeholders was a significant factor of why the final version of the intervention was so well received. Patients and carers welcomed the Question Prompt List (QPL) and expected that the tool would be made available to them. According to their statements, the Question Prompt List was especially useful in the early stages of the disease just after diagnosis. This is a significant finding given the current paucity of tools to disclose the diagnosis of heart failure and initiate patient-centred conversations[331, 332].

Transferable Key Research Aims	Thesis Methodology	Advantages	Disadvantages	Alternative Method(s)
To determine whether end-of-life care which included ACP resulted in improved EOL care outcomes in heart failure compared to EOL care which did not incorporate ACP	Systematic Lit. Review and Meta-analyses	Systematic assessment of the quality and *quantitative* direction of evidence; efficient meta-analyses of the impact of ACP on important EOLC outcomes	Need to have sufficient data from RCTs; otherwise paucity of eligible trials may lead to a potential risk of drawing unclear conclusions	Delphi Technique
To synthesise the evidence for interventions with the greatest potential to engage clinicians with the implementation of ACP in heart failure	Systematic Literature Review and Intervention Component Analysis	Identifies the core and non-core intervention components, their effect sizes based on RCTs and cRCTs	Risk of large heterogeneity of data due to different follow-up periods, outcome measures, type of intervention components	Co-design groups
To summarize the evidence from qualitative studies investigating the barriers and facilitators to the implementation of ACP by clinicians in heart failure	Exploratory Systematic Literature Review	Systematic assessment of the *qualitative* evidence base of important barriers facilitators for the intervention	Risk of over-representation of high quality of evidence and potential for small study publication bias	Interview study
To guide the selection of specific components for an early model of the intervention	Model Guided-Synthesis[23] approach informed RAG's selection of intervention components	Enables selection of the most suitable intervention components by combining quantitative and qualitative findings for implementation	Time-consuming, depends on having a large data set with sufficient detail for intervention component analysis and description	Common components hybrid approach [23]
To strengthen the iterative process of intervention synthesis by exploring the views of clinicians on the suitability of an early model of the intervention for clinical practice	Clinician Interview Series	Generates contextual data and in-depth insight into barriers and facilitators for intervention implementation into routine clinical practice	Comparatively small sample size, time consuming to analyse qualitative data	Ethnographic research[407]
To refine distinct intervention components and synthesise the final version of the intervention by including relevant key stakeholders	Focus Group Study	Designs the final version of the intervention by including a 360 degree perspective from all key stakeholders including patients and carers	Comparatively small sample size; time consuming to analyse qualitative data	Survey
To develop a CTU approved trial protocol for a trial to assess the feasibility and acceptability of delivering the intervention	Feasibility Cluster RCT	Pragmatic and cost-sensitive method to test study design, recruitment, acceptability of the intervention, outcomes, procedures and adherence to study protocol	Not able to generalise results to a larger sample; risk of over-estimating the adherence and deliverability of the intervention	Observational study design
Abbreviations:	**ACP:** advance care planning; **BCT:** behaviour change technique; **COPD:** chronic obstructive pulmonary disease; **cRCT**: cluster randomised controlled trial; **EOLC**: end-of-life care; **EPOC:** Effective Practice and Organisation of Care Group; **MND:** moto neurone disease; **RAG**: Research Advisory Group; **RCT**: randomised controlled trial;			

Table 35.Alternative research methodologies

The Choices of Care Table (CoC) filled a gap of evidence-based tools that enabled a shared decision-making (SDM) process between patients and their clinicians on all available

treatment options. No shared decision-making tools for palliative care in heart failure existed prior to this study[87]. Given that need, GPs and nurses experienced the Choices of Care Table generally as very useful in starting an ACP conversation on end-of-life issues. Patients and carers welcomed the tool because the Choices of Care Table gave them an overview of available treatment options ranging from curative to palliative in case they would become seriously ill.

The concise format of the ACP Reminder Sheet (ARS) was one acknowledged reason in the literature[217] why our healthcare professionals welcomed the reminder sheet. Furthermore, doctors and nurses favourably commented on the inclusion of patient-approved phrases to prompt ACP conversations in clinical practice. Another helpful component of the ARS was a box that prompted communication between primary and secondary care colleagues on the need of having an ACP discussion.

8.2.5 Limitations to Intervention Development

Another potential limitation of the intervention development is the non-inclusion of ethnic minorities. Since there is evidence that ethnic minorities have a lower engagement with ACP, their views on the suitability of the intervention components are important and still outstanding. This limitation has been addressed in the study protocol for the feasibility cluster RCT and future training. Ethnic minorities are included in the recruitment procedures of the proposed trial. Furthermore, clinicians will be made aware of different approaches to ACP among ethnic minorities during training.

Another limitation of intervention development may seem that it did not investigate patient-directed interventions to ACP completion or identify patient-reported barriers. Since the

intervention includes patient-directed components (Que4ion Prompt List, Choices of Care Table), it is reasonable to expect that the investigation of patient-directed interventions was part of the intervention synthesis process.

According to the Effective Practice Organisation of Care Taxonomy, a subset of clinician-targeted interventions are patient-mediated interventions[104, 219]. These are interventions that are directed at patients to empower them to engage with their clinicians and consequently change *clinicians'* behaviour[219]. The literature review and meta-analysis in Chapter Three included that intervention category. In fact, a main finding of that review was that one of the most effective intervention strategies included patient-mediated components. Consequently, the design of the early model of the intervention included patient-mediated components in the form of the Question Prompt List and the Choices of Care Table. Patient-reported barriers were not formally assessed in these literature reviews because the focus of this thesis was on clinician-reported barriers and how to overcome these. In contrast to clinician-reported barriers to ACP, patient-reported barriers are well published in a number of systematic literature reviews[97, 99, 134]. That said, patient-reported barriers to ACP were highlighted by clinicians and patients in the course of the clinician interview series and focus group study. For example, one of the main themes of the focus group study was "Patient Concerns" which included their hesitancy of starting an ACP conversation if their clinician did not take the initiative. The Question Prompt List addressed that barrier by giving patients 'the permission' to ask their healthcare professional questions about their care and thus had the potential to start the process of ACP.

8.3 LESSONS FOR OPTIMISATION RESEARCH

The following sections set out some lessons that I learnt for optimisation research:

8.3.1 Synergistic Effect of Intervention Components

The literature discusses the view of the additive, synergistic effect of intervention components. There is some evidence that suggests that providing several interventions will have a greater effect on changing behaviour of the target group than focussing on a single intervention component[408, 409]. Findings from the clinician interview series, the focus group study and clinicians' feedback from the ACP Training Session support that notion. For example, the Question Prompt List can function independently from the other intervention components but may have a synergistic effect when used in prior sequence with the Choices of Care Table. According to study participants, patients as well as healthcare professionals, the Question Prompt List is well suited to start end-of-life conversations. In that way, the topic has been raised and early barriers to a discussion may have been addressed. As such, the Question Prompt List may prepare the way for talking about more serious issues should the patient become very ill.

Supporting the conversation about end-of-life issues at a later stage in the illness trajectory, the Choices of Care Table seemed an acceptable means to give an overview of curative and palliative treatment options. While the literature makes it clear that there is currently no consensus on how to optimise combinations of components of the intervention[410], a question in the interview topic guide of the proposed study is designed to investigate possible interactions. Based on the quantitative and qualitative evidence, **Table 36** shows the potential impact of the intervention components on patients, their healthcare professionals and their organisations.

In summary, I attribute the positive reception of the intervention by clinicians and patients primarily to the fact that the development and design of its content and context involved all key stakeholders from the beginning of this study.

Intervention component	Likely impact on		
	Patients and Carers	**Healthcare Professionals**	**Healthcare Organisations**
QPL	*may improve the quality of life of patients *may improve patient satisfaction with end-of-life care *may help patients to clarify and communicate their care preferences with family and doctors	*may help healthcare professionals to see what is and what is not important to a patient in end-of-life care	* may help organisations to support patients to live well and die well in the place and the manner of their choosing[19]
CoC	*may improve patients' understanding of all available care choices *may help patients and carers making an *informed* decision on what care they wish or don't wish to receive *may improve patient satisfaction with end-of-life care	*may help clinicians to inform their patients on *all* available choices of care[20]	*may reduce unnecessary hospital admissions and unwanted, aggressive interventions[21]
ARS		*reminds clinicians to address *all* important aspects of ACP and end-of-life care	*may improve communication between the hospice, secondary care and General Practice[22]
APT		* increases abilities of doctors and nurses to talk to their patients and plan for good end-of-life care	* may improve end-of-life care skills of medical staff

Table 36. Potential impact of the intervention

8.3.2 Time-Efficiency of Optimisation Research

Conducting two exhaustive literature reviews and meta-analyses into the effect of ACP and the effect of clinician targeted interventions was very time consuming. However, without knowing whether ACP made a difference to palliative care in heart failure, I would have had no evidence-base for designing an intervention that promoted its implementation amongst

clinicians. While the second literature review was very time consuming too, the analysis highlighted the importance of patient-mediated interventions as a potential part of an overall intervention strategy. Without the evidence from the intervention component analysis, the research advisory group would not have been able to select the most promising intervention components for the early model of the intervention. The exploratory review on the barriers and facilitators of ACP in heart failure was conducted after these two quantitative reviews were concluded. This qualitative review seemed the next logical step in systematically developing an evidence base to address the barriers to ACP and identify the facilitators. That said, by setting time limits for my literature reviews, I might have been able to extend the sampling frame for my qualitative enquiries and conducted some of the proposed empirical feasibility work of the cluster RCT on design parameters within three years.

Based on the recommendations of my end-of-first-year assessors, I did not run a feasibility study as part of this thesis. Consequently, the intervention has not been formally tested within a controlled trial. I am not able to say anything about its effectiveness in terms of changes in implementing ACP in heart failure or present data from a cost-benefit analysis. However, the study protocol for the proposed feasibility cluster RCT includes detailed cost descriptions for all aspects of the trial such as costs for the materials to make the intervention available, the time required for clinicians, patients and trainers to participate in the trial, the renting of premises as well as costs relating to staff support from the clinical trials unit (CTU) of the Nuffield Department of Primary Care Health Sciences (NDPCHS). The CTU had reviewed and approved a study protocol for a funding application.

8.4 IMPLICATIONS FOR CLINICAL PRACTICE

Quantitative and qualitative findings informed a model of how the intervention might contribute to the care of patients suffering from heart failure. **Figure 35** shows the current lack of ACP and shared decision-making especially in the early stages of heart failure. I have adapted the model from a graph by McIlvennan et al.[7]. The figure illustrates how the intensity of treatment for heart failure is dominated by traditional, curative approaches even in view of the high proportion of sudden deaths within the first year after diagnosis. Palliative or supportive care tend to play an insignificant role during that phase, leaving patients and carers unprepared in view of the high rates of mortality. **Figure 36** shows how the intervention components could address these shortcomings targeting the different stages in the management of heart failure. The value of the intervention seemed particularly relevant to the timing in using the Question Prompt List and the Choices of Care Table.

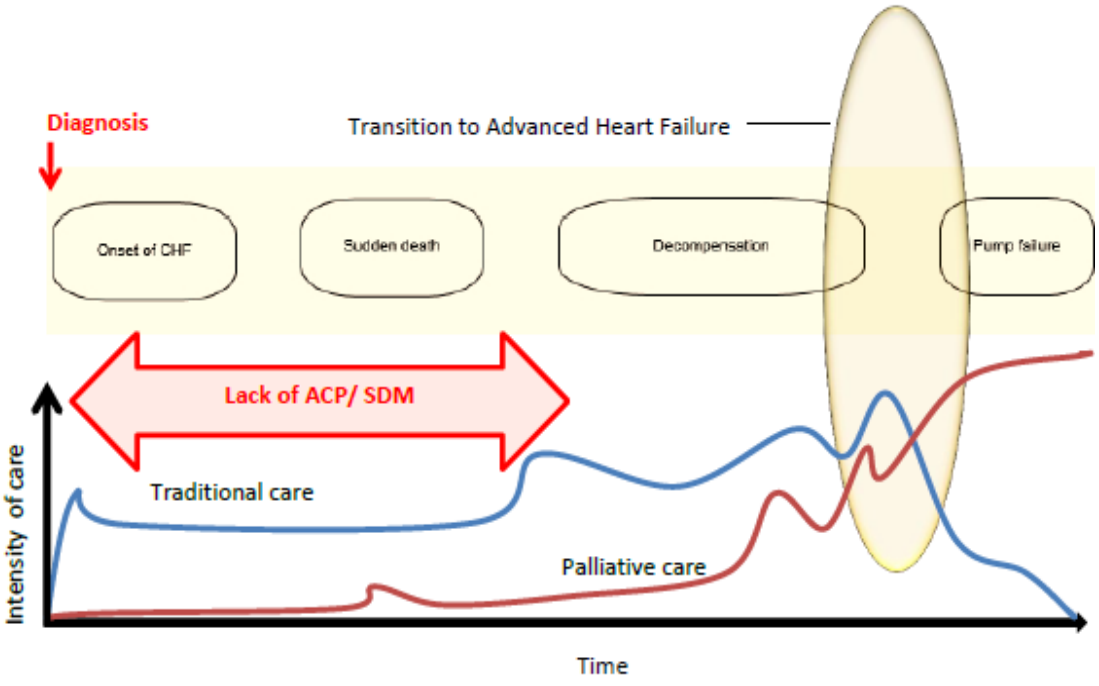


Figure 35. Current model of managing heart failure

Based on findings from reviews, interviews and focus groups, the Question Prompt List seemed suitable especially during the early stages of heart failure. Patients, carers and

clinicians welcomed the capacity of the tool for disclosing the diagnosis in a patient-centred way. The Choices of Care Table appeared well suited to be used at a later stage in the illness trajectory. The tool enabled patients to make an informed choice on available disease-targeted treatment as well as palliative options. Clinicians responded favourably to the Choices of Care Table since it gave them a means to engage with patients on their preferred choices of care. Once adopted by healthcare trusts, the ACP Reminder Sheet has the potential to become a permanent part of local healthcare systems. For example, an electronic version of the ACP Reminder Sheet could become an integral part of mobile electronic devices (e.g. tablets) that heart failure specialist nurses, district nurses or palliative care nurses could use when visiting patients at home. Reviewing and updating ACP information on such a non-complicated template may engage clinicians further to deliver high quality palliative and end-of-life care. The ACP Training Session was well received by clinicians from primary and secondary care. The concise format, content and delivery of this training package might have an application not only for continuous professional development targeting established healthcare professionals but also as part of undergraduate and postgraduate training. In this way, the intervention might be able to permeate the medical workforce and reach parts that other interventions might not be able to.

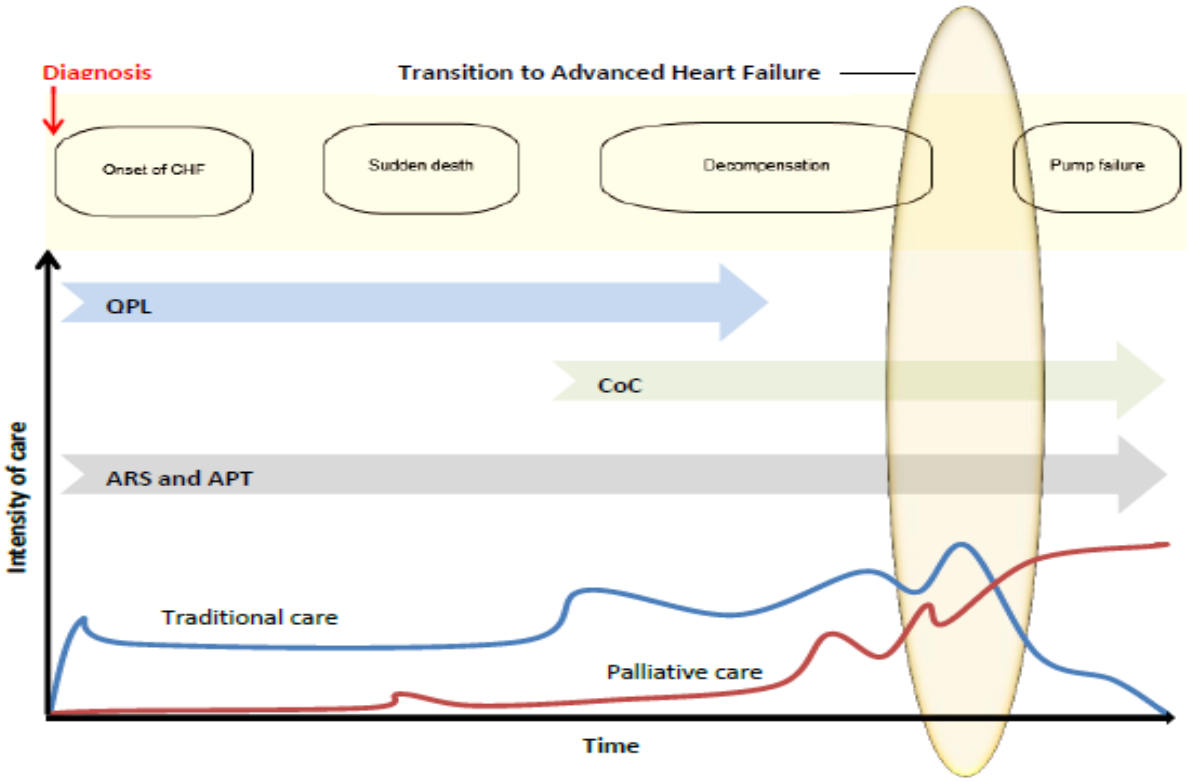


Figure 36. Model showing the involvement of the intervention

8.4.1 Implications for General Practice

The latest figures from the King's Fund[411] show that the average UK practice has a list size of approximately 8000 patients. Given a heart failure prevalence of 1% of the General Practice Population[412], this would amount to reviewing the medical records of approximately 80 heart failure patients to assess who are suitable to engage with an ACP.

Based on the evidence presented in this thesis, a multidisciplinary team approach might be required before inviting eligible patients for an appointment. For example, a GP might want to communicate with the local district nurse or cardiologist and ascertain whether starting the process of advance care planning appears appropriate, timely and whether a family member or healthcare proxy should be involved. The final pool of patients per practice to be contacted may therefore depend on a number of factors: a) the professional judgement of the clinicians, b) the patient's willingness to engage with ACP, c) the stage of disease in the patient's heart

failure disease trajectory, and d) reaching consensus with other clinicians and family members on the suitability and timing of ACP.

The first appointment may take 10 to 15 minutes to explore a patient's need for information, awareness of care preferences and willingness to engage with one of the intervention components like the Question Prompt List or the Choices of Care Table. The Question Prompt List might be reasonably implemented during that first appointment for any class of heart failure ranging from NYHA class I to NYHA class IV. This recommendation is based on the evidence of acceptability and effectiveness reported in the thesis. The Choices of Care Table should not be implemented at the first meeting until further research, such as my proposed trial, to provide additional evidence.

Evidence from this thesis suggests that ACP should not be limited to a single appointment but include at least one or two follow-up meetings or points of contact to allow for the clarification of care preferences and give patients sufficient time and opportunity to consider the information of the first appointment. Based on the findings from this thesis, the Question Prompt List might be reasonably implemented to support patients for that purpose.

Findings from the thesis suggested that the follow-up appointment may take longer and require the booking of a double appointment (15-20 minutes) to allow for more time to address any questions the patient may want to have clarified. Alternatively, a home visit may provide another occasion to discuss more time consuming issues. Based on findings from this thesis, the ACP reminder template might be reasonably implemented to support clinicians in documenting and covering any aspects of ACP during these meetings.

Given the time required to undertake advance care planning, clinicians will experience extra workload due to implementing the intervention. However, clinicians may want to consider these workload issues in view of the evidence that ACP improves the quality of life for patients suffering from heart failure.

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LIST OF APPENDICES

Appendix 1. The Effective Practice and Organisation of Care (EPOC) Taxonomy



EPOC Category	Definition
Audit and feedback	A summary of a health workers performance over a specific period of time, given to them in a written, verbal or electronic format
Educational materials	Distribution to individuals, or groups, of educational materials to support clinical care, i.e., any intervention in which knowledge is distributed. For example this may be facilitated by the internet, learning critical appraisal skills
Educational meetings	Courses, workshops, conferences or other educational meetings
Educational outreach visits or academic detailing	Personal visits by a trained person to health workers in their own settings, to provide information with the aim of changing practice
Inter-professional education	Continuing education for health professionals that involves more than one profession in joint, interactive learning including information and communication technology
Patient-mediated interventions	Intervention aimed at changing the performance of healthcare professionals through interaction with patients, or information provided by or to patients
Reminders	Manual or computerised interventions that prompt health workers to perform an action during a consultation with a patient, for example computer decision support systems
Routine patient-reported outcome measures	Routine administration and reporting of patient-reported outcome measures to providers and/or patients
Tailored interventions	Interventions to change practice that are selected based on an assessment of barriers to change, for example through interviews or surveys
Local opinion leaders	The identification and use of identifiable local opinion leaders to promote good clinical practice

Appendix 2. Behaviour Change Taxonomy (V1)

Grouping and BCTs	Grouping and BCTs	Grouping and BCTs
1. Goals and planning	**6. Comparison of behaviour**	**12. Antecedents**
1.1. Goal setting (behavior) 1.2. Problem solving 1.3. Goal setting (outcome) 1.4. Action planning 1.5. Review behavior goal(s) 1.6. Discrepancy between current behavior and goal 1.7. Review outcome goal(s) 1.8. Behavioral contract 1.9. Commitment	6.1. Demonstration of the behavior 6.2. Social comparison 6.3. Information about others' approval	12.1. Restructuring the physical environment 12.2. Restructuring the social environment 12.3. Avoidance/reducing exposure to cues for the behavior 12.4. Distraction 12.5. Adding objects to the environment 12.6. Body changes
2. Feedback and monitoring	**7. Associations**	**13. Identity**
2.1. Monitoring of behavior by others without feedback 2.2. Feedback on behaviour 2.3. Self-monitoring of behaviour 2.4. Self-monitoring of outcome(s) of behaviour 2.5. Monitoring of outcome(s) of behavior without feedback 2.6. Biofeedback 2.7. Feedback on outcome(s) of behavior	7.1. Prompts/cues 7.2. Cue signalling reward 7.3. Reduce prompts/cues 7.4. Remove access to the reward 7.5. Remove aversive stimulus 7.6. Satiation 7.7. Exposure 7.8. Associative learning	13.1. Identification of self as role model 13.2. Framing/reframing 13.3. Incompatible beliefs 13.4. Valued self-identify 13.5. Identity associated with changed behavior
3. Social support	**8. Repetition and substitution**	**14. Scheduled consequences**
3.1. Social support (unspecified) 3.2. Social support (practical) 3.3. Social support (emotional)	8.1. Behavioral practice/rehearsal 8.2. Behavior substitution 8.3. Habit formation 8.4. Habit reversal 8.5. Overcorrection 8.6. Generalisation of target behavior 8.7. Graded tasks	14.1. Behavior cost 14.2. Punishment 14.3. Remove reward 14.4. Reward approximation 14.5. Rewarding completion 14.6. Situation-specific reward 14.7. Reward incompatible behavior 14.8. Reward alternative behavior 14.9. Reduce reward frequency 14.10. Remove punishment
4. Shaping knowledge	**9. Comparison of outcomes**	**15. Self-belief**
4.1. Instruction on how to perform the behavior 4.2. Information about Antecedents 4.3. Re-attribution 4.4. Behavioral experiments	9.1. Credible source 9.2. Pros and cons 9.3. Comparative imagining of future outcomes	15.1. Verbal persuasion about capability 15.2. Mental rehearsal of successful performance 15.3. Focus on past success 15.4. Self-talk
5. Natural consequences	**10. Reward and threat**	**16. Covert learning**
5.1. Information about health consequences 5.2. Salience of consequences 5.3. Information about social and environmental consequences 5.4. Monitoring of emotional consequences 5.5. Anticipated regret 5.6. Information about emotional consequences	10.1. Material incentive (behavior) 10.2. Material reward (behavior) 10.3. Non-specific reward 10.4. Social reward 10.5. Social incentive 10.6. Non-specific incentive 10.7. Self-incentive 10.8. Incentive (outcome) 10.9. Self-reward 10.10. Reward (outcome) 10.11. Future punishment	16.1. Imaginary punishment 16.2. Imaginary reward 16.3. Vicarious consequences
	11. Regulation	
	11.1. Pharmacological support 11.2. Reduce negative emotions 11.3. Conserving mental resources 11.4. Paradoxical instructions	

Appendix 3. The Template for Intervention Description and Replication (TIDieR)

TIDieR
Template for Intervention Description and Replication

Item	Where located **	
Information to include when describing an intervention and the location of the information	Primary paper (page or appendix number)	Other (details)
BRIEF NAME Provide the name or a phrase that describes the intervention.	_____	_____
WHY Describe any rationale, theory, or goal of the elements essential to the intervention.	_____	_____
WHAT Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	_____	_____
Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	_____	_____
WHO PROVIDED For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	_____	_____
HOW Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	_____	_____
WHERE Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	_____	_____
WHEN and HOW MUCH Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	_____	_____
TAILORING If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	_____	_____
MODIFICATIONS If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	_____	_____
HOW WELL Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	_____	_____
Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	_____	_____

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).
‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

Appendix 4. MEDLINE search strategy for the impact of ACP on heart failure

# ▲	Searches	Results
1	exp Heart Failure/	94848
2	Heart assist devices/ or Defibrillators, Implantable/	22243
3	((heart or cardiac) adj2 failure).ti,ab.	129990
4	((left ventric* or right ventric* or biventric*) adj2 failure).ti,ab.	5955
5	(hf or ahf or chf).ti,ab.	40460
6	((heart or ventric*) adj2 assist device?).ti,ab.	7431
7	(implant* adj2 (defibrillator? or cardiover*)).ti,ab.	10940
8	1 or 2 or 3 or 4 or 5 or 6 or 7	199952
9	exp Advance Care Planning/	7421
10	palliative care/ or exp terminal care/	79503
11	Terminally Ill/	5761
12	(advance* adj2 (care plan* or directive* or statement*)).ti,ab.	4248
13	living will*.ti,ab.	1091
14	"do not resuscitate".ti,ab.	1630
15	"right to die".ti,ab.	897
16	(resuscitation adj3 (plan* or order* or wish*)).ti,ab.	371
17	((write or written or writing or make? or made or making) adj3 will?).ti,ab.	9935
18	((write or written or writing or make? or made or making) adj3 care plan*).ti,ab.	253
19	("end-of-life" adj3 (plan* or care)).ti,ab.	7225
20	("end-of-life" adj3 place*).ti,ab.	57
21	("end-of-life" adj3 (rite? or wish or wishes)).ti,ab.	143
22	("end-of-life" adj3 (home? or hospital? or hospice?)).ti,ab.	499
23	(palliative care or palliative therap* or palliative treat*).ti,ab.	24188
24	(terminal care or terminal therap* or terminal treat* or terminal* ill*).ti,ab.	7241
25	((death or dying) adj3 plan*).ti,ab.	1153
26	((death or dying or die?) adj3 place*).ti,ab.	2970
27	((death or dying or final) adj2 (rite? or wish or wishes)).ti,ab.	193
28	((death or dying or die?) adj3 (home? or hospital? or hospice?)).ti,ab.	14210
29	euthanasia.ti,ab.	8639
30	(assisted adj2 (death or dying or suicide)).ti,ab.	3198
31	"Tissue and Organ Procurement"/	14806
32	(organ adj3 (donor* or donation)).ti,ab.	9864
33	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	145997
34	8 and 33	3247
35	limit 34 to "reviews (maximizes specificity)"	55
36	randomized controlled trial.pt.	417977
37	controlled clinical trial.pt.	92294
38	randomized.ab.	340812
39	placebo.ab.	170698
40	drug therapy.fs.	1862631
41	randomly.ab.	245702
42	trial.ab.	355125
43	groups.ab.	1528732
44	36 or 37 or 38 or 39 or 40 or 41 or 42 or 43	3718221
45	exp animals/ not humans.sh.	4156219
46	44 not 45	3199708
47	34 and 46	840
48	35 or 47	**869**

Appendix 5. Characteristics of excluded studies impact of ACP

	Study	Reason for exclusion
1.	Alexander 2006	No heart failure patients
2.	Bailey 2014	Not a randomised controlled trial
3.	Blom 2016	No heart failure patients
4.	Blue 2001	No study relevant advance care planning outcomes reported
5.	Bocchi 2008	No study relevant advance care planning outcomes reported
6.	Clayton 2007	No heart failure patients
7.	Coleman 1996	Not a randomised controlled trial
8.	Cugliari 1995	Not a randomised controlled trial
9.	Curtis 2011	No study relevant advance care planning outcomes reported
10.	Denvir 2014	Consultation process only
11.	Dipko 2003	Not a randomised controlled trial
12.	Ditto 2001	No study relevant ACP outcomes reported
13.	Doughty 2002	No study relevant advance care planning outcomes reported
14.	El-Jawahri 2010	No study relevant advance care planning outcomes reported
15.	Green 2011	Unit of randomisation was medical students
16.	Greenberg 1993	Unit of randomisation was medical students
17.	Griffiths 1995	No study relevant outcomes reported
18.	Grimaldo 2001	No heart failure patients
19.	Grubaugh 1998	Not a randomised controlled trial
20.	Guo 2010	Not a randomised controlled trial
21.	Gutheil 2005	No study relevant ACP outcomes reported
22.	Hamel 2002	Not a randomised controlled trial
23.	Hammes 1998	Not a randomised controlled trial
24.	Happ 2002	Not a randomised controlled trial
25.	Henoch 2013	No heart failure patients
26.	Ho 2000	Not a randomised controlled trial but a prospective cohort study
27.	Holloran 1995	Not a randomised controlled trial
28.	Houben 2014	Consultation process and study protocol only
29.	Jones 2011	No heart failure patients
30.	Kim 2007	Not a randomized controlled trial
31.	Kirchhoff 2010	No study relevant outcomes reported
32.	Lautrette 2007	No study relevant ACP outcomes reported
33.	Lindner 2007	Not a randomised controlled trial
34.	Livingston 2013	Not a randomised controlled trial
35.	Lundstrom 2005	Not a randomised controlled trial
36.	Luptak 1994	Not a randomised controlled trial
37.	Marbella 1998	No study relevant ACP outcomes reported
38.	Markson 1994	Not a randomised controlled trial
39.	Medvene 2002	Not a randomised controlled trial
40.	Medvene 2003	Not a randomised controlled trial
41.	Meier Fuss 1996	No study relevant ACP outcomes reported
42.	Meier Gold 1996	No study relevant ACP outcomes reported
43.	Molloy 2000	No heart failure patients
44.	Moore 1994	No study relevant ACP outcomes reported
45.	Murray 2008	Consultation process only
46.	Murray 2010	No study relevant advance care planning outcomes reported
47.	Reilly 1995	Not a randomised controlled trial
48.	Resnick 2002	Descriptive study only
49.	Sampson 2008	Consultation process only
50.	Schellinger 2011	Not a randomised controlled trial
51.	Schirm 1996	Not a randomised controlled trial
52.	Schmitten 2014	Not a randomised trial
53.	Schneiderman 1992	No study relevant ACP outcomes reported
54.	Schwartz 2002	No study relevant ACP outcomes reported
55.	Siegert 1996	No study relevant ACP outcomes were reported
56.	Singer 1997	No study relevant ACP outcomes reported
57.	Smucker 1993	No study relevant ACP outcomes reported
58.	Song 2005	No study relevant ACP outcomes were reported
59.	Song 2009	No study relevant ACP outcomes were reported
60.	SUPPORT 1995	No study relevant ACP outcomes reported
61.	Szmuilowicz 2010	No heart failure patients
62.	Temel 2010	No heart failure patients

63.	Teno 1997	No study relevant ACP outcomes reported
64.	Thoonsen 2011	Consultation process only
65.	Tolle 1998	Not a randomised controlled trial
66.	Walczak 2014	Consultation process only
67.	Walker 1999	Not a randomised controlled trial
68.	White 2012	Not a randomised controlled trial
69.	Wissow 2004	Not a randomised controlled trial
70.	Volandes 2009a (JAMDA)	No study relevant ACP outcomes reported
71.	Volandes 2009b (BMJ)	No study relevant ACP outcomes reported

Appendix 6. Data extraction form for impact of ACP on heart failure

<table>
<tr><th colspan="2">Study ID:</th></tr>
<tr><td>Methods</td><td>Country:

Setting:

Design:

Objective:

Methods of analysis:

Clustering adjustment made: clear/ unclear/ not made/ not applicable</td></tr>
<tr><td>Participants

<u>Therapist</u>

<br

<table>
<tr><td></td><td>Eligible for study:

Randomised:

Completed:

Age:

Gender female:</td></tr>
<tr><td>Interventions
Copy and paste this table for each intervention as required.
The description of the intervention is informed by:

CONSORT
http://www.consort-statement.org/extensions

TIDieR
http://dx.doi.org/10.1136/bmj.g1687

EPOC
http://epoc.cochrane.org/epoc-taxonomy</td><td>Brief name

[1] Provide the name or a phrase that describes the intervention.

Why
[2] Describe any rationale, theory, or goal of the elements essential to the intervention.

What
[3] Materials: Describe any physical or informational material used in the intervention delivery or in training or intervention providers. Provide information on where the materials can be accessed such as online appendix, URL.

Are any of the following intervention components present?

<table>
<tr><th>Intervention component</th><th>Yes</th><th>No</th></tr>
<tr><td>ACP</td><td></td><td></td></tr>
<tr><td>Subgroups of ACP Intervention</td><td></td><td></td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td></tr>
</table>

[4] Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling, training or support activities

Who provided
[5] For each category of intervention provider (such as psychologist, nursing assistant), describe their expertise, background and any specific training given.

How
[6] Describe the modes of delivery (such as face to face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.

Where
[7] Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.

When and how much
[8] Describe then number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity, or dose.

Tailoring
[9] If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.

Modifications
[10] If the intervention was modified during the course of the study, describe the changes (what, why, when and how).</td></tr>
</table>

How well
[11] Planned: Describe if intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.

[12] Actual: Describe if intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.

Outcomes
The description of outcomes is informed by:

CONSORT
http://www.consort-statement.org/extensions

SPIRIT
http://dx.doi.org/10.1136/bmj.e7586

Primary outcome (method of aggregation continuous)	**Yes**	**No**
1. Quality of Life		
2. Patient satisfaction with end-of-life care		

Secondary outcomes (method of aggregation continuous)	**Yes**	**No**
Did the study measure the following outcomes?		
1. Quality of end-of-life communication		
2. Confidence of clinicians in communicating end-of-life issues		

For each outcomes, please describe:
a) How the outcome was measured (e.g. by notes review, telephone interview)

b) Any instrument that was used to measure the outcome (e.g. rating scales)

c) By whom the outcome was measured (e.g. by researcher, self-reported by GP)

d) Whether outcome measures pertain to the cluster level, the individual participant level or both.

Limitations of the study

Comments

Risk of bias
The 1st column describes the biases to look out for. Informed by
The Cochrane Handbook:
http://handbook.cochrane.org/chapter_8/8_assessing_risk_of_bias_in_included_studies.htm

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation *(selection bias)*		
Allocation concealment *(selection bias)*		
Blinding (*performance bias and detection bias*) of participants		

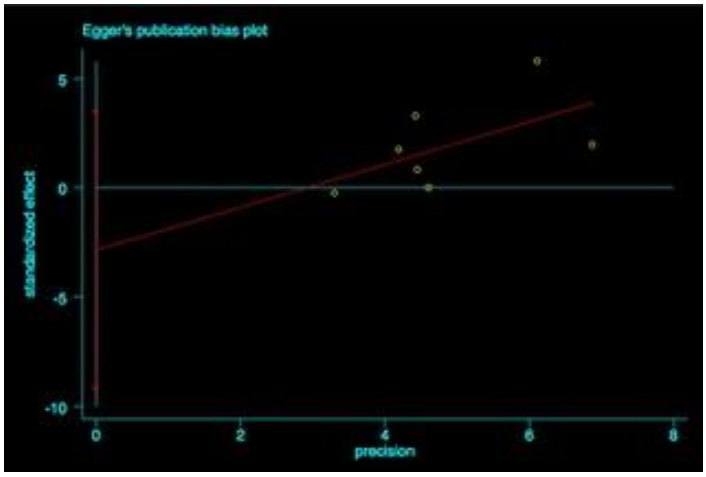
Blinding (*performance bias and detection bias*) of outcome assessors		
Incomplete outcome data (*attrition bias*) All outcomes		
Selective reporting (*reporting bias*)		
Other bias		
Comparability of intervention and control group characteristics at baseline		
Protection against contamination		
Selective recruitment of participants		

RESULTS	**Description as stated in report/paper**					
Comparison	Standard Care					
Outcome						
Time point						
Note whether results are post-intervention, from baseline, adjusted or un-adjusted	**Intervention: ACP**			**Control:**		
	p-value; Mean diff; SE	SMD (95% CI)	No. participants	Mean diff	SD	No. participants
No. of missing participants and reasons						
RESULTS	**Description as stated in report/paper**					
Comparison						
Outcome						
Time point						
Note whether results are post-intervention, from baseline, adjusted or un-adjusted	**Intervention:**			**Intervention:**		
	No. (%) p-value Mean	SMD (95% CI); SD (or other variance)	No. participants	No. (%) p-value Mean	SMD (or other variance)	No. participants
No. of missing participants and reasons						

Appendix 7. Egger's tests for impact of ACP on heart failure outcomes

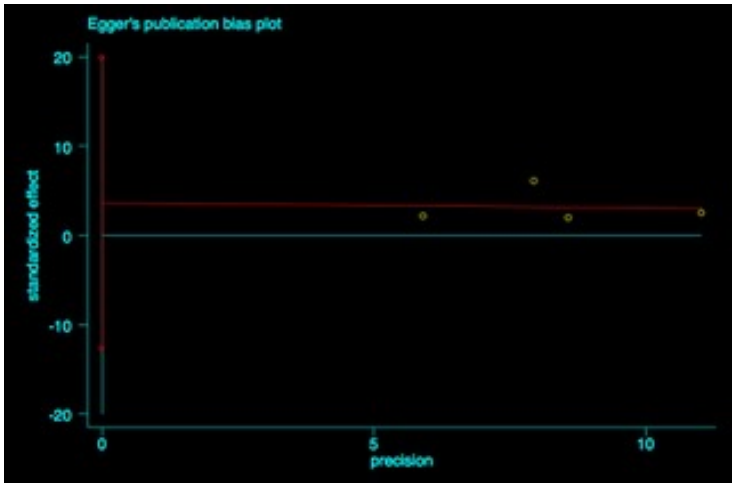
- **Egger's test for Quality of Life**

Std_Eff	Coef.	Std. Err.	t	**P>|t|**	[90% Conf. Interval]	
slope	.9782199	.6309125	1.55	0.182	-.2930994	2.249539
bias	-2.853483	3.146204	-0.91	**0.406**	-9.193237	3.486271



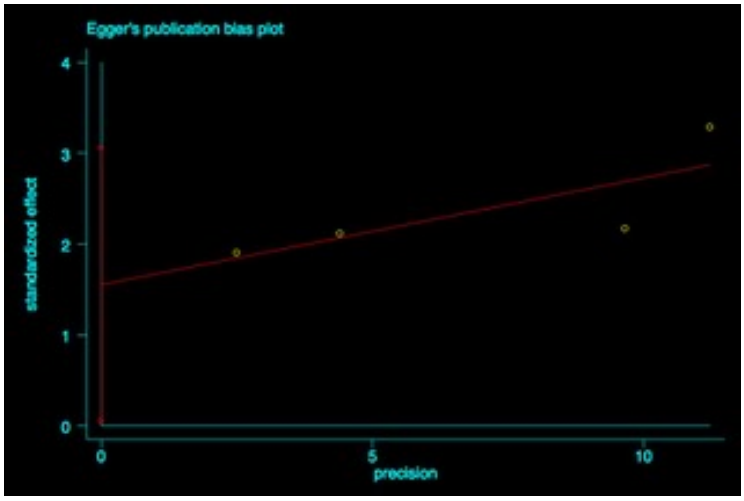
- **Egger's test for Patient Satisfaction with EOL Care**

Std_Eff	Coef.	Std. Err.	t	**P>|t|**	[90% Conf. Interval]	
slope	-.0526091	.6511327	-0.08	0.943	-1.953907	1.848689
bias	3.609039	5.579834	0.65	**0.584**	-12.68399	19.90207



- **Egger's test for Quality of EOL Communication**

Std_Eff	Coef.	Std. Err.	t	**P>|t|**	[90% Conf. Interval]	
slope	.1175376	.0657554	1.79	0.216	-.0744671	.3095423
bias	1.551492	.514475	3.02	**0.095**	.0492329	3.053752



Appendix 8. MEDLINE search for intervention component analysis

# ▼	Searches	Results
1	exp Advance Care Planning/	7552
2	(advance* adj2 (care plan* or directive* or statement*)).ti,ab.	4028
3	living will*.ti,ab.	1141
4	"do not resuscitate".ti,ab.	1568
5	"right to die".ti,ab.	931
6	(resuscitation adj3 (order* or wish*)).ti,ab.	285
7	((write or written or writing or make? or made or making) adj3 will?).ti,ab.	9402
8	((write or written or writing or make? or made or making) adj3 care plan*).ti,ab.	229
9	("end-of-life" adj3 plan*).ti,ab.	372
10	("end-of-life" adj3 place*).ti,ab.	49
11	("end-of-life" adj3 (rite? or wish or wishes)).ti,ab.	125
12	("end-of-life" adj3 (home* or hospital* or hospice*)).ti,ab.	486
13	((palliative care or palliative therap* or palliative treat*) adj3 plan*).ti,ab.	152
14	((palliative care or palliative therap* or palliative treat*) adj3 (wish or wishes)).ti,ab.	13
15	((death or dying) adj3 plan*).ti,ab.	1045
16	((death or dying or die?) adj3 place*).ti,ab.	2798
17	((death or dying or final) adj2 (rite? or wish or wishes)).ti,ab.	178
18	((death or dying or die?) adj3 (home* or hospital* or hospice*)).ti,ab.	18226
19	euthanasia.ti,ab.	8336
20	(assisted adj2 (death or dying)).ti,ab.	682
21	"Tissue and Organ Procurement"/	14206
22	(organ adj3 (donor* or donation)).ti,ab.	9387
23	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	70141
24	exp Health Personnel/	385677
25	(physician? or doctor? or cardiologist? or general practitioner? or gp or gps or clinician? or medical staff* or clinical staff* or specialist?).ti,ab.	612032
26	nurse?.ti,ab.	197243
27	((care or health or healthcare) adj2 (personnel or staff* or assistant?)).ti,ab.	15866
28	((palliative care or "end-of-life" or terminal*) adj2 (personnel or staff* or assistant?)).ti,ab.	124
29	24 or 25 or 26 or 27 or 28	1021566
30	23 and 29	12901
31	Employee Incentive Plans/	1636
32	Physician Incentive Plans/	2081
33	reimbursement mechanisms/ or reimbursement, incentive/	14427
34	persuasive communication/	3107
35	Motivation/	54169
36	Coercion/	4412
37	(pay* adj3 (perform* or result* or penalt* or improv* or chang*)).ti,ab.	3840
38	(incentive? or reward? or bonus or bonuses or compensat* or imburs* or reimburs* or reimburs* or disburs*).ti,ab.	187616
39	(promot* or encourag* or enabl* or motivat* or facilitat* or persuad* or persuasive or persuasion).ti,ab.	1359553
40	(coerc* or challeng* or barrier* or threat*).ti,ab.	742276
41	exp Inservice Training/	24719
42	education/ or exp education, professional/ or teaching/	285257
43	Mentors/	7883
44	exp Professional Competence/	88324
45	Physician's Practice Patterns/	43836
46	(educat* or training or ((staff or professional or practice) adj2 develop*)).ti,ab.	622149
47	((professional or clinical) adj5 (competenc* or capacit* or capabilit* or skill*)).ti,ab.	15902
48	((professional or clinical) adj5 (intervention? or initiative? or scheme? or program*)).ti,ab.	32770
49	((competenc* or capacit* or capabilit* or skill*) adj5 (intervention? or initiative? or scheme? or program*)).ti,ab.	11267
50	(mentor* or academic detail* or ((opinion or academic or practice) adj2 leader*)).ti,ab.	10704
51	((physician? or doctor? or cardiologist? or general practitioner? or gp or gps or clinician? or professional? or staff* or specialist? or nurse?) adj5 (leader* or influen* or motivat* or champion?)).ti,ab.	19809
52	(peer* adj5 (group? or led* or educat* or support or intervention* or program*)).ti,ab.	9745
53	(behavio?r* adj3 (chang* or intervention? or initiative? or program*)).ti,ab.	54499
54	interpersonal relations/ or exp professional-patient relations/	179875
55	communication barriers/	5007

56 ((communicat* or (decision* adj3 mak*) or discuss*) adj5 (intervention? or initiative? or scheme? or program*)).ti,ab. 20485
57 ((communicat* or (decision* adj3 mak*) or discuss*) adj5 (competenc* or capacit* or capabilit* or skill*)).ti,ab. 15464
58 (communicat* or (decision* adj3 mak*) or discuss*).ti. 93172
59 exp Clinical Audit/ 19493
60 Benchmarking/ 10598
61 benchmark*.ti,ab. 19728
62 audit*.ti,ab. 110534
63 capacity building/ 861
64 social control, formal/ or government regulation/ or exp social control policies/ 147959
65 (policy or policies or regulat*).ti. 414369
66 (governance or governing).ti,ab. 29078
67 (organi?ation* adj5 (intervention? or initiative? or program* or scheme* or infrastructure? or structure? or innovation? or influen*)).ti,ab. 20295
68 (organi?ation* adj5 (policy or policies or regulat*)).ti,ab. 7302
69 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 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 67 or 68 3674496
70 30 and 696773
71 exp Health Personnel/ed 48546
72 23 and 71366
73 70 or 72 6834
74 limit 73 to "reviews (maximizes specificity)" 94
75 randomized controlled trial.pt. 399441
76 controlled clinical trial.pt. 90638
77 randomized.ab. 318743
78 placebo.ab. 163621
79 drug therapy.fs. 1782347
80 randomly.ab. 228453
81 trial.ab. 332417
82 groups.ab. 1436405
83 75 or 76 or 77 or 78 or 79 or 80 or 81 or 82 3524893
84 exp animals/ not humans.sh. 4090273
85 (rat or rats or rodent? or mice or mouse or cow or cows or cattle or calf or calves or ewe? or sheep or goat or ruminant? or pig or pigs or minipig? or chicken? or horse or horses or murine or bovine or ovine or porcine or animal?).ti. 1687213
86 83 not (84 or 85) 2987800
87 73 and 86915
88 multicenter study.pt. 188007
89 pragmatic clinical trial.pt. 82
90 (randomis* or randomiz*).ti,ab. 416348
91 (trial or multicenter or multi center or multicentre or multi centre).ti. 162049
92 (intervention? or effect? or impact? or controlled or control group? or (before adj5 after) or (pre adj5 post) or ((pretest or pre test) and (posttest or post test)) or quasiexperiment* or quasi experiment* or evaluat* or time series or time point? or repeated measur*).ti,ab. 6825650
93 88 or 89 or 90 or 91 or 92 6988406
94 73 and 932278
95 94 not (84 or 85) 2266
96 73 not (84 or 85) 6809
97 96 not (94 or 87 or 74) **4129**

Selection of terms for search strategy
Behavioural intervention, Behavioural medicine, Behavioural strategies, Advance care planning, End-of-life care, conversation, Advance directive, Future care, Palliative Care, Training, Clinician, Education, Heart Failure, Cardiovascular disease

Appendix 9. Characteristics of excluded studies for ICA

Characteristics of excluded studies [ordered by study ID]		
	Study	**Reason for exclusion**
1.	Allen 2012	Consultation process only; no advance care plan (ACP) outcomes reported
2.	Allen 2008	Not a randomised controlled trial
3.	Bailey 2014	No advance care plan outcomes reported; no control group;
4.	Betz-Brown 1999	No heart failure patients
5.	Blue 2001	No advance care planning outcomes reported
6.	Bocchi 2008	No advance care planning outcomes reported
7.	Briggs 2006	Unit randomisation was patient/ surrogate dyad; trained facilitators delivered ACP interview; patient not encouraged to see clinician
8.	Brown 2001	No advance care planning outcomes reported
9.	Butow 1994	No advance care planning outcomes reported
10.	Casper 2008	No heart failure patients
11.	Cintron 2006	No heart failure patients
12.	Clayton 2007	No heart failure patients
13.	Coleman 1996	Not a randomised controlled trial
14.	Connors 1995	No advance care planning outcomes reported, only single care choice preferences, nurse delivered discussion with patients but no intervention involved to train her
15.	Cugliari 1995	No heart failure patients
16.	Curtis 2011	No advance care planning outcomes reported
17.	Denvir 2014	Consultation process only – no advance care planning outcomes reported
18.	Der Schmitten 2014	Sample not randomly allocated
19.	Dipko 2003	Samples not randomised;
20.	Ditto 2001	No project relevant ACP outcomes reported, only effects of ACP on
21.	Doughty 2002	No advance care planning outcomes reported
22.	El-Jawahri 2010	No project relevant advance care planning outcomes reported
23.	Epstein 2013	No heart failure patients
24.	Fisher 2015	No heart failure patients
25.	Green 2011	Unit of randomisation was medical students, not healthcare professionals
26.	Greenberg 1993	Unit of randomisation was medical students, not healthcare professionals
27.	Griffiths 1995	No ACP outcomes reported; only CPR preferences of patients
28.	Grimaldo 2001	No heart failure patients
29.	Grubaugh 1998	Not a randomised controlled trial
30.	Guo 2010	Not a randomised controlled trial: retrospective medical records review
31.	Gutheil 2005	No ACP outcomes reported
32.	Hamel 2002	Not a randomised controlled trial
33.	Hammes 1998	Not a randomised controlled trial
34.	Happ 2002	Not a randomised controlled trial
35.	Hare 1991	No heart failure patients
36.	High 1993	No heart failure patients
37.	Hill 2015	Not a randomised controlled trial
38.	Ho 2000	Not a randomised controlled trial but a prospective cohort study
39.	Holloran 1995	Not a randomised controlled trial
40.	Houben 2014	Consultation process and study protocol only
41.	Jacobsen 2011	No heart failure patients
42.	Johnson 2006	Not a randomised controlled trial
43.	Jones 2011	Using trained mediators to carry out ACP; clinician behavior was not meant to be changed by the intervention
44.	Kim 2007	Not a randomized controlled trial, a qualitative study
45.	Kinley 2014	No heart failure patients
46.	Kirchhoff 2012	No project relevant ACP outcomes reported
47.	Kularik 2002	No heart failure patients
48.	Landry 1997	No heart failure patients
49.	Lautrette 2007	No project relevant ACP outcomes reported
50.	Lemont 2011	Not a randomised controlled trial
51.	Lindner 2007	No control group; sample not randomly allocated;
52.	Livingston 2013	Sample not randomly allocated, no control group
53.	Lundstrom 2005	Sample not randomly allocated
54.	Luptak 1994	Not a randomised controlled trial
55.	Marbella 1998	No project relevant ACP outcomes reported
56.	Markson 1994	No control group, sample not randomly allocated;
57.	Medvene 2002	Not a randomised controlled trial

58.	Medvene 2003	Longitudinal study, not a randomised controlled trial
59.	Meier Fuss 1996	No involvement of heath care professionals
60.	Meier Gold 1996	Not a randomised controlled trial
61.	Molloy 2000	No heart failure patients
62.	Momen 2011	Not a randomised controlled trial
63.	Moore 1994	no advance care planning outcomes reported; describes only emotional impact of ACP
64.	Morrison 2005	No heart failure patients
65.	Murray 2008	Consultation process only – no advance care planning outcomes reported;
66.	Murray 2010	No project relevant advance care planning outcomes reported
67.	Pearlman 2005	No heart failure patients
68.	Perry 2005	No heart failure patients
69.	Ponikowski 2014	Not a randomised controlled trial
70.	Reilly 1995	3 years time series intervention trial: samples were not randomly allocated; no control group for the "intervention" or "education" phase of the study;
71.	Resnick 2002	Descriptive study only
72.	Richter 1995	No heart failure patients
73.	Sachs 1992	No heart failure patients
74.	Sampson 2011	Researchers carrying out ACP; patients with severe dementia, unit of analysis were patient and carer dyads; carers were not encouraged to discuss ACP with clinician, clinician behavior was not intended to be changed by intervention
75.	Sampson 2008	Consultation process only, no advance care planning outcomes reported
76.	Schellinger 2011	Not a randomised controlled trial
77.	Schirm 1996	Not a randomised controlled trial
78.	Schmitten 2014	Not a randomised trial
79.	Schneiderman 1992	Reports impact of ACP but not effectiveness of interventions to promote ACP; no project relevant ACP outcomes reported
80.	Schwartz 2002	No project relevant ACP outcomes reported
81.	Sidebottom 2015	Unit of randomisation was patients; using trained facilitators to carry out ACP a process independent from clinicians. Clinician behavior was not intended to be affected by the intervention.
82.	Siegert 1996	No project relevant ACP outcomes were reported
83.	Sinclair 2017	No heart failure patients
84.	Singer 1995	Intervention was not intended to change clinician behaviour
85.	Singer 1997	No project relevant ACP outcomes reported
86.	Smucker 1993	No project relevant ACP outcomes reported
87.	Song 2005	No project relevant ACP outcomes were reported; unit of randomisation and analysis was patients
88.	Song 2009	No project relevant ACP outcomes were reported; unit of randomisation and analysis was patients
89.	Song 2010	Unit of randomisation was patients i.e. homeless persons not healthcare providers, counsellors just delivered the intervention; clinician behaviour was not intended to be changed by the intervention
90.	Sulmasy 1996	No heart failure patients
91.	SUPPORT 1995	No project relevant ACP outcomes reported
92.	Swanson 2006	No heart failure patients
93.	Thoonsen 2011	Consultation process only, no advance care planning outcomes reported
94.	Teno 1997	Unit of randomisation was patients not healthcare providers; nurse delivered ACP; no project relevant ACP outcomes reported, only impact of ACP on hospital resources
95.	Tolle 1998	Not a randomised controlled trial
96.	Walczak 2014	Consultation process only, unit of randomisation was patients and care giver dyads
97.	Walker 1999	No heart failure patients; not a RCT
98.	White 2012	Samples not randomly allocated; intervention targeted at surrogate decision makers
99.	Wissow 2004	Quasi experimental trial, samples not randomly allocated; no control group;
10(	Volandes 2009a (JAMDA)	No project relevant ACP outcomes reported
101	Volandes 2009b (BMJ)	No project relevant ACP outcomes reported
10:	Yamada 1999	No heart failure patients

Appendix 10. Data extraction form for the intervention component analysis

Study ID:

Methods

Country:

Setting:

Design:

Objective:

Methods of analysis:

Clustering adjustment made: clear/ unclear/ not made/ not applicable

Participants

Therapist description:

Therapist

	Primary Care	Secondary Care*
Doctor		
Nurse		
Counsellor		
Social Worker		
Nursing home staff		
Research staff		
Other		
Not known		

(*Please describe speciality of secondary care doctor)

Eligible for study:

Unit of randomisation:

Unit of analysis:

Completed:

Year since qualification:

Previous training in advance care planning?	Yes	No	n/k

Age:

Gender female:

Patient

Patient description:

	Primary Care	Secondary Care*
Acutely ill		
Chronically ill		
Terminally ill		
Hospice		
Nursing home resident		
Other		
Not known		

<table>
<tr><td></td><td>Eligible for study:

Randomised:

Completed:

Age:

Gender female:</td></tr>
<tr><td>Interventions
Copy and paste this table for each intervention as required.
The description of the intervention is informed by:

CONSORT
http://www.consort-statement.org/extensions

TIDieR
http://dx.doi.org/10.1136/bmj.g1687

EPOC
http://epoc.cochrane.org/epoc-taxonomy</td><td>Brief name

[1] Provide the name or a phrase that describes the intervention.

Why
[2] Describe any rationale, theory, or goal of the elements essential to the intervention.

What
[3] Materials: Describe any physical or informational material used in the intervention delivery or in training or intervention providers. Provide information on where the materials can be accessed such as online appendix, URL.

Are any of the following intervention components present?

<table><tr><th>Intervention component</th><th>Yes</th><th>No</th></tr><tr><td>Educational meetings</td><td></td><td></td></tr><tr><td>Audit and feedback</td><td></td><td></td></tr><tr><td>Reminder systems</td><td></td><td></td></tr><tr><td>Patient-mediated interventions</td><td></td><td></td></tr></table>
[4] Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling, training or support activities

Who provided
[5] For each category of intervention provider (such as psychologist, nursing assistant), describe their expertise, background and any specific training given.

How
[6] Describe the modes of delivery (such as face to face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.

Where
[7] Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.

When and how much
[8] Describe then number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity, or dose.

Tailoring
[9] If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.

Modifications</td></tr>
</table>

[10] If the intervention was modified during the course of the study, describe the changes (what, why, when and how).

How well
[11] Planned: Describe if intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.

[12] Actual: Describe if intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.

Outcomes
The description of outcomes is informed by:

CONSORT
http://www.consort-statement.org/extensions

SPIRIT
http://dx.doi.org/10.1136/bmj.e7586

Primary outcomes (method of aggregation dichotomous)	**Yes**	**No**
1. Completion of an advance care plan (ACP) document		
Subgroups of ACP document completion:		
a. Advance care plan (ACP) document		
b. Advance directive (AD) document		
c. Living will (LW) document		
d. Durable Power of Healthcare Attorney (DPHCA) document		
e. Healthcare proxy (HP) document		
f. Other end-of-life (EOL) document:		
2. Occurrence of an advance care plan conversation		
Subgroups of ACP conversations:		
a. ACP conversations		
b. AD conversation		
c. LW conversation		
d. DPHCA conversation		
e. HP conversation		
f. Other EOL conversation		

Secondary outcomes (method of aggregation continuous)	**Yes**	**No**
Did the study measure the following outcomes?		
1. Confidence of clinicians in communicating end-of-life issues		
2. Quality of end-of-life communication		
3. Patient satisfaction with end-of-life care		

For each outcomes, please describe:
a) How the outcome was measured (e.g. by notes review, telephone interview)

b) Any instrument that was used to measure the outcome (e.g. rating scales)

c) By whom the outcome was measured (e.g. by researcher, self-reported by GP)

d) Whether outcome measures pertain to the cluster level, the individual participant level or both.

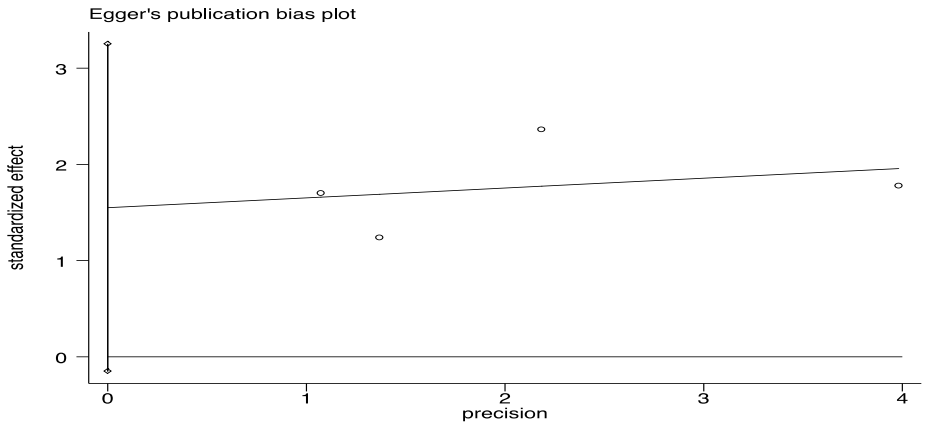
Limitations of the study

Comments

Risk of bias The 1st column describes the biases to look out for. Informed by **The Cochrane Handbook**: http://handbook.cochrane.org/chapter_8/8_assessing_risk_of_bias_in_included_studies.htm		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation *(selection bias)*		
Allocation concealment *(selection bias)*		
Blinding (*performance bias and detection bias*) of participants		
Blinding (*performance bias and detection bias*) of outcome assessors		
Incomplete outcome data (*attrition bias*) All outcomes		
Selective reporting (*reporting bias*)		
Other bias		
Comparability of intervention and control group characteristics at baseline		
Protection against contamination		
Selective recruitment of participants		

Appendix 11. Egger's Test for clinician targeted interventions

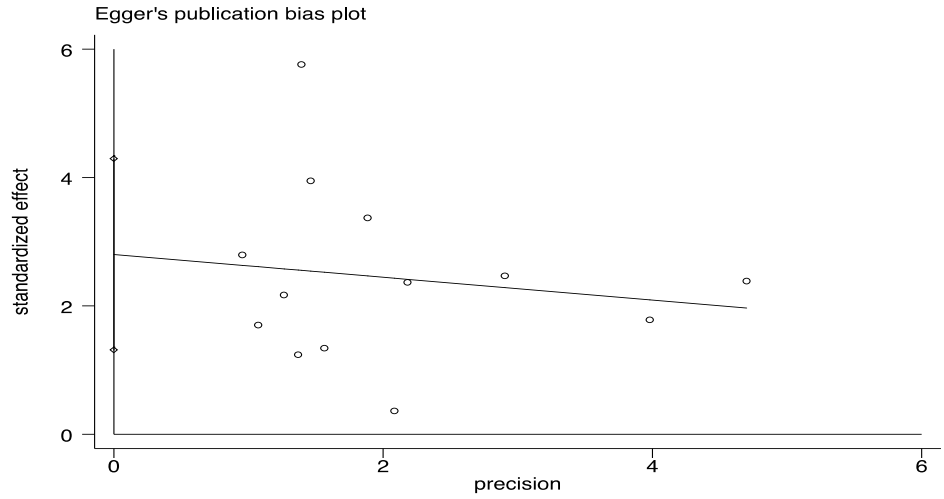
Heart Failure Patients only



Egger's test (n=4)

	Std_Eff	Coef.	Std. Err.	P>|t|	[90% Conf.	Interval]
slope	.1020839	.2393979	0.43	0.711	-.5969544	.8011222
bias	1.550026	.5821463	2.66	**0.117**	-.1498331	3.249885

Heart Failure and other EOLC Patients



Egger's test (n=13)

	Std_Eff	Coef.	Std. Err.	P>|t|	[90% Conf.	Interval]
slope	-.1773835	.3546158	-0.50	0.627	-.8142326	.4594656
bias	2.800633	.8294832	3.38	**0.006**	1.310977	4.290289

Appendix 12. Coding booklet to supplement the BCTTv1 for BCTs in heart failure

Label	Coding rules to supplement the BCTTv1 for ACP in heart failure	Examples
1. Goals and planning		
1.1 Goal setting (behaviour)	• Set or agree on a goal defined in terms of the behavior to be achieved • Note: only code goal-setting if there is sufficient evidence that goal set as part of intervention; if goal unspecified or a behavioral outcome, code 1.3, Goal setting (outcome); if the goal defines a specific context, frequency, duration or intensity for the behavior, also code 1.4, Action planning • Use content of reported outcomes to decide whether to code *Goal setting (outcome)* and/or *Goal setting (behaviour*). • If unclear if one or other, code both (see 1.3)	Defined as setting or agreeing on the *process* of achieving the completion of an ACP document. For example, this included the specific steps of acquiring better knowledge and skills in order to complete an ACP by undergoing training.
1.2 Problem Solving	• Analyze, or prompt the person to analyses factors influencing the behavior and generate or select strategies that include overcoming barriers and/ or increasing facilitators • Otherwise no additional coding rules beyond BCTTv1.	No additional coding rules beyond BCTTv1.
1.3 Goal setting (outcome)	• Use content of reported outcomes to decide whether to code *Goal setting (outcome)* and/or *Goal setting (behaviour)*. • If unclear if one or other, code both (see 1.1)	Described as using the content of a completed ACP document to decide whether an advance care plan was actually achieved. This could include the identification of care preferences or the appointment of a healthcare proxy.
1.4 Action Planning	• As described in BCTTv1, only code if at least one of: context, frequency, duration or intensity — are detailed, otherwise consider *Goal Setting (behaviour) and/or Goal setting (outcome)*.	No additional coding rules beyond BCTTv1.
1.5 Review behaviour goal(s)	• Provision of feedback is not sufficient to code. The behaviour goal must be altered, re-set or agreed not to be changed to be coded.	No additional coding rules beyond BCTTv1.
1.6 Discrepancy between current behaviour and goal	• Draw attention to discrepancies between a person's current behavior (in terms of the *form, frequency, duration, or intensity* of that behavior) and the person's previously set outcome goals, behavioral goals or action plans (goes beyond self-monitoring of behavior)	No additional coding rules beyond BCTTv1.
1.7 Review outcome goal(s)	• Provision of feedback is not sufficient to code. The behaviour goal must be altered, re-set or agreed not to be changed to be coded. • Create a written specification of the behavior to be performed, agreed on by the person, and witnessed by another	No additional coding rules beyond BCTTv1.
1.8 Behavioral contract	• Create a written specification of the behavior to be performed, agreed on by the person, and witnessed by another	No additional coding rules beyond BCTTv1.
2. Feedback and monitoring		
2.1 Monitoring of behaviour by others without feedback	• Must be active and in service of changing behaviour, not simply routine data collection that is already in place.	No additional coding rules beyond BCTTv1.

2.2 Feedback on behaviour	• Monitor and provide informative or evaluative feedback on performance of the behavior *(e.g. form, frequency, duration, intensity)* • Only code when clearly feedback about the HCP's behaviour. This code implies a monitoring process providing the feedback data.	Monitor and provide informative feedback on the performance of delivering ACP by a healthcare professional, for example, in the context of a directly observed discussion with a patient.
2.3 Self-monitoring of behaviour	• Establish a method for the person to monitor and record their behavior(s) as part of a behavior change strategy. • Must be active and in service of changing behaviour, and not simply routine data collection that is already in place. Use supporting content to determine whether it is outcome and/or behaviour being monitored.	No additional coding rules beyond BCTTv1.
2.4 Self-monitoring of outcomes of behaviour	• Establish a method for the person to monitor and record the **outcome(s)** of their behavior as part of a behavior change strategy. • Must be active and in service of changing behaviour, and not simply routine data collection that is already in place. Use supporting content to determine whether it is outcome and/or behaviour being monitored.	No additional coding rules beyond BCTTv1.
2.5 Monitoring of behaviour by others without feedback	• Observe or record outcomes of behavior with the person's knowledge as part of a behavior change strategy. • The individual being monitored must be aware of the monitoring of their behaviour and it must be in service of changing behaviour, and not simply routine data collection that is already in place. Use supporting content to determine whether it is outcome and/or behaviour being monitored.	No additional coding rules beyond BCTTv1.
2.6 Biofeedback	• Provide feedback about the body *(e.g. physiological or biochemical state)* using an external monitoring device as part of a behavior change strategy • Not sufficiently different from *feedback on outcomes of behaviour* in this context; always code as *feedback on outcomes of behaviour*	No additional coding rules beyond BCTTv1.
2.7 Feedback on outcomes of behaviour	• Monitor and provide feedback on the outcome of performance of the behavior • Only code when clearly feedback about outcomes of the HCP's behaviour. This code implies a monitoring process providing the feedback data.	No additional coding rules beyond BCTTv1.
3. Social support		
3.1 Social support (unspecified)	• Advise on, arrange or provide social support *(e.g. from friends, relatives, colleagues,' buddies' or staff)* or non-contingent praise or reward for performance of the behavior. It includes encouragement and counselling, but only when it is directed at the **behavior.**	Advise the person that they can call a mentor when they experience uncertainty on end-of-life care choices.
3.2 Social support (practical)	• Advise on, arrange, or provide **practical** help *(e.g. from friends, relatives, colleagues, 'buddies' or staff)* for performance of the behavior • Someone new (e.g. case manager, pharmacist) or existing (e.g. other team member) facilitates/helps (rather than replaces) an existing HCP to provide their existing care processes. If a new person introduced or	No additional coding rules beyond BCTTv1.

	existing team member replaces what was already performed, consider coding *restructure social environment*.	
4. Shaping knowledge		
4.1 Instruction on how to perform the behaviour	• Advise or agree on how to perform the behavior (includes '**Skills training**') *Note: when the person attends classes, code **4.1, Instruction on how to perform the behavior, 8.1, Behavioral practice/rehearsal** and **6.1, Demonstration of the behavior*** • Included in person or video-mediated skills training or instruction • Only additionally code at 8.1 (behavioural practice/rehearsal) and 6.1 (demonstration of behaviour) when the person has undergone some practical involvement or witnessed a demonstration.	Advising or agreeing on how to perform the completion of an ACP. This BCT applied when healthcare professionals attended a training event like a workshop on the completion of advance care planning.
4.2 Information about antecedents	• To be an antecedent, there must be a clear and recurring link between the antecedent and the behaviour: the presence of the antecedent must regularly be followed by the behaviour (e.g., a particular social situation, event, cognition).	No additional coding rules beyond BCTTv1.
4.3 Re-attribution	• Elicit perceived causes of behavior and suggest alternative explanations *(e.g. external or internal and stable or unstable).*	No additional coding rules beyond BCTTv1.
5. Natural consequences		
5.1 Information about health consequences	• Provide information (e.g. written, verbal, visual) about health consequences of performing the behavior. • Code when education is provided. In this case, the health consequences are the consequences for the patient due to the HCPs' behavior.	Defined as providing HCPs with written, verbal or visual information about the health consequences of completing an ACP. This could include educating clinicians in the context of an educational programme about the pros and cons of delivering ACP.
5.2 Salience of consequences	• Use methods specifically designed to **emphasise** the consequences of performing the behaviour with the aim of making them more memorable (goes beyond informing about consequences).	No additional coding rules beyond BCTTv1.
5.6 Information about emotional consequences	• Provide information (e.g. written, verbal, visual) about **emotional** consequences of performing the behavior.	Explain that delivering ACP increases job satisfaction and patient satisfaction with end-of-life care.
6. Comparison of behavior		
6.1 Demonstration of the behaviour	• Provide an observable sample of the performance of the behaviour, directly in person or indirectly e.g. via film, pictures, for the person to aspire to or imitate (includes '**Modelling**'). *Note:* if advised to practice, also code, ***8.1, Behavioural practice and rehearsal;*** *If provided with instructions on how to perform, also code **4.1, Instruction on how to perform the behaviour***	Provide an observable sample of an ACP discussion by demonstrating to healthcare professionals how to initiate and conduct an ACP conversation via role-play (includes 'modelling').
6.2 Social comparison	• Draw attention to others' performance to allow comparison with the person's own performance. • No additional coding rules beyond BCTTv1.	Show GPs the proportion of patients who died in their preferred place of care by other GPs who engaged with ACP and compare with their own data.

6.3 Information about others' approval	• Provide information about what other people think about the behavior. The information clarifies whether others will like, approve or disapprove of what the person is doing or will do. • Can be delivered second hand, as examples of what 'most people' do, or specific examples provided first hand (including via audio-visual means). • Must be information that is explicitly given (not merely implied). Includes views and perspectives of colleagues/other healthcare professional staff if and only if explicitly stated	No additional coding rules beyond BCTTv1.
7. Associations		
7.1 Prompt/cues	• Introduce or define environmental or social stimulus with the purpose of prompting or cueing the behavior. The prompt or cue would normally occur at the time or place of performance. • Education advice "reinforced" is not a prompt/cue May not necessarily occur at the exact time or place of performance, but can prompt the action when needed. For example, booklets or visual materials which didn't constitute 'adding objects to the environment' (12.5) were coded here.	Defined as introducing an environmental or social stimulus with the purpose of completing an ACP document. This could take the form of a reminder system in patients' notes or in electronic records to prompt clinicians to complete an ACP.
7.3 Reduce prompts/cues	• Withdraw gradually prompts to perform the behavior. • Code when the frequency of prompts reduces. The reduction that needs to be clearly stated.	No additional coding rules beyond BCTTv1.
7.7 Exposure	• Provide systematic confrontation with a feared stimulus to reduce the response to a later encounter.	An actor is playing a patient who is denying the fact that s/he has heart failure. The clinician is exposed to that feared stimulus during role-play to reduce the response to a later encounter.
8. Repetition and substitution		
8.1 Behavioural practice/ rehearsal	• Prompt practice or rehearsal of the performance of the behavior one or more times in a context or at a time when the performance may not be necessary, in order to increase habit and skill • Note: if aiming to associate performance with the context, also code 8.3, Habit formation including in the context of role-play during training.	Prompt the practice or rehearsal of conducting ACP one or more times in the context of an educational training session (e.g. role-play)
8.3 Habit formation	• Prompt rehearsal and repetition of the behavior in the same context repeatedly so that the context elicits the behavior • Note: also code 8.1, Behavioral practice/rehearsal	Prompt clinicians to assess whether a heart failure patients needs an ACP review every time such a patient comes for an appointment.
8.6 Generalisation of a target behavior	• Advise to perform the wanted behaviour, which is already performed in a particular situation, in another situation.	Advise to use the QPL for heart failure patient in primary care to be used for heart failure patients seen in secondary care.
8.7 Graded tasks	• Set easy-to-perform tasks, making them increasingly difficult, but achievable, until behavior is performed	Use different role-play scenarios that require increasingly complex communication and negotiation skills to deliver ACP for heart failure patients.

9. Comparison of outcomes		
9.1 Credible source	• Present verbal or visual communication from a credible source in favour of or against the behavior • Note: code this BCT if source generally agreed on as credible e.g., health professionals, celebrities or words used to indicate expertise or leader in field and if the communication has the aim of persuading; if information about health consequences, also code 5.1, Information about health consequences. • Consider clinical champions like EOL Care leads or patients with experience of heart failure who formally shared these in a training video as credible sources.	Present a verbal or visual communication from a clinical champion in the field of ACP, heart failure and palliative care on the significance of advance care planning
9.2 Pros and cons	• Advise the person to identify and compare reasons for wanting (pros) and not wanting to (cons) change the behavior (includes '**Decisional balance'**). • Note: if providing information about health consequences, also code 5.1, **Information about health consequences**; if providing information about emotional consequences, also code 5.6**, Information about emotional consequences**;	Advise the clinician to use a shared decision-making tool to list and compare the advantages and disadvantages of a range of treatment options for a given heart failure complication
10. Reward and threat		
10.1 Material incentive (behaviour)	• Only code if stated that participants were told that they *would (**in the future***) be provided with a valued object if and only if there has been effort/progress towards the behaviour (as stated in the BCTTv1). • If incentive is provided contingent on recruitment of patients into a group that receives anything beyond usual care, code as reward (as this incentivises performance of the intervention protocol and thus the clinician behaviours). • Do not code incentive if only for recruitment to usual care.	No additional coding rules beyond BCTTv1.
10.2 Material reward (behaviour)	• Only code if clearly stated that a reward was provided **after** there has been effort and/or progress.	No additional coding rules beyond BCTTv1.
10.4 Social reward	• Arrange verbal or non-verbal reward if and only if there has been effort and/or progress in performing the behavior (includes '**Positive reinforcement'**).	No examples encountered.
11. Regulation		
11.1 Pharmacological support	• Only code if the pharmacological support is specifically designed to help *behaviour change*	No examples encountered
12. Antecedents		
12.1 Restructuring physical environment	• Change, or advise to change the **physical** environment in order to facilitate performance of the wanted behavior or create barriers to the unwanted behavior (other than prompts/cues, rewards and punishments). • Code only if it is a change to an ***existing*** physical or virtual (ie software/web) structure.	Introduce an ACP template to the practice IT system that modifies the existing software.

	• If something physically ***new*** is added to the environment that facilitates the behaviour change, code as 12.5 *Add objects to the environment*.	
12.2 Restructuring the social environment	• This is beyond support; code when the social environment changes to help care being provided. Code when ***someone new*** takes on responsibility for providing care that was previously provided by someone else, or someone part of the existing team takes on new care responsibilities. Can be someone added to a core team or shifting care to someone outside the core team (e.g. pharmacist). • Also code when remote services are added (e.g. telecare) as this changes the standard social environment for the clinician.	Increase time spent with a heart failure patient to have an ACP by, for example, creating a double appointment or going on a home visit.
12.5 Adding objects to the environment	• Add objects to the environment in order to facilitate performance of the behavior • *Note: Provision of information (e.g. written, verbal, visual) in a booklet or leaflet is insufficient. If this is accompanied by social support, also code **3.2, Social support (practical)**; if the environment is changed beyond the addition of objects, also code **12.1, Restructuring the physical environment*** • Code for the addition of **new** physical or virtual (software) aimed at facilitating behaviour change. If something existing is changed, consider coding to *restructuring physical environment.*	Provide a Question Prompt List to a GP Surgery Waiting Room. Introduce a **new** ACP Decision making software to IT system.
13. Identity		
13.1 Identification of self as role model	• Inform that one's own behavior may be an example to others.	Inform GPs that if they deliver ACP other colleagues may follow their example.
13.2 Framing/re-framing	• Suggest the deliberate adoption of a perspective or new perspective on behavior (e.g. its purpose) in order to change cognitions or emotions about performing the behavior (includes '**Cognitive structuring**'). • If information about consequences then code **5.1, Information about health consequences, 5.6, Information about emotional consequences** or **5.3, Information about social and environmental consequences** instead of **13.2, Framing/reframing**	Suggest that GPs doing ACP may better meet patients' expectations, reduce unnecessary hospital admissions, or contribute to greater patient satisfaction with end-of-life care.
14. Scheduled consequences		
14.5 Rewarding completion	• Build up behavior by arranging reward following final component of the behavior; gradually add the components of the behavior that occur earlier in the behavioral sequence (includes 'Backward chaining').	No examples encountered.
15. Self-belief		
15.1 Verbal persuasion about capability	• Tell the person that they can successfully perform the wanted behavior, arguing against self-doubts and asserting that they can and will succeed.	Tell GPs that they can successfully conduct and ACP conversation despite their fears and concerns.

Appendix 13. MEDLINE search strategy for barriers and facilitators for ACP in heart failure

# ▲	Searches	Results
1	exp Heart Failure/	94848
2	Heart assist devices/ or Defibrillators, Implantable/	22243
3	((heart or cardiac) adj2 failure).ti,ab.	129990
4	((left ventric* or right ventric* or biventric*) adj2 failure).ti,ab.	5955
5	(hf or ahf or chf).ti,ab.	40460
6	((heart or ventric*) adj2 assist device?).ti,ab.	7431
7	(implant* adj2 (defibrillator? or cardiover*)).ti,ab.	10940
8	1 or 2 or 3 or 4 or 5 or 6 or 7	199952
9	exp Advance Care Planning/	7421
10	palliative care/ or exp terminal care/	79503
11	Terminally Ill/	5761
12	(advance* adj2 (care plan* or directive* or statement*)).ti,ab.	4248
13	living will*.ti,ab.	1091
14	"do not resuscitate".ti,ab.	1630
15	"right to die".ti,ab.	897
16	(resuscitation adj3 (plan* or order* or wish*)).ti,ab.	371
17	((write or written or writing or make? or made or making) adj3 will?).ti,ab.	9935
18	((write or written or writing or make? or made or making) adj3 care plan*).ti,ab.	253
19	("end-of-life" adj3 (plan* or care)).ti,ab.	7225
20	("end-of-life" adj3 place*).ti,ab.	57
21	("end-of-life" adj3 (rite? or wish or wishes)).ti,ab.	143
22	("end-of-life" adj3 (home? or hospital? or hospice?)).ti,ab.	499
23	(palliative care or palliative therap* or palliative treat*).ti,ab.	24188
24	(terminal care or terminal therap* or terminal treat* or terminal* ill*).ti,ab.	7241
25	((death or dying) adj3 plan*).ti,ab.	1153
26	((death or dying or die?) adj3 place*).ti,ab.	2970
27	((death or dying or final) adj2 (rite? or wish or wishes)).ti,ab.	193
28	((death or dying or die?) adj3 (home? or hospital? or hospice?)).ti,ab.	14210
29	euthanasia.ti,ab.	8639
30	(assisted adj2 (death or dying or suicide)).ti,ab.	3198
31	"Tissue and Organ Procurement"/	14806
32	(organ adj3 (donor* or donation)).ti,ab.	9864
33	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	145997
34	(barrier* or challenge* or constraint? or hinder* or hindrance or obstacl* or disempower* or discourag* or inequit* or inequalit*).ti,ab.	749909
35	(facilitat* or opportunit* or empower* or enab* or encourag* or equit* or equalit*).ti,ab.	893955
36	(implement* or adopt* or transfer* or translat* or integrat* or cooperat* or co-operat* or coordinat* or co-ordinat* or collaborat* or tailor*).ti,ab.	1781026
37	34 or 35 or 36	3018365
38	8 and 33 and 37	**653**

Appendix 14. Characteristics of excluded studies Exploratory Review

Study ID	Reason for exclusion
Allen 2012	Low focus on review question; not a qualitative study; paper is an executive summary on decision-making in advanced heart failure
Boyd 2009	Low quality CASP score of study and focus on review question
Denvir 2015	Low focus on review question; not a qualitative study; paper describes future care planning and staged implementation of ACP, anticipatory care planning in heart failure; low focus on barriers and facilitators to the implementation of ACP by healthcare professionals
Detering 2014	Lack of focus on review question; paper describes the evaluation of a brief multimodality education programme
Gibbs 2002	Not a qualitative study; paper describes the role palliative care for patients living and dying from heart failure
Gibbs 2006	Survey of specialist palliative care services for heart failure; paper has a low focus on review objective;
Haga 2012	Low focus on the study objective: paper describes an observational cohort of 138 community based patients but does not focus on HCPs barriers and facilitators to the implementation of ACP
Hanratty 2006	Low focus on study objective: does not go into detail on barriers and facilitators of ACP in heart failure
Jaarsma 2009	Descriptive paper but not a qualitative study; paper is a position statement from the heart failure association of the European Society of Cardiology
Johnson 2006	Not a qualitative study and low focus on study objective; paper describes issues with palliative care service provision for heart failure
Johnson 2007	Not a qualitative study; paper describes management of end-stage heart failure; lack of focus on research objective
Kavalieratos 2014	Lack of focus on review objectives; aim of the paper is to characterize unresolved symptom and treatment needs with which heart failure patients present
Knauft 2005	Lack of focus on heart failure: paper looks at patients suffering from COPD
LeMond 2011	Not a qualitative study; paper describes palliative management for heart failure
LeMond 2015	Lack of focus on review question: paper describes concept on shared decision-making but does not address in detail barriers and facilitators to ACP
McIlvennan 2016	Lack of focus on review question: focus of the paper is to describe palliative care for heart failure more from a clinical management point of view
Murray 2002	Low of focus on review questions: did not address barriers and facilitators to ACP for HCPs
Murray 2004	Lack of focus on review question: did not address barriers and facilitators to ACP for HCPs
Simon 2015	Paper focusses exclusively on patients, does not include the perspectives of HCPs on barriers and facilitators to the implementation of ACP in heart failure

Appendix 15. SURE Framework

Level	Factors affecting implementation
Recipients of care	Knowledge and skills
	Attitudes regarding programme acceptability, appropriateness and credibility
	Motivation to change or adopt new behavior
Providers of care	Knowledge and skills
	Attitudes regarding programme acceptability, appropriateness and credibility
	Motivation to change or adopt new behavior
Other stakeholders (including other healthcare providers, community health committees, community leaders, programme managers, donors, policymakers and opinion leaders)	Knowledge and skills
	Attitudes regarding programme acceptability, appropriateness and credibility
	Motivation to change or adopt new behavior
Health system constraints	Accessiblity of care
	Financial resources
	Human resources
	Educational and training system, including recruitment and selection
	Clinical supervision, support structures and guidelines
	Internal communication
	External communication
	Allocation of authority
	Accountability
	Community participation
	Management and/or leadership
	Information systems
	Scale of private sector care
	Facilities
	Patient flow processes
	Procurement and distribution systems
	Incentives
	Bureaucracy
	Relationship with norms and standards
Social and political constraints	Ideology
	Governance
	Short-term thinking
	Contracts
	Legislation or regulation
	Donor policies
	Influential people
	Corruption
	Political stability and commitment

Appendix 16. Participant Information Sheet for the clinician interview series

NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES

Optimising the implementation of advance care planning in heart failure

Participant Information Sheet (Qualitative Clinician Interviews)
REC reference: **R44601/RE001**

We would like to invite you to take part in this research study. Before you decide whether or not you would like to take part it is important that you understand why the study is being done and what it would involve for you. Please take time to read the following information carefully. It explains why we are doing this study, what your involvement would be, and hopefully answers any questions you may have at this stage. Please feel free to contact us if there is anything you do not understand, or would like more information about.

What is the purpose of the study?
Many patients suffering from heart failure are not aware that the illness leads to inevitable decline and their clinicians find it difficult to tell them this. This can have an effect on the care patients receive. We know that clinicians find it difficult to initiate discussions about future end of life care. This is a process also known as advance care planning. Conversely, patients are willing to engage in advance care planning, but studies show that the emphasis needs to be on enabling conversations with skilled and trained clinicians rather than just focusing on the completion of a document. Difficulties for clinicians in implementing advance care planning can be due to a number of barriers like time constraints, a lack of confidence in communicating end of life issues or other competing clinical pressures. As a result, patient care suffers leading, for instance, to unnecessary hospital admissions or an excessive amount of investigations. This study wants to develop an intervention to support GPs and nurses to engage with their patients in a competent, timely and sensitive way on planning their future care.

We have been conducting three systematic literature reviews and meta-analyses. The findings of these reviews demonstrate significant effects of several intervention components to support clinicians in the implementation of advance care planning but also highlight a number of barriers in doing so. The main aim of the interview study is to identify in much greater detail what your experience is with advance care planning and how you think its implementation can be achieved given your pressurized clinical workload.

Why have I been invited to take part?
Our research team is designing and carrying out interviews with healthcare professionals, who have indicated an interest in participating in this study. Your name was chosen from a list of participants who have registered an interest as a response to an invitation in person or advertised through local and national organizations. Therefore, we are very interested in any contribution you may have to support clinicians in planning the future care of their patients suffering from heart failure. We will be contacting approximately a total of 50 participants about this research.

What would taking part in the study involve?

To help us to understand ways of supporting clinicians in delivering advance care planning for their patients, we want to run a number of qualitative interviews, each lasting maximal 30-45 minutes. Interviews are informed by research findings but predominantly give you the opportunity

to express your views on advance care planning and how end of life care for patients suffering from heart failure might be improved. To help us get the most out of what you tell us, we would like to record some of your answers. Your answers will be anonymized (your name will not be included) and be treated in strict confidence. The researcher can discuss the study with you before the interview begins, and answer any questions you may have.

Where and when will answering the interviews take place?

The interviews can take place at your surgery or at the Nuffield Department of Primary Care in Oxford at a time of your choosing. If you elect to come to the Nuffield Department of Primary Care, we will send you directions once we agreed on the specific date and time.

Do I have to take part?
No. Taking part is entirely voluntary. If you decide to take part but later change your mind, you can withdraw from the study without penalty at any time and do not have to give a reason. No one will be upset if you do this.

What are the possible benefits of taking part?
Participating in the research will give you and us a greater understanding of what enables GPs and nurses to deliver advance care planning for patients suffering from heart failure. This will contribute to the development of an intervention. We believe this will ultimately result in improved clinician skills and improved patient care. What you tell us will probably benefit other healthcare professionals like cardiologists and heart failure specialist nurses as well since they talk to people who may approach the end of their life.

What are the possible disadvantages of taking part?
There are no specific risks associated with taking part in this study. Participating in the interviews is completely independent from any medical care you may deliver.

Will my taking part in this study be kept confidential?
Any information that you give us during the research will not be used or made available for any purpose other than for this research. Only authorized individuals at the research institution (if necessary for monitoring research quality) will have access to the study data. All authorized individuals will have a duty of confidentiality to you as a research participant. Any paper records of the study will be stored in a locked room, which is only accessible to the research team. They will be stored separately from any record of your identity. Any information stored on computers will be protected with passwords. If you choose to withdraw from the research, any information that has been collected about you will be destroyed. At the end of the research, the confidential records will be kept securely for 5 years and then destroyed.

What will happen to the results of the study?
The research results will be used to help develop an intervention for health professionals involved in care for patients suffering from heart failure. The findings will be submitted for publication in medical journals, and for presentation at relevant conferences. We will not present the findings in any way that could allow the identification of individual people. If you would like to receive a copy of the research findings we would be happy to arrange this for you. They will be available by post and accessible on a website.

What if I have concerns about this study, or there is a problem?

If you have any concerns about any aspect of this study, or the way it has been carried out, please speak to the lead researcher, Dr. Markus Schichtel. He can be contacted at the Nuffield Department of Primary Care Health Sciences, University of Oxford, Radcliffe Observatory Quarter, Woodstock Road, Oxford OX2 6GG. Telephone 01865 289 300, or by email: markus.schichtel@phc.ox.ac.uk. He will do his best to answer your query. The researcher should acknowledge your concern within 10 working days and give you an indication of how he intends to deal with it. If you remain unhappy or wish to make a formal complaint, please contact the chair of the Research Ethics Committee at the University of Oxford (Chair, Medical Sciences Inter-Divisional Research Ethics Committee; Email: ethics@medsci.ox.ac.uk; Address: Research Services, University of Oxford, Wellington Square, Oxford, OX1 2JD). The chair will seek to resolve the matter in a reasonably expeditious manner.

Who is funding and organizing the study?
The study is not funded by any funding body but by the lead researcher himself, and is being carried out by a collaborative research group from the University of Oxford.

Who has reviewed the study?
This study has been reviewed and given a favourable opinion by the Research Ethics Committee, reference number R44601/RE001.

What should I do next?
Whether you decide to take part or not, we would be grateful if you would complete the Study Reply Form accompanying this information leaflet, and return it to us in the FREEPOST envelope provided. If you have decided not to take part we will make no further contact with you. If you have indicated that you would like to take part in the study, we will contact you to arrange your participation in one of the interviews. Please feel free to get in touch with us if you have any questions about what you have read, or if you want to talk about the study. We ask that you keep this Information Sheet for future reference.

If you would like further information about this study please contact Dr. Markus Schichtel on 01865 289 300, email markus.schichtel@phc.ox.ac.uk, or write to his at the address below.

Thank you for taking the time to read this leaflet!

Nuffield Department of Primary Care Health Sciences, University of Oxford, Gibson Building, Radcliffe Observatory Quarter, Woodstock Road, Oxford OX2 6GG.

Appendix 17. Consent form for the clinician interviews

NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES

UNIVERSITY OF OXFORD

Optimising the implementation of advance care planning in heart failure

The purpose of this study is to develop an intervention that optimises the implementation of advance care planning in heart failure.

INTERVIEW CONSENT FORM

REC reference: R44601/RE001

	Declarations	Please initial the box
1.	I confirm that I understand that this project has been reviewed, and received ethics clearance through, the university of Oxford Central University Research Ethics Committee.	
2.	I confirm that I understand who will have access to personal data provided, how the data will be stored, and what will happen to the data at the end of the project.	
3.	I confirm that I understand how to raise a concern and make a complaint.	
4.	I confirm that I have read and understood the participant information sheet for this study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
5.	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without legal rights being affected.	
6.	I agree that the interview may be audio-recorded, and I agree that any words that I may say during the discussion can be used anonymously in the presentation of the research.	
7.	I understand that data collected during the study (including audio-recordings) will be kept for five years and then destroyed.	
8.	I agree to take part in the above study.	

Name of participant	Date	Signature

Dr Markus Schichtel

Name of interviewer	Date	Signature

1 Copy for Participant / 1 Copy for Researcher

The Nuffield Department of Primary Care Health Sciences is part of the NIHR School for Primary Care Research. Head of Department: Professor Richard Hobbs FRCGP FRCP FESC FMedSci

Athena SWAN Silver Award

UNIVERSITY OF OXFORD
NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES

Contact details of researchers:

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Nuffield Department of Primary Care Health Sciences, Gibson Building, 1st floor, Walton Street, Jericho, OX2 6NW, Tel: 01865 289 300

Postal address: Radcliffe Observatory Quarter, Woodstock Road, OX2 6GG

Appendix 18. Interview topic guide

Interview topic guide for qualitative interview series with GPs and nurses to optimise the implementation of Advance Care Planning in heart failure

Interview Topic Guide

The purpose of this study is about heart failure and about reducing stress for GPs and nurses to do advance care planning (ACP) for patients suffering from heart failure. Even if you don't have much experience with ACP, your perspective is much appreciated since you know your own clinical environment and the pressures of your daily routine best.

Interview Format

Part One – unstructured, narrative section
"Alternative" in the text below indicates alternative questions that I may use to see whether that version of the question is easier understood.

General Questions

The following are some general questions to start the interview with:

- "Please, tell me about your experience(s) with ACP."
  Alternative: Could you tell me about a time when you did ACP with one of your patients?
- What are your issues with implementing Advance Care Planning?
- What would make advance care planning easier for you?
  Alternative: What might reduce the problems you have found with your stress levels in doing advance care planning?
- What are your issues with implementing ACP in heart failure?
  Alternative: What would make advance care planning in heart failure easier for you?
  Alternative: What might reduce the problems you have found when doing ACP for HF patients?

Part Two – semi-structured section

When the narrative is finished, a semi-structured interview guide will be used to explore any potentially relevant issues that had not already emerged such as barriers and facilitators of ACP. As follows are some examples of specific questions about barriers and facilitators to the implementation of ACP.

Specific Questions
Barriers to the implementation of ACP

- What are barriers for you to undertake ACP as a GP or nurse?
  Alternative: What is the main factor that prevents you from doing ACP?

In the course of that conversation, I may explore how significant the following barriers are:

- Lack of time
  Examples: "What are your main time constraints in undertaking ACP with patients suffering from heart failure?"
  "Does the complexity of heart failure treatment affect you in having an ACP conversation with your patient?

- **CoC**: An early version of the CoC is given to a participant and its purpose is explained. The following questions are asked: "What do you think about this table to discuss treatment options with patients suffering from heart failure in case they experience complications?" "Would this table help or hinder you in discussing heart failure treatment options and advance care planning?"

- Lack of knowledge about ACP
  Example: What training have you received in ACP?
  - **ARS:** A participant is shown an early version of the ACP Reminder Sheet with its components of anticipatory management, ACP, and priorities of care. Participants are asked: "Do you find the ARS useful, would add, subtract or modify any item?"

- Lack of EOL communication skills
  Example: Please, could you tell me an occasion when you communicated with a patient about end-of-life issues?
  - **APT:** In the context of communication skills, participants are asked some of the following questions: "What type of communication training would you find most helpful?" "What do you think about forum theatre role-play to practice communication skills?" Participants are given an explanation of what forum theatre role-play is and what the differences are compared to traditional role-play.

- Lack of confidence
  Example: What promotes or erodes your confidence in communicating end-of-life issues?
- Unpredictable disease trajectory of heart failure
  Example: Is there anything about heart failure that might promote or inhibit you having an ACP discussion?
  What knowledge about ACP and heart failure do you find most useful?

Facilitators of implementing ACP

Question we asked to explore the usefulness of facilitators to implement ACP are:

- What are factors that would help you in undertaking ACP? "Would you find it helpful if a patient asks you a question about ACP?" In that context, questions about the QPL are asked.
  - **QPL:** A participant is given an early version of the QPL and is asked some of the following questions: "What do you think about the usefulness of this list?" "Would you change or modify any item on this list?"

Another question re facilitators of ACP is:

- What is the factor that would help you most in doing ACP in heart failure?

Appendix 19. NVivo Coding Tree for Interview Study

- **Barriers to ACP**
  - Confidentiality
  - Cultural Taboos
  - Hierarchical gap
    - Hierarchical gap between clinicians
    - Hierarchical gap between patient and clinician
  - Lack of competence
    - Death and dying
    - Knowledge about heart failure
  - Lack of experience
  - Lack of confidence
  - Lack of service resources
  - Lack of time
  - Limited opportunities
  - Lack of continuity
    - Out of Hours Services
    - Part-time GP
    - Salaried GP,
    - Locum GP
  - Poor communication
  - Poor Information Sharing/ IT systems
  - Unpredictable disease trajectory of heart failure
  - New forms of treatment
- **Benefits of ACP in heart failure**
  - EOL Care Planning
  - Hospital admissions
  - Quality of EOL Care
- **Facilitators of ACP**
  - Appropriate communication between clinician/ patient
    - Confidence in communicating End-of-life issues
  - Better resources
    - Community resources
    - Continuity of care
    - Drugs for EOL Care available
    - Human resources
    - Time
    - Training resources
  - Knowing patients and family
    - Identifying the right patient group
    - Knowing relatives, carers or proxy
    - Knowing the wider family
  - Knowledge of Palliative Care in heart failure
    - Local Palliative Care Guidelines
    - Access to care and referral pathways
  - Role Models
    - EOL Care Lead
  - Skills
    - Communication Skills in ACP
    - Heart Failure Specialist Treatment skills
- **Fears of delivering ACP in heart failure**
  - Fear of causing alarm
  - Fear of destroying hope
  - Fear of failure

Suggestions to optimise the implementation of ACP

ACP Reminder Sheet
Question prompt list
Patient-led tools
Training Session
Treatment options table/ CoC

Appendix 20. Early version of the QPL

Question Prompt List for Patients suffering from Heart Failure

By Dr Markus Schichtel

Introduction

Some patients find it helpful to think about questions that clarify their understanding of heart failure and the kind of treatment they would like. This can make it easier for you to make decisions and to talk about it with people you love and those who look after your health. Your doctor or nurse will be delighted to answer any questions you may have.

Questions you may want to ask yourself

Here are some questions you may want to ask yourself. You can use the rating scales below to clarify what is important to you. Scale point 1 tends to be the lowest rating and scale point 5 the highest rating for each answer. Your answers may change over time and that is ok.

Question	1	2	3	4	5
How much do I want to know about my condition?	I prefer not to know anything about my condition.				I want to know as much as I can.
How much do I want to get involved in my care?	I do not want to get involved in my care.				I want to have a say in all decisions.
How long do I want to receive medical care?	I want to live as long as possible, no matter what				Quality of life is more important to me than length of life.
How involved to I want my loved ones to be?	I don't want my loved ones to know anything about my health.				I am comfortable with my loved ones to know everything about my health.
Who do I want to be involved in my care?					
Who do I <u>not</u> want to be involved in my care?					
What is most important to me about my care?					

Questions you may want to ask your healthcare professional
Here are some questions you may want to ask your healthcare professional about. Your doctor or nurse will be delighted to answer any of these questions. The table gives you also the possibility to mark with a tick how important these questions are to you. This will help your doctor or nurse, and they can spend more time to explain to you the answer.

Question	Not important	Of interest	Very important
What is heart failure? (What are the causes of heart failure?)			
What is the treatment for heart failure?			
How serious is heart failure?			
Where can I get more support? (e.g. benefits)			
What are my options to prepare for the future? (What is important to me if I become very ill?)			

Appendix 21. Early version of the ARS

Details of patient, family member, carer or proxy				Details of Healthcare Professional			
	Name	Address	Contact		Name	Address	Contact
Patient				Cardiologist			
Spouse				Gerontologist			
Family member				GP			
Carer				Heart Failure Nurse			
Proxy				Palliative Care Nurse			
				District Nurse			
				Palliative Care Clinician			

Anticipatory Management and Advance Care Planning latest by NYHA-III - Priorities of Care latest by NYHA-IV						
	NYHA-I	NYHA-II	NYHA-III	NYHA-IV	Date	Professional Role
Anticipatory Management						
Question Prompt List discussed						
Medication Review						
Social Care Review						
Advance Care Planning						
Treatment Options Table discussed						
End-of-life conversation has taken place						
Lasting Power of Attorney clarified						
DNAR Status clarified						
Advance decision to refuse treatment						
Device in situ: ICD/CRT/CRT-D						
Device deactivation planned						
Device deactivated						
Priorities of Care						
Preferred place of care discussed						
Palliative care measures only						
Care Benefits (e.g. DS 1500)						
Gold Standards Framework Register						
Fast Track Summary for A&E/ OOHhrs						

Possible steps in an ACP conversations	Sample phrases
1. Clarify what the patient knows and/ or wants to know	What would you most like to talk about?
	Tell me about your heart failure; how have you been doing lately?
	How much would you like to know about your heart failure?
2. Identify goals and preferences	If you become more ill, what is most important to you?
	Are there any aspects of your future care that you would like to avoid?
	What is your biggest concern right now?
	How involved do you want your loved ones to be?
3. Tailor treatments and decisions to goals of patients and family	How do you see the benefit of…?
	How do you see the drawback of…?
	Who is helping to look after you?
	Who would you like to make decisions on your behalf if you are not able to?
	How long do you want to receive medical care?

A selection of resources		
Heart Failure	British Heart Foundation (BHF)	https://www.bhf.org.uk/heart-health/conditions/heart-failure.aspx
	Heart Failure Matters	http://www.heartfailurematters.org/en_GB
	NICE	http://cks.nice.org.uk/heart-failure-chronic#
	HealthTalkOnline	http://www.healthtalk.org/peoples-experiences/heart-disease/
End-of-life care (EOL)	Preferred Priorities for Care	http://www.nhsiq.nhs.uk/resource-search/publications/eolc-planning-for-future-care.aspx
	Gold Standards Framework	http://www.goldstandardsframework.org.uk/home
	Better Together (BHF)	https://www.bhf.org.uk/publications/living-with-a-heart-condition/
	Patient UK	http://patient.info/doctor/Palliative-Care-of-Heart-Failure
	RCGP Matters of Life and Death	http://www.rcgp.org.uk/Clinical-and-research/Clinical-resources/
Advance Care Planning	National Council for Palliative Care	http://www.ncpc.org.uk/freedownloads
	E-learning for Healthcare	http://www.e-lfh.org.uk/programmes/end-of-life-care/
	Dying Matters	http://www.dyingmatters.org/page/advance-care-planning
	Royal College of Physicians (RCP)	https://www.rcplondon.ac.uk/guidelines-policy/advance-care-planning

Appendix 22. Participant information sheet for focus group study

NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES

Improving advance care planning in heart failure

Participant Information Sheet (Group Discussion/ Patient)
Version 3, 12/10/2016
REC reference:16/SC/0300 IRAS ID: 207451

We would like to invite you to take part in this research study. Before you decide whether or not you would like to take part it is important that you understand why the study is being done and what it would involve for you. Please take time to read the following information carefully. It explains why we are doing this study, what your involvement would be, and hopefully answers any questions you may have at this stage. Please feel free to contact us if there is anything you do not understand, or would like more information about.

What is the purpose of the study?
Many patients suffering from heart failure are not aware that the illness leads to inevitable decline and their clinicians find it difficult to tell them this. This can have an effect on the care patients receive. We know that clinicians find it difficult to initiate discussions about future end of life care. This is a process also known as advance care planning. On the other hand, patients are willing to engage in advance care planning, but studies show that the emphasis needs to be on enabling conversations with skilled and trained clinicians rather than just focusing on the completion of a document. Difficulties for clinicians in doing advance care planning can be due to a number of barriers like time constraints, a lack of confidence in communicating end of life issues or other clinical pressures. As a result, patient care suffers leading, for instance, to unnecessary hospital admissions or an excessive amount of investigations. This study wants to develop a guide to support GPs and nurses to engage with their patients in a skilled, timely and sensitive way on planning their future care. The study is part of an educational project of the chief investigator, Dr Markus Schichtel. He is a GP and clinical researcher by background. This study is part of his DPhil/PhD project with the University of Oxford.

Findings from previous studies show that patients find a question prompt list useful in understanding their condition and planning their future care. A question prompt list is a set of questions about their disease that patients may want to ask their clinicians. It can help to clarify care choices and provide a starting point of discussion between patients and doctors. We will show you an example of a question prompt list for patients suffering from heart failure. The main aim of our group discussion is to find out what you think about the usefulness of that list. We aim to develop a list that is practical and easy to use by patients and doctors alike.

Why have I been invited to take part?
Our research team is designing and carrying out group discussions with healthcare professionals, patients, carers and researchers who have indicated an interest in participating in this study. Your name was chosen from a list of participants who have registered an interest as a response to an invitation in person or advertised through local and national organizations. Therefore, we are very interested in any contribution you may have to support clinicians in planning the future care of their patients. We will be contacting approximately 40 participants about this research.

What would taking part in the study involve?

To help us to understand ways of supporting clinicians in delivering advance care planning for their patients, we want to run a number of group discussions, each lasting maximal 60-90 minutes.

You may be asked to attend the group discussion on more than one occasion. The group discussions are informed by research findings but give you the opportunity to express your views on whether or how the question prompt list might work. Everyone will be given an opportunity to make a contribution to the discussion group. To help us get the most out of what the group tells us, we would like to record some of your answers. Your answers will be anonymized (your name will not be included) and be treated in strict confidence. The researcher can discuss the study with you before the group discussion begins, and answer any questions you may have. We aim to provide light refreshments and pay travel expenses.

Where and when will the group discussion take place?

The group discussion can take place at a surgery, at the Nuffield Department of Primary Care in Oxford or in one of the seminar rooms of the Oxford University Hospital Trust. We will identify and coordinate the most suitable times and place with all group participants and send you directions once this has been agreed.

Do I have to take part?
No. Taking part is entirely voluntary. If you decide to take part but later change your mind, you can withdraw from the study without penalty at any time and do not have to give a reason. No one will be upset if you do this.

What are the possible benefits of taking part?
Participating in the research will give you and us a greater understanding of what enables GPs and nurses to deliver advance care planning for patients suffering from heart failure. We believe this will ultimately result in improved clinician skills and improved patient care. What you tell us will probably benefit other healthcare professionals like cardiologists and heart failure specialist nurses as well since they talk to people who may approach the end of their life.

What are the possible disadvantages of taking part?
There are no specific risks associated with taking part in this study. Participating in the group discussion is completely independent from any medical care you may receive.

Will my taking part in this study be kept confidential?
Any information that you give us during the research will not be used or made available for any purpose other than for this research. Only authorized individuals at the research institution (if necessary for monitoring research quality) will have access to the study data. All authorized individuals will have a duty of confidentiality to you as a research participant. Any paper records of the study will be stored in a locked room, which is only accessible to the research team. They will be stored separately from any record of your identity. Any information stored on computers will be protected with passwords. If you choose to withdraw from the research, any information that has been collected about you will be destroyed. At the end of the research, the confidential records will be kept securely for 5 years and then destroyed.

What will happen to the results of the study?
The research results will be used to help develop a guide for health professionals to improve the care of patients suffering from heart failure. The findings will be submitted for publication in medical journals, and for presentation at relevant conferences. We will not present the findings in any way that could allow the identification of individual people. If you would like to receive a copy of the research findings we would be happy to arrange this for you. They will be available by post and accessible on a website.

What if I have concerns about this study, or there is a problem?

If you have any concerns about any aspect of this study, or the way it has been carried out, please speak to the lead researcher, Dr. Markus Schichtel. He can be contacted at the Nuffield Department of Primary Care Health Sciences, University of Oxford, Radcliffe Observatory Quarter, Woodstock Road, Oxford OX2 6GG. Telephone 01865 617 589, or by email: markus.schichtel@phc.ox.ac.uk. He will do his best to answer your query. The researcher should acknowledge your concern within 10 working days and give you an indication of how he intends to deal with it. Alternatively, you can contact the Patient advice and liaison services (PALS) in Oxfordshire at the John Radcliffe Hospital, Headley Way, Headington, Oxford, OX3 9DU, Tel: 01865 221473,

Who is funding and organizing the study?
The study is not funded by any funding body but by the lead researcher himself, and is being carried out by a collaborative research group from the University of Oxford, the Oxford University Hospital Trust and Sir Michael Sobell House Study Centre. The study is part of the DPhil/ PhD project of the lead researcher.

Who has reviewed the study?
This study has been reviewed and given a favourable opinion by the Research Ethics Committee, reference number ...

What should I do next?
Whether you decide to take part or not, we would be grateful if you would complete the Study Reply Form accompanying this information leaflet, and return it to us in the FREEPOST envelope provided. If you have decided not to take part we will make no further contact with you. If you have indicated that you would like to take part in the study, we will contact you to arrange your participation in one of the group discussions. Please feel free to get in touch with us if you have any questions about what you have read, or if you want to talk about the study. We ask that you keep this Information Sheet for future reference.

If you would like further information about this study please contact Dr. Markus Schichtel on 01865 617 589, email markus.schichtel@phc.ox.ac.uk, or write to his at the address below.

Thank you for taking the time to read this leaflet!

Nuffield Department of Primary Care Health Sciences, University of Oxford, Gibson Building, Radcliffe Observatory Quarter, Woodstock Road, Oxford OX2 6GG.

Appendix 23. Topic guide for focus groups

Topic guide for focus groups with clinicians, patients, carers and researchers to optimise the implementation of advance care planning in heart failure

Focus Group Topic Guide

Introduction The purpose of this focus group study is about identifying the most suitable ways to support clinicians to engage with advance care planning (ACP). Even if focus group participants don't have much experience with ACP, their perspective is much appreciated since they know their own clinical environment and the pressures of their daily routine best.

Focus group format

Part One – unstructured section
"Alternative" in the text below indicates alternative questions that I may use to see whether that version of the question is easier understood.

General Questions

The following are some general questions to start the focus group with:

- What would make advance care planning easier for you?
  Alternative: What might reduce the problems you have found with your stress levels in doing advance care planning?
- What are your issues with implementing ACP in heart failure?
  Alternative: What would make advance care planning in heart failure easier for you?
  Alternative: What might reduce the problems you have found when doing/ participating in ACP?

Part Two – structured section

When the unstructured section is finished, a more structured approach might be used to explore any potentially relevant issues with proposed intervention components. As follows are some examples of specific questions and topics about some specific issues that may arise with different intervention components:

Specific questions and topics

The following are examples of intervention components that will be further explored during focus groups:

1) Question prompt lists for patients

- Do you think the language of the question prompt list (QPL) is easy to understand and unambiguous?
- Do you think the content of the QPL covers all essential areas?
- Timing of handing out and discussing the QPL

2) ACP Training Session into GP Surgeries

- What do you think about the content and structure of the ACP training session?
- What current national and local issues should be included in the training?

- What do you think about the proposed duration and frequency of the training? For example, the proposed duration of the training was suggested to be between 2 and 3 hours, once yearly. Should this be longer/ shorter, more or less frequently?

Other topics explored were the location of the training, e.g. at the local GP surgery or at an external venue, desired outcomes of the training from a participant's perspective like enhanced knowledge, communication skills etc., the target audience like GPs with special interest, Heart Failure Specialist Nurse, Palliative Care Nurse

3) ACP Reminder Sheet

- What do you think about the content of the ACP reminder template?
- What would improve the navigation of the template for you?
- What further resources should be included in the template?

Other topics covered were contact names, numbers of clinicians involved or the usefulness of a communication prompt between primary and secondary care clinicians.

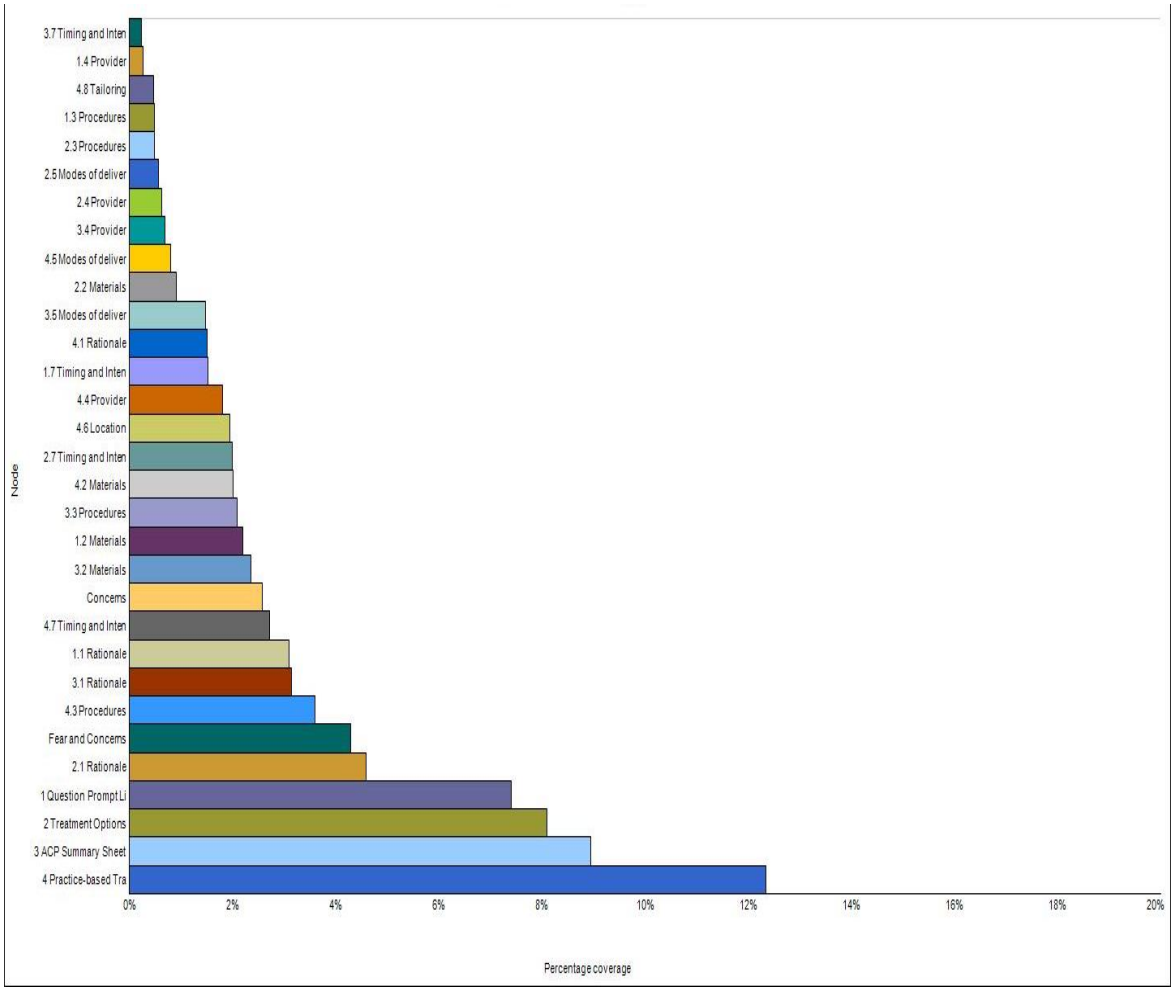
4) ACP Choices of Care Table

- Do you think the language of the choices of care (CoC) table is easy to understand and unambiguous?
- Do you think the content of the CoC covers all essential areas?
- Timing of handing out and discussing CoC.

Additional questions we may ask to explore the usefulness of above intervention components are:

- What are the elements of the QPL/ educational outreach, ACP Reminder, CoC that you consider most helpful?
- What are the elements of the QPL/ educational outreach, ACP Reminder, CoC that you consider least helpful?

Appendix 24. Coding structure by node for a clinician focus group



Word cloud for a clinician focus group



Appendix 25. Evaluation of the ACP Practice-Based Training

Background

In early summer 2017, I conducted APT with 14 healthcare professionals in Oxford to generate the first quantitative and qualitative data on the effect of the training and the acceptability of the intervention components. The aim was to refine the delivery of APT by conducting the training together with a consultant heart failure specialist nurse (HJ) and a palliative care specialist nurse (SO).

Objectives

The objectives were as follows:

- To assess the effect of the training on the abilities and confidence of healthcare professionals to provide advance care planning for patients suffering from heart failure
- To establish whether participants intended to use the intervention in their clinical practice
- To generate qualitative feedback on the usefulness of the training

The educational methods used for APT and a detailed training programme were presented in Chapter Seven. I calculated the mean difference (MD) with 95% Confidence Intervals (CI) between pre- and post-training scores using RevMan 5.3.5 to evaluate the impact of APT on a) participants' understanding of their roles and responsibilities regarding ACP in end-of-life care and heart failure, b) participants' ability to provide a professional ACP conversation for a patient suffering from heart failure, and c) participants' ability to produce an advance care plan in line with a patient's wishes. The following section briefly describes the main results to inform the discussion on the strengths and limitations of the intervention.

Results

I assessed the effect of the training by using an evaluation form that included demographics, a clinician's self-assessment tool for their competence and confidence in initiating ACP in heart failure, a scale to rate the performance of the instructors, and questions asking whether participants would use the intervention in their clinical practice.

- **Characteristics of Participants**

A total of 14 healthcare professionals participated in the training session. The majority of all participants (see **Table**) were nurses, female and of white British Origin.

Sample	n = 14 participants
Composition of sample	4 (28.57%) GPs from Oxford, 4 (28.57%) Community Heart Failure Nurses from Oxfordshire, 3 (21.42%) Nurse Practitioners from Oxfordshire, 2 (14.28%) Advanced Nurse Practitioners in Heart Failure from the Cardiology Department of the John Radcliffe Hospital, one (7.15%) Medical Student from the University of Oxford
Sex	13 (92.85%) female and one (7.15%) male
Ethnicity	12 (85.71%) White British 2 (14.29%) Asian British
Median age	41.35 years
Age range	26-51 years

Table Characteristics of participants

- **Training effect on the ability of participants to deliver ACP in heart failure**

The table below shows the Mean Difference (MD) in scores for each item before and after training. APT was statistically significant in improving participants' understanding of their roles and responsibilities regarding ACP in end-of-life care and heart failure, their ability to provide a professional ACP conversation for a patient suffering from heart failure, and their ability to produce an advance care plan in line with a patient's wishes.

	Pre-Course			Post-Course				Mean Difference (MD)
Rating Scale Item	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95%CI**
Understanding the purpose of ACP in Heart Failure	2.5	0.94	14	4.21	0.578	14	31,7%	1.71 (1.13-2.29)
Able to provide a professional ACP conversation	2.35	1	14	4.14	0.662	14	26.9%	1.79 (1.16-2.42)
Able to produce an ACP with a patient suffering from HF	2	0.78	14	3.78	0.57	14	41.4%	1.78 (1.27-2.29)
Total (95% CI)			**42**			**42**	**100%**	**1.76 (1.43-2.09)**

Table Effect of APT on participants' ability and confidence to perform ACP

The test for the overall effect of APT was statistically significant, MD 1.76, 95% CI (1.43-2.09), p< 0.00001.

- **Intention of Participants to Use the Intervention**

Table X shows the intention of participants to use the different components of the intervention after they had completed the training. Healthcare professionals rated their intention to use the QPL, CoC and ARS or recommend the training to a colleague as very highly.

Item	No	Yes
As required, would you use the Question Prompt List (QPL)?	0%	100%
As required, would you use the Choices of Care Table (CoC)?	0%	100%
As required, would you use the ACP Reminder Sheet (ARS)?	0%	100%
Would you recommend the training to a colleague?	0%	100%

Table Healthcare professionals' intention to use the intervention

Summary

Overall, the first pilot session supported the format, content, training methods and sequencing of the training components of the training session. Initial findings indicate that APT is welcomed by a range of healthcare professionals and suitable for further evaluation in the proposed feasibility trial.

Appendix 26. Proposed interview topic guide for feasibility study

- **Patient Topic Guide for Feasibility cRCT**

1. Role of the Integrated Palliative Care Oucome Scale (IPOS), EQ-5D, QPL and CoC
Aim: To explore the patients' experience of the acceptability and effect, if any, of using these tools

Facilitators and barriers to completion:

- Do you recall completing any of these tools? (show IPOS, EQ-5D, QPL, and CoC)
- Tell me about your experience of filling this in?
    - Probes: Easy/difficult, useful/ burdensome, did it include the areas of most concern for you?
- Do you recall any conversation about ACP or hospital admission?
- What was your experience of participating in this study?
    - Probes: challenges, benefits

- **Clinician Topic Guide for Feasibility cluster RCT**

1. Role of the QPL, CoC, and ARS
Aim: To explore the clinicians' perception of the acceptability and effect, if any, of using these tools in clinical practice

Facilitators and barriers to completion:

- Do you recall using or completing any of these tools? (show QPL, CoC, ARS etc.)
    - Probes: reason, timing
- What challenges did you encounter on giving patients the QPL, CoC to complete?
    - Probes: concerns about raising the topic of ACP, patients' ability to read the tools, patient comprehension of questions, time taken to complete
- What was your experience of introducing the QPL, CoC, ARS into your clinical practice?
    - Probes: challenges, benefits
- Do you recall any conversation about ACP or hospital admission with your patients as a result of using these tools?
- What was your experience of participating in this study?
    - Probes: challenges, benefits