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TITLE: Future Care Planning for patients approaching end-of-life with advanced heart disease: an interview study with patients, carers and healthcare professionals exploring the rationale and design of a randomised clinical trial

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ABSTRACT

Objective: To explore the optimal design of a clinical trial of an end-of-life intervention for advanced heart disease with patients, carers and healthcare professionals

Design: Qualitative interview and focus group study

Setting: Community and hospital-based focus groups and interviews

Participants: Stable community-dwelling patients, informal carers (PC, n=15) and primary and secondary care based healthcare professionals (HCP, n=11)

Results: PC highlighted fragmentation of services and difficulty in accessing specialist care as key barriers to good care. They felt that time for discussion with HCP was inadequate within current NHS health care systems. HCP highlighted uncertainty of prognosis, explaining mortality-risk to patients and switching from curative to palliative approaches as key challenges. Patient selection, nature of the intervention and relevance of trial outcomes were identified by HCP as key challenges in the design of a clinical trial.

Conclusions: PC and HCP share a number of common concerns in relation to providing high quality care in advanced heart disease. Poor prognosis and increased patient-needs were identified as key factors in selecting eligible patients. The findings of this study are being used to support a phase II randomised clinical trial of future care planning in advanced heart disease.

Strengths and limitations of the study

- This qualitative interview study has provided a 360 degree perspective from patients, carers and healthcare professionals on the content and mode of delivery of an intervention that could be tested in a clinical trial and that could impact on quality of life
- The findings suggest that a randomised (early versus delayed) protocol is broadly acceptable, that clinical prognostic scores could be used to identify eligible patients in the hospital setting, that care-needs should also be incorporated into the eligibility criteria and that the intervention should include components that address the current gaps in high quality holistic care (as identified by patients and their carers)
- The relatively small number of participants may have impacted on the findings of this study
- Engaging patients and carers in the rationale, content and design of a randomised clinical trial

INTRODUCTION

Patients with cancer have well developed palliative care services while patients with advanced heart disease do not. The Department of Health in England and Wales [1] and Scottish Government Action Plan "Living and Dying Well" [2] promote care in the last year of life that is person-centred regardless of diagnosis. The recent NHS quality Improvement Scotland Clinical Standards for Heart Disease recommend a palliative care assessment in all forms of advanced heart disease.[3] Recent publications relating to end-of-life care in heart disease have focused on congestive heart failure (CHF) but coronary disease and valvular heart disease commonly co-exist in CHF patients so an integrated approach to all end-stage heart disease is appropriate.

We recently explored ways of identifying patients who are approaching end of life (EOL) in an acute cardiology ward. Using the Gold Standards Framework criteria and validated prognostic tools we demonstrated that most patients with advanced heart failure [4] and a lesser proportion with acute coronary events [5] have a very limited prognosis despite optimal evidence-based care. Poor prognosis is a marker of lower quality of life, increased hospitalisation, multi-morbidity [6] and is an indirect marker of increasing patient needs. There are well validated prognostic tools for patients with congestive heart failure (CHF) [7] and acute coronary syndrome (ACS).[8] Once a patient with a poor prognosis is identified, this should ideally be followed by an evidence-based intervention [9-11] that could improve quality of life for the patient and their family. In keeping with palliative care models [12] this intervention should be patient-focused and should address individual needs. Ideally the intervention should integrate patient preferences with clinical priorities using "shared decision-making".[13] From these discussions a Future Care Plan (FCP) may be derived and

written in terms that the patient understands. The FCP should contain a clinical plan of how to manage acute events of deteriorating health with mechanisms to inform out-of-hours services and maintain continuity of care. The plan should be reviewed regularly in the context of the patient's evolving multidimensional needs. Such an intervention could be initiated by the patient's cardiologist and delivered by a specialist heart disease nurse working in partnership with the primary care team and palliative care specialists.

Trials of palliative care are recognised to be extremely difficult to design and implement.[14] One previous randomised trial suggested that routine palliative care in addition to normal oncological care could improve quality of life in people with lung cancer.[12] A robust feasibility trial, as recommended by the Medical Research Council in its guidance for complex interventions,[15] is needed as a first step towards achieving a similar goal for people with advanced heart disease.

The proposed study outlined here incorporates these issues using a mixed methods, Phase 1 and Phase 2 trial, design and is similar to methodologies used elsewhere to develop complex palliative care interventions for non-cancer illnesses. [16, 17] The proposed trial is novel in that it includes a broad group of patients with CHF and ACS, it will assess whether well-validated clinical prognostic tools can be used to identify patients approaching end-of-life and will develop a feasible care planning intervention. In addition to assessing prognosis as a trigger the study also seeks to explore the interface between acute cardiology services, primary care and specialist palliative care services.

Here we describe the findings of a qualitative interview study using patient-carer focus groups (PCFG) and a range of healthcare professionals (HCP) to explore ways in which an holistic intervention could be tested in a randomised clinical trial setting.

METHODS

The basic design for a clinical trial outline was developed by the authors as part of a submission for research funding using their background knowledge and experience and based on other trial designs of a similar nature [16,17]. This was approved by the funder and by the local ethics committee on the understanding that the design of the study could be modified following a consultation/modelling phase which would involve focus groups of patients and carers and one-to one interviews with a range of healthcare professionals about the proposed trial design. Patient-carer focus groups (PCFG) were then undertaken with the members of an established hospital based heart failure forum (n=7) and a second focus group was undertaken in conjunction with a local heart disease charity (n=8 participants) each lasting for 2 hours. Discussions were facilitated by an experienced qualitative researcher (GH) using an agreed set of questions related to the proposed design of a randomised controlled trial. A separate series of one-to-one interviews were conducted with a range of healthcare professionals (HCP, total n=11, palliative care consultant n= 3, cardiology consultant n=3, heart failure specialist nurse n=1, medicine of the elderly specialist n=1, cardiology ward charge nurse n=1, general practitioner n=1, district nurse n=1) by an experienced qualitative researcher.

Both types of participants were provided with a sample "Future Care Plan" and a proposed design of a clinical trial prior to the interviews and these acted as focal points for discussion. Interviews and focus groups were transcribed and analysed using NVivo to extract themes related to the rationale and design of a clinical trial of an holistic intervention addressing a range of issues related to end-of-life care.

The findings from these interviews and focus group discussions were then used to modify the proposed design of a trial of an intervention to support patients with advanced heart disease identified as being at high risk of death within the next 12 months.

The study was approved by the local ethics committee and all participants gave signed informed consent.

RESULTS

Patient's and carer's views : care for cardiac patients

PCFG highlighted increasing difficulties associated with multiple care-providers working in apparent isolation as a major difficulty in ensuring holistic care. From a PCFG perspective, care appears increasingly fragmented and ill-designed to manage the needs of frail, elderly patients with multiple chronic conditions.

PCFG also identified the variation in access to specialist services as a key problem in providing holistic, patient centred care. This applied in particular to heart failure nurse care where many services adhere to strict eligibility criteria which include left ventricular systolic dysfunction and recent hospital admission. Patients with access to the heart failure specialist nurse service were very appreciative of their support, but they expressed concern that this service was not available to everyone with heart failure and people with other types of advanced heart conditions.

PCFG welcomed the idea of future or anticipatory care planning, and appeared to recognise its value. However, a minority felt that this could be a very difficult process to engage in, expressing views that it needs to be carefully targeted and people should be able to choose, without pressure, not to engage in the process (table 1). PCFG highlighted the fact that

some patients will already be well informed about their condition and its prognosis. However, it was also expressed that for those who have less insight into their condition, doctors and nurses should consider carefully how they will allay and minimise fears about engaging in a process of future care planning.

Patient-carer views: Fragmentation of Care

"Once you get to our age, you discover that you've got more than one problem, and you see the various consultants who deal with the various problems, and they deal with you like a car. They put the carburettor right, they put the radiator right, but the holistic approach is missing" (patient)

"My condition is primarily a chronic lung condition but I also have a heart condition. So I have two separate areas of contact and they both know about each of the conditions but they're really only concentrating on the one they're dealing with, they soon forget, 'oh, you've got a heart condition, oh right!' And it's worrying particularly if you're being administered fairly serious medication and you've got to remember that you've got all these conditions" (patient)

Variation in access to specialist services

"We have a very good rapport and have chats with her (The Heart Failure Nurse). If there's something we don't understand, she's very good at explaining what's involved, so we're very happy" (patient)

"Having a nurse, it gives you a bit more confidence because you just know she's there. Everyone should have one, because it does make a heck of a difference" (patient)

Patient's and carer's views : proposed trial of future care planning

There was a general consensus in the PCFG that the draft Future Care Plan planned for use in the trial (see appendix 1) was comprehensive and addressed a number of concerns that families had about planning for the future (table 2). However, one carer made the point that a patient-centred anticipatory care plan must be flexible enough to accommodate those who are acting on behalf of their loved one possibly using power of attorney. Others

suggested that it would be helpful to ensure that all contact details of the medical teams caring for a patient are included particularly for those with multiple co-morbidities. One patient also questioned the appropriateness of asking patients to identify which potentially life-saving treatments they may or may not want.

PCFG were supportive of the proposal for a clinical trial and were satisfied with the basic design of the study. Opposing views about eligibility criteria were expressed by two participants in the same focus group with one indicating that eligibility should include people with advanced heart disease that were currently stable in the community and not necessarily those recently admitted to hospital. PCFG emphasised the need for families to be well informed and prepared before being approached about a trial testing the proposed intervention.

Patient-carer views: Draft Patient-held Future care plan (see appendix 1 "My Thinking Ahead Plan")

"I have thought about all the questions (in the proposed patient-held Future Care Plan), and I think it's very, very good. Even for yourself to write down your thoughts and wishes. Everybody's wishes are different so therefore, if it's all written down and you've got this plan, I think, yes, it's very useful for the future" (patient)

"….personally, ignorance is bliss in some cases" (patient)

"What would worry me slightly about this, especially if you're filling it out on your own (Future Care Plan), is that suddenly an end, shall we say, opens up, the fact that you're filling in something that's to do with palliative care – ooh, a horrible word – I don't know if people with heart failure are taken through this before this or do they need to be sitting with a doctor or nurse who can take them through the fact that it's not as bad as it sounds. That would worry me ….. getting something like this and filling it in isolation, it's frightening "(patient)

"Well, if you follow all the questions, really I don't think you miss much at all. Because you're asking what people are interested in and what things they do at the moment and what they hope to continue, and in a way, I think that's very good for the professionals looking after us

to know that – whether in fact you're doing anything or if you're doing nothing with your life, because I think it makes a big difference" (patient)

Views of healthcare professionals – end of life care for patients with heart disease

Irrespective of role, all HCP that were interviewed identified the issue of managing the uncertainty of prognosis in people with advanced heart disease as a major challenge. Most agreed that prognostic uncertainty can cause HCP to prevaricate because they are worried about 'getting it wrong'. They also expressed concerns that discussions about end-of-life could remove hope for the patient and their family.

Healthcare professional's views : Prognostic uncertainty

"…it's hard for health professionals to know where they (patients) are in their disease process, because we know they go up and down and they probably never come right back up to where they were the last time, but they're still functioning, and …. at what point do you have that conversation? " (District Nurse)

"A lot of health professionals because of the trajectory of the disease and the up and down nature of it, nobody knows when the point of true palliation should kick in and people are very frightened because with some antibiotics or some steroids they could bounce back, not to the same state of health, each time declining and getting less well, but still not at the point where you would be comfortable saying, right, we're at the point of pure palliation" (Palliative Care Consultant)

"*we've all seen patients who survive against the odds for a long time – if they outlive your expectations, that's OK … you might get the timing a bit wrong because you can't predict, but usually you are right that the decline has started" (Heart Failure Specialist Nurse)*

"You don't want your patients to become obsessed and totally focused on their disease – (they've) got to get on with life as well" (Medicine of the Elderly Consultant)

Healthcare professional's views : Risk of dying from a long term condition

"I don't think they see it, to the same extent as cancer patients - COPD patients as well. They (patients) see it as a limiting condition, it stops them doing things, it's not foremost in their mind that this is the thing they're going to die of" (District Nurse)

"Sometimes I think when it gets to the stage that you're doing DNAR forms … it often comes as a big shock to either them or their family.. it comes as a shock when they're told, 'we think this is it this time', because they've been in and out, bounced back and forward, got better, gone home" (Community Palliative Care Nurse)

Views of healthcare professionals – proposed trial of future care planning

Several HCP participants drew a distinction between different types of patients with advanced heart disease and wanted more clarity about what type of patient would be eligible for the proposed trial. One cardiologist's view was that it would be relatively straightforward to recruit patients with coronary disease although it would be more complex to identify patients with heart failure since it is hard to pinpoint at which point in their illness trajectory they would become eligible. For this group, one cardiologist suggested, it may be useful to use repeated hospital admissions, or functional status as a criteria for eligibility.

Care of the elderly physicians raised concerns about including patients in the trial with multi-morbidity including those with cognitive impairment. Such patients are typically seen in acute medical-takes and while they would be a group who may benefit considerably from Future Care Planning they would be difficult to assess, recruit and retain in the proposed trial. However, this HCP stated that to omit these patients would be unfair and could miss a key opportunity.

There were no significant concerns raised with regard to using a clinical prognostic tool, such as the GRACE score, as a way of identifying patients for a palliative care intervention. However, it was highlighted by a number of HCPs that this approach has significant limitations and using such a tool in isolation may exclude many patients who could benefit from a future care planning approach who have a high level of need and a low estimated 12 month mortality risk. In addition, it was highlighted that prognostic scores do not predict time to death nor do they accurately identify those who may benefit from a palliative care intervention.

Healthcare professional's Views: Proposed trial of Future Care Planning

Patient selection:

"One group is those with advanced heart failure for whom we already have some structure to post-discharge care through our HF nurse service and the second group…are those with end stage coronary disease, so these are patients with angina for whom there's not an awful lot more can be done for them by way of bypass surgery and invasive treatments, and where these patients are intermittently hospitalised when their angina reaches crisis point " (Consultant Cardiologist)

"A score based on a patient's functional status is useful because it identifies when quality of life is impaired to the extent that the patient needs more support" (Consultant Cardiologist)

Eligibility for the trial:

"…harder to put frail elderly patients into a protocol-driven trial because they are so different and they've got such a mix of co-morbidities and such a mix of drugs" (Consultant in Medicine of the Elderly)

"I think using (a cut-off of) 20% (12 month mortality risk) is fair" (Community Palliative Care Nurse)

" It's still pretty high. If it's less than 20% people shouldn't imminently be dying so it gives you a chance to see what effect the intervention has" (Consultant Cardiologist)

"…So it's about identifying the point when you can have a reasonable conversation with somebody about deterioration, and is 20% (estimated mortality risk) right ..If you make it higher you'll miss some people but you'll make the discussion more real and liveable, and that's your balance" (Palliative Care Consultant)

"A 20% risk threshold would include lots and lots of frail elderly people. Many of them would have a 1 in 5 chance of dying within a year even without their heart failure. It's probably not an unreasonable threshold" (Medicine of the Elderly Consultant)

Trial outcome measures:

".. if you're trying to prevent hospital admissions, if they're frequent fliers, then I would have thought they're the ones, the unstable ones. If you've been able to tweak something at home that prevented the admission, I suppose this is what this would do" (District Nurse)

" Obviously, you do have to look at bed days but ultimately they're spending more time in hospital, from their point of view.. that's possibly better for them" (Community Palliative Care Nurse)

"… there's a subtle distinction, for example, between trying to measure differences in quality of life on a day to day basis, and measuring overall levels of comfort, security". (Medicine of the elderly consultant)

Without exception, the HCPs we interviewed had no ethical concerns with a design utilising an early versus late intervention which they regarded as a standard approach for a trial (see figure 1).

Achieving and maintaining staff engagement and thinking ahead to what happens at the end of the trial were identified as important issues. In particular HCPs identified the importance of keeping staff informed about the trial, consideration of how the trial might dovetail with existing service developments and the importance of providing ongoing support beyond the trial period to participants who continue to require additional supportive care.

Hospital bed-days utilisation during follow-up was generally considered to be an appropriate outcome, although several expressed caution in interpreting what these data actually mean. Quality of life measures were also considered to be an appropriate outcome although it was pointed out that these measures can also be difficult to interpret in this setting. Some HCPs suggested the inclusion of place of death and preference for place of death as outcome measures.

The initial study design of the randomised clinical trial has been modified to take account of the views of patients and healthcare professionals interviewed in this study (figure 1). The findings from this modelling phase are being used to support the implementation of a phase II randomised clinical trial of an holistic intervention (figure 2) for patients with advanced heart disease.

DISCUSSION

This qualitative study examining patient and healthcare professional's (HCP) views on a clinical trial of Future Care Planning for patients with advanced heart disease has highlighted a number of important issues. Patients and carers expressed views indicating that such a trial should redress the current inadequacies in a typical doctor-patient interaction which they felt had limited time and lacked an holistic approach particularly in cardiology clinic settings. The healthcare professional participants highlighted the challenges in using meaningful selection criteria for the trial and the complexity of identifying precisely which component of any proposed intervention might influence outcomes. Factors such as the content of the initial discussion/interview with the consultant, the content of the written future care plan and ongoing support from a familiar healthcare professional were highlighted by HCPs as important components. These views from patients, carers and professionals suggests that a clinical trial in this setting should focus on providing adequate time to discuss the patient's current and future care needs and those of their carer, it should select patients on the basis of prognosis and needs, it should provide ongoing support with both primary and secondary care working closely together to ensure good coordination of care and it should allow for adaptation of any care plan in a dynamic way that is aligned with the changing needs of the patient and their carer.

While this message is clear, delivering such a trial using non-palliative care physicians in an acute cardiology environment will be challenging. Finding the words to explain an uncertain prognosis is always difficult, [23] and cardiologists with a firm culture of curative approaches may struggle to find that language. These challenges may delay the conversation until it's too late, or they may encourage the use of more vague, ambiguous or even contradictory

language which can sometimes mislead the patient and their family or fail to communicate the seriousness of their condition adequately. Finding language that is balanced, caring and which makes sense of an uncertain future is one of the challenges of all palliative care even where the prognosis, good or bad, is more certain. However, the majority of the HCPs that we interviewed agreed that it should be possible in most cardiac patients with advanced disease. Surviving with a chronic condition that has an uncertain illness trajectory can mean that these patients, unlike cancer patients, can reach a fairly advanced stage in their illness without realising that they have a condition that could and probably will cause their death.

Our findings have also highlighted a persisting tendency for patients and healthcare professionals to associate palliative care with dying. This perception may prevent or discourage healthcare teams from offering palliative and supportive care to patients with significant symptom burden who may not have reached the end of their lives but who may benefit form additional supportive care. Healthcare professionals held the view that patients and carers may be reluctant to accept a form of support which they associate with end of life. This may reflect reluctance on the part of the healthcare professionals as much as the patient. This is an important issue if we are to develop a model of integrating palliative care earlier in the illness trajectory of cardiac disease by the heart team caring for the patient. In addition to learning and developing the skills required to do this, these teams will also need to change attitudes and culture. Indeed, while this culture is increasingly acknowledged as important for patients with chronic heart failure there is also a clear need for this approach in patients with other forms of advanced cardiac disease such as coronary and valvular heart disease.

The barriers to achieving good holistic care for patients nearing the end of their lives , well described in other settings [24, 25] apply equally well in the acute cardiology setting.[26] There is insufficient time to discuss such sensitive issues, the hospital environment is not ideal (particularly in multi-bedded rooms), cardiologists are not adequately trained and in cardiology there is a culture of doing more and never giving up. However, particularly in elderly patients and even with optimal interventions the combination of congestive heart failure, coronary heart disease, valvular heart disease and other non-cardiac comorbidities is associated with poor prognosis.[27, 28] Indeed, the increasing use of Transcatheter Aortic Valve Implantation (TAVI) in patients that are deemed unsuitable for conventional surgery is increasingly recognised as a clinical challenge balancing aggressive intervention with supportive end of life care.[29, 30]

Hence, patients with advanced heart disease and poor prognosis are clearly a target for better clinical care encompassing an approach that acknowledges that the patient may be nearing the end of life. These patients rarely receive care that addresses their individual needs and those of their informal carers. This care need not be labelled as palliative but can be delivered in the understanding that the future is uncertain and the risk of death, either sudden or with progressive symptoms, is significantly increased. This need not exclude a positive attitude to the patient's clinical care and where possible the healthcare professional should emphasise the need for ongoing active and responsive care. The challenge, and arguable the key issue, is maintaining a positive attitude while simultaneously acknowledging a poor prognosis. However, if this approach can be adopted by the patient, their family, GP and cardiologist then it can potentially improve communication and understanding in a way that leads to better care. Any such intervention should be patient-

centred in all aspects of its design and the impact on healthcare measures must be seen as secondary to the primary aim of improving quality of life. This is challenging even in cancer care where there have been few clinical trials adequately powered to show clinically meaningful benefits using an holistic approach.[12] If improved clinical outcomes could be demonstrated in a clinical trial involving patients with advanced heart disease then this would be extremely valuable to patients and the wider cardiology community.

This study has clearly demonstrated that patients, carers and healthcare professionals share a number of common concerns in relation to providing high quality holistic care for patients with advanced heart disease. The findings are currently being used to support implementation of a phase II randomised clinical trial of an holistic intervention involving Future Care Planning for patients with advanced heart disease.

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FIGURE LEGENDS

Figure 1 – Protocol for a randomised trial of Future Care Planning for patients with advanced heart disease: *Patients admitted directly to an acute cardiology ward with either acute coronary syndrome or heart failure as the primary reason for admission will be screened for eligibility. Eligibility includes an estimated 12 month mortality risk of 20% or greater at the time of discharge using the GRACE discharge score [8] or the EFFECT score [7]. Eligible patients need to survive to discharge and have capacity to consent for the study. Informal carers will also participate where identified by the patient. Proposed outcomes include quality of life assessed by questionnaire (EuroQoL-5D) and readmissions to hospital. Patients randomised to early intervention will be interviewed prior to discharge and those randomised to delayed intervention will receive the same interview 12 weeks following discharge.*

Figure 2 – Future Care Plan Intervention : *the intervention will last for 12 weeks. Patients randomised to early intervention will have a 1 hour interview with a cardiologist prior to discharge where they will discuss their heart condition, other medical conditions and their concerns and plans for the future. The cardiologist, trained in Advanced Communication Skills, will aim to address a range of issues including (1) a future care plan , agreed with the patient and their carer, which includes advice to Healthcare professionals about what could and should be done if the patient's condition deteriorates once again, (2) whether the patient and their family have arranged Power of Attorney (or similar), (3) whether the patient wishes to consider the issue of DNACPR (Do Not Attempt Cardiopulmonary*

Resuscitation), (4) whether the patient wishes to express a preferred place of care should their condition deteriorate again, (5) whether the patient would consider being added to their GP's Palliative Care register and (6) permission to share the content of the Future Care Plan electronically with out-of-hours medical services (NHS24/NHS Direct). Patients will also be encouraged to complete "Thinking Ahead Plan", a locally developed patient-held anticipatory care plan (see supplemental file). Patients randomised to delayed intervention will undergo the same interview 12 weeks after discharge. During the follow-up period of 12 weeks, the trial nurse will visit the patient/carer in their home at 6 weeks and 12 weeks after the baseline interview in order to update the FCP with any changes and to review any DNACPR orders or make any necessary changes to the plan of care. An updated version of the FCP record will be communicated in writing to the GP at each of these time points. The nurse will be available to communicate with the patient by telephone at any time and will ensure optimal communication and coordination of care between GP, cardiologist, community-based nursing teams and palliative care teams (where appropriate).

Figure 1

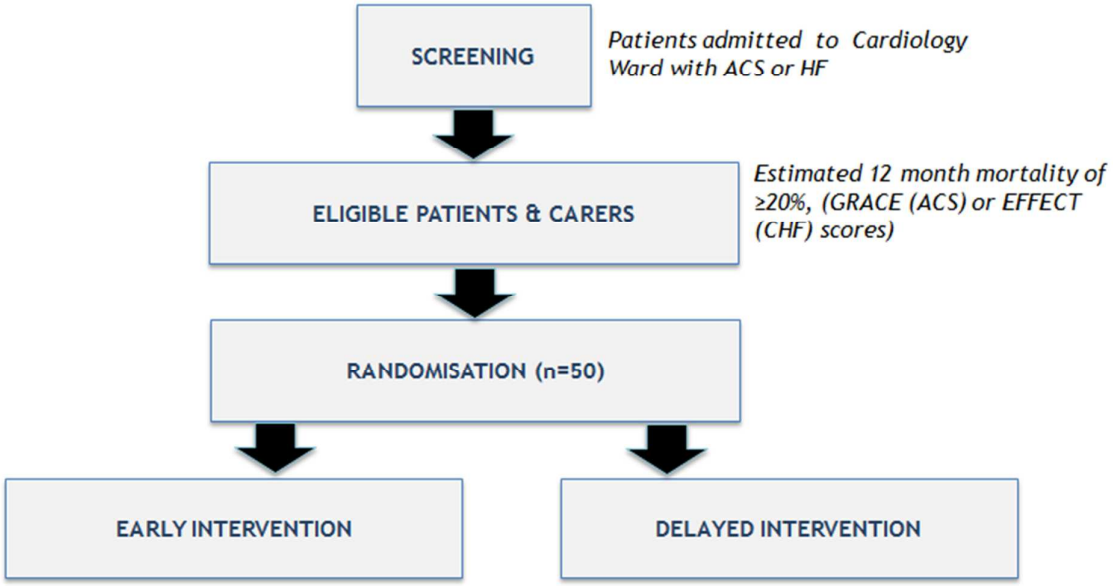
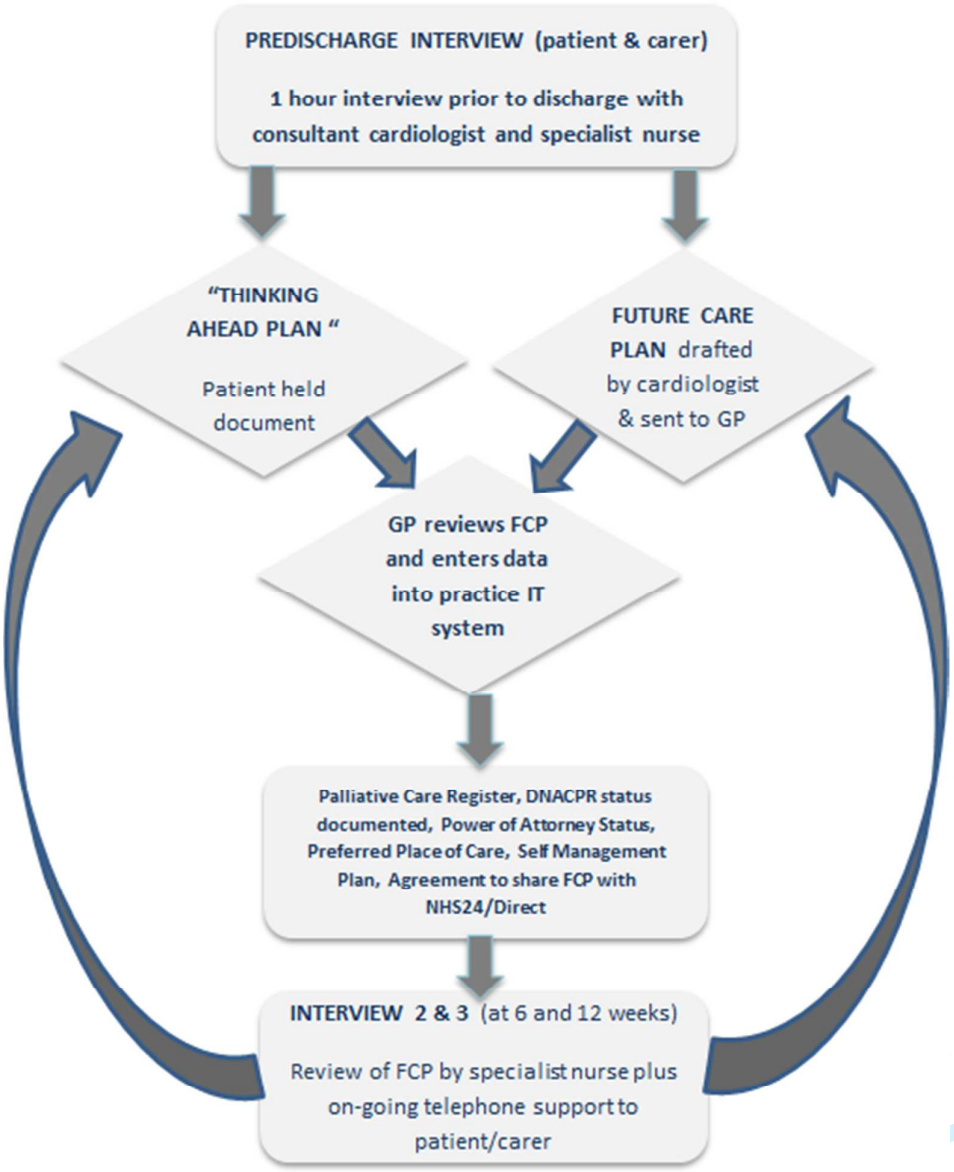
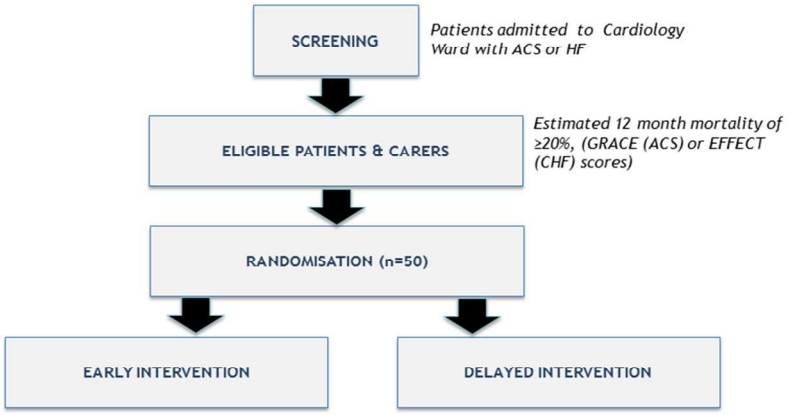
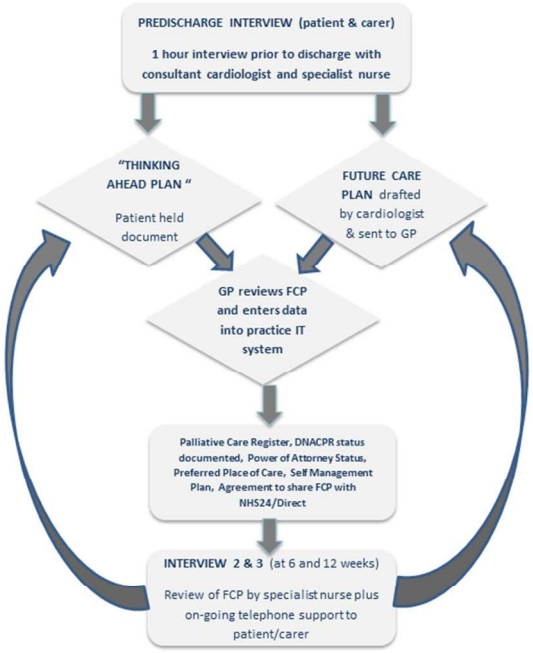


Figure 2


PREDISCHARGE INTERVIEW (patient & carer)
1 hour interview prior to discharge with consultant cardiologist and specialist nurse
"THINKING AHEAD PLAN "
Patient held document
FUTURE CARE PLAN drafted by cardiologist & sent to GP
GP reviews FCP and enters data into practice IT system
Palliative Care Register, DNACPR status documented, Power of Attorney Status, Preferred Place of Care, Self Management Plan, Agreement to share FCP with NHS24/Direct
INTERVIEW 2 & 3 (at 6 and 12 weeks)
Review of FCP by specialist nurse plus on-going telephone support to patient/carer



Protocol for a randomised trial of Future Care Planning for patients with advanced heart disease
254x190mm (96 x 96 DPI)



Future Care Plan Intervention
254x190mm (96 x 96 DPI)

THE UNIVERSITY of EDINBURGH

NHS Lothian

Thinking ahead

planning together

My name:

Some information about this plan

What is future care planning?

To be able to give the best care to people with serious illnesses we need to talk about what is important to each person and their family now and if things change in the future.

A 'future care plan' can help you to think about what things are important to you so you can talk about them with your family and friends.

The people who are looking after you would like to help you with your plan and talk about how we can use it to give you the best care we can.

What goes in the plan?

You can use the plan in any way you like. Most people start by writing things down that are important for them and their family at the moment. Some people like to put in information about the kind of care and treatment they would like to have now and in the future.

How do I fill it in?

The plan has some boxes which give you a few ideas about what you might want to think about. Some people use all the boxes, some just one or two. You might choose to add a box or page of your own. You can fill your plan bit by bit and you can change or add to it whenever you want.

Who can help me fill it in?

A few people like to fill in their plan by themselves. Many people do it with their family or close friends, or with help from the people who are looking after them. If someone does help you, you might want to write their name in at the end. It is important to talk about things you add or change in your plan with your family, and the people who are looking after you.

Where should I keep my plan?

You should keep your plan at home so you can show it to any health professionals who come to see you. It is a good idea to take your plan with you if you go to see your GP, or if you go to hospital for anything. This helps everyone who is involved with your care know what is important to you and your family.

Can I get a version for my computer?

Yes, if you would like a copy of the Thinking Ahead and Planning Together booklet to put on your computer so you can update it that way, please ask. It is still a good idea to print off a copy of the most up to date plan to have at home as well, so that you can take this to any appointments.

Important things right now

It is a good idea to start by thinking about how things are now.

What do people looking after me need to know about me and my family?

What would help me most?

Planning ahead

You might want to write about things you are looking forward to, important events that are coming up for you or your family, or things you want to do or carry on doing.

What could help me with these things?

Are there any other things that I might be able to do?

Looking after me well

The people looking after you want to make sure you have all the information you need about your health problems and would like to find out what is important to you.

Are there any things about my treatment and care now, or in the future that are important to me?

My concerns

You can write about any worries that you might have here. These could be about yourself, your family or even your pet.

Are there things that worry me now, or have I any worries about what might happen in the future?

Have I any plans about what we might do if any of these things did happen?

Things some people want to know more about:

Some people and their families like to know more about things that can be important when someone has a serious illness.

Some of these are:

Benefits advice

- Asking a person I can trust to speak for me and help make decisions about my health if in the future I am not able to myself (a Welfare Attorney)
- A living will or advance decision to refuse a specific treatment
- Cardiopulmonary resuscitation decisions (DNA CPR): attempting to restart a person's heart
- Making a will

Things I would like to ask about are:

Keeping track

Each time you write in this Plan, you might like to write down in this section the date and the name of anyone who helped you.

Useful Contacts

My GP's name and telephone:

My District Nurse's name and telephone:

My Chemist:

NHS24:

Other people involved in my care:

We would welcome any comments or suggestions about this booklet. Contact us...

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BMJ Open

Future Care Planning for patients approaching end-of-life with advanced heart disease: an interview study with patients, carers and healthcare professionals exploring the content, rationale and design of a randomised clinical trial

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TITLE: Future Care Planning for patients approaching end-of-life with advanced heart disease: an interview study with patients, carers and healthcare professionals exploring the content, rationale and design of a randomised clinical trial

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Key words: advanced heart disease, care planning, randomised clinical trial, palliative care, end-of-life care

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ABSTRACT

Objective: To explore the optimal content and design of a clinical trial of an end-of-life intervention for advanced heart disease with patients, carers and healthcare professionals

Design: Qualitative interview and focus group study

Setting: Community and hospital-based focus groups and interviews

Participants: Stable community-dwelling patients, informal carers (PC, n=15) and primary and secondary care based healthcare professionals (HCP, n=11)

Results: PC highlighted fragmentation of services and difficulty in accessing specialist care as key barriers to good care. They felt that time for discussion with HCP was inadequate within current NHS health care systems. HCP highlighted uncertainty of prognosis, explaining mortality-risk to patients and switching from curative to palliative approaches as key challenges. Patient selection, nature of the intervention and relevance of trial outcomes were identified by HCP as key challenges in the design of a clinical trial.

Conclusions: PC and HCP expressed a number of concerns relevant to the nature and content of an end-of-life intervention for patients with advanced heart disease. The findings of this study are being used to support a phase II randomised clinical trial of future care planning in advanced heart disease.

Strengths and limitations of the study

- This qualitative interview study has provided a 360 degree perspective from patients, carers and healthcare professionals on the content, nature and mode of delivery of an intervention that could be tested in a clinical trial and that could impact on quality of life.
- The findings suggest that a randomised (early versus delayed) protocol is broadly acceptable, that clinical prognostic scores could be used to identify eligible patients in the hospital setting, that care-needs should also be incorporated into the eligibility criteria and that the intervention should include components that address the current gaps in high quality holistic care (as identified by patients and their carers).
- The relatively small number of patients and healthcare professionals participating in the study and the fact that all patients were in a stable community-based setting may have impacted on the findings.
- Engaging patients and carers in the rationale, content and design of a randomised clinical trial is challenging and requires careful design and planning.

INTRODUCTION

Patients with cancer have well developed palliative care services while patients with advanced heart disease do not as highlighted in two major reports by The Department of Health in England and Wales [1] and Scottish Government Action Plan “Living and Dying Well” [2]. These documents promote the provision of care in the last year of life that is person-centred regardless of diagnosis. The recent NHS quality Improvement Scotland Clinical Standards for Heart Disease recommend a palliative care assessment in all forms of advanced heart disease.[3] Recent publications relating to end-of-life care in heart disease have focused on congestive heart failure (CHF) but coronary disease and valvular heart disease commonly co-exist in CHF patients so an integrated approach to all end-stage heart disease is appropriate.

We recently explored ways of identifying patients who are approaching end of life (EOL) in an acute cardiology ward. Using the Gold Standards Framework criteria and validated prognostic tools we demonstrated that most patients with advanced heart failure [4] and a lesser proportion with acute coronary events [5] have a very limited prognosis despite optimal evidence-based care. Poor prognosis is a marker of lower quality of life, increased hospitalisation, multi-morbidity [6] and is an indirect marker of increasing patient needs. There are well validated prognostic tools for patients with congestive heart failure (CHF) [7] and acute coronary syndrome (ACS).[8] Once a patient with a poor prognosis is identified, this should ideally be followed by an evidence-based intervention [9-11] that could improve quality of life for the patient and their family. In keeping with palliative care models [12] this intervention should be patient-focused and should address individual needs. Ideally

the intervention should integrate patient preferences with clinical priorities using "shared decision-making".[13] From these discussions a Future Care Plan (FCP) may be derived and written in terms that the patient understands. The FCP should contain a clinical plan of how to manage acute events of deteriorating health with mechanisms to inform out-of-hours services and maintain continuity of care. The plan should be reviewed regularly in the context of the patient's evolving multidimensional needs. Such an intervention could be initiated by the patient's cardiologist and delivered by a specialist heart disease nurse working in partnership with the primary care team and palliative care specialists.

Trials of palliative care are recognised to be extremely difficult to design and implement.[14] One previous randomised trial suggested that routine palliative care in addition to normal oncological care could improve quality of life in people with lung cancer.[12] A robust phase II trial, as recommended by the Medical Research Council in its guidance for complex interventions,[15] is needed as a first step towards achieving a similar goal for people with advanced heart disease.

The proposed study outlined here incorporates these issues using a mixed methods, Phase 1 and Phase 2 trial, design and is similar to methodologies used elsewhere to develop complex palliative care interventions for non-cancer illnesses. [16, 17] The proposed trial is novel in that it includes a broad group of patients with CHF and ACS, it will assess whether well-validated clinical prognostic tools can be used to identify patients approaching end-of-life and will develop a feasible care planning intervention. In addition to assessing prognosis as a trigger the study also seeks to explore the interface between acute cardiology services, primary care and specialist palliative care services.

Here we describe the findings of a qualitative interview study using patient-carer focus groups (PCFG) and a range of healthcare professionals (HCP) to explore ways in which an holistic intervention could be tested in a randomised clinical trial setting.

METHODS

The basic design for a clinical trial outline was developed by the authors as part of a submission for research funding using their background knowledge and experience and based on other trial designs of a similar nature. [16,17] This was approved by the funder and by the local ethics committee on the understanding that the design of the study could be modified following a consultation/modelling phase which would involve focus groups of patients and carers and one-to one interviews with a range of healthcare professionals about the proposed trial design. Patient-carer focus groups (PCFG) were then undertaken with the members of an existing hospital based heart failure patient-carer forum (n=7) and a second focus group was undertaken in conjunction with a local heart disease charity (n=8 participants) each lasting for 2 hours. Discussions were facilitated by an experienced qualitative researcher (GH) using a set of questions, designed by the authors, addressing their experiences with clinical care and the proposed design of the randomised controlled trial (see appendix 1A). Various options associated with the trial were presented and discussed with patients and carers including eligibility criteria and whether the control group should or should not receive end-of-life intervention.

A separate series of one-to-one interviews were conducted with a range of healthcare professionals (HCP, total n=11, palliative care consultant n= 3, cardiology consultant n=3, heart failure specialist nurse n=1, medicine of the elderly specialist n=1, cardiology ward charge nurse n=1, general practitioner n=1, district nurse n=1)

by an experienced qualitative researcher using a set of questions incorporating themes related to clinical care, palliative care and clinical trials design (see appendix 1B).

Discussions regarding the proposed design of the trial were initially broad and later in the interview focused more on the eligibility criteria, types of patients that should be included and whether an active control group should be incorporated. Both types of participants were provided with a sample “Future Care Plan” and a flow diagram of the basic proposed design of the clinical trial prior to the interviews. These documents acted as focal points for discussion. Interviews and focus groups were transcribed and analysed using NVivo to extract themes related to the rationale and design of a clinical trial of an holistic intervention addressing a range of issues related to end-of-life care.

The findings from these interviews and focus group discussions were then used to modify the proposed design of a trial of an intervention to support patients with advanced heart disease identified as being at high risk of death within the next 12 months.

The study was approved by the local ethics committee and all participants gave signed informed consent.

RESULTS

Patient's and carer's views : care for cardiac patients

PCFG highlighted increasing difficulties associated with multiple care-providers working in apparent isolation as a major difficulty in ensuring holistic care. From a PCFG perspective, care appears increasingly fragmented and ill-designed to manage the needs of frail, elderly patients with multiple chronic conditions.

PCFG also identified the variation in access to specialist services as a key problem in providing holistic, patient centred care. This applied in particular to heart failure nurse care where many services adhere to strict eligibility criteria which include left ventricular systolic dysfunction and recent hospital admission. Patients with access to the heart failure specialist nurse service were very appreciative of their support, but they expressed concern that this service was not available to everyone with heart failure and people with other types of advanced heart conditions.

PCFG welcomed the idea of future or anticipatory care planning, and appeared to recognise its value. However, a minority felt that this could be a very difficult process to engage in, expressing views that it needs to be carefully targeted and people should be able to choose, without pressure, not to engage in the process (table 1). PCFG highlighted the fact that some patients will already be well informed about their condition and its prognosis. However, it was also expressed that for those who have less insight into their condition, doctors and nurses should consider carefully how they will allay and minimise fears about engaging in a process of future care planning.

Patient-carer views: Fragmentation of Care

"Once you get to our age, you discover that you've got more than one problem, and you see the various consultants who deal with the various problems, and they deal with you like a car. They put the carburettor right, they put the radiator right, but the holistic approach is missing" (patient)

"My condition is primarily a chronic lung condition but I also have a heart condition. So I have two separate areas of contact and they both know about each of the conditions but they're really only concentrating on the one they're dealing with, they soon forget, 'oh, you've got a heart condition, oh right!' And it's worrying particularly if you're being administered fairly serious medication and you've got to remember that you've got all these conditions" (patient)

Variation in access to specialist services

"We have a very good rapport and have chats with her (The Heart Failure Nurse). If there's something we don't understand, she's very good at explaining what's involved, so we're very happy" (patient)

"Having a nurse, it gives you a bit more confidence because you just know she's there. Everyone should have one, because it does make a heck of a difference" (patient)

Patient's and carer's views : proposed trial of future care planning

There was a general consensus in the PCFG that the draft Future Care Plan planned for use in the trial (see appendix 2) was comprehensive and addressed a number of concerns that families had about planning for the future (table 2). However, one carer made the point that a patient-centred anticipatory care plan must be flexible enough to accommodate those who are acting on behalf of their loved one possibly using power of attorney. Others suggested that it would be helpful to ensure that all contact details of the medical teams caring for a patient are included particularly for those with multiple co-morbidities. One patient also questioned the appropriateness of asking patients to identify which potentially life-saving treatments they may or may not want.

PCFG were supportive of the proposal for a clinical trial and were satisfied with the basic design of the study. Opposing views about eligibility criteria were expressed by two participants in the same focus group with one indicating that eligibility should include people with advanced heart disease that were currently stable in the community and not necessarily those recently admitted to hospital. PCFG emphasised the need for families to be well informed and prepared before being approached about a trial testing the proposed intervention. Eligibility for the trial using a threshold value for estimated 12 month mortality was debated and discussed and a value of 20% was reached as one which would include a set of patients with a significantly higher then average mortality risk for cardiac patients. One further aspect of the final design of the trial which was discussed and agreed by the PCFG was whether to have a control group with no intervention or whether to have a group of patients where an intervention was provided but 12 weeks after discharge. It was generally agreed that it would be unethical not to provide an intervention of some sort to all patients who agreed to take part and so a delayed intervention group design was finally agreed (see figure 1).

Patient-carer views: Draft Patient-held Future care plan (see appendix 2 "My Thinking Ahead Plan")

"I have thought about all the questions (in the proposed patient-held Future Care Plan), and I think it's very, very good. Even for yourself to write down your thoughts and wishes. Everybody's wishes are different so therefore, if it's all written down and you've got this plan, I think, yes, it's very useful for the future" (patient)

"….personally, ignorance is bliss in some cases" (patient)

"What would worry me slightly about this, especially if you're filling it out on your own (Future Care Plan), is that suddenly an end, shall we say, opens up, the fact that you're filling in something that's to do with palliative care – ooh, a horrible word – I don't know if people with heart failure are taken through this before this or do they need to be sitting with a doctor or nurse who can take them through the fact that it's

not as bad as it sounds. That would worry me ….. getting something like this and filling it in isolation, it's frightening "(patient)

"Well, if you follow all the questions, really I don't think you miss much at all. Because you're asking what people are interested in and what things they do at the moment and what they hope to continue, and in a way, I think that's very good for the professionals looking after us to know that – whether in fact you're doing anything or if you're doing nothing with your life, because I think it makes a big difference" (patient)

Views of healthcare professionals – end of life care for patients with heart disease

Irrespective of role, all HCP that were interviewed identified the issue of managing the uncertainty of prognosis in people with advanced heart disease as a major challenge. Most agreed that prognostic uncertainty can cause HCP to prevaricate because they are worried about 'getting it wrong'. They also expressed concerns that discussions about end-of-life could remove hope for the patient and their family.

Healthcare professional's views : Prognostic uncertainty

"…it's hard for health professionals to know where they (patients) are in their disease process, because we know they go up and down and they probably never come right back up to where they were the last time, but they're still functioning, and …. at what point do you have that conversation? " (District Nurse)

"A lot of health professionals because of the trajectory of the disease and the up and down nature of it, nobody knows when the point of true palliation should kick in and people are very frightened because with some antibiotics or some steroids they could bounce back, not to the same state of health, each time declining and getting less well, but still not at the point where you would be comfortable saying, right, we're at the point of pure palliation" (Palliative Care Consultant)

"*we've all seen patients who survive against the odds for a long time – if they outlive your expectations, that's OK … you might get the timing a bit wrong because you can't predict, but usually you are right that the decline has started" (Heart Failure Specialist Nurse)*

"You don't want your patients to become obsessed and totally focused on their disease – (they've) got to get on with life as well" (Medicine of the Elderly Consultant)

Healthcare professional's views : Risk of dying from a long term condition

"I don't think they see it, to the same extent as cancer patients - COPD patients as well. They (patients) see it as a limiting condition, it stops them doing things, it's not foremost in their mind that this is the thing they're going to die of" (District Nurse)

"Sometimes I think when it gets to the stage that you're doing DNAR forms … it often comes as a big shock to either them or their family.. it comes as a shock when they're told, 'we think this is it this time', because they've been in and out, bounced back and forward, got better, gone home" (Community Palliative Care Nurse)

Views of healthcare professionals – proposed trial of future care planning

Several HCP participants drew a distinction between different types of patients with advanced heart disease and wanted more clarity about what type of patient would be eligible for the proposed trial. One cardiologist's view was that it would be relatively straightforward to recruit patients with coronary disease although it would be more complex to identify patients with heart failure since it is hard to pinpoint at which point in their illness trajectory they would become eligible. For this group, one cardiologist suggested, it may be useful to use repeated hospital admissions, or functional status as a criteria for eligibility.

Care of the elderly physicians raised concerns about including patients in the trial with multi-morbidity including those with cognitive impairment. Such patients are typically seen in acute medical-takes and while they would be a group who may benefit considerably from Future Care Planning they would be difficult to assess, recruit and retain in the proposed trial. However, this HCP stated that to omit these patients would be unfair and could miss a key opportunity.

There were no significant concerns raised with regard to using a clinical prognostic tool, such as the GRACE score, as a way of identifying patients for a palliative care intervention. However, it was highlighted by a number of HCPs that this approach

has significant limitations and using such a tool in isolation may exclude many patients who could benefit from a future care planning approach who have a high level of need and a low estimated 12 month mortality risk. In addition, it was highlighted that prognostic scores do not predict time to death nor do they accurately identify those who may benefit from a palliative care intervention.

Healthcare professional's Views: Proposed trial of Future Care Planning

Patient selection:

"One group is those with advanced heart failure for whom we already have some structure to post-discharge care through our HF nurse service and the second group…are those with end stage coronary disease, so these are patients with angina for whom there's not an awful lot more can be done for them by way of bypass surgery and invasive treatments, and where these patients are intermittently hospitalised when their angina reaches crisis point " (Consultant Cardiologist)

"A score based on a patient's functional status is useful because it identifies when quality of life is impaired to the extent that the patient needs more support" (Consultant Cardiologist)

Eligibility for the trial:

"…harder to put frail elderly patients into a protocol-driven trial because they are so different and they've got such a mix of co-morbidities and such a mix of drugs" (Consultant in Medicine of the Elderly)

"I think using (a cut-off of) 20% (12 month mortality risk) is fair" (Community Palliative Care Nurse)

" It's still pretty high. If it's less than 20% people shouldn't imminently be dying so it gives you a chance to see what effect the intervention has" (Consultant Cardiologist)

"…So it's about identifying the point when you can have a reasonable conversation with somebody about deterioration, and is 20% (estimated mortality risk) right ..If you make it higher you'll miss some people but you'll make the discussion more real and liveable, and that's your balance" (Palliative Care Consultant)

"A 20% risk threshold would include lots and lots of frail elderly people. Many of them would have a 1 in 5 chance of dying within a year even without their heart failure. It's probably not an unreasonable threshold" (Medicine of the Elderly Consultant)

Trial outcome measures:

".. if you're trying to prevent hospital admissions, if they're frequent fliers, then I would have thought they're the ones, the unstable ones. If you've been able to tweak something at home that prevented the admission, I suppose this is what this would do" (District Nurse)

" Obviously, you do have to look at bed days but ultimately they're spending more time in hospital, from their point of view.. that's possibly better for them" (Community Palliative Care Nurse)

"… there's a subtle distinction, for example, between trying to measure differences in quality of life on a day to day basis, and measuring overall levels of comfort, security". (Medicine of the elderly consultant)

Without exception, the HCPs we interviewed had no ethical concerns with a design utilising an early versus late intervention which they regarded as a standard approach for a trial (see figure 1).

Achieving and maintaining staff engagement and thinking ahead to what happens at the end of the trial were identified as important issues. In particular HCPs identified the importance of keeping staff informed about the trial, consideration of how the trial might dovetail with existing service developments and the importance of providing ongoing support beyond the trial period to participants who continue to require additional supportive care.

Hospital bed-days utilisation during follow-up was generally considered to be an appropriate outcome, although several expressed caution in interpreting what these data actually mean. Quality of life measures were also considered to be an appropriate outcome although it was pointed out that these measures can also be difficult to interpret in this setting. Some HCPs suggested the inclusion of place of death and preference for place of death as outcome measures.

The initial study design of the clinical trial did not strictly define the types of patients that could be included, the eligibility criteria, the threshold mortality risk for inclusion and whether an intervention should be included for the control group. The final trial design (figure 1) represents a modified version taking account of the views of patients and healthcare professionals interviewed in this study. This fundamental design of the proposed trial was similar to the original design presented to the PCFG and the HCP during the interviews and focus groups. There was general agreement

that a broad range of acute cardiac patents should be included and agreement was reached to include heart failure (with either reduced or preserved left ventricular systolic function) and patients with any acute coronary syndrome. There was discussion as to whether a delayed intervention was needed in the control group. Since current clinical services provided little or no end-of-life intervention for such patients a final consensus, mainly driven by comments from patients and carers, was made to offer a delayed intervention to the control group given that the intervention addressed a clear need which was patient-centred and which could provide an apparent benefit to those who participated. The final component of the design which was agreed following the PCFG and HCP interviews was the threshold at which to set the 12 month mortality used as eligibility for the trial. The authors had proposed this to be somewhere between 20 and 40% and this was discussed by both groups. The final agreement of 20% was made largely by the PCFG after lengthy discussions as to what the typical mortality risk was for CCF and ACS patients admitted acutely to hospital.

The findings from this modelling phase are currently being used to support the implementation of a phase II randomised clinical trial of an holistic intervention (figure 2) for patients with advanced heart disease.

DISCUSSION

This qualitative study examining patient and healthcare professional's (HCP) views on a the content and design of a clinical trial of Future Care Planning for patients with advanced heart disease has highlighted a number of important issues. The concerns raised by patients and carers regarding the current inadequate levels of care as cardiac patients approach end-of-life provides an important back-drop to the main theme of the work which was to seek their views on the content and design of a clinical trial. Patients and carers expressed views indicating that such a trial should redress the current inadequacies in a typical doctor-patient interaction which they felt had limited time and lacked an holistic approach particularly in cardiology out-patient clinic settings. The healthcare professional participants highlighted the challenges in using meaningful selection criteria for the trial and the complexity of identifying precisely which component of any proposed intervention might influence outcomes. The findings of this work therefore re-affirm many of the findings of others in the field [18, 19]. However, the novel aspect of the work is that the focus groups and interviews were extended beyond a general discussion stage to seek views on how the inadequacies in care could be redressed and a model developed which could be subsequently tested using a randomised trial approach.

Factors which might influence the outcomes which emerged from the PCFG discussions included the content and quality of the baseline or first discussion/interview with the consultant, the content of the written future care plan and ongoing support, for both patient and carer, from a familiar healthcare professional. The views from patients, carers and professionals indicated that a

clinical trial should focus on providing adequate time to discuss the patient's current and future care needs and those of their carer, it should select patients on the basis of prognosis and needs, it should provide ongoing support with both primary and secondary care working closely together to ensure good coordination of care and it should allow for adaptation of any care plan in a dynamic way that is aligned with the changing needs of the patient and their carer.

While this message is clear, delivering such a trial using non-palliative care physicians in an acute cardiology environment will be challenging. Finding the appropriate language to explain an uncertain prognosis is always difficult, [20] and cardiologists with a firm culture of curative approaches may struggle to find that language. These challenges may delay the conversation until it's too late, or they may encourage the use of more vague, ambiguous or even contradictory language which can sometimes mislead the patient and their family or fail to communicate the seriousness of their condition adequately. Finding language that is balanced, caring and which makes sense of an uncertain future is one of the challenges of all palliative care even where the prognosis, good or bad, is more certain. However, the majority of the HCPs that we interviewed agreed that it should be possible in most cardiac patients with advanced disease. Surviving with a chronic condition that has an uncertain illness trajectory can mean that these patients, unlike cancer patients, can reach a fairly advanced stage in their illness without realising that they have a condition that could and probably will cause their death.

Our findings have also highlighted a persisting tendency for patients and healthcare professionals to associate palliative care with dying. This perception may prevent or discourage healthcare teams from offering palliative and supportive care to patients with significant symptom burden who may not have reached the end of their lives but

who may benefit form additional supportive care. Healthcare professionals held the view that patients and carers may be reluctant to accept a form of support which they associate with end of life. This may reflect reluctance on the part of the healthcare professionals as much as the patient. This is an important issue if we are to develop a model of integrating palliative care earlier in the illness trajectory of cardiac disease by the heart team caring for the patient. In addition to learning and developing the skills required to do this, these teams will also need to change attitudes and culture. Indeed, while this culture is increasingly acknowledged as important for patients with chronic heart failure there is also a clear need for this approach in patients with other forms of advanced cardiac disease such as coronary and valvular heart disease.

The barriers to achieving good holistic care for patients nearing the end of their lives, well described in other settings [21, 22] apply equally well in the acute cardiology setting. [23] There is insufficient time to discuss such sensitive issues, the hospital environment is not ideal (particularly in multi-bedded rooms), cardiologists are not adequately trained and in cardiology there is a culture of doing more and never giving up. However, particularly in elderly patients and even with optimal interventions the combination of congestive heart failure, coronary heart disease, valvular heart disease and other non-cardiac comorbidities is associated with poor prognosis.[24, 25] Indeed, the increasing use of Transcatheter Aortic Valve Implantation (TAVI) in patients that are deemed unsuitable for conventional surgery is increasingly recognised as a clinical challenge balancing aggressive intervention with supportive end of life care.[26, 27]

Hence, patients with advanced heart disease and poor prognosis are clearly a target for better clinical care encompassing an approach that acknowledges that the patient may be nearing the end of life. These patients rarely receive care that addresses

their individual needs and those of their informal carers. This care need not be labelled as palliative but can be delivered in the understanding that the future is uncertain and the risk of death, either sudden or with progressive symptoms, is significantly increased. This need not exclude a positive attitude to the patient's clinical care and where possible the healthcare professional should emphasise the need for ongoing active and responsive care. The challenge, and arguable the key issue, is maintaining a positive attitude while simultaneously acknowledging a poor prognosis. However, if this approach can be adopted by the patient, their family, GP and cardiologist then it can potentially improve communication and understanding in a way that leads to better care without loss of hope for the patient. Any such intervention should be patient-centred in all aspects of its design and the impact on healthcare measures must be seen as secondary to the primary aim of improving quality of life. This is challenging even in cancer care where there have been few clinical trials adequately powered to show clinically meaningful benefits using an holistic approach.[12] If improved clinical outcomes could be demonstrated in a clinical trial involving patients with advanced heart disease then this would be extremely valuable to patients and the wider cardiology community.

This study has clearly demonstrated that patients, carers and healthcare professionals have a number of concerns in relation to providing high quality holistic care for patients with advanced heart disease. The approach reported here of seeking views on the inadequacies in service provision, designing an intervention model that could improve care and incorporating this into the design of a randomised trial is both novel and important given the dearth of clinical trials in end-of-life care. The findings are currently being used to support implementation of a phase II

randomised clinical trial of an holistic intervention involving Future Care Planning for patients with advanced heart disease.

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FIGURE LEGENDS

Figure 1 – **Adapted protocol for a randomised trial of Future Care Planning for patients with advanced heart disease**: *Original flow diagram did not define the types of patients to be included, the threshold mortality risk for eligibility and the control group intervention. This final and agreed version identifies patients admitted to an acute cardiology ward with either acute coronary syndrome or heart failure and will be screened for eligibility - 12 month mortality risk of 20% or greater at the time of discharge using the GRACE discharge score [8] or the EFFECT score [7]. Eligible patients need to survive to discharge and have capacity to consent for the study. Informal carers will also participate where identified by the patient. Proposed outcomes include quality of life assessed by questionnaire (EuroQoL-5D) and readmissions to hospital. Patients randomised to early intervention will be interviewed prior to discharge and those randomised to delayed intervention will receive the same interview 12 weeks following discharge.*

Figure 2 – Future Care Plan Intervention : *the intervention will last for 12 weeks. Patients randomised to early intervention will have a 1 hour interview with a cardiologist prior to discharge where they will discuss their heart condition, other medical conditions and their concerns and plans for the future. The cardiologist, trained in Advanced Communication Skills, will aim to address a range of issues including (1) a future care plan , agreed with the patient and their carer, which includes advice to Healthcare professionals about what could and should be done if the patient's condition deteriorates once again, (2) whether the patient and their family have arranged Power of Attorney (or similar), (3) whether the patient wishes to*

consider the issue of DNACPR (Do Not Attempt Cardiopulmonary Resuscitation), (4) whether the patient wishes to express a preferred place of care should their condition deteriorate again, (5) whether the patient would consider being added to their GP's Palliative Care register and (6) permission to share the content of the Future Care Plan electronically with out-of-hours medical services (NHS24/NHS Direct). Patients will also be encouraged to complete "Thinking Ahead Plan", a locally developed patient-held anticipatory care plan (see appendix 2). Patients randomised to delayed intervention will undergo the same interview 12 weeks after discharge. During the follow-up period of 12 weeks, the trial nurse will visit the patient/carer in their home at 6 weeks and 12 weeks after the baseline interview in order to update the FCP with any changes and to review any DNACPR orders or make any necessary changes to the plan of care. An updated version of the FCP record will be communicated in writing to the GP at each of these time points. The nurse will be available to communicate with the patient by telephone at any time and will ensure optimal communication and coordination of care between GP, cardiologist, community-based nursing teams and palliative care teams (where appropriate).

TITLE: Future Care Planning for patients approaching end-of-life with advanced heart disease: an interview study with patients, carers and healthcare professionals exploring the content, rationale and design of a randomised clinical trial

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Key words: advanced heart disease, care planning, randomised clinical trial, palliative care, end-of-life care

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ABSTRACT

Objective: To explore the optimal content and design of a clinical trial of an end-of-life intervention for advanced heart disease with patients, carers and healthcare professionals

Design: Qualitative interview and focus group study

Setting: Community and hospital-based focus groups and interviews

Participants: Stable community-dwelling patients, informal carers (PC, n=15) and primary and secondary care based healthcare professionals (HCP, n=11)

Results: PC highlighted fragmentation of services and difficulty in accessing specialist care as key barriers to good care. They felt that time for discussion with HCP was inadequate within current NHS health care systems. HCP highlighted uncertainty of prognosis, explaining mortality-risk to patients and switching from curative to palliative approaches as key challenges. Patient selection, nature of the intervention and relevance of trial outcomes were identified by HCP as key challenges in the design of a clinical trial.

Conclusions: PC and HCP expressed a number of concerns relevant to the nature and content of an end-of-life intervention for patients with advanced heart disease. The findings of this study are being used to support a phase II randomised clinical trial of future care planning in advanced heart disease.

Strengths and limitations of the study

- This qualitative interview study has provided a 360 degree perspective from patients, carers and healthcare professionals on the content, nature and mode of delivery of an intervention that could be tested in a clinical trial and that could impact on quality of life.
- The findings suggest that a randomised (early versus delayed) protocol is broadly acceptable, that clinical prognostic scores could be used to identify eligible patients in the hospital setting, that care-needs should also be incorporated into the eligibility criteria and that the intervention should include components that address the current gaps in high quality holistic care (as identified by patients and their carers).
- The relatively small number of patients and healthcare professionals participating in the study and the fact that all patients were in a stable community-based setting may have impacted on the findings.
- Engaging patients and carers in the rationale, content and design of a randomised clinical trial is challenging and requires careful design and planning.

INTRODUCTION

Patients with cancer have well developed palliative care services while patients with advanced heart disease do not as highlighted in two major reports by The Department of Health in England and Wales [1] and Scottish Government Action Plan "Living and Dying Well" [2]. These documents promote the provision of care in the last year of life that is person-centred regardless of diagnosis. The recent NHS quality Improvement Scotland Clinical Standards for Heart Disease recommend a palliative care assessment in all forms of advanced heart disease.[3] Recent publications relating to end-of-life care in heart disease have focused on congestive heart failure (CHF) but coronary disease and valvular heart disease commonly co-exist in CHF patients so an integrated approach to all end-stage heart disease is appropriate.

We recently explored ways of identifying patients who are approaching end of life (EOL) in an acute cardiology ward. Using the Gold Standards Framework criteria and validated prognostic tools we demonstrated that most patients with advanced heart failure [4] and a lesser proportion with acute coronary events [5] have a very limited prognosis despite optimal evidence-based care. Poor prognosis is a marker of lower quality of life, increased hospitalisation, multi-morbidity [6] and is an indirect marker of increasing patient needs. There are well validated prognostic tools for patients with congestive heart failure (CHF) [7] and acute coronary syndrome (ACS).[8] Once a patient with a poor prognosis is identified, this should ideally be followed by an evidence-based intervention [9-11] that could improve quality of life for the patient and their family. In keeping with palliative care models [12] this intervention should be patient-focused and should address individual needs. Ideally

the intervention should integrate patient preferences with clinical priorities using "shared decision-making".[13] From these discussions a Future Care Plan (FCP) may be derived and written in terms that the patient understands. The FCP should contain a clinical plan of how to manage acute events of deteriorating health with mechanisms to inform out-of-hours services and maintain continuity of care. The plan should be reviewed regularly in the context of the patient's evolving multidimensional needs. Such an intervention could be initiated by the patient's cardiologist and delivered by a specialist heart disease nurse working in partnership with the primary care team and palliative care specialists.

Trials of palliative care are recognised to be extremely difficult to design and implement.[14] One previous randomised trial suggested that routine palliative care in addition to normal oncological care could improve quality of life in people with lung cancer.[12] A robust phase II trial, as recommended by the Medical Research Council in its guidance for complex interventions,[15] is needed as a first step towards achieving a similar goal for people with advanced heart disease.

The proposed study outlined here incorporates these issues using a mixed methods, Phase 1 and Phase 2 trial, design and is similar to methodologies used elsewhere to develop complex palliative care interventions for non-cancer illnesses. [16, 17] The proposed trial is novel in that it includes a broad group of patients with CHF and ACS, it will assess whether well-validated clinical prognostic tools can be used to identify patients approaching end-of-life and will develop a feasible care planning intervention. In addition to assessing prognosis as a trigger the study also seeks to explore the interface between acute cardiology services, primary care and specialist palliative care services.

Here we describe the findings of a qualitative interview study using patient-carer focus groups (PCFG) and a range of healthcare professionals (HCP) to explore ways in which an holistic intervention could be tested in a randomised clinical trial setting.

METHODS

The basic design for a clinical trial outline was developed by the authors as part of a submission for research funding using their background knowledge and experience and based on other trial designs of a similar nature. [16,17] This was approved by the funder and by the local ethics committee on the understanding that the design of the study could be modified following a consultation/modelling phase which would involve focus groups of patients and carers and one-to one interviews with a range of healthcare professionals about the proposed trial design. Patient-carer focus groups (PCFG) were then undertaken with the members of an existing hospital based heart failure patient-carer forum (n=7) and a second focus group was undertaken in conjunction with a local heart disease charity (n=8 participants) each lasting for 2 hours. Discussions were facilitated by an experienced qualitative researcher (GH) using a set of questions, designed by the authors, addressing their experiences with clinical care and the proposed design of the randomised controlled trial (see appendix 1A). Various options associated with the trial were presented and discussed with patients and carers including eligibility criteria and whether the control group should or should not receive end-of-life intervention.

A separate series of one-to-one interviews were conducted with a range of healthcare professionals (HCP, total n=11, palliative care consultant n= 3, cardiology consultant n=3, heart failure specialist nurse n=1, medicine of the elderly specialist n=1, cardiology ward charge nurse n=1, general practitioner n=1, district nurse n=1)

by an experienced qualitative researcher using a set of questions incorporating themes related to clinical care, palliative care and clinical trials design (see appendix 1B).

Discussions regarding the proposed design of the trial were initially broad and later in the interview focused more on the eligibility criteria, types of patients that should be included and whether an active control group should be incorporated. Both types of participants were provided with a sample "Future Care Plan" and a flow diagram of the basic proposed design of the clinical trial prior to the interviews. These documents acted as focal points for discussion. Interviews and focus groups were transcribed and analysed using NVivo to extract themes related to the rationale and design of a clinical trial of an holistic intervention addressing a range of issues related to end-of-life care.

The findings from these interviews and focus group discussions were then used to modify the proposed design of a trial of an intervention to support patients with advanced heart disease identified as being at high risk of death within the next 12 months.

The study was approved by the local ethics committee and all participants gave signed informed consent.

RESULTS

Patient's and carer's views : care for cardiac patients

PCFG highlighted increasing difficulties associated with multiple care-providers working in apparent isolation as a major difficulty in ensuring holistic care. From a PCFG perspective, care appears increasingly fragmented and ill-designed to manage the needs of frail, elderly patients with multiple chronic conditions.

PCFG also identified the variation in access to specialist services as a key problem in providing holistic, patient centred care. This applied in particular to heart failure nurse care where many services adhere to strict eligibility criteria which include left ventricular systolic dysfunction and recent hospital admission. Patients with access to the heart failure specialist nurse service were very appreciative of their support, but they expressed concern that this service was not available to everyone with heart failure and people with other types of advanced heart conditions.

PCFG welcomed the idea of future or anticipatory care planning, and appeared to recognise its value. However, a minority felt that this could be a very difficult process to engage in, expressing views that it needs to be carefully targeted and people should be able to choose, without pressure, not to engage in the process (table 1). PCFG highlighted the fact that some patients will already be well informed about their condition and its prognosis. However, it was also expressed that for those who have less insight into their condition, doctors and nurses should consider carefully how they will allay and minimise fears about engaging in a process of future care planning.

Patient-carer views: Fragmentation of Care

"Once you get to our age, you discover that you've got more than one problem, and you see the various consultants who deal with the various problems, and they deal with you like a car. They put the carburettor right, they put the radiator right, but the holistic approach is missing" (patient)

"My condition is primarily a chronic lung condition but I also have a heart condition. So I have two separate areas of contact and they both know about each of the conditions but they're really only concentrating on the one they're dealing with, they soon forget, 'oh, you've got a heart condition, oh right!' And it's worrying particularly if you're being administered fairly serious medication and you've got to remember that you've got all these conditions" (patient)

Variation in access to specialist services

"We have a very good rapport and have chats with her (The Heart Failure Nurse). If there's something we don't understand, she's very good at explaining what's involved, so we're very happy" (patient)

"Having a nurse, it gives you a bit more confidence because you just know she's there. Everyone should have one, because it does make a heck of a difference" (patient)

Patient's and carer's views : proposed trial of future care planning

There was a general consensus in the PCFG that the draft Future Care Plan planned for use in the trial (see appendix 2) was comprehensive and addressed a number of concerns that families had about planning for the future (table 2). However, one carer made the point that a patient-centred anticipatory care plan must be flexible enough to accommodate those who are acting on behalf of their loved one possibly using power of attorney. Others suggested that it would be helpful to ensure that all contact details of the medical teams caring for a patient are included particularly for those with multiple co-morbidities. One patient also questioned the appropriateness of asking patients to identify which potentially life-saving treatments they may or may not want.

PCFG were supportive of the proposal for a clinical trial and were satisfied with the basic design of the study. Opposing views about eligibility criteria were expressed by two participants in the same focus group with one indicating that eligibility should include people with advanced heart disease that were currently stable in the community and not necessarily those recently admitted to hospital. PCFG emphasised the need for families to be well informed and prepared before being approached about a trial testing the proposed intervention. Eligibility for the trial using a threshold value for estimated 12 month mortality was debated and discussed and a value of 20% was reached as one which would include a set of patients with a significantly higher then average mortality risk for cardiac patients. One further aspect of the final design of the trial which was discussed and agreed by the PCFG was whether to have a control group with no intervention or whether to have a group of patients where an intervention was provided but 12 weeks after discharge. It was generally agreed that it would be unethical not to provide an intervention of some sort to all patients who agreed to take part and so a delayed intervention group design was finally agreed (see figure 1).

Patient-carer views: Draft Patient-held Future care plan (see appendix 2 "My Thinking Ahead Plan")

"I have thought about all the questions (in the proposed patient-held Future Care Plan), and I think it's very, very good. Even for yourself to write down your thoughts and wishes. Everybody's wishes are different so therefore, if it's all written down and you've got this plan, I think, yes, it's very useful for the future" (patient)

"….personally, ignorance is bliss in some cases" (patient)

"What would worry me slightly about this, especially if you're filling it out on your own (Future Care Plan), is that suddenly an end, shall we say, opens up, the fact that you're filling in something that's to do with palliative care – ooh, a horrible word – I don't know if people with heart failure are taken through this before this or do they need to be sitting with a doctor or nurse who can take them through the fact that it's

not as bad as it sounds. That would worry me ….. getting something like this and filling it in isolation, it's frightening "(patient)

"Well, if you follow all the questions, really I don't think you miss much at all. Because you're asking what people are interested in and what things they do at the moment and what they hope to continue, and in a way, I think that's very good for the professionals looking after us to know that – whether in fact you're doing anything or if you're doing nothing with your life, because I think it makes a big difference" (patient)

Views of healthcare professionals – end of life care for patients with heart disease

Irrespective of role, all HCP that were interviewed identified the issue of managing the uncertainty of prognosis in people with advanced heart disease as a major challenge. Most agreed that prognostic uncertainty can cause HCP to prevaricate because they are worried about 'getting it wrong'. They also expressed concerns that discussions about end-of-life could remove hope for the patient and their family.

Healthcare professional's views : Prognostic uncertainty

"…it's hard for health professionals to know where they (patients) are in their disease process, because we know they go up and down and they probably never come right back up to where they were the last time, but they're still functioning, and …. at what point do you have that conversation? " (District Nurse)

"A lot of health professionals because of the trajectory of the disease and the up and down nature of it, nobody knows when the point of true palliation should kick in and people are very frightened because with some antibiotics or some steroids they could bounce back, not to the same state of health, each time declining and getting less well, but still not at the point where you would be comfortable saying, right, we're at the point of pure palliation" (Palliative Care Consultant)

"*we've all seen patients who survive against the odds for a long time – if they outlive your expectations, that's OK … you might get the timing a bit wrong because you can't predict, but usually you are right that the decline has started" (Heart Failure Specialist Nurse)*

"You don't want your patients to become obsessed and totally focused on their disease – (they've) got to get on with life as well" (Medicine of the Elderly Consultant)

Healthcare professional's views : Risk of dying from a long term condition

"I don't think they see it, to the same extent as cancer patients - COPD patients as well. They (patients) see it as a limiting condition, it stops them doing things, it's not foremost in their mind that this is the thing they're going to die of" (District Nurse)

"Sometimes I think when it gets to the stage that you're doing DNAR forms … it often comes as a big shock to either them or their family.. it comes as a shock when they're told, 'we think this is it this time', because they've been in and out, bounced back and forward, got better, gone home" (Community Palliative Care Nurse)

Views of healthcare professionals – proposed trial of future care planning

Several HCP participants drew a distinction between different types of patients with advanced heart disease and wanted more clarity about what type of patient would be eligible for the proposed trial. One cardiologist's view was that it would be relatively straightforward to recruit patients with coronary disease although it would be more complex to identify patients with heart failure since it is hard to pinpoint at which point in their illness trajectory they would become eligible. For this group, one cardiologist suggested, it may be useful to use repeated hospital admissions, or functional status as a criteria for eligibility.

Care of the elderly physicians raised concerns about including patients in the trial with multi-morbidity including those with cognitive impairment. Such patients are typically seen in acute medical-takes and while they would be a group who may benefit considerably from Future Care Planning they would be difficult to assess, recruit and retain in the proposed trial. However, this HCP stated that to omit these patients would be unfair and could miss a key opportunity.

There were no significant concerns raised with regard to using a clinical prognostic tool, such as the GRACE score, as a way of identifying patients for a palliative care intervention. However, it was highlighted by a number of HCPs that this approach

has significant limitations and using such a tool in isolation may exclude many patients who could benefit from a future care planning approach who have a high level of need and a low estimated 12 month mortality risk. In addition, it was highlighted that prognostic scores do not predict time to death nor do they accurately identify those who may benefit from a palliative care intervention.

Healthcare professional's Views: Proposed trial of Future Care Planning

Patient selection:

"One group is those with advanced heart failure for whom we already have some structure to post-discharge care through our HF nurse service and the second group…are those with end stage coronary disease, so these are patients with angina for whom there's not an awful lot more can be done for them by way of bypass surgery and invasive treatments, and where these patients are intermittently hospitalised when their angina reaches crisis point " (Consultant Cardiologist)

"A score based on a patient's functional status is useful because it identifies when quality of life is impaired to the extent that the patient needs more support" (Consultant Cardiologist)

Eligibility for the trial:

"…harder to put frail elderly patients into a protocol-driven trial because they are so different and they've got such a mix of co-morbidities and such a mix of drugs" (Consultant in Medicine of the Elderly)

"I think using (a cut-off of) 20% (12 month mortality risk) is fair" (Community Palliative Care Nurse)

" It's still pretty high. If it's less than 20% people shouldn't imminently be dying so it gives you a chance to see what effect the intervention has" (Consultant Cardiologist)

"…So it's about identifying the point when you can have a reasonable conversation with somebody about deterioration, and is 20% (estimated mortality risk) right ..If you make it higher you'll miss some people but you'll make the discussion more real and liveable, and that's your balance" (Palliative Care Consultant)

"A 20% risk threshold would include lots and lots of frail elderly people. Many of them would have a 1 in 5 chance of dying within a year even without their heart failure. It's probably not an unreasonable threshold" (Medicine of the Elderly Consultant)

Trial outcome measures:

".. if you're trying to prevent hospital admissions, if they're frequent fliers, then I would have thought they're the ones, the unstable ones. If you've been able to tweak something at home that prevented the admission, I suppose this is what this would do" (District Nurse)

" Obviously, you do have to look at bed days but ultimately they're spending more time in hospital, from their point of view.. that's possibly better for them" (Community Palliative Care Nurse)

"… there's a subtle distinction, for example, between trying to measure differences in quality of life on a day to day basis, and measuring overall levels of comfort, security". (Medicine of the elderly consultant)

Without exception, the HCPs we interviewed had no ethical concerns with a design utilising an early versus late intervention which they regarded as a standard approach for a trial (see figure 1).

Achieving and maintaining staff engagement and thinking ahead to what happens at the end of the trial were identified as important issues. In particular HCPs identified the importance of keeping staff informed about the trial, consideration of how the trial might dovetail with existing service developments and the importance of providing ongoing support beyond the trial period to participants who continue to require additional supportive care.

Hospital bed-days utilisation during follow-up was generally considered to be an appropriate outcome, although several expressed caution in interpreting what these data actually mean. Quality of life measures were also considered to be an appropriate outcome although it was pointed out that these measures can also be difficult to interpret in this setting. Some HCPs suggested the inclusion of place of death and preference for place of death as outcome measures.

The initial study design of the clinical trial did not strictly define the types of patients that could be included, the eligibility criteria, the threshold mortality risk for inclusion and whether an intervention should be included for the control group. The final trial design (figure 1) represents a modified version taking account of the views of patients and healthcare professionals interviewed in this study. This fundamental design of the proposed trial was similar to the original design presented to the PCFG and the HCP during the interviews and focus groups. There was general agreement

that a broad range of acute cardiac patents should be included and agreement was reached to include heart failure (with either reduced or preserved left ventricular systolic function) and patients with any acute coronary syndrome. There was discussion as to whether a delayed intervention was needed in the control group. Since current clinical services provided little or no end-of-life intervention for such patients a final consensus, mainly driven by comments from patients and carers, was made to offer a delayed intervention to the control group given that the intervention addressed a clear need which was patient-centred and which could provide an apparent benefit to those who participated. The final component of the design which was agreed following the PCFG and HCP interviews was the threshold at which to set the 12 month mortality used as eligibility for the trial. The authors had proposed this to be somewhere between 20 and 40% and this was discussed by both groups. The final agreement of 20% was made largely by the PCFG after lengthy discussions as to what the typical mortality risk was for CCF and ACS patients admitted acutely to hospital.

The findings from this modelling phase are currently being used to support the implementation of a phase II randomised clinical trial of an holistic intervention (figure 2) for patients with advanced heart disease.

DISCUSSION

This qualitative study examining patient and healthcare professional's (HCP) views on a the content and design of a clinical trial of Future Care Planning for patients with advanced heart disease has highlighted a number of important issues. The concerns raised by patients and carers regarding the current inadequate levels of care as cardiac patients approach end-of-life provides an important back-drop to the main theme of the work which was to seek their views on the content and design of a clinical trial. Patients and carers expressed views indicating that such a trial should redress the current inadequacies in a typical doctor-patient interaction which they felt had limited time and lacked an holistic approach particularly in cardiology out-patient clinic settings. The healthcare professional participants highlighted the challenges in using meaningful selection criteria for the trial and the complexity of identifying precisely which component of any proposed intervention might influence outcomes. The findings of this work therefore re-affirm many of the findings of others in the field [18, 19]. However, the novel aspect of the work is that the focus groups and interviews were extended beyond a general discussion stage to seek views on how the inadequacies in care could be redressed and a model developed which could be subsequently tested using a randomised trial approach.

Factors which might influence the outcomes which emerged from the PCFG discussions included the content and quality of the baseline or first discussion/interview with the consultant, the content of the written future care plan

and ongoing support, for both patient and carer, from a familiar healthcare professional. The views from patients, carers and professionals indicated that a clinical trial should focus on providing adequate time to discuss the patient's current and future care needs and those of their carer, it should select patients on the basis of prognosis and needs, it should provide ongoing support with both primary and secondary care working closely together to ensure good coordination of care and it should allow for adaptation of any care plan in a dynamic way that is aligned with the changing needs of the patient and their carer.

While this message is clear, delivering such a trial using non-palliative care physicians in an acute cardiology environment will be challenging. Finding the appropriate language to explain an uncertain prognosis is always difficult, [20] and cardiologists with a firm culture of curative approaches may struggle to find that language. These challenges may delay the conversation until it's too late, or they may encourage the use of more vague, ambiguous or even contradictory language which can sometimes mislead the patient and their family or fail to communicate the seriousness of their condition adequately. Finding language that is balanced, caring and which makes sense of an uncertain future is one of the challenges of all palliative care even where the prognosis, good or bad, is more certain. However, the majority of the HCPs that we interviewed agreed that it should be possible in most cardiac patients with advanced disease. Surviving with a chronic condition that has an uncertain illness trajectory can mean that these patients, unlike cancer patients, can reach a fairly advanced stage in their illness without realising that they have a condition that could and probably will cause their death.

Our findings have also highlighted a persisting tendency for patients and healthcare professionals to associate palliative care with dying. This perception may prevent or

discourage healthcare teams from offering palliative and supportive care to patients with significant symptom burden who may not have reached the end of their lives but who may benefit form additional supportive care. Healthcare professionals held the view that patients and carers may be reluctant to accept a form of support which they associate with end of life. This may reflect reluctance on the part of the healthcare professionals as much as the patient. This is an important issue if we are to develop a model of integrating palliative care earlier in the illness trajectory of cardiac disease by the heart team caring for the patient. In addition to learning and developing the skills required to do this, these teams will also need to change attitudes and culture. Indeed, while this culture is increasingly acknowledged as important for patients with chronic heart failure there is also a clear need for this approach in patients with other forms of advanced cardiac disease such as coronary and valvular heart disease.

The barriers to achieving good holistic care for patients nearing the end of their lives, well described in other settings [21, 22] apply equally well in the acute cardiology setting. [23] There is insufficient time to discuss such sensitive issues, the hospital environment is not ideal (particularly in multi-bedded rooms), cardiologists are not adequately trained and in cardiology there is a culture of doing more and never giving up. However, particularly in elderly patients and even with optimal interventions the combination of congestive heart failure, coronary heart disease, valvular heart disease and other non-cardiac comorbidities is associated with poor prognosis.[24, 25] Indeed, the increasing use of Transcatheter Aortic Valve Implantation (TAVI) in patients that are deemed unsuitable for conventional surgery is increasingly recognised as a clinical challenge balancing aggressive intervention with supportive end of life care.[26, 27]

Hence, patients with advanced heart disease and poor prognosis are clearly a target for better clinical care encompassing an approach that acknowledges that the patient may be nearing the end of life. These patients rarely receive care that addresses their individual needs and those of their informal carers. This care need not be labelled as palliative but can be delivered in the understanding that the future is uncertain and the risk of death, either sudden or with progressive symptoms, is significantly increased. This need not exclude a positive attitude to the patient's clinical care and where possible the healthcare professional should emphasise the need for ongoing active and responsive care. The challenge, and arguable the key issue, is maintaining a positive attitude while simultaneously acknowledging a poor prognosis. However, if this approach can be adopted by the patient, their family, GP and cardiologist then it can potentially improve communication and understanding in a way that leads to better care without loss of hope for the patient. Any such intervention should be patient-centred in all aspects of its design and the impact on healthcare measures must be seen as secondary to the primary aim of improving quality of life. This is challenging even in cancer care where there have been few clinical trials adequately powered to show clinically meaningful benefits using an holistic approach.[12] If improved clinical outcomes could be demonstrated in a clinical trial involving patients with advanced heart disease then this would be extremely valuable to patients and the wider cardiology community.

This study has clearly demonstrated that patients, carers and healthcare professionals have a number of concerns in relation to providing high quality holistic care for patients with advanced heart disease. The approach reported here of seeking views on the inadequacies in service provision, designing an intervention model that could improve care and incorporating this into the design of a randomised

trial is both novel and important given the dearth of clinical trials in end-of-life care. The findings are currently being used to support implementation of a phase II randomised clinical trial of an holistic intervention involving Future Care Planning for patients with advanced heart disease.

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Competing interests: The authors had no financial relationships with any organisations that might have an interest in the submitted work in the previous 3 years and no other relationships or activities that could appear to have influenced the submitted work.

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FIGURE LEGENDS

Figure 1 – Adapted protocol for a randomised trial of Future Care Planning for patients with advanced heart disease: *Original flow diagram did not define the types of patients to be included, the threshold mortality risk for eligibility and the control group intervention. This final and agreed version identifies patients admitted to an acute cardiology ward with either acute coronary syndrome or heart failure and will be screened for eligibility - 12 month mortality risk of 20% or greater at the time of discharge using the GRACE discharge score [8] or the EFFECT score [7]. Eligible patients need to survive to discharge and have capacity to consent for the study. Informal carers will also participate where identified by the patient. Proposed outcomes include quality of life assessed by questionnaire (EuroQoL-5D) and readmissions to hospital. Patients randomised to early intervention will be interviewed prior to discharge and those randomised to delayed intervention will receive the same interview 12 weeks following discharge.*

Figure 2 – Future Care Plan Intervention : *the intervention will last for 12 weeks. Patients randomised to early intervention will have a 1 hour interview with a cardiologist prior to discharge where they will discuss their heart condition, other medical conditions and their concerns and plans for the future. The cardiologist, trained in Advanced Communication Skills, will aim to address a range of issues including (1) a future care plan , agreed with the patient and their carer, which includes advice to Healthcare professionals about what could and should be done if*

the patient's condition deteriorates once again, (2) whether the patient and their family have arranged Power of Attorney (or similar), (3) whether the patient wishes to consider the issue of DNACPR (Do Not Attempt Cardiopulmonary Resuscitation), (4) whether the patient wishes to express a preferred place of care should their condition deteriorate again, (5) whether the patient would consider being added to their GP's Palliative Care register and (6) permission to share the content of the Future Care Plan electronically with out-of-hours medical services (NHS24/NHS Direct). Patients will also be encouraged to complete "Thinking Ahead Plan", a locally developed patient-held anticipatory care plan (see appendix 2). Patients randomised to delayed intervention will undergo the same interview 12 weeks after discharge. During the follow-up period of 12 weeks, the trial nurse will visit the patient/carer in their home at 6 weeks and 12 weeks after the baseline interview in order to update the FCP with any changes and to review any DNACPR orders or make any necessary changes to the plan of care. An updated version of the FCP record will be communicated in writing to the GP at each of these time points. The nurse will be available to communicate with the patient by telephone at any time and will ensure optimal communication and coordination of care between GP, cardiologist, community-based nursing teams and palliative care teams (where appropriate).

Figure 1

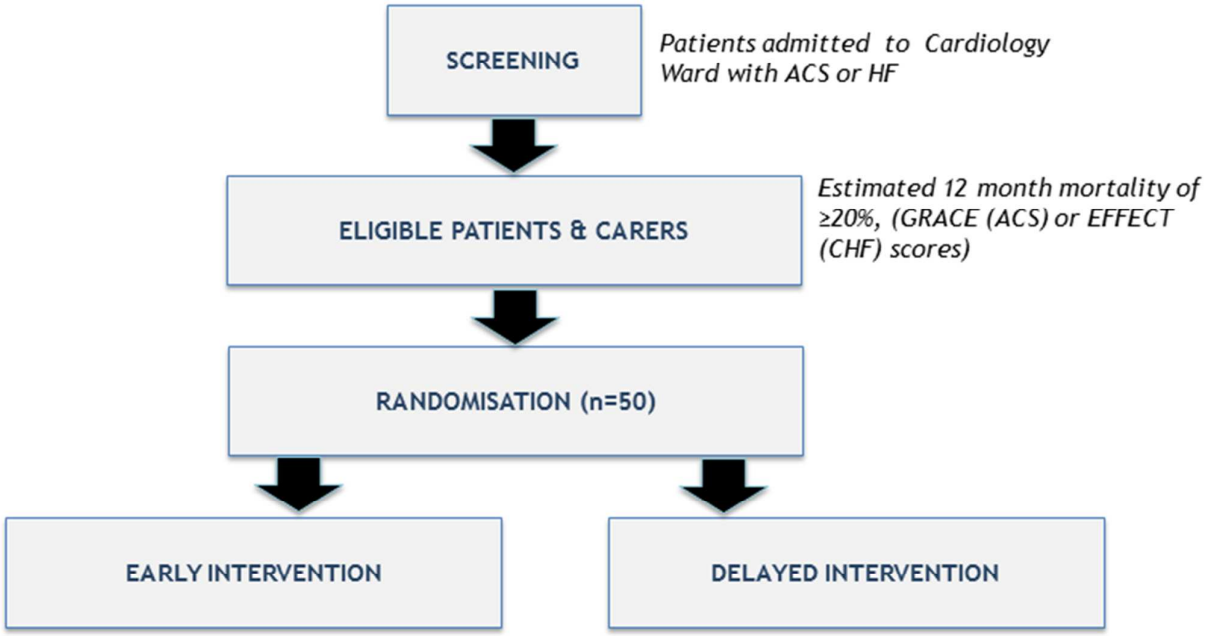
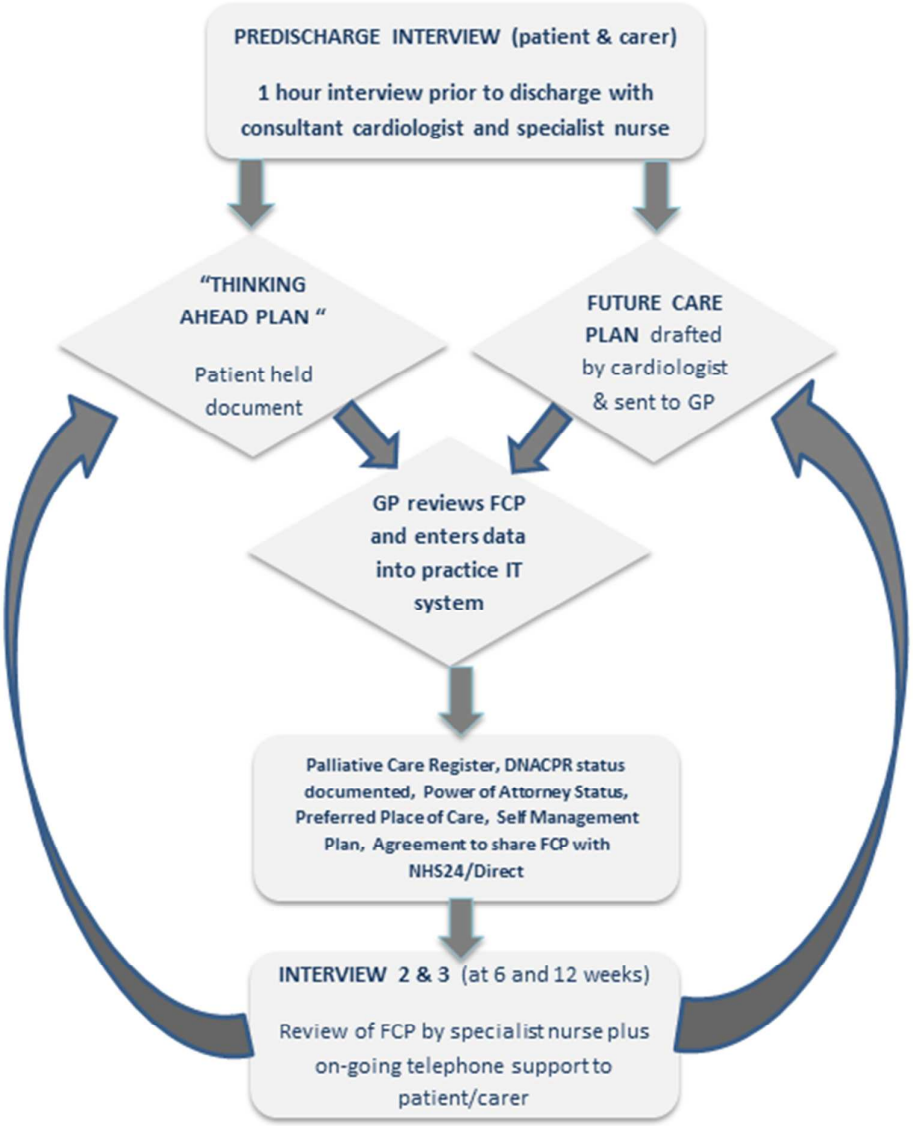


Figure 2


PREDISCHARGE INTERVIEW (patient & carer)
1 hour interview prior to discharge with consultant cardiologist and specialist nurse
"THINKING AHEAD PLAN "
Patient held document
FUTURE CARE PLAN drafted by cardiologist & sent to GP
GP reviews FCP and enters data into practice IT system
Palliative Care Register, DNACPR status documented, Power of Attorney Status, Preferred Place of Care, Self Management Plan, Agreement to share FCP with NHS24/Direct
INTERVIEW 2 & 3 (at 6 and 12 weeks)
Review of FCP by specialist nurse plus on-going telephone support to patient/carer

Appendix 1A

Interview topic guide for patients/carers– modelling phase

Future Care planning for people with advanced heart disease

This interview is part of a research study funded by Marie Curie Cancer Research which aims to test new ways of providing care for people with advanced heart disease. The first phase of the study involves seeking views and comments from people who have heart disease and their families.

The aim of this guide is to support a structured approach to interviews and focus groups associated with the research study. The suggested topics are intended to provide a broad framework to encourage discussion and comment.

The interviewer will introduce himself/herself to the interviewee and explain the purpose of the interview. The interviewer will check that the consent form has been signed and that the interviewee remains in agreement to take part and that the interview can be recorded.

1. Do you feel that patients with advanced heart disease have adequate opportunity to discuss their condition, its treatment and their outlook with healthcare staff generally? What factors should trigger such discussions? What are the barriers to this? What things help? When is the best time to discuss these issues?

2. Do think it would be helpful to create a care-plan for patients with advanced heart disease? If so, when would be a good time to start thinking and talking about this? Do you think that these discussions should take place in hospital or at home? what details should be included in this plan? Who should be involved in completing and agreeing this plan? What would you perceive to be the barriers to including and excluding some items? Who do you think should have access to this care plan?

(Interviewer now shows example FCP)

3. In the example “Future Care Plan”, do you feel the layout and content are appropriate?

4. In the example “Future Care Plan”, which items do you feel should be included and which excluded? (see FCP example), Describe your concerns about these.

5. Do you have broader general concerns about this type of care plan and its uses by doctors and nurses?

6. In the example we have provided, should the updating and management of the contents be done by a community nurse, the GP or a hospital consultant or other people?

7. Should the patient and their family have a copy? How do we keep this updated?

8. In addition to, or instead of, this care plan, do you feel there is a need for more care or different care for people with advanced heart disease? If so, what do you think would help? Please give general and specific ideas if you have them.

9. We are planning to test new ways of providing care for people with advanced heart disease in a randomised research trial which will involve the use of the "care plan" discussed above combined with a special nurse to provide extra-supportive care . What are your views about doing such a research study? Do you think it is ethically acceptable for some people to have extra care services while others do not? Would you and your family have concerns about being involved in this type of research?

Appendix 1B

Interview topic guide for Healthcare professionals– modelling phase

Future Care planning for people with advanced heart disease

This interview is part of a research study funded by Marie Curie Cancer Research which aims to test new ways of providing supportive care for people with very advanced heart disease. The first phase of the study includes interviews with healthcare professionals to gather views on the design and delivery of the trial.

The aim of this guide is to support a structured approach to interviews and focus groups associated with the research study. The suggested topics are intended to provide a broad framework to encourage discussion and comment.

The interviewer will introduce himself/herself to the interviewee and explain the purpose of the interview. The interviewer will check that the consent form has been signed and that the interviewee remains in agreement to take part and that the interview can be recorded.

1. Do you feel that patients with advanced heart disease have adequate opportunity to discuss their condition, its treatment and their outlook with healthcare staff generally? What factors should trigger conversations with patients about this? What are the barriers to this? What things help? When is the best time to discuss these issues?

2. Do think it would be helpful to create a care-plan for patients with advanced heart disease? If so, what details should be included in this plan? Who should be involved in completing and agreeing this plan? What would you perceive to be the barriers to including and excluding some items? Who do you think should have access to this care plan?

(Interviewer now shows example FCP)

3. In the example “Future Care Plan”, do you feel the layout and content are appropriate?

4. In the example “Future Care Plan”, which items do you feel should be included and which excluded? (see FCP example), Describe your concerns about these.

5. Do you have broader general concerns about this type of care plan and its use by healthcare professionals?

6. In the example we have provided, should the updating and management of the contents be done by a community nurse, the GP or a hospital consultant or other people?

7. Should the patient and their family have a copy? How do we keep this updated?

8. In addition to, or instead of, this care plan, do you feel there is a need for more care or different care for people with advanced heart disease? If so, what do you think would help? Please give general and specific ideas if you have them.

9. We are planning to perform a small randomised trial which will involve the use of the “care plan” discussed above combined with a special nurse to provide extra-supportive care. What are your views about doing such a research study? Do you think it is ethically acceptable for some people to have extra care services while others do not? What are your views on a trial involving people with such advanced disease ?

10. In a trial of an intervention for people with advanced heart disease, what end points do you feel would be meaningful for patients and healthcare professionals.

Appendix 2 – “My Thinking Ahead Plan” – see attached file

Appendix 1A

Interview topic guide for patients/carers– modelling phase

Future Care planning for people with advanced heart disease

This interview is part of a research study funded by Marie Curie Cancer Research which aims to test new ways of providing care for people with advanced heart disease. The first phase of the study involves seeking views and comments from people who have heart disease and their families.

T*he aim of this guide is to support a structured approach to interviews and focus groups associated with the research study. The suggested topics are intended to provide a broad framework to encourage discussion and comment.*

The interviewer will introduce himself/herself to the interviewee and explain the purpose of the interview. The interviewer will check that the consent form has been signed and that the interviewee remains in agreement to take part and that the interview can be recorded.

1. Do you feel that patients with advanced heart disease have adequate opportunity to discuss their condition, its treatment and their outlook with healthcare staff generally? What factors should trigger such discussions? What are the barriers to this? What things help? When is the best time to discuss these issues?

2. Do think it would be helpful to create a care-plan for patients with advanced heart disease? If so, when would be a good time to start thinking and talking about this? Do you think that these discussions should take place in hospital or at home? what details should be included in this plan? Who should be involved in completing and agreeing this plan? What would you perceive to be the barriers to including and excluding some items? Who do you think should have access to this care plan?

   (Interviewer now shows example FCP)

3. In the example “Future Care Plan”, do you feel the layout and content are appropriate?

4. In the example “Future Care Plan”, which items do you feel should be included and which excluded? (see FCP example), Describe your concerns about these.

5. Do you have broader general concerns about this type of care plan and its uses by doctors and nurses?

6. In the example we have provided, should the updating and management of the contents be done by a community nurse, the GP or a hospital consultant or other people?

7. Should the patient and their family have a copy? How do we keep this updated?

8. In addition to, or instead of, this care plan, do you feel there is a need for more care or different care for people with advanced heart disease? If so, what do you think would help? Please give general and specific ideas if you have them.

9. We are planning to test new ways of providing care for people with advanced heart disease in a randomised research trial which will involve the use of the “care plan” discussed above combined with a special nurse to provide extra-supportive care . What are your views about doing such a research study? Do you think it is ethically acceptable for some people to have extra care services while others do not? Would you and your family have concerns about being involved in this type of research?

Appendix 1B

Interview topic guide for Healthcare professionals– modelling phase

Future Care planning for people with advanced heart disease

This interview is part of a research study funded by Marie Curie Cancer Research which aims to test new ways of providing supportive care for people with very advanced heart disease. The first phase of the study includes interviews with healthcare professionals to gather views on the design and delivery of the trial.

T*he aim of this guide is to support a structured approach to interviews and focus groups associated with the research study. The suggested topics are intended to provide a broad framework to encourage discussion and comment.*

The interviewer will introduce himself/herself to the interviewee and explain the purpose of the interview. The interviewer will check that the consent form has been signed and that the interviewee remains in agreement to take part and that the interview can be recorded.

1. Do you feel that patients with advanced heart disease have adequate opportunity to discuss their condition, its treatment and their outlook with healthcare staff generally? What factors should trigger conversations with patients about this? What are the barriers to this? What things help? When is the best time to discuss these issues?

2. Do think it would be helpful to create a care-plan for patients with advanced heart disease? If so, what details should be included in this plan? Who should be involved in completing and agreeing this plan? What would you perceive to be the barriers to including and excluding some items? Who do you think should have access to this care plan?

(Interviewer now shows example FCP)

3. In the example “Future Care Plan”, do you feel the layout and content are appropriate?

4. In the example “Future Care Plan”, which items do you feel should be included and which excluded? (see FCP example), Describe your concerns about these.

5. Do you have broader general concerns about this type of care plan and its use by healthcare professionals?

6. In the example we have provided, should the updating and management of the contents be done by a community nurse, the GP or a hospital consultant or other people?

7. Should the patient and their family have a copy? How do we keep this updated?

8. In addition to, or instead of, this care plan, do you feel there is a need for more care or different care for people with advanced heart disease? If so, what do you think would help? Please give general and specific ideas if you have them.

9. We are planning to perform a small randomised trial which will involve the use of the “care plan” discussed above combined with a special nurse to provide extra-supportive care. What are your views about doing such a research study? Do you think it is ethically acceptable for some people to have extra care services while others do not? What are your views on a trial involving people with such advanced disease ?

10. In a trial of an intervention for people with advanced heart disease, what end points do you feel would be meaningful for patients and healthcare professionals.

THE UNIVERSITY of EDINBURGH

NHS Lothian

Thinking ahead
planning together

My name:

Some information about this plan

What is future care planning?

To be able to give the best care to people with serious illnesses we need to talk about what is important to each person and their family now and if things change in the future.

A 'future care plan' can help you to think about what things are important to you so you can talk about them with your family and friends.

The people who are looking after you would like to help you with your plan and talk about how we can use it to give you the best care we can.

What goes in the plan?

You can use the plan in any way you like. Most people start by writing things down that are important for them and their family at the moment. Some people like to put in information about the kind of care and treatment they would like to have now and in the future.

How do I fill it in?

The plan has some boxes which give you a few ideas about what you might want to think about. Some people use all the boxes, some just one or two. You might choose to add a box or page of your own. You can fill your plan bit by bit and you can change or add to it whenever you want.

Who can help me fill it in?

A few people like to fill in their plan by themselves. Many people do it with their family or close friends, or with help from the people who are looking after them. If someone does help you, you might want to write their name in at the end. It is important to talk about things you add or change in your plan with your family, and the people who are looking after you.

Where should I keep my plan?

You should keep your plan at home so you can show it to any health professionals who come to see you. It is a good idea to take your plan with you if you go to see your GP, or if you go to hospital for anything. This helps everyone who is involved with your care know what is important to you and your family.

Can I get a version for my computer?

Yes, if you would like a copy of the Thinking Ahead and Planning Together booklet to put on your computer so you can update it that way, please ask. It is still a good idea to print off a copy of the most up to date plan to have at home as well, so that you can take this to any appointments.

Important things right now

It is a good idea to start by thinking about how things are now.

What do people looking after me need to know about me and my family?

What would help me most?

Planning ahead

You might want to write about things you are looking forward to, important events that are coming up for you or your family, or things you want to do or carry on doing.

What could help me with these things?

Are there any other things that I might be able to do?

Looking after me well

The people looking after you want to make sure you have all the information you need about your health problems and would like to find out what is important to you.

Are there any things about my treatment and care now, or in the future that are important to me?

My concerns

You can write about any worries that you might have here. These could be about yourself, your family or even your pet.

Are there things that worry me now, or have I any worries about what might happen in the future?

Have I any plans about what we might do if any of these things did happen?

Things some people want to know more about:

Some people and their families like to know more about things that can be important when someone has a serious illness.

Some of these are:

Benefits advice

- Asking a person I can trust to speak for me and help make decisions about my health if in the future I am not able to myself (a Welfare Attorney)
- A living will or advance decision to refuse a specific treatment
- Cardiopulmonary resuscitation decisions (DNA CPR): attempting to restart a person's heart
- Making a will

Things I would like to ask about are:

Keeping track

Each time you write in this Plan, you might like to write down in this section the date and the name of anyone who helped you.

Useful Contacts

My GP's name and telephone:

My District Nurse's name and telephone:

My Chemist:

NHS24:

Other people involved in my care:

We would welcome any comments or suggestions about this booklet. Contact us...

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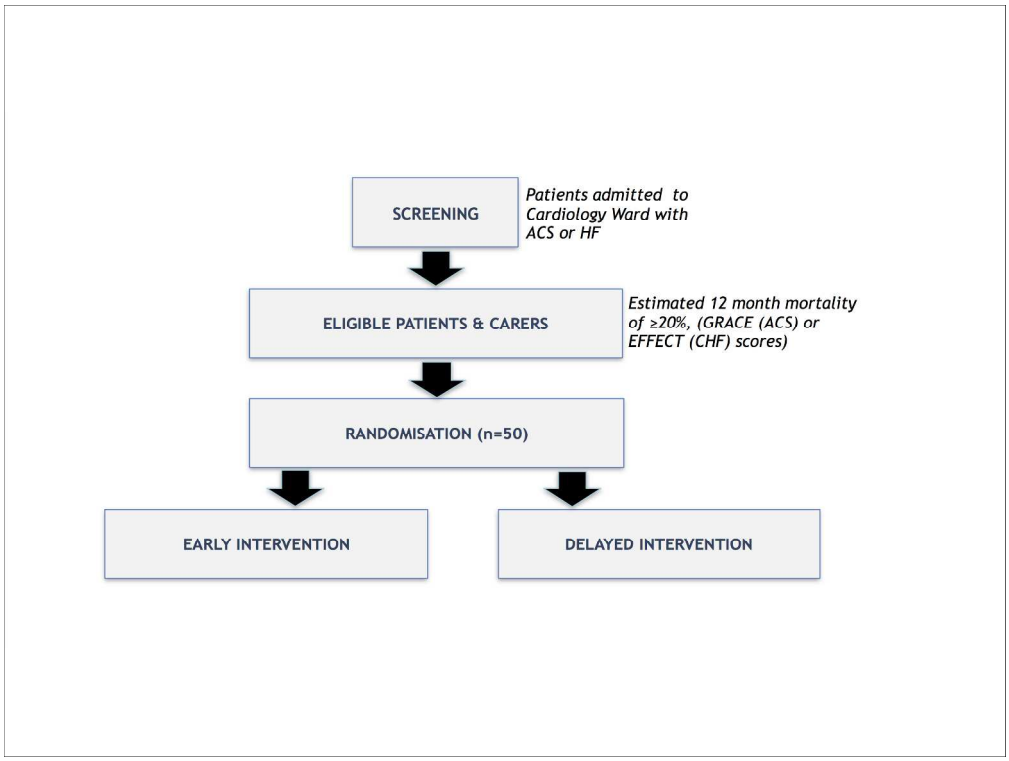

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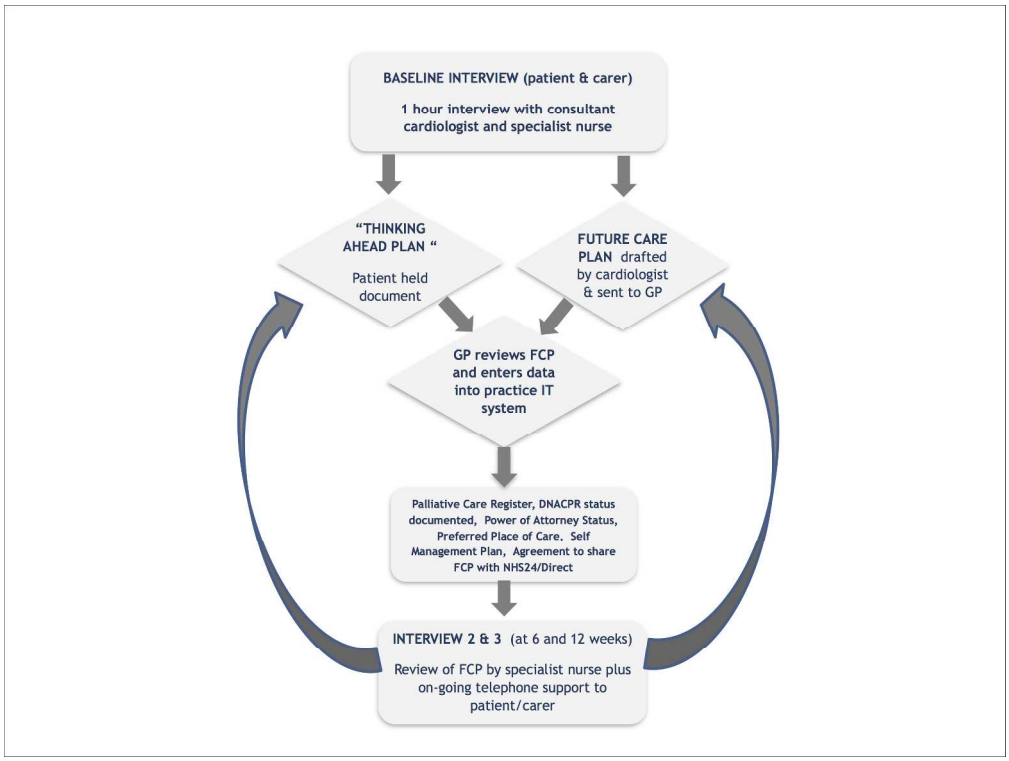

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Future Care Planning for patients approaching end-of-life with advanced heart disease: an interview study with patients, carers and healthcare professionals exploring the content, rationale and design of a randomised clinical trial

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TITLE: Future Care Planning for patients approaching end-of-life with advanced heart disease: an interview study with patients, carers and healthcare professionals exploring the content, rationale and design of a randomised clinical trial

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ABSTRACT

Objective: To explore the optimal content and design of a clinical trial of an end-of-life intervention for advanced heart disease with patients, carers and healthcare professionals

Design: Qualitative interview and focus group study

Setting: Community and hospital-based focus groups and interviews

Participants: Stable community-dwelling patients, informal carers (PC, n=15) and primary and secondary care based healthcare professionals (HCP, n=11)

Results: PC highlighted fragmentation of services and difficulty in accessing specialist care as key barriers to good care. They felt that time for discussion with HCP was inadequate within current NHS health care systems. HCP highlighted uncertainty of prognosis, explaining mortality-risk to patients and switching from curative to palliative approaches as key challenges. Patient selection, nature of the intervention and relevance of trial outcomes were identified by HCP as key challenges in the design of a clinical trial.

Conclusions: PC and HCP expressed a number of concerns relevant to the nature and content of an end-of-life intervention for patients with advanced heart disease. The findings of this study are being used to support a phase II randomised clinical trial of future care planning in advanced heart disease.

Strengths and limitations of the study

- This qualitative interview study has provided a 360 degree perspective from patients, carers and healthcare professionals on the content, nature and mode of delivery of an intervention that could be tested in a clinical trial and that could impact on quality of life.
- The findings suggest that a randomised (early versus delayed) protocol is broadly acceptable, that clinical prognostic scores could be used to identify eligible patients in the hospital setting, that care-needs should also be incorporated into the eligibility criteria and that the intervention should include components that address the current gaps in high quality holistic care (as identified by patients and their carers).
- The relatively small number of patients and healthcare professionals participating in the study and the fact that all patients were stable in a community setting may have impacted on the findings.
- Engaging patients and carers in the rationale, content and design of a randomised clinical trial is challenging and requires careful design and planning.

INTRODUCTION

Patients with cancer have well developed palliative care services while patients with advanced heart disease do not as highlighted in two major reports by The Department of Health in England and Wales [1] and Scottish Government Action Plan "Living and Dying Well" [2]. These documents promote the provision of care in the last year of life that is person-centred regardless of diagnosis. The recent NHS quality Improvement Scotland Clinical Standards for Heart Disease recommend a palliative care assessment in all forms of advanced heart disease.[3] Recent publications relating to end-of-life care in heart disease have focused on congestive heart failure (CHF) but coronary disease and valvular heart disease commonly co-exist in CHF patients so an integrated approach to all end-stage heart disease is appropriate.

We recently explored ways of identifying patients who are approaching end of life (EOL) in an acute cardiology ward. Using the Gold Standards Framework criteria and validated prognostic tools we demonstrated that most patients with advanced heart failure [4] and a lesser proportion with acute coronary events [5] have a very limited prognosis despite optimal evidence-based care. Poor prognosis is a marker of lower quality of life, increased hospitalisation, multi-morbidity [6] and is an indirect marker of increasing patient needs. There are well validated prognostic tools for patients with congestive heart failure (CHF) [7] and acute coronary syndrome (ACS).[8] Once a patient with a poor prognosis is identified, this should ideally be followed by an evidence-based intervention [9-11] that could improve quality of life for the patient and their family. In keeping with palliative care models [12] this intervention should be patient-focused and should address individual needs. Ideally the intervention should integrate patient preferences with clinical priorities using "shared decision-

making".[13] From these discussions a Future Care Plan (FCP) may be derived and written in terms that the patient understands. The FCP should contain a clinical plan of how to manage acute events of deteriorating health with mechanisms to inform out-of-hours services and maintain continuity of care. The plan should be reviewed regularly in the context of the patient's evolving multidimensional needs. Such an intervention could be initiated by the patient's cardiologist and delivered by a specialist heart disease nurse working in partnership with the primary care team and palliative care specialists.

Trials of palliative care are recognised to be extremely difficult to design and implement.[14] One previous randomised trial suggested that routine palliative care in addition to normal oncological care could improve quality of life in people with lung cancer.[12] A robust phase II trial, as recommended by the Medical Research Council in its guidance for complex interventions,[15] is needed as a first step towards achieving a similar goal for people with advanced heart disease.

The proposed study outlined here incorporates these issues using a mixed methods, Phase 1 and Phase 2 trial, design and is similar to methodologies used elsewhere to develop complex palliative care interventions for non-cancer illnesses. [16, 17] The proposed trial is novel in that it includes a broad group of patients with CHF and ACS, it will assess whether well-validated clinical prognostic tools can be used to identify patients approaching end-of-life and will develop a feasible care planning intervention. In addition to assessing prognosis as a trigger the study also seeks to explore the interface between acute cardiology services, primary care and specialist palliative care services.

Here we describe the findings of a qualitative interview study using patient-carer focus groups (PCFG) and a range of healthcare professionals (HCP) to explore ways in which an holistic intervention could be tested in a randomised clinical trial setting.

METHODS

The basic design for a clinical trial outline was developed by the authors as part of a submission for research funding using their background knowledge and experience and based on other trial designs of a similar nature. [16,17] This was approved by the funder and by the local ethics committee on the understanding that the design of the study could be modified following a consultation/modelling phase which would involve focus groups of patients and carers and one-to one interviews with a range of healthcare professionals about the proposed trial design. Patient-carer focus groups (PCFG) were then undertaken with the members of an existing hospital based heart failure patient-carer forum (n=7) and a second focus group was undertaken in conjunction with a local heart disease charity (n=8 participants) each lasting for 2 hours. Discussions were facilitated by an experienced qualitative researcher (GH) using a set of questions, designed by the authors, addressing their experiences with clinical care and the proposed design of the randomised controlled trial (see appendix 1A). Various options associated with the trial were presented and discussed with patients and carers including eligibility criteria and whether the control group should or should not receive end-of-life intervention.

A separate series of one-to-one interviews were conducted with a range of healthcare professionals (HCP, total n=11, palliative care consultant n= 3, cardiology consultant n=3, heart failure specialist nurse n=1, medicine of the elderly specialist n=1, cardiology ward charge nurse n=1, general practitioner n=1, district nurse n=1) by an experienced qualitative researcher using a set of questions incorporating themes related to clinical care, palliative care and clinical trials design (see appendix 1B).

Discussions regarding the proposed design of the trial were initially broad and later in the interview focused more on the eligibility criteria, types of patients that should be included and

whether an active control group should be incorporated. Both types of participants were provided with a sample "Future Care Plan" and a flow diagram of the basic proposed design of the clinical trial prior to the interviews. These documents acted as focal points for discussion. Interviews and focus groups were transcribed and analysed using NVivo to extract themes related to the rationale and design of a clinical trial of an holistic intervention addressing a range of issues related to end-of-life care.

The findings from these interviews and focus group discussions were then used to modify the proposed design of a trial of an intervention to support patients with advanced heart disease identified as being at high risk of death within the next 12 months.

The study was approved by the local ethics committee and all participants gave signed informed consent.

RESULTS

Patient's and carer's views : care for cardiac patients

PCFG highlighted increasing difficulties associated with multiple care-providers working in apparent isolation as a major difficulty in ensuring holistic care. From a PCFG perspective, care appears increasingly fragmented and ill-designed to manage the needs of frail, elderly patients with multiple chronic conditions.

PCFG also identified the variation in access to specialist services as a key problem in providing holistic, patient centred care. This applied in particular to heart failure nurse care where many services adhere to strict eligibility criteria which include left ventricular systolic dysfunction and recent hospital admission. Patients with access to the heart failure specialist nurse service were very appreciative of their support, but they expressed concern that this service was not available to everyone with heart failure and people with other types of advanced heart conditions.

PCFG welcomed the idea of future or anticipatory care planning, and appeared to recognise its value. However, a minority felt that this could be a very difficult process to engage in, expressing views that it needs to be carefully targeted and people should be able to choose, without pressure, not to engage in the process (table 1). PCFG highlighted the fact that some patients will already be well informed about their condition and its prognosis. However, it was also expressed that for those who have less insight into their condition, doctors and nurses should consider carefully how they will allay and minimise fears about engaging in a process of future care planning.

Patient-carer views: Fragmentation of Care

"Once you get to our age, you discover that you've got more than one problem, and you see the various consultants who deal with the various problems, and they deal with you like a car. They put the carburettor right, they put the radiator right, but the holistic approach is missing" (patient)

"My condition is primarily a chronic lung condition but I also have a heart condition. So I have two separate areas of contact and they both know about each of the conditions but they're really only concentrating on the one they're dealing with, they soon forget, 'oh, you've got a heart condition, oh right!' And it's worrying particularly if you're being administered fairly serious medication and you've got to remember that you've got all these conditions" (patient)

Variation in access to specialist services

"We have a very good rapport and have chats with her (The Heart Failure Nurse). If there's something we don't understand, she's very good at explaining what's involved, so we're very happy" (patient)

"Having a nurse, it gives you a bit more confidence because you just know she's there. Everyone should have one, because it does make a heck of a difference" (patient)

Patient's and carer's views : proposed trial of future care planning

There was a general consensus in the PCFG that the draft Future Care Plan planned for use in the trial (see appendix 2) was comprehensive and addressed a number of concerns that families had about planning for the future (table 2). However, one carer made the point that a patient-centred anticipatory care plan must be flexible enough to accommodate those who are acting on behalf of their loved one possibly using power of attorney. Others suggested that it would be helpful to ensure that all contact details of the medical teams caring for a patient are included particularly for those with multiple co-morbidities. One patient also questioned the appropriateness of asking patients to identify which potentially life-saving treatments they may or may not want.

PCFG were supportive of the proposal for a clinical trial and were satisfied with the basic design of the study. Opposing views about eligibility criteria were expressed by two participants in the same focus group with one indicating that eligibility should include people with advanced heart disease that were currently stable in the community and not necessarily those recently admitted to hospital. PCFG emphasised the need for families to be well informed and prepared before being approached about a trial testing the proposed intervention. Eligibility for the trial using a threshold value for estimated 12 month mortality was debated and discussed and a value of 20% was reached as one which would include a set of patients with a significantly higher than average mortality risk for cardiac patients. One further aspect of the final design of the trial which was discussed and agreed by the PCFG was whether to have a control group with no intervention or whether to have a group of patients where an intervention was provided but 12 weeks after discharge. It was generally agreed that it would be unethical not to provide an intervention of some sort to all patients who agreed to take part and so a delayed intervention group design was finally agreed (see figure 1).

Patient-carer views: Draft Patient-held Future care plan (see appendix 2 "My Thinking Ahead Plan")

"I have thought about all the questions (in the proposed patient-held Future Care Plan), and I think it's very, very good. Even for yourself to write down your thoughts and wishes. Everybody's wishes are different so therefore, if it's all written down and you've got this plan, I think, yes, it's very useful for the future" (patient)

"….personally, ignorance is bliss in some cases" (patient)

"What would worry me slightly about this, especially if you're filling it out on your own (Future Care Plan), is that suddenly an end, shall we say, opens up, the fact that you're filling in something that's to do with palliative care – ooh, a horrible word – I don't know if people with heart failure are taken through this before this or do they need to be sitting with a doctor or nurse who can take them through the fact that it's not as bad as it sounds. That would worry me ….. getting something like this and filling it in isolation, it's frightening "(patient)

"Well, if you follow all the questions, really I don't think you miss much at all. Because you're asking what people are interested in and what things they do at the moment and what they hope to continue, and in a way, I think that's very good for the professionals looking af-

ter us to know that – whether in fact you're doing anything or if you're doing nothing with your life, because I think it makes a big difference" (patient)

Views of healthcare professionals – end of life care for patients with heart disease

Irrespective of role, all HCP that were interviewed identified the issue of managing the uncertainty of prognosis in people with advanced heart disease as a major challenge. Most agreed that prognostic uncertainty can cause HCP to prevaricate because they are worried about 'getting it wrong'. They also expressed concerns that discussions about end-of-life could remove hope for the patient and their family.

Healthcare professional's views : Prognostic uncertainty

"…it's hard for health professionals to know where they (patients) are in their disease process, because we know they go up and down and they probably never come right back up to where they were the last time, but they're still functioning, and …. at what point do you have that conversation? " (District Nurse)

"A lot of health professionals because of the trajectory of the disease and the up and down nature of it, nobody knows when the point of true palliation should kick in and people are very frightened because with some antibiotics or some steroids they could bounce back, not to the same state of health, each time declining and getting less well, but still not at the point where you would be comfortable saying, right, we're at the point of pure palliation" (Palliative Care Consultant)

"*we've all seen patients who survive against the odds for a long time – if they outlive your expectations, that's OK … you might get the timing a bit wrong because you can't predict, but usually you are right that the decline has started" (Heart Failure Specialist Nurse)*

"You don't want your patients to become obsessed and totally focused on their disease – (they've) got to get on with life as well" (Medicine of the Elderly Consultant)

Healthcare professional's views : Risk of dying from a long term condition

"I don't think they see it, to the same extent as cancer patients - COPD patients as well. They (patients) see it as a limiting condition, it stops them doing things, it's not foremost in their mind that this is the thing they're going to die of" (District Nurse)

"Sometimes I think when it gets to the stage that you're doing DNAR forms … it often comes as a big shock to either them or their family.. it comes as a shock when they're told, 'we think this is it this time', because they've been in and out, bounced back and forward, got better, gone home" (Community Palliative Care Nurse)

Views of healthcare professionals – proposed trial of future care planning

Several HCP participants drew a distinction between different types of patients with advanced heart disease and wanted more clarity about what type of patient would be eligible for the proposed trial. One cardiologist's view was that it would be relatively straightforward to recruit patients with coronary disease although it would be more complex to identify patients with heart failure since it is hard to pinpoint at which point in their illness trajectory they would become eligible. For this group, one cardiologist suggested, it may be useful to use repeated hospital admissions, or functional status as a criteria for eligibility.

Care of the elderly physicians raised concerns about including patients in the trial with multimorbidity including those with cognitive impairment. Such patients are typically seen in acute medical-takes and while they would be a group who may benefit considerably from Future Care Planning they would be difficult to assess, recruit and retain in the proposed trial. However, this HCP stated that to omit these patients would be unfair and could miss a key opportunity.

There were no significant concerns raised with regard to using a clinical prognostic tool, such as the GRACE score, as a way of identifying patients for a palliative care intervention. However, it was highlighted by a number of HCPs that this approach has significant limitations and using such a tool in isolation may exclude many patients who could benefit from a future care planning approach who have a high level of need and a low estimated 12 month mortality risk. In addition, it was highlighted that prognostic scores do not predict time to death nor do they accurately identify those who may benefit from a palliative care intervention.

Healthcare professional's Views: Proposed trial of Future Care Planning

Patient selection for the trial:

"One group is those with advanced heart failure for whom we already have some structure to post-discharge care through our HF nurse service and the second group…are those with end

stage coronary disease, so these are patients with angina for whom there's not an awful lot more can be done for them by way of bypass surgery and invasive treatments, and where these patients are intermittently hospitalised when their angina reaches crisis point " (Consultant Cardiologist)

"A score based on a patient's functional status is useful because it identifies when quality of life is impaired to the extent that the patient needs more support" (Consultant Cardiologist)

Eligibility for the trial:

"…harder to put frail elderly patients into a protocol-driven trial because they are so different and they've got such a mix of co-morbidities and such a mix of drugs" (Consultant in Medicine of the Elderly)

"I think using (a cut-off of) 20% (12 month mortality risk) is fair" (Community Palliative Care Nurse)

" It's still pretty high. If it's less than 20% people shouldn't imminently be dying so it gives you a chance to see what effect the intervention has" (Consultant Cardiologist)

"…So it's about identifying the point when you can have a reasonable conversation with somebody about deterioration, and is 20% (estimated mortality risk) right ..If you make it higher you'll miss some people but you'll make the discussion more real and liveable, and that's your balance" (Palliative Care Consultant)

"A 20% risk threshold would include lots and lots of frail elderly people. Many of them would have a 1 in 5 chance of dying within a year even without their heart failure. It's probably not an unreasonable threshold" (Medicine of the Elderly Consultant)

Trial outcome measures:

".. if you're trying to prevent hospital admissions, if they're frequent fliers, then I would have thought they're the ones, the unstable ones. If you've been able to tweak something at home that prevented the admission, I suppose this is what this would do" (District Nurse)

" Obviously, you do have to look at bed days but ultimately they're spending more time in hospital, from their point of view.. that's possibly better for them" (Community Palliative Care Nurse)

"… there's a subtle distinction, for example, between trying to measure differences in quality of life on a day to day basis, and measuring overall levels of comfort, security". (Medicine of the elderly consultant)

Without exception, the HCPs we interviewed had no ethical concerns with a design utilising an early versus late intervention which they regarded as a standard approach for a trial (see figure 1).

Achieving and maintaining staff engagement and thinking ahead to what happens at the end of the trial were identified as important issues. In particular HCPs identified the importance

of keeping staff informed about the trial, consideration of how the trial might dovetail with existing service developments and the importance of providing ongoing support beyond the trial period to participants who continue to require additional supportive care.

Hospital bed-days utilisation during follow-up was generally considered to be an appropriate outcome, although several expressed caution in interpreting what these data actually mean. Quality of life measures were also considered to be an appropriate outcome although it was pointed out that these measures can also be difficult to interpret in this setting. Some HCPs suggested the inclusion of place of death and preference for place of death as outcome measures.

The initial study design of the clinical trial did not strictly define the types of patients that could be included, the eligibility criteria, the threshold mortality risk for inclusion and whether an intervention should be included for the control group. The final trial design (figure 1) represents a modified version taking account of the views of patients and healthcare professionals interviewed in this study. This fundamental design of the proposed trial was similar to the original design presented to the PCFG and the HCP during the interviews and focus groups. There was general agreement that a broad range of acute cardiac patents should be included and agreement was reached to include heart failure (with either reduced or preserved left ventricular systolic function) and patients with any acute coronary syndrome. There was discussion as to whether a delayed intervention was needed in the control group. Since current clinical services provided little or no end-of-life intervention for such patients a final consensus, mainly driven by comments from patients and carers, was made to offer a delayed intervention to the control group given that the intervention addressed a clear need which was patient-centred and which could provide an apparent benefit to those who participated. The final component of the design which was agreed following the PCFG and HCP interviews was the threshold at which to set the 12 month mortality used as eligibility for the trial. The

authors had proposed this to be somewhere between 20 and 40% and this was discussed by both groups. The final agreement of 20% was made largely by the PCFG after lengthy discussions as to what the typical mortality risk was for CCF and ACS patients admitted acutely to hospital.

The findings from this modelling phase are currently being used to support the implementation of a phase II randomised clinical trial of an holistic intervention (figure 2) for patients with advanced heart disease.

DISCUSSION

This qualitative study examining patients', carers' and healthcare professionals' (HCP) views on the content and design of a clinical trial of Future Care Planning for patients with advanced heart disease has highlighted a number of important issues. The concerns raised by patients and carers regarding the current inadequate levels of care as cardiac patients approach end-of-life provides an important back-drop to the main theme of the work which was to seek their views on the content and design of a clinical trial. Patients and carers expressed views indicating that such a trial should redress the current inadequacies in a typical doctor-patient interaction which they felt had limited time and lacked an holistic approach particularly in cardiology out-patient clinic settings. The healthcare professional participants highlighted the challenges in using meaningful selection criteria for the trial and the complexity of identifying precisely which component of any proposed intervention might influence outcomes. The findings of this work therefore re-affirm many of the findings of others in the field [18, 19]. However, the novel aspect of the work is that the focus groups and interviews were extended beyond a general discussion stage to seek views on how the inadequacies in care could be redressed and a model developed which could be subsequently tested using a randomised trial approach.

Factors which might influence the outcomes which emerged from the PCFG discussions included the content and quality of the baseline or first discussion/interview with the consultant, the content of the written future care plan and ongoing support, for both patient and carer, from a familiar healthcare professional. The views from patients, carers and professionals indicated that a clinical trial should focus on providing adequate time to discuss the patient's current and future care needs and those of their carer, it should select patients on the basis of

prognosis and needs, it should provide ongoing support with both primary and secondary care working closely together to ensure good coordination of care and it should allow for adaptation of any care plan in a dynamic way that is aligned with the changing needs of the patient and their carer.

While this message is clear, delivering such a trial using non-palliative care physicians in an acute cardiology environment will be challenging. Finding the appropriate language to explain an uncertain prognosis is always difficult, [20] and cardiologists with a firm culture of curative approaches may struggle to find that language. These challenges may delay the conversation until it's too late, or they may encourage the use of more vague, ambiguous or even contradictory language which can sometimes mislead the patient and their family or fail to communicate the seriousness of their condition adequately. Finding language that is balanced, caring and which makes sense of an uncertain future is one of the challenges of all palliative care even where the prognosis, good or bad, is more certain. However, the majority of the HCPs that we interviewed agreed that it should be possible in most cardiac patients with advanced disease. Surviving with a chronic condition that has an uncertain illness trajectory can mean that these patients, unlike cancer patients, can reach a fairly advanced stage in their illness without realising that they have a condition that could and probably will cause their death.

Our findings have also highlighted a persisting tendency for patients and healthcare professionals to associate palliative care with dying. This perception may prevent or discourage healthcare teams from offering palliative and supportive care to patients with significant symptom burden who may not have reached the end of their lives but who may benefit form additional supportive care. Healthcare professionals held the view that patients and carers may be reluctant to accept a form of support which they associate with end of life. This may reflect reluctance on the part of the healthcare professionals as much as the patient. This is an

important issue if we are to develop a model of integrating palliative care earlier in the illness trajectory of cardiac disease by the heart team caring for the patient. In addition to learning and developing the skills required to do this, these teams will also need to change attitudes and culture. Indeed, while this culture is increasingly acknowledged as important for patients with chronic heart failure there is also a clear need for this approach in patients with other forms of advanced cardiac disease such as coronary and valvular heart disease.

The barriers to achieving good holistic care for patients nearing the end of their lives, well described in other settings [21, 22] apply equally well in the acute cardiology setting. [23] There is insufficient time to discuss such sensitive issues, the hospital environment is not ideal (particularly in multi-bedded rooms), cardiologists are not adequately trained and in cardiology there is a culture of doing more and never giving up. However, particularly in elderly patients and even with optimal interventions the combination of congestive heart failure, coronary heart disease, valvular heart disease and other non-cardiac comorbidities is associated with poor prognosis.[24, 25] Indeed, the increasing use of Transcatheter Aortic Valve Implantation (TAVI) in patients that are deemed unsuitable for conventional surgery is increasingly recognised as a clinical challenge balancing aggressive intervention with supportive end of life care. [26-29]

Hence, patients with advanced heart disease and poor prognosis are clearly a target for better clinical care encompassing an approach that acknowledges that the patient may be nearing the end of life. These patients rarely receive care that addresses their individual needs and those of their informal carers. This care need not be labelled as palliative but can be delivered in the understanding that the future is uncertain and the risk of death, either sudden or with progressive symptoms, is significantly increased. This need not exclude a positive attitude to the patient's clinical care and where possible the healthcare professional should emphasise the need for ongoing active and responsive care. The challenge, and arguably the key issue, is

maintaining a positive attitude while simultaneously acknowledging a poor prognosis. However, if this approach can be adopted by the patient, their family, GP and cardiologist then it can potentially improve communication and understanding in a way that leads to better care without loss of hope for the patient. Any such intervention should be patient-centred in all aspects of its design and the impact on healthcare measures must be seen as secondary to the primary aim of improving quality of life. This is challenging even in cancer care where there have been few clinical trials adequately powered to show clinically meaningful benefits using an holistic approach.[12] If improved clinical outcomes could be demonstrated in a clinical trial involving patients with advanced heart disease then this would be extremely valuable to patients and the wider cardiology community.

This study has clearly demonstrated that patients, carers and healthcare professionals have a number of concerns in relation to providing high quality holistic care for patients with advanced heart disease. The approach reported here of seeking views on the inadequacies in service provision, designing an intervention model that could improve care and incorporating this into the design of a randomised trial is both novel and important given the dearth of clinical trials in end-of-life care. The findings are currently being used to support implementation of a phase II randomised clinical trial of an holistic intervention involving Future Care Planning for patients with advanced heart disease.

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FIGURE LEGENDS

Figure 1 – Adapted protocol for a randomised trial of Future Care Planning for patients with advanced heart disease: *Original flow diagram did not define the types of patients to be included, the threshold mortality risk for eligibility and the control group intervention. This final and agreed version identifies patients admitted to an acute cardiology ward with either acute coronary syndrome or heart failure and will be screened for eligibility - 12 month mortality risk of 20% or greater at the time of discharge using the GRACE discharge score [8] or the EFFECT score [7]. Eligible patients need to survive to discharge and have capacity to consent for the study. Informal carers will also participate where identified by the patient. Proposed outcomes include quality of life assessed by questionnaire (EuroQoL-5D) and readmissions to hospital. Patients randomised to early intervention will be interviewed prior to discharge and those randomised to delayed intervention will receive the same interview 12 weeks following discharge.*

Figure 2 – Future Care Plan Intervention : *the intervention will last for 12 weeks. Patients randomised to early intervention will have a 1 hour interview with a cardiologist prior to discharge where they will discuss their heart condition, other medical conditions and their concerns and plans for the future. The cardiologist, trained in Advanced Communication Skills, will aim to address a range of issues including (1) a future care plan , agreed with the patient and their carer, which includes advice to Healthcare professionals about what could and should be done if the patient's condition deteriorates once again, (2) whether the patient*

and their family have arranged Power of Attorney (or similar), (3) whether the patient wishes to consider the issue of DNACPR (Do Not Attempt Cardiopulmonary Resuscitation), (4) whether the patient wishes to express a preferred place of care should their condition deteriorate again, (5) whether the patient would consider being added to their GP's Palliative Care register and (6) permission to share the content of the Future Care Plan electronically with out-of-hours medical services (NHS24/NHS Direct). Patients will also be encouraged to complete "Thinking Ahead Plan", a locally developed patient-held anticipatory care plan (see appendix 2). Patients randomised to delayed intervention will undergo the same interview 12 weeks after discharge. During the follow-up period of 12 weeks, the trial nurse will visit the patient/carer in their home at 6 weeks and 12 weeks after the baseline interview in order to update the FCP with any changes and to review any DNACPR orders or make any necessary changes to the plan of care. An updated version of the FCP record will be communicated in writing to the GP at each of these time points. The nurse will be available to communicate with the patient by telephone at any time and will ensure optimal communication and coordination of care between GP, cardiologist, community-based nursing teams and palliative care teams (where appropriate).

TITLE: Future Care Planning for patients approaching end-of-life with advanced heart disease: an interview study with patients, carers and healthcare professionals exploring the content, rationale and design of a randomised clinical trial

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Key words: advanced heart disease, care planning, randomised clinical trial, palliative care, end-of-life care

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ABSTRACT

Objective: To explore the optimal content and design of a clinical trial of an end-of-life intervention for advanced heart disease with patients, carers and healthcare professionals

Design: Qualitative interview and focus group study

Setting: Community and hospital-based focus groups and interviews

Participants: Stable community-dwelling patients, informal carers (PC, n=15) and primary and secondary care based healthcare professionals (HCP, n=11)

Results: PC highlighted fragmentation of services and difficulty in accessing specialist care as key barriers to good care. They felt that time for discussion with HCP was inadequate within current NHS health care systems. HCP highlighted uncertainty of prognosis, explaining mortality-risk to patients and switching from curative to palliative approaches as key challenges. Patient selection, nature of the intervention and relevance of trial outcomes were identified by HCP as key challenges in the design of a clinical trial.

Conclusions: PC and HCP expressed a number of concerns relevant to the nature and content of an end-of-life intervention for patients with advanced heart disease. The findings of this study are being used to support a phase II randomised clinical trial of future care planning in advanced heart disease.

Strengths and limitations of the study

- This qualitative interview study has provided a 360 degree perspective from patients, carers and healthcare professionals on the content, nature and mode of delivery of an intervention that could be tested in a clinical trial and that could impact on quality of life.
- The findings suggest that a randomised (early versus delayed) protocol is broadly acceptable, that clinical prognostic scores could be used to identify eligible patients in the hospital setting, that care-needs should also be incorporated into the eligibility criteria and that the intervention should include components that address the current gaps in high quality holistic care (as identified by patients and their carers).
- The relatively small number of patients and healthcare professionals participating in the study and the fact that all patients were in a stable community-based setting may have impacted on the findings.
- Engaging patients and carers in the rationale, content and design of a randomised clinical trial is challenging and requires careful design and planning.

INTRODUCTION

Patients with cancer have well developed palliative care services while patients with advanced heart disease do not as highlighted in two major reports by The Department of Health in England and Wales [1] and Scottish Government Action Plan "Living and Dying Well" [2]. These documents promote the provision of care in the last year of life that is person-centred regardless of diagnosis. The recent NHS quality Improvement Scotland Clinical Standards for Heart Disease recommend a palliative care assessment in all forms of advanced heart disease.[3] Recent publications relating to end-of-life care in heart disease have focused on congestive heart failure (CHF) but coronary disease and valvular heart disease commonly co-exist in CHF patients so an integrated approach to all end-stage heart disease is appropriate.

We recently explored ways of identifying patients who are approaching end of life (EOL) in an acute cardiology ward. Using the Gold Standards Framework criteria and validated prognostic tools we demonstrated that most patients with advanced heart failure [4] and a lesser proportion with acute coronary events [5] have a very limited prognosis despite optimal evidence-based care. Poor prognosis is a marker of lower quality of life, increased hospitalisation, multi-morbidity [6] and is an indirect marker of increasing patient needs. There are well validated prognostic tools for patients with congestive heart failure (CHF) [7] and acute coronary syndrome (ACS).[8] Once a patient with a poor prognosis is identified, this should ideally be followed by an evidence-based intervention [9-11] that could improve quality of life for the patient and their family. In keeping with palliative care models [12] this intervention should be patient-focused and should address individual needs. Ideally the intervention should integrate patient preferences with clinical priorities using "shared decision-

making".[13] From these discussions a Future Care Plan (FCP) may be derived and written in terms that the patient understands. The FCP should contain a clinical plan of how to manage acute events of deteriorating health with mechanisms to inform out-of-hours services and maintain continuity of care. The plan should be reviewed regularly in the context of the patient's evolving multidimensional needs. Such an intervention could be initiated by the patient's cardiologist and delivered by a specialist heart disease nurse working in partnership with the primary care team and palliative care specialists.

Trials of palliative care are recognised to be extremely difficult to design and implement.[14] One previous randomised trial suggested that routine palliative care in addition to normal oncological care could improve quality of life in people with lung cancer.[12] A robust phase II trial, as recommended by the Medical Research Council in its guidance for complex interventions,[15] is needed as a first step towards achieving a similar goal for people with advanced heart disease.

The proposed study outlined here incorporates these issues using a mixed methods, Phase 1 and Phase 2 trial, design and is similar to methodologies used elsewhere to develop complex palliative care interventions for non-cancer illnesses. [16, 17] The proposed trial is novel in that it includes a broad group of patients with CHF and ACS, it will assess whether well-validated clinical prognostic tools can be used to identify patients approaching end-of-life and will develop a feasible care planning intervention. In addition to assessing prognosis as a trigger the study also seeks to explore the interface between acute cardiology services, primary care and specialist palliative care services.

Here we describe the findings of a qualitative interview study using patient-carer focus groups (PCFG) and a range of healthcare professionals (HCP) to explore ways in which an holistic intervention could be tested in a randomised clinical trial setting.

METHODS

The basic design for a clinical trial outline was developed by the authors as part of a submission for research funding using their background knowledge and experience and based on other trial designs of a similar nature. [16,17] This was approved by the funder and by the local ethics committee on the understanding that the design of the study could be modified following a consultation/modelling phase which would involve focus groups of patients and carers and one-to one interviews with a range of healthcare professionals about the proposed trial design. Patient-carer focus groups (PCFG) were then undertaken with the members of an existing hospital based heart failure patient-carer forum (n=7) and a second focus group was undertaken in conjunction with a local heart disease charity (n=8 participants) each lasting for 2 hours. Discussions were facilitated by an experienced qualitative researcher (GH) using a set of questions, designed by the authors, addressing their experiences with clinical care and the proposed design of the randomised controlled trial (see appendix 1A). Various options associated with the trial were presented and discussed with patients and carers including eligibility criteria and whether the control group should or should not receive end-of-life intervention.

A separate series of one-to-one interviews were conducted with a range of healthcare professionals (HCP, total n=11, palliative care consultant n= 3, cardiology consultant n=3, heart failure specialist nurse n=1, medicine of the elderly specialist n=1, cardiology ward charge nurse n=1, general practitioner n=1, district nurse n=1) by an experienced qualitative researcher using a set of questions incorporating themes related to clinical care, palliative care and clinical trials design (see appendix 1B).

Discussions regarding the proposed design of the trial were initially broad and later in the interview focused more on the eligibility criteria, types of patients that should be included and

whether an active control group should be incorporated. Both types of participants were provided with a sample "Future Care Plan" and a flow diagram of the basic proposed design of the clinical trial prior to the interviews. These documents acted as focal points for discussion. Interviews and focus groups were transcribed and analysed using NVivo to extract themes related to the rationale and design of a clinical trial of an holistic intervention addressing a range of issues related to end-of-life care.

The findings from these interviews and focus group discussions were then used to modify the proposed design of a trial of an intervention to support patients with advanced heart disease identified as being at high risk of death within the next 12 months.

The study was approved by the local ethics committee and all participants gave signed informed consent.

RESULTS

Patient's and carer's views : care for cardiac patients

PCFG highlighted increasing difficulties associated with multiple care-providers working in apparent isolation as a major difficulty in ensuring holistic care. From a PCFG perspective, care appears increasingly fragmented and ill-designed to manage the needs of frail, elderly patients with multiple chronic conditions.

PCFG also identified the variation in access to specialist services as a key problem in providing holistic, patient centred care. This applied in particular to heart failure nurse care where many services adhere to strict eligibility criteria which include left ventricular systolic dysfunction and recent hospital admission. Patients with access to the heart failure specialist nurse service were very appreciative of their support, but they expressed concern that this service was not available to everyone with heart failure and people with other types of advanced heart conditions.

PCFG welcomed the idea of future or anticipatory care planning, and appeared to recognise its value. However, a minority felt that this could be a very difficult process to engage in, expressing views that it needs to be carefully targeted and people should be able to choose, without pressure, not to engage in the process (table 1). PCFG highlighted the fact that some patients will already be well informed about their condition and its prognosis. However, it was also expressed that for those who have less insight into their condition, doctors and nurses should consider carefully how they will allay and minimise fears about engaging in a process of future care planning.

Patient-carer views: Fragmentation of Care

"Once you get to our age, you discover that you've got more than one problem, and you see the various consultants who deal with the various problems, and they deal with you like a car. They put the carburettor right, they put the radiator right, but the holistic approach is missing" (patient)

"My condition is primarily a chronic lung condition but I also have a heart condition. So I have two separate areas of contact and they both know about each of the conditions but they're really only concentrating on the one they're dealing with, they soon forget, 'oh, you've got a heart condition, oh right!' And it's worrying particularly if you're being administered fairly serious medication and you've got to remember that you've got all these conditions" (patient)

Variation in access to specialist services

"We have a very good rapport and have chats with her (The Heart Failure Nurse). If there's something we don't understand, she's very good at explaining what's involved, so we're very happy" (patient)

"Having a nurse, it gives you a bit more confidence because you just know she's there. Everyone should have one, because it does make a heck of a difference" (patient)

Patient's and carer's views : proposed trial of future care planning

There was a general consensus in the PCFG that the draft Future Care Plan planned for use in the trial (see appendix 2) was comprehensive and addressed a number of concerns that families had about planning for the future (table 2). However, one carer made the point that a patient-centred anticipatory care plan must be flexible enough to accommodate those who are acting on behalf of their loved one possibly using power of attorney. Others suggested that it would be helpful to ensure that all contact details of the medical teams caring for a patient are included particularly for those with multiple co-morbidities. One patient also questioned the appropriateness of asking patients to identify which potentially life-saving treatments they may or may not want.

PCFG were supportive of the proposal for a clinical trial and were satisfied with the basic design of the study. Opposing views about eligibility criteria were expressed by two participants in the same focus group with one indicating that eligibility should include people with advanced heart disease that were currently stable in the community and not necessarily those recently admitted to hospital. PCFG emphasised the need for families to be well informed and prepared before being approached about a trial testing the proposed intervention. Eligibility for the trial using a threshold value for estimated 12 month mortality was debated and discussed and a value of 20% was reached as one which would include a set of patients with a significantly higher than average mortality risk for cardiac patients. One further aspect of the final design of the trial which was discussed and agreed by the PCFG was whether to have a control group with no intervention or whether to have a group of patients where an intervention was provided but 12 weeks after discharge. It was generally agreed that it would be unethical not to provide an intervention of some sort to all patients who agreed to take part and so a delayed intervention group design was finally agreed (see figure 1).

Patient-carer views: Draft Patient-held Future care plan (see appendix 2 "My Thinking Ahead Plan")

"I have thought about all the questions (in the proposed patient-held Future Care Plan), and I think it's very, very good. Even for yourself to write down your thoughts and wishes. Everybody's wishes are different so therefore, if it's all written down and you've got this plan, I think, yes, it's very useful for the future" (patient)

"....personally, ignorance is bliss in some cases" (patient)

"What would worry me slightly about this, especially if you're filling it out on your own (Future Care Plan), is that suddenly an end, shall we say, opens up, the fact that you're filling in something that's to do with palliative care – ooh, a horrible word – I don't know if people with heart failure are taken through this before this or do they need to be sitting with a doctor or nurse who can take them through the fact that it's not as bad as it sounds. That would worry me ..... getting something like this and filling it in isolation, it's frightening "(patient)

"Well, if you follow all the questions, really I don't think you miss much at all. Because you're asking what people are interested in and what things they do at the moment and what they hope to continue, and in a way, I think that's very good for the professionals looking af-

ter us to know that – whether in fact you're doing anything or if you're doing nothing with your life, because I think it makes a big difference" (patient)

Views of healthcare professionals – end of life care for patients with heart disease

Irrespective of role, all HCP that were interviewed identified the issue of managing the uncertainty of prognosis in people with advanced heart disease as a major challenge. Most agreed that prognostic uncertainty can cause HCP to prevaricate because they are worried about 'getting it wrong'. They also expressed concerns that discussions about end-of-life could remove hope for the patient and their family.

Healthcare professional's views : Prognostic uncertainty

"…it's hard for health professionals to know where they (patients) are in their disease process, because we know they go up and down and they probably never come right back up to where they were the last time, but they're still functioning, and …. at what point do you have that conversation? " (District Nurse)

"A lot of health professionals because of the trajectory of the disease and the up and down nature of it, nobody knows when the point of true palliation should kick in and people are very frightened because with some antibiotics or some steroids they could bounce back, not to the same state of health, each time declining and getting less well, but still not at the point where you would be comfortable saying, right, we're at the point of pure palliation" (Palliative Care Consultant)

"*we've all seen patients who survive against the odds for a long time – if they outlive your expectations, that's OK … you might get the timing a bit wrong because you can't predict, but usually you are right that the decline has started" (Heart Failure Specialist Nurse)*

"You don't want your patients to become obsessed and totally focused on their disease – (they've) got to get on with life as well" (Medicine of the Elderly Consultant)

Healthcare professional's views : Risk of dying from a long term condition

"I don't think they see it, to the same extent as cancer patients - COPD patients as well. They (patients) see it as a limiting condition, it stops them doing things, it's not foremost in their mind that this is the thing they're going to die of" (District Nurse)

"Sometimes I think when it gets to the stage that you're doing DNAR forms … it often comes as a big shock to either them or their family.. it comes as a shock when they're told, 'we think this is it this time', because they've been in and out, bounced back and forward, got better, gone home" (Community Palliative Care Nurse)

Views of healthcare professionals – proposed trial of future care planning

Several HCP participants drew a distinction between different types of patients with advanced heart disease and wanted more clarity about what type of patient would be eligible for the proposed trial. One cardiologist's view was that it would be relatively straightforward to recruit patients with coronary disease although it would be more complex to identify patients with heart failure since it is hard to pinpoint at which point in their illness trajectory they would become eligible. For this group, one cardiologist suggested, it may be useful to use repeated hospital admissions, or functional status as a criteria for eligibility.

Care of the elderly physicians raised concerns about including patients in the trial with multimorbidity including those with cognitive impairment. Such patients are typically seen in acute medical-takes and while they would be a group who may benefit considerably from Future Care Planning they would be difficult to assess, recruit and retain in the proposed trial. However, this HCP stated that to omit these patients would be unfair and could miss a key opportunity.

There were no significant concerns raised with regard to using a clinical prognostic tool, such as the GRACE score, as a way of identifying patients for a palliative care intervention. However, it was highlighted by a number of HCPs that this approach has significant limitations and using such a tool in isolation may exclude many patients who could benefit from a future care planning approach who have a high level of need and a low estimated 12 month mortality risk. In addition, it was highlighted that prognostic scores do not predict time to death nor do they accurately identify those who may benefit from a palliative care intervention.

Healthcare professional's Views: Proposed trial of Future Care Planning

Patient selection for the trial:

"One group is those with advanced heart failure for whom we already have some structure to post-discharge care through our HF nurse service and the second group…are those with end

stage coronary disease, so these are patients with angina for whom there's not an awful lot more can be done for them by way of bypass surgery and invasive treatments, and where these patients are intermittently hospitalised when their angina reaches crisis point " (Consultant Cardiologist)

"A score based on a patient's functional status is useful because it identifies when quality of life is impaired to the extent that the patient needs more support" (Consultant Cardiologist)

Eligibility for the trial:

"...harder to put frail elderly patients into a protocol-driven trial because they are so different and they've got such a mix of co-morbidities and such a mix of drugs" (Consultant in Medicine of the Elderly)

"I think using (a cut-off of) 20% (12 month mortality risk) is fair" (Community Palliative Care Nurse)

" It's still pretty high. If it's less than 20% people shouldn't imminently be dying so it gives you a chance to see what effect the intervention has" (Consultant Cardiologist)

"...So it's about identifying the point when you can have a reasonable conversation with somebody about deterioration, and is 20% (estimated mortality risk) right ..If you make it higher you'll miss some people but you'll make the discussion more real and liveable, and that's your balance" (Palliative Care Consultant)

"A 20% risk threshold would include lots and lots of frail elderly people. Many of them would have a 1 in 5 chance of dying within a year even without their heart failure. It's probably not an unreasonable threshold" (Medicine of the Elderly Consultant)

Trial outcome measures:

".. if you're trying to prevent hospital admissions, if they're frequent fliers, then I would have thought they're the ones, the unstable ones. If you've been able to tweak something at home that prevented the admission, I suppose this is what this would do" (District Nurse)

" Obviously, you do have to look at bed days but ultimately they're spending more time in hospital, from their point of view.. that's possibly better for them" (Community Palliative Care Nurse)

"... there's a subtle distinction, for example, between trying to measure differences in quality of life on a day to day basis, and measuring overall levels of comfort, security". (Medicine of the elderly consultant)

Without exception, the HCPs we interviewed had no ethical concerns with a design utilising an early versus late intervention which they regarded as a standard approach for a trial (see figure 1).

Achieving and maintaining staff engagement and thinking ahead to what happens at the end of the trial were identified as important issues. In particular HCPs identified the importance

of keeping staff informed about the trial, consideration of how the trial might dovetail with existing service developments and the importance of providing ongoing support beyond the trial period to participants who continue to require additional supportive care.

Hospital bed-days utilisation during follow-up was generally considered to be an appropriate outcome, although several expressed caution in interpreting what these data actually mean. Quality of life measures were also considered to be an appropriate outcome although it was pointed out that these measures can also be difficult to interpret in this setting. Some HCPs suggested the inclusion of place of death and preference for place of death as outcome measures.

The initial study design of the clinical trial did not strictly define the types of patients that could be included, the eligibility criteria, the threshold mortality risk for inclusion and whether an intervention should be included for the control group. The final trial design (figure 1) represents a modified version taking account of the views of patients and healthcare professionals interviewed in this study. This fundamental design of the proposed trial was similar to the original design presented to the PCFG and the HCP during the interviews and focus groups. There was general agreement that a broad range of acute cardiac patents should be included and agreement was reached to include heart failure (with either reduced or preserved left ventricular systolic function) and patients with any acute coronary syndrome. There was discussion as to whether a delayed intervention was needed in the control group. Since current clinical services provided little or no end-of-life intervention for such patients a final consensus, mainly driven by comments from patients and carers, was made to offer a delayed intervention to the control group given that the intervention addressed a clear need which was patient-centred and which could provide an apparent benefit to those who participated. The final component of the design which was agreed following the PCFG and HCP interviews was the threshold at which to set the 12 month mortality used as eligibility for the trial. The

authors had proposed this to be somewhere between 20 and 40% and this was discussed by both groups. The final agreement of 20% was made largely by the PCFG after lengthy discussions as to what the typical mortality risk was for CCF and ACS patients admitted acutely to hospital.

The findings from this modelling phase are currently being used to support the implementation of a phase II randomised clinical trial of an holistic intervention (figure 2) for patients with advanced heart disease.

DISCUSSION

This qualitative study examining patients', carers' and healthcare professionals' (HCP) views on the content and design of a clinical trial of Future Care Planning for patients with advanced heart disease has highlighted a number of important issues. The concerns raised by patients and carers regarding the current inadequate levels of care as cardiac patients approach end-of-life provides an important back-drop to the main theme of the work which was to seek their views on the content and design of a clinical trial. Patients and carers expressed views indicating that such a trial should redress the current inadequacies in a typical doctor-patient interaction which they felt had limited time and lacked an holistic approach particularly in cardiology out-patient clinic settings. The healthcare professional participants highlighted the challenges in using meaningful selection criteria for the trial and the complexity of identifying precisely which component of any proposed intervention might influence outcomes. The findings of this work therefore re-affirm many of the findings of others in the field [18, 19]. However, the novel aspect of the work is that the focus groups and interviews were extended beyond a general discussion stage to seek views on how the inadequacies in care could be redressed and a model developed which could be subsequently tested using a randomised trial approach.

Factors which might influence the outcomes which emerged from the PCFG discussions included the content and quality of the baseline or first discussion/interview with the consultant, the content of the written future care plan and ongoing support, for both patient and carer, from a familiar healthcare professional. The views from patients, carers and professionals indicated that a clinical trial should focus on providing adequate time to discuss the patient's current and future care needs and those of their carer, it should select patients on the basis of

prognosis and needs, it should provide ongoing support with both primary and secondary care working closely together to ensure good coordination of care and it should allow for adaptation of any care plan in a dynamic way that is aligned with the changing needs of the patient and their carer.

While this message is clear, delivering such a trial using non-palliative care physicians in an acute cardiology environment will be challenging. Finding the appropriate language to explain an uncertain prognosis is always difficult, [20] and cardiologists with a firm culture of curative approaches may struggle to find that language. These challenges may delay the conversation until it's too late, or they may encourage the use of more vague, ambiguous or even contradictory language which can sometimes mislead the patient and their family or fail to communicate the seriousness of their condition adequately. Finding language that is balanced, caring and which makes sense of an uncertain future is one of the challenges of all palliative care even where the prognosis, good or bad, is more certain. However, the majority of the HCPs that we interviewed agreed that it should be possible in most cardiac patients with advanced disease. Surviving with a chronic condition that has an uncertain illness trajectory can mean that these patients, unlike cancer patients, can reach a fairly advanced stage in their illness without realising that they have a condition that could and probably will cause their death.

Our findings have also highlighted a persisting tendency for patients and healthcare professionals to associate palliative care with dying. This perception may prevent or discourage healthcare teams from offering palliative and supportive care to patients with significant symptom burden who may not have reached the end of their lives but who may benefit form additional supportive care. Healthcare professionals held the view that patients and carers may be reluctant to accept a form of support which they associate with end of life. This may reflect reluctance on the part of the healthcare professionals as much as the patient. This is an

important issue if we are to develop a model of integrating palliative care earlier in the illness trajectory of cardiac disease by the heart team caring for the patient. In addition to learning and developing the skills required to do this, these teams will also need to change attitudes and culture. Indeed, while this culture is increasingly acknowledged as important for patients with chronic heart failure there is also a clear need for this approach in patients with other forms of advanced cardiac disease such as coronary and valvular heart disease.

The barriers to achieving good holistic care for patients nearing the end of their lives, well described in other settings [21, 22] apply equally well in the acute cardiology setting. [23] There is insufficient time to discuss such sensitive issues, the hospital environment is not ideal (particularly in multi-bedded rooms), cardiologists are not adequately trained and in cardiology there is a culture of doing more and never giving up. However, particularly in elderly patients and even with optimal interventions the combination of congestive heart failure, coronary heart disease, valvular heart disease and other non-cardiac comorbidities is associated with poor prognosis.[24, 25] Indeed, the increasing use of Transcatheter Aortic Valve Implantation (TAVI) in patients that are deemed unsuitable for conventional surgery is increasingly recognised as a clinical challenge balancing aggressive intervention with supportive end of life care.[26-29]

Hence, patients with advanced heart disease and poor prognosis are clearly a target for better clinical care encompassing an approach that acknowledges that the patient may be nearing the end of life. These patients rarely receive care that addresses their individual needs and those of their informal carers. This care need not be labelled as palliative but can be delivered in the understanding that the future is uncertain and the risk of death, either sudden or with progressive symptoms, is significantly increased. This need not exclude a positive attitude to the patient's clinical care and where possible the healthcare professional should emphasise the need for ongoing active and responsive care. The challenge, and arguably the key issue, is

maintaining a positive attitude while simultaneously acknowledging a poor prognosis. However, if this approach can be adopted by the patient, their family, GP and cardiologist then it can potentially improve communication and understanding in a way that leads to better care without loss of hope for the patient. Any such intervention should be patient-centred in all aspects of its design and the impact on healthcare measures must be seen as secondary to the primary aim of improving quality of life. This is challenging even in cancer care where there have been few clinical trials adequately powered to show clinically meaningful benefits using an holistic approach.[12] If improved clinical outcomes could be demonstrated in a clinical trial involving patients with advanced heart disease then this would be extremely valuable to patients and the wider cardiology community.

This study has clearly demonstrated that patients, carers and healthcare professionals have a number of concerns in relation to providing high quality holistic care for patients with advanced heart disease. The approach reported here of seeking views on the inadequacies in service provision, designing an intervention model that could improve care and incorporating this into the design of a randomised trial is both novel and important given the dearth of clinical trials in end-of-life care. The findings are currently being used to support implementation of a phase II randomised clinical trial of an holistic intervention involving Future Care Planning for patients with advanced heart disease.

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Contributorship statement: MD, KB and SM designed the study, analysed the findings and co-wrote the manuscript. GH facilitated and transcribed the interviews and analysed the data. SR, SC and KH helped interpret the findings. JR and AN supported the focus group work and helped interpret the findings of the study.

Competing interests: The authors had no financial relationships with any organisations that might have an interest in the submitted work in the previous 3 years and no other relationships or activities that could appear to have influenced the submitted work.

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FIGURE LEGENDS

Figure 1 – Adapted protocol for a randomised trial of Future Care Planning for patients with advanced heart disease: *Original flow diagram did not define the types of patients to be included, the threshold mortality risk for eligibility and the control group intervention. This final and agreed version identifies patients admitted to an acute cardiology ward with either acute coronary syndrome or heart failure and will be screened for eligibility - 12 month mortality risk of 20% or greater at the time of discharge using the GRACE discharge score [8] or the EFFECT score [7]. Eligible patients need to survive to discharge and have capacity to consent for the study. Informal carers will also participate where identified by the patient. Proposed outcomes include quality of life assessed by questionnaire (EuroQoL-5D) and re-admissions to hospital. Patients randomised to early intervention will be interviewed prior to discharge and those randomised to delayed intervention will receive the same interview 12 weeks following discharge.*

Figure 2 – Future Care Plan Intervention : *the intervention will last for 12 weeks. Patients randomised to early intervention will have a 1 hour interview with a cardiologist prior to discharge where they will discuss their heart condition, other medical conditions and their concerns and plans for the future. The cardiologist, trained in Advanced Communication Skills, will aim to address a range of issues including (1) a future care plan , agreed with the patient and their carer, which includes advice to Healthcare professionals about what could and should be done if the patient's condition deteriorates once again, (2) whether the patient and their family have arranged Power of Attorney (or similar), (3) whether the patient wishes to consider the issue of DNACPR (Do Not Attempt Cardiopulmonary Resuscitation), (4) whether the patient wishes to express a preferred place of care should their condition deteri-*

orate again, (5) whether the patient would consider being added to their GP's Palliative Care register and (6) permission to share the content of the Future Care Plan electronically with out-of-hours medical services (NHS24/NHS Direct). Patients will also be encouraged to complete "Thinking Ahead Plan", a locally developed patient-held anticipatory care plan (see appendix 2). Patients randomised to delayed intervention will undergo the same interview 12 weeks after discharge. During the follow-up period of 12 weeks, the trial nurse will visit the patient/carer in their home at 6 weeks and 12 weeks after the baseline interview in order to update the FCP with any changes and to review any DNACPR orders or make any necessary changes to the plan of care. An updated version of the FCP record will be communicated in writing to the GP at each of these time points. The nurse will be available to communicate with the patient by telephone at any time and will ensure optimal communication and coordination of care between GP, cardiologist, community-based nursing teams and palliative care teams (where appropriate).

Figure 1

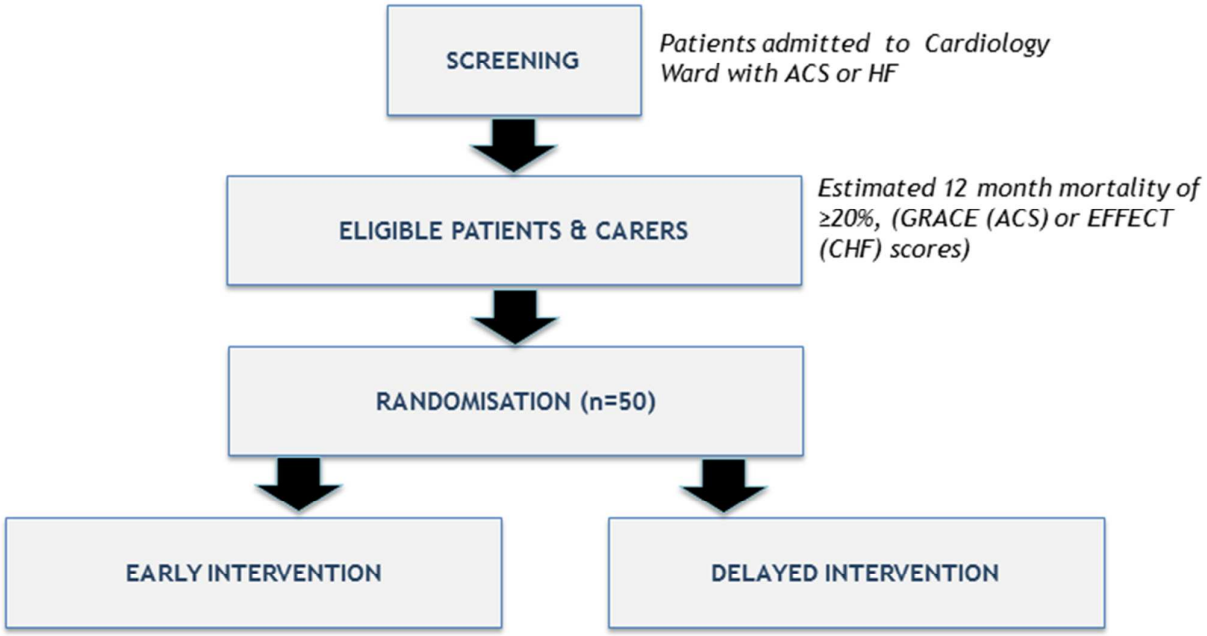
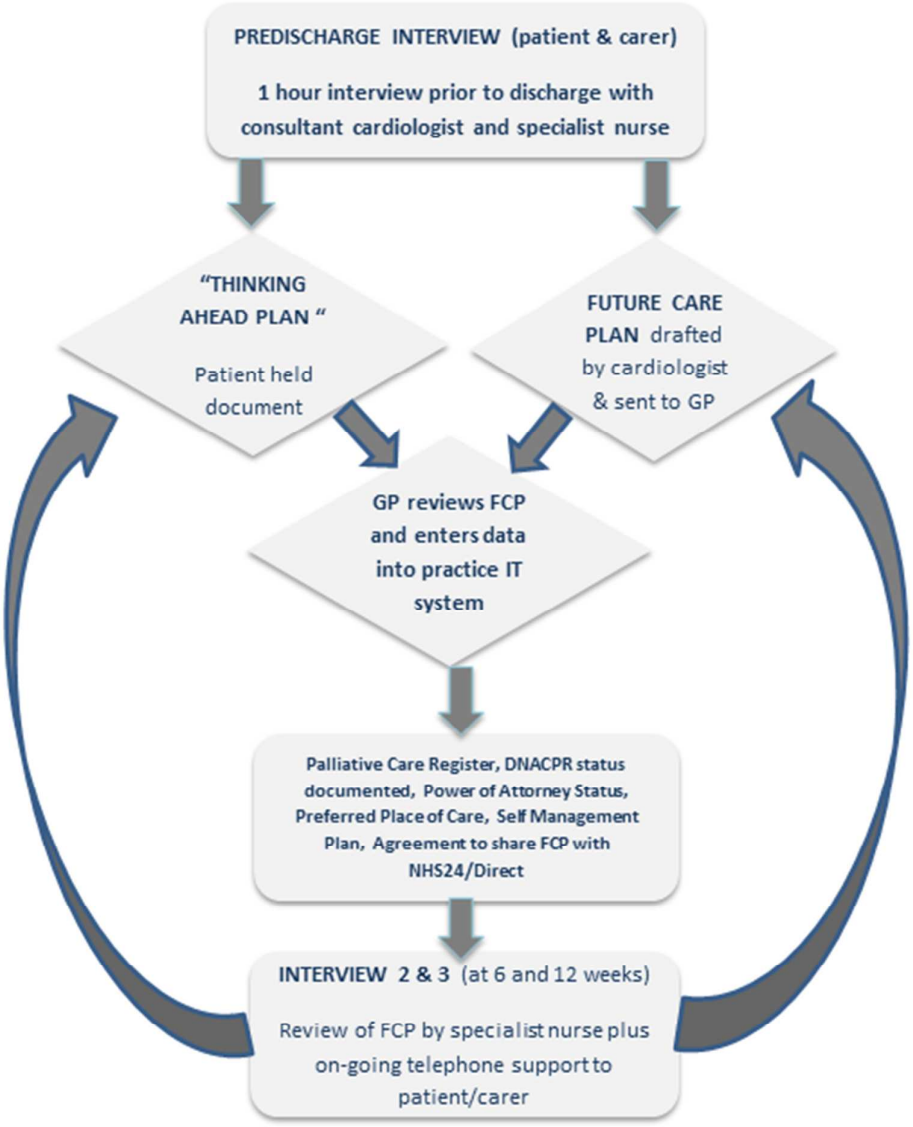


Figure 2


PREDISCHARGE INTERVIEW (patient & carer)
1 hour interview prior to discharge with consultant cardiologist and specialist nurse
"THINKING AHEAD PLAN "
Patient held document
FUTURE CARE PLAN drafted by cardiologist & sent to GP
GP reviews FCP and enters data into practice IT system
Palliative Care Register, DNACPR status documented, Power of Attorney Status, Preferred Place of Care, Self Management Plan, Agreement to share FCP with NHS24/Direct
INTERVIEW 2 & 3 (at 6 and 12 weeks)
Review of FCP by specialist nurse plus on-going telephone support to patient/carer

Appendix 1A

Interview topic guide for patients/carers– modelling phase

Future Care planning for people with advanced heart disease

This interview is part of a research study funded by Marie Curie Cancer Research which aims to test new ways of providing care for people with advanced heart disease. The first phase of the study involves seeking views and comments from people who have heart disease and their families.

The aim of this guide is to support a structured approach to interviews and focus groups associated with the research study. The suggested topics are intended to provide a broad framework to encourage discussion and comment.

The interviewer will introduce himself/herself to the interviewee and explain the purpose of the interview. The interviewer will check that the consent form has been signed and that the interviewee remains in agreement to take part and that the interview can be recorded.

Do you feel that patients with advanced heart disease have adequate opportunity to discuss their condition, its treatment and their outlook with healthcare staff generally? What factors should trigger such discussions? What are the barriers to this? What things help? When is the best time to discuss these issues?

Do think it would be helpful to create a care-plan for patients with advanced heart disease? If so, when would be a good time to start thinking and talking about this? Do you think that these discussions should take place in hospital or at home? what details should be included in this plan? Who should be involved in completing and agreeing this plan? What would you perceive to be the barriers to including and excluding some items? Who do you think should have access to this care plan?

(Interviewer now shows example FCP)

In the example "Future Care Plan", do you feel the layout and content are appropriate?

In the example "Future Care Plan", which items do you feel should be included and which excluded? (see FCP example), Describe your concerns about these.

Do you have broader general concerns about this type of care plan and its uses by doctors and nurses.

In the example we have provided, should the updating and management of the contents be done by a community nurse, the GP or a hospital consultant or other people?

Should the patient and their family have a copy? How do we keep this updated?

In addition to, or instead of, this care plan, do you feel there is a need for more care or different care for people with advanced heart disease? If so, what do you think would help? Please give general and specific ideas if you have them.

We are planning to test new ways of providing care for people with advanced heart disease in a randomised research trial which will involve the use of the "care plan" discussed above combined with a special nurse to provide extra-supportive care . What are your views about doing such a research study? Do you think it is ethically acceptable for some people to have extra care services while others do not? Would you and your family have concerns about being involved in this type of research?

Appendix 1B

Interview topic guide for Healthcare professionals– modelling phase

Future Care planning for people with advanced heart disease

This interview is part of a research study funded by Marie Curie Cancer Research which aims to test new ways of providing supportive care for people with very advanced heart disease. The first phase of the study includes interviews with healthcare professionals to gather views on the design and delivery of the trial.

The aim of this guide is to support a structured approach to interviews and focus groups associated with the research study. The suggested topics are intended to provide a broad framework to encourage discussion and comment.

The interviewer will introduce himself/herself to the interviewee and explain the purpose of the interview. The interviewer will check that the consent form has been signed and that the interviewee remains in agreement to take part and that the interview can be recorded.

Do you feel that patients with advanced heart disease have adequate opportunity to discuss their condition, its treatment and their outlook with healthcare staff generally? What factors should trigger conversations with patients about this? What are the barriers to this? What things help? When is the best time to discuss these issues?

Do think it would be helpful to create a care-plan for patients with advanced heart disease? If so, what details should be included in this plan? Who should be involved in completing and agreeing this plan? What would you perceive to be the barriers to including and excluding some items? Who do you think should have access to this care plan?

(Interviewer now shows example FCP)

In the example "Future Care Plan", do you feel the layout and content are appropriate?

In the example "Future Care Plan", which items do you feel should be included and which excluded? (see FCP example), Describe your concerns about these.

Do you have broader general concerns about this type of care plan and its use by healthcare professionals?

In the example we have provided, should the updating and management of the contents be done by a community nurse, the GP or a hospital consultant or other people?

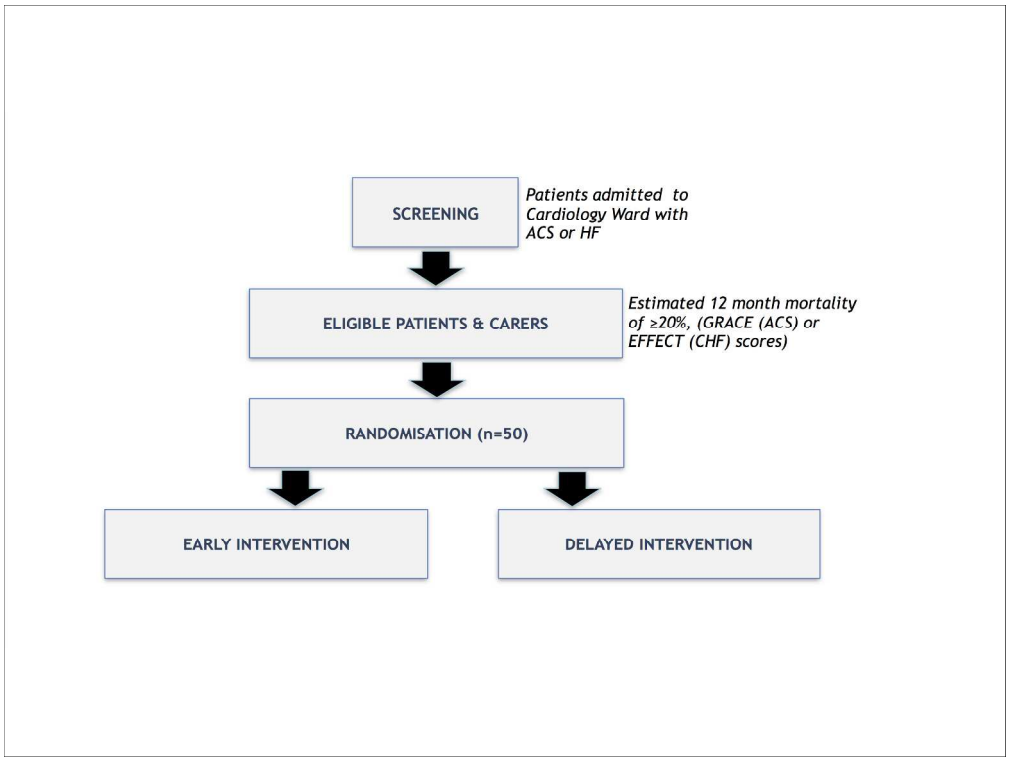
Should the patient and their family have a copy? How do we keep this updated?

In addition to, or instead of, this care plan, do you feel there is a need for more care or different care for people with advanced heart disease? If so, what do you think would help? Please give general and specific ideas if you have them.

We are planning to perform a small randomised trial which will involve the use of the "care plan" discussed above combined with a special nurse to provide extra-supportive care. What are your views about doing such a research study? Do you think it is ethically acceptable for some people to have extra care services while others do not? What are your views on a trial involving people with such advanced disease ?

In a trial of an intervention for people with advanced heart disease, what end points do you feel would be meaningful for patients and healthcare professionals.

Appendix 2 – “My Thinking Ahead Plan” – see attached file



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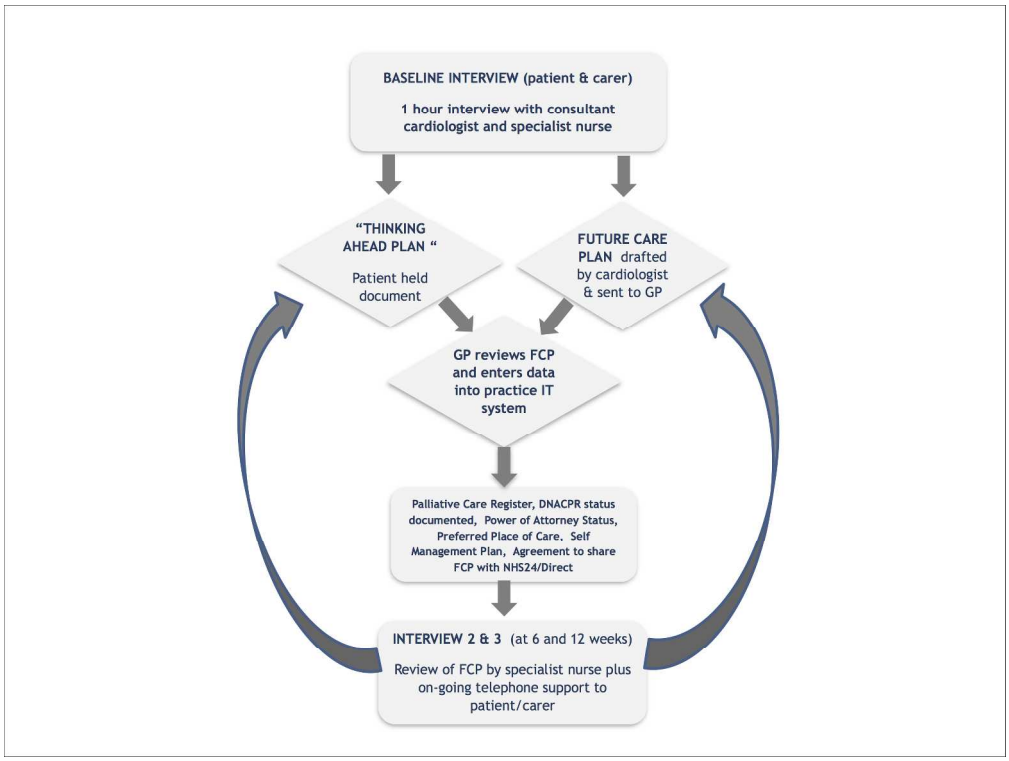

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Appendix 1A

Interview topic guide for patients/carers– modelling phase

Future Care planning for people with advanced heart disease

This interview is part of a research study funded by Marie Curie Cancer Research which aims to test new ways of providing care for people with advanced heart disease. The first phase of the study involves seeking views and comments from people who have heart disease and their families.

T*he aim of this guide is to support a structured approach to interviews and focus groups associated with the research study. The suggested topics are intended to provide a broad framework to encourage discussion and comment.*

The interviewer will introduce himself/herself to the interviewee and explain the purpose of the interview. The interviewer will check that the consent form has been signed and that the interviewee remains in agreement to take part and that the interview can be recorded.

1. Do you feel that patients with advanced heart disease have adequate opportunity to discuss their condition, its treatment and their outlook with healthcare staff generally? What factors should trigger such discussions? What are the barriers to this? What things help? When is the best time to discuss these issues?

2. Do think it would be helpful to create a care-plan for patients with advanced heart disease? If so, when would be a good time to start thinking and talking about this? Do you think that these discussions should take place in hospital or at home? what details should be included in this plan? Who should be involved in completing and agreeing this plan? What would you perceive to be the barriers to including and excluding some items? Who do you think should have access to this care plan?

   (Interviewer now shows example FCP)

3. In the example “Future Care Plan”, do you feel the layout and content are appropriate?

4. In the example “Future Care Plan”, which items do you feel should be included and which excluded? (see FCP example), Describe your concerns about these.

5. Do you have broader general concerns about this type of care plan and its uses by doctors and nurses?

6. In the example we have provided, should the updating and management of the contents be done by a community nurse, the GP or a hospital consultant or other people?

7. Should the patient and their family have a copy? How do we keep this updated?

8. In addition to, or instead of, this care plan, do you feel there is a need for more care or different care for people with advanced heart disease? If so, what do you think would help? Please give general and specific ideas if you have them.

9. We are planning to test new ways of providing care for people with advanced heart disease in a randomised research trial which will involve the use of the “care plan” discussed above combined with a special nurse to provide extra-supportive care . What are your views about doing such a research study? Do you think it is ethically acceptable for some people to have extra care services while others do not? Would you and your family have concerns about being involved in this type of research?

Appendix 1B

Interview topic guide for Healthcare professionals– modelling phase

Future Care planning for people with advanced heart disease

This interview is part of a research study funded by Marie Curie Cancer Research which aims to test new ways of providing supportive care for people with very advanced heart disease. The first phase of the study includes interviews with healthcare professionals to gather views on the design and delivery of the trial.

T*he aim of this guide is to support a structured approach to interviews and focus groups associated with the research study. The suggested topics are intended to provide a broad framework to encourage discussion and comment.*

The interviewer will introduce himself/herself to the interviewee and explain the purpose of the interview. The interviewer will check that the consent form has been signed and that the interviewee remains in agreement to take part and that the interview can be recorded.

1. Do you feel that patients with advanced heart disease have adequate opportunity to discuss their condition, its treatment and their outlook with healthcare staff generally? What factors should trigger conversations with patients about this? What are the barriers to this? What things help? When is the best time to discuss these issues?

2. Do think it would be helpful to create a care-plan for patients with advanced heart disease? If so, what details should be included in this plan? Who should be involved in completing and agreeing this plan? What would you perceive to be the barriers to including and excluding some items? Who do you think should have access to this care plan?

   (Interviewer now shows example FCP)

3. In the example “Future Care Plan”, do you feel the layout and content are appropriate?

4. In the example “Future Care Plan”, which items do you feel should be included and which excluded? (see FCP example), Describe your concerns about these.

5. Do you have broader general concerns about this type of care plan and its use by healthcare professionals?

6. In the example we have provided, should the updating and management of the contents be done by a community nurse, the GP or a hospital consultant or other people?

7. Should the patient and their family have a copy? How do we keep this updated?

8. In addition to, or instead of, this care plan, do you feel there is a need for more care or different care for people with advanced heart disease? If so, what do you think would help? Please give general and specific ideas if you have them.

9. We are planning to perform a small randomised trial which will involve the use of the “care plan” discussed above combined with a special nurse to provide extra-supportive care. What are your views about doing such a research study? Do you think it is ethically acceptable for some people to have extra care services while others do not? What are your views on a trial involving people with such advanced disease ?

10. In a trial of an intervention for people with advanced heart disease, what end points do you feel would be meaningful for patients and healthcare professionals.

THE UNIVERSITY of EDINBURGH

NHS Lothian

Thinking ahead
planning together

My name:

Some information about this plan

What is future care planning?

To be able to give the best care to people with serious illnesses we need to talk about what is important to each person and their family now and if things change in the future.

A 'future care plan' can help you to think about what things are important to you so you can talk about them with your family and friends.

The people who are looking after you would like to help you with your plan and talk about how we can use it to give you the best care we can.

What goes in the plan?

You can use the plan in any way you like. Most people start by writing things down that are important for them and their family at the moment. Some people like to put in information about the kind of care and treatment they would like to have now and in the future.

How do I fill it in?

The plan has some boxes which give you a few ideas about what you might want to think about. Some people use all the boxes, some just one or two. You might choose to add a box or page of your own. You can fill your plan bit by bit and you can change or add to it whenever you want.

Who can help me fill it in?

A few people like to fill in their plan by themselves. Many people do it with their family or close friends, or with help from the people who are looking after them. If someone does help you, you might want to write their name in at the end. It is important to talk about things you add or change in your plan with your family, and the people who are looking after you.

Where should I keep my plan?

You should keep your plan at home so you can show it to any health professionals who come to see you. It is a good idea to take your plan with you if you go to see your GP, or if you go to hospital for anything. This helps everyone who is involved with your care know what is important to you and your family.

Can I get a version for my computer?

Yes, if you would like a copy of the Thinking Ahead and Planning Together booklet to put on your computer so you can update it that way, please ask. It is still a good idea to print off a copy of the most up to date plan to have at home as well, so that you can take this to any appointments.

Important things right now

It is a good idea to start by thinking about how things are now.

What do people looking after me need to know about me and my family?

What would help me most?

Planning ahead

You might want to write about things you are looking forward to, important events that are coming up for you or your family, or things you want to do or carry on doing.

What could help me with these things?

Are there any other things that I might be able to do?

Looking after me well

The people looking after you want to make sure you have all the information you need about your health problems and would like to find out what is important to you.

Are there any things about my treatment and care now, or in the future that are important to me?

My concerns

You can write about any worries that you might have here. These could be about yourself, your family or even your pet.

Are there things that worry me now, or have I any worries about what might happen in the future?

Have I any plans about what we might do if any of these things did happen?

Things some people want to know more about:

Some people and their families like to know more about things that can be important when someone has a serious illness.

Some of these are:

Benefits advice

- Asking a person I can trust to speak for me and help make decisions about my health if in the future I am not able to myself (a Welfare Attorney)
- A living will or advance decision to refuse a specific treatment
- Cardiopulmonary resuscitation decisions (DNA CPR): attempting to restart a person's heart
- Making a will

Things I would like to ask about are:

Keeping track

Each time you write in this Plan, you might like to write down in this section the date and the name of anyone who helped you.

Useful Contacts

My GP's name and telephone:

My District Nurse's name and telephone:

My Chemist:

NHS24:

Other people involved in my care:

We would welcome any comments or suggestions about this booklet. Contact us...

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