Experiences of Being Maintained on a Ventricular Assist Device

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Table of Word Count

Thesis Section	Text	Appendices (Including references)	Total
Abstract	262	N/A	262
Literature Review	5,888	6,573	12,461
Research Paper	8,159	1,234	9,393
Critical Appraisal	3,777	587	4,364
Ethics Section	4,826	17,132	21,958
Totals	22,912	25,526	48,438

The word length of the thesis conforms to the permitted maximum.

Experiences of Being Maintained on a Ventricular Assist Device

Thesis Abstract

This thesis explores the experiences of patients receiving cardiac support from two different types of ventricular assist device (VAD). The literature review focuses on the decision-making experience of patients and caregivers considering implantation of a left ventricular assist device (LVAD). The LVAD is a type of long-term/durable VAD which enables patients to be discharged from hospital. The literature review employed a thematic synthesis of the qualitative literature arriving at three major themes Context, Mechanism and Outcome. The synthesis proposes that decision-making is affected by Context and Mechanisms for both patients and caregivers which in turn leads to the theme Outcome. Context and Mechanism can be better understood by healthcare professionals by the third theme of Outcome.

The research paper explores the experiences of patients who have undergone short-term ventricular assist device (ST-VAD) support as an emergency procedure. The short-term ventricular assist device provides temporary cardiac support while a patient is in hospital. Participants in the research paper completed interviews which were then analysed using an Interpretative Phenomenological Analysis framework. Four superordinate themes are presented following the participants journey; (1) Crisis and the fragile nature of life, (2) "You adapt, you've got no choice", (3) Moving on, (4) The change in me.

The final section of the thesis comprises the author's critical appraisal and reflections during the research process. The critical appraisal provides an opportunity for further reflection on the existential aspect of the VAD, the author's professional development in the area of clinical health psychology, involving participants in the research process and clinical implications.

Declaration

This thesis reports research undertaken between April 2016 and October 2017 for the Lancaster University Doctorate in Clinical Psychology. The work presented within this thesis is my own except for those instances where due reference has been given to other authors. This thesis has not been submitted for the award of a higher degree elsewhere.

Name: Eleanor Taylor

Signature

Date

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Section One: Literature Review

The Experiences of Patients and Carers in Decision-Making for Left Ventricular Assist Device: Thematic Synthesis of Qualitative Studies

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[1] See Appendix 1-A for Journal of Cardiovascular Nursing manuscript guidelines

Abstract

Background: The use of left ventricular assist device (LVAD) in end stage heart failure is increasingly common. The decision-making process can be complex for patients and caregivers and there has been a rise in qualitative studies exploring their experiences of this.

Objectives: The aim of this study was to synthesise the qualitative literature regarding patients and caregivers' experiences of decision-making related to LVAD.

Methods: A search of CINAHL, PubMed, Academic Search Complete, PsychINFO and Web of Science was conducted on the topic of LVAD and decision-making. The articles were synthesised using a formal process of thematic synthesis.

Results: Three domains surrounding LVAD decision-making were identified: Context, Mechanism and Outcome. Context and Mechanism related to specific thoughts and emotions which fed in to the decision. Outcome related to the thoughts and feelings following the decision.

Conclusions: Decision-making surrounding LVAD can be emotive and stressful and there may be factors involved that are not fully supported and understood by healthcare professionals. As well as the factors which make up Context and Mechanism, it is important for healthcare professionals to understand the "Outcome" described by patients and caregivers. It can be understood that Outcome can feedback into the understanding of Context and Mechanism and as such aid in tailoring support. Professionals can then support patients and caregivers in the most suitable ways. In this way, "Outcome" feeds back into the understanding of "Context" and "Mechanism".

Key Words: Left ventricular assist device, LVAD, Decision-making, Heart failure

According to the National Heart Failure Audit (2015-2016)[1], approximately 900,000 people in the United Kingdom have heart failure. Heart failure encompasses problems with heart function, due to the heart being unable to fill or empty effectively. In the UK the commonest reason for heart failure is the inability of the left ventricle to contract strongly enough to push the blood around the body. This leads to an increase in pressure in the left atrium which prevents the blood leaving the lungs. Symptoms of heart failure include breathlessness, fatigue and swollen ankles.[1] Patients with New York Heart Association (NYHA) class IV are considered as having end stage heart failure (exhibit symptoms of heart failure at rest) and are eligible for transplant or LVAD.[2] End stage heart failure is also typified by "discomfort with any physical activity"(p. 4) and the need for complete rest.[2]

Heart failure can be managed by pharmacological treatment and invasive procedures, such as heart transplant.[3] Heart transplant is the treatment of choice for end stage heart failure but there is a scarcity of donor organs. Amongst patients under the age of 60 between 10 and 15 patients per million need a heart transplant. There are sufficient donors for two per million which means that there are around 150 transplants a year in the UK.[4,5] Left ventricular assist devices (LVAD) were devised as a bridge to transplant or recovery for those awaiting a donor heart.[2] LVADs are implanted pumps that assist the heart in pumping blood throughout the body. These devices have a cable that connects the pump to a controller and power source which is worn outside of the body[6] see Figure 1. Left ventricular assist devices (LVADs) have become more common (as a bridge to transplant or recovery) due to the waiting periods for donor hearts or when transplantation is not appropriate (as a destination therapy (DT)).[6, 7] In the UK currently LVAD is not licensed as a destination therapy however in other countries such the USA it is. Between 1 April 2004 and 31 March 2014 438 patients were bridged to transplant with LVAD.[8]

Figure 1 here: The left ventricular assist device (LVAD)

These devices enable patients to be discharged from hospital. LVAD support is intended to extend life expectancy and improve quality of life for patients with chronic end-stage heart failure.[10] However, the patient can experience complications, including respiratory failure, ventricular arrhythmia, right heart failure, arterial arrhythmia, renal failure, device malfunction, stroke (haemorrhagic or thrombotic), gastrointestinal bleeding and driveline infection. [11] These are serious problems that can impact negatively on quality of life and prognosis for patients supported with LVAD. Ben-Gal and Jaarsma[12] state that the new generations of LVAD have a high success rate, however along with the potential medical complications there are lifestyle challenges involved. The patient needs to carry a battery pack, they must not get the battery pack and controller wet and they must avoid damage to the driveline exit site which restricts their movement in bed. The complications and changes to lifestyle need to be fully understood by patients and make the decision-making process of considering LVAD implantation very difficult especially when the alternative is, at best, restricted quality of life . This decision is illustrated in Figure 2.

Insert Figure 2.

A number of studies have been conducted into the impact of living with an LVAD on different aspects of life, such as the psychosocial impact,[13,14] life style adjustments[15,16] and quality of life.[17,18] More recently, a meta-synthesis was conducted into the adaptation and coping of patients with an LVAD.[19] It reported four distinct stages: Pre-LVAD, implant hospitalisation, early home adaptation and late home adaptation. During the Pre-LVAD stage patients spoke of wanting to relieve the heavy symptom burden due to heart failure (particularly shortness of breath and mobility over a prolonged time) and this reinforced the decision to have LVAD implanted. It was also reported that the undesirable nature of being dependent on another person and this dependence having an impact on the patient's role and

personal identity. The patients' pursuit of independence was often thwarted by complications following implantation.[19]

The perspective of caregivers has also received attention. A recent qualitative meta-synthesis[20] regarding caregivers' perceptions about caring for an adult LVAD patient reported three stages: "early stage", "middle stage" and "late stage". Within each domain there were different themes. Caregiving in the "early stage" involved an "emotional rollercoaster" when understanding how sick the patient was followed by their key role in decision-making regarding LVAD placement (theme: "decision: no option"). Once the LVAD was in place caregivers described where they learnt the necessary skills to look after the patient but were anxious about being able to manage emergencies at home (theme "leave it [the LVAD] at the hospital"). The "middle stage" covered the period at home for caregivers and patients. Caregivers described "fragility of the patient and the associated anxiety, fear and hypervigilance" followed by "recognition of a need to adapt". After caregivers adapted to their new caregiving role they recognised their "transformed life". The "Late stage" referred to the end of the LVAD; this varied between those who went on to have transplant or those who had LVAD fitted as destination therapy.

Rationale for the present review

Previous qualitative studies and reviews have focused on the impact of LVAD on the experiences of patients and caregivers, their quality of life, adaptation and coping.[12-20] However, there has been a recent rise in qualitative studies that have examined the experience and process of decision-making surrounding LVAD, for both patients and caregivers. Despite the growing importance of this process there has been no detailed synthesis of the data concerning the patient and caregiver experience of decision-making. This thematic synthesis[21] was therefore conducted to gain an overview of the decision-making experiences of patients and caregivers concerning LVAD. Therefore, the question this thematic synthesis

addressed is: "How do patients and caregivers experience and view decision-making related to LVAD?" This review will increase our understanding, which will help multidisciplinary healthcare professionals to support patients and their families' pre-decision-making, during, and post-decision-making surrounding LVAD.

Method

Data Search

Potential studies for this thematic synthesis were obtained through searching the following databases: CINAHL, PubMed, Academic Search Complete, PsychINFO and Web of Science. Appropriate search terms were used, augmented by using the thesaurus or MeSH terms, and the appropriate Boolean operators, as shown in Table 1. A librarian was consulted to help refine the search terms and strategies to ensure all relevant studies were found. The searches were conducted between the 26th and 31st December 2016.

Table 1: Search terms table

Inclusion and exclusion criteria

Articles were included in the thematic synthesis if they: (1) were written in English; (2) were published in peer-reviewed journals, as these are subject to quality assessment; (3) employed whole or in part qualitative methods with written quotes from patients or caregivers; (4) included the experiences of patients or caregivers in decision-making regarding or during LVAD. The articles were required to explore patient or caregiver experience of decision-making concerning LVAD as a theme or component of the results reported. Articles were excluded if their focus was on children because of the complexity of decision-making for parents of young children which would likely be different experiences for a spouse, parent or caregiver of an adult. If the article focused solely on end of life decision-making it was excluded from the analysis. Articles were also excluded if they: (1) did not elicit data from

patients or caregivers themselves; or (2) where the quotes might be attributed to healthcare professionals.

Results of search

The results of the search strategy are outlined in the PRISMA[22] diagram (Figure 2). Initially 678 articles were reviewed using their titles, abstracts, once duplicates were removed. Those that appeared to meet the criteria were subject to detailed analysis via reading full text to determine whether they met the inclusion criteria. Studies were not included if they were: not specifically about VAD, focused on children, were centre reports, reviews or medical commentaries, quantitative or systematic reviews with economic evaluation. Hand searching the references in the relevant articles yielded two articles that were suitable for inclusion, and two articles were excluded during full text reviewing. When multiple reports of the same study were found, the articles were compared and only selected if each article presented distinct findings based on different study aims and questions about the same material. Following the implementation of the inclusion and exclusion criteria nine articles were relevant. Hand searching of references yielded two further studies. This resulted in 11 papers reporting the experience of decision-making surrounding LVAD of patients (n=167, 22 were the same sample in two studies) and caregivers (n=97).

Figure 2: PRISMA flowchart

Table 2 provides details of the 11 articles [23-33] (aims, method, summary of findings). The experience of patients was reported in eight articles and caregivers in six articles. Nine of the articles originated from the USA where the use of LVAD is well established. All of the articles originated from jurisdictions where LVAD is licensed both as bridge to transplant and destination therapy. As they are qualitative studies it is not surprising that the largest

number of participants in any study was 45. The articles considered were not homogenous, differing in their purpose and study design.

Table 2: Article Characteristics

Quality Assessment

The Critical Appraisal Skills Programme (CASP)[34] was used to consider the quality of the studies used in the thematic synthesis. The CASP has two screening questions regarding clarity of the aims and appropriateness of the methodology, followed by eight quality questions that range from in depth methodological appropriateness to ethical relevance. Each of the studies passed the screening questions. Each paper was evaluated using the CASP items in conjunction with the rating system proposed by Downe[35] (Table 3).

Table 3: Researcher's CASP score

An experienced colleague and the researcher independently appraised each of the 11 selected papers and rated them according to the perceived reliability of their conclusions which were discussed as there was initially some discord in ratings. The researcher's views can be seen in Table 3 and the consensus is shown in Table 4.

Table 4: CASP Consensus

The CASP scores were not used to exclude papers but to compare, examine and critique the research to add context to the results.[36] The ratings given are related to the quality of reporting and not necessarily the quality of the study itself. The quality of the studies was good to excellent, with eight papers showing no or few flaws at consensus.

Thematic synthesis

The aim of this literature review was to analyse and synthesise published qualitative research to explore decision-making experiences of patients and caregivers. Thematic synthesis aims

to achieve analytical abstraction at a higher level by rigorously examining common and overlapping elements.[21] This approach takes into account the concerns of both meta-ethnography and grounded theory.[37] Free codes of findings are organized into 'descriptive' themes, which are then further interpreted to yield 'analytical' themes.[38] Thematic synthesis was employed to focus on patient and caregiver experiences of decision-making in the context of LVAD. This methodology was chosen for two reasons. Firstly, it enabled the analysis of substantive literature in decision-making across the duration of LVAD. Secondly, it enabled the description of influencing factors on decision-making for this population and the development of analytical themes that could be applied across the decision timeline.

From an epistemological perspective, thematic synthesis may be classified as critical realist, where our knowledge of reality is mediated by our perceptions and beliefs.[39] The technique involves the development of descriptive and analytical themes that aim to "go beyond the primary studies to generate new interpretive constructs, explanations, or hypotheses"[21] (p.1). The chosen thematic synthesis approach involved examining all the text labelled as 'results' or 'findings' in study reports. The three stage system of thematic synthesis was employed;[21] organising line by line codes into descriptive themes and developing analytical themes from them. The individual sources were input into and analysed in NVivo.[40] Figure 3 details the descriptive to analytical themes and Table 5 for theme translational table.

Stage 1: Each line of text is coded according to meaning and content. This technique allows the comparison and translation of concepts from one study to another. The use of line by line coding enabled the comparison and translation of concepts from one study to another.[41]

Stage 2: Similarities and differences between codes were noted, where appropriate codes were grouped and given meaningful labels. This process resulted in 17 descriptive themes.

Stage 3: Stage three involved generating analytical themes, going beyond the findings of the primary studies to generate additional concepts, understandings or hypotheses. This iterative process involved sorting and aggregating the descriptive themes until a clear pattern emerged with minimal overlap between the new themes.[21]

Figure 3: Descriptive to analytical themes

Table 5: Theme translational table

Synthesis

Three major themes, with sub-themes, were identified as being central to decision-making:

1. Context (illness and quality of life, medical professionals, emotions)
2. Mechanism (information and understanding, values)
3. Outcome (adjusting expectations, decision regret, optimism)

The relationship between the themes are illustrated in Figure 4. The themes of Context and Mechanism feed into the decision-making process. The Outcome theme concerns the way participants deal with consequences of their decision. For healthcare professionals understanding the Outcome of decision-making is important in helping the patient to make an informed decision.

Figure 4: Thematic Map

The themes which were extracted from the analysis of the data were “Context”, “Mechanism” and “Outcome”, while not precluding alternative interpretations, this fits most closely with a critical realist approach.[39] The strength of a critical realist approach is that it recognises that patients apply the evidence to their individual and personal circumstances. The information provided and understanding of that information is the “Mechanism,”

individual and personal circumstance is the "Context" and the "Outcome" reflects the effects of the decision.

Theme 1: Context

The theme "Context" encompassed the patients' current level of illness and quality of life as a way to understand decisions regarding the LVAD. Ten of the 11 papers reviewed described quality of life and illness impacting on decision-making.[23-32] Low quality of life and high symptom burden would suggest that the LVAD would be a necessary intervention; for example: *"...it [heart failure] was killing him. He had no strength. He had no quality of life. He was just existing*"[31] (p174). Those who declined LVAD believed that although their quality of life was decreasing, LVAD would not improve this sufficiently enough to justify going through the implantation of the LVAD.[29] Blumenthal-Barby and colleagues reported: *"In rare cases where patients heard about the LVAD option earlier and medical management was still an option, they preferred to postpone the decision until they absolutely had to*.[23] (p1185). Indeed, one decliner stated: *"I feel good…I haven't felt like I need something right now" [24]* (p838). Decliners also reported that further complications due to LVAD would deter them from the device:

> "And I know I'm going to have problems. So you know, like what's the point? And why would I want to deal with that you know? It's just…life is complicated enough as it is, you know? I don't need any more complications"[29] (p68).

The second important aspect of context was the advice provided by medical professionals described in nine of the 11 papers.[23,25,27-33] A good relationship between the medical team, patient and caregivers was necessary. Patient and caregiver decision-making was "*rooted in conversation with their health care team*"[33] (p370) and decisions were often guided by the

good faith, trust and confidence that patients and caregivers had in the medical team. Indeed, Blumenthal-Barby and colleagues quoted the following participant in their study:

> "They said that the LVAD is probably the best way to go. And I trust these doctors with his life. And when they said that, that's what we decided. I didn't really ask for statistics. I just went with what they said. They said it would work, so I trusted them"[23] (p1185).

The way in which the LVAD was explained was also an important factor for patients and caregivers: "*I was able to think over the need of implanting an LVAD, because doctors did not communicate this option in an aggressive way; they described its potential as a bridge to transplant"*[32] (p224).

The third aspect of context was the emotional nature of making decisions and the stress and anxiety described by patients and caregivers. Caregivers felt less fear and anxiety when the final decision was made by the patient. It was described that "*emotion was pervasive*"[29] (p68) and *"patients became emotional and even shed tears during their interviews when recalling the decision-making time period" [30]* (p378) but less was understood about the mechanism of emotion during the decision-making process and as such this could be seen as context. Emotion was present for those who accepted and declined the LVAD. One decliner stated; "*I just said, when it's my time I'm ready. (starting to choke up…cry). I mean I know what's on the other side. So it doesn't really bother me" [30]*(p377). Furthermore at times emotions were unspoken:

> "At the time of decision-making, most caregivers reported feeling [destination therapy] LVAD would offer the patient more time and improved quality of life. Less often articulated was the fear that the patient would not survive surgery or would experience persistent complications" [31] (p174).

Theme 2: "Mechanism"

The theme "Mechanism" encompassed the thoughts, feelings and attitudes of patients and their caregivers making decisions, whether the decision was to accept or decline an LVAD. Ten of the eleven reviewed papers discussed aspects of the mechanisms of decision-making.[23,24,26-33] Decision makers tended to fall into two categories, those who were reflexive and would make a decision without deliberation and those who were reflective who would weigh up the risks and benefits of the decision. Thus, according to McIlvennan and colleagues:

> "nearly all patients clearly fell into one of two decision-making approaches: (1) an automatic process of decision-making where fear of death and a singular focus on [destination therapy] LVAD as a chance to prolong life over-rode any weighing of additional risks and benefits and (2) a reflective process where participants reasoned through risks and benefits of [destination therapy] LVAD"[30] (p77).

Information and understanding

Seven articles reviewed [23,24,26,28-30,33] described the nature of information sharing and understanding of this. For patients, they described the impact of medication and illness on receiving and understanding medication.[26,28,30] During decision-making patients and caregivers described that there was a lot of information to take in and people often felt overloaded by the amount and technical nature of the information. One caregiver said:

> "Well, I mean, I hear what he said. They did explain it and they had a video that explained what the VAD was and everything. The gist of it was that he was too sick to understand it. And I was too tired to totally get the gist of it. I mean you understood. I don't think he did"[26] (p811).

There were benefits for caregivers being present when information was discussed, as Blumenthal-Barby and colleagues reported:

> "The doctor would say stuff and I would hear what I thought the doctor said. But me hearing it and then trying to tell her [my wife] —I'm telling her what I thought I heard. So, by the time it gets back around to the doctor, he's confused and we're all confused"[23] (p1186).

Caregivers were often the people who helped patients to receive and translate the information that was given regarding decisions. *"I have been through so many things with my husband, and I write everything down, and I research. You see this book [referring to book of notes]? It's too important. That's my husband's life"* [23] (p1186). Patients and caregivers described that hearing from others both before and after LVAD implantation was important in the decision-making process. Indeed, *"talking to other patients who are living with [LVAD for destination therapy] was cited as the most valuable information one could receive*" [33] (p372).

Overall caregivers were grateful for the information shared. Patients and caregivers, when asked, described a range of informational needs regarding LVAD placement including change to lifestyle, complications, prognosis and financial.[23] Lifestyle included aspects such as changes to mobility, impact on hobbies, the prospect of being a burden or losing independence and medication regimes. Information needs regarding complications included infections, bleeding and what to do in an emergency. Aspects of prognosis that patients and caregivers wanted information about included life expectancy without the VAD, length of LVAD treatment and probability of transplant. In terms of financial information, patients and caregivers felt they need to know about out of pocket costs, changes to work life and changes to insurance cost.

Values

Values played a strong role in decision-making as described in nine of the 11 articles.[23,24,27-33] Values related to being able to engage with the world and increase quality of life, to live longer for family, to be with family, and bodily integrity including not wanting to be "opened up" or choosing an LVAD as it enabled them to "keep the same heart".[23,24] For caregivers there was a struggle between wanting the patient to live and respecting the patient's decision:

> "Factors included apprehension about being widowed, a need for help with responsibilities, such as raising grandchildren, or the perceived inability of a family with other recent trauma to cope with further loss. In contrast, a few caregivers focused heavily on their belief that this was an extremely personal decision, and the patient should not be influenced by others' opinions" [31](p175).

One of the most frequently discussed aspects of decision-making was that "*there was no alternative*" and "*you either want to live or you don't*"[23] (p1185). For some patients and caregivers, LVAD signified the only option for patients to continue to live. For those who declined the LVAD they believed that "*death was an acceptable alternative to continuing a life of pain or suffering*"[30] (p377). McIlvennan and colleagues stated that those who used a reflective decision process "*viewed death as an option worthy of consideration, examined the meaning of their lives, and reflected on their values, particularly around quality versus quantity of life preferences*"[30] (p377). Magid and colleagues described that both accepters and decliners of LVAD wanted to relieve distress. However, acceptors felt that the LVAD would enable this, "*I wanted to be alive or dead. I don't like to be sick"*[29] (p67), whereas decliners felt that the LVAD would not "*...you are coughing and choking and one day you are up and the next day you're down. It's just… I've had enough of it"*[29] (p67).

Further value related influences included: spirituality, finances, and the media - the Cheyney effect;[29,30] McIlvennan and colleagues reported that one patient had said *"...it*

wasn't really a deciding factor…but I found out that Vice-President Cheyney had an LVAD in him and he had it for 12 years before he had a heart transplant…that is a pretty good indication there that it would work" [30](p378) the information stated by patients in terms of the media was not always accurate. Further values reported by decliners included LVAD effecting mobility, it being an experimental intervention, and concerns that it would affect their chance of receiving a heart transplant. [24]

Theme 3: Outcome

The theme "Outcome" encompassed the thoughts, feelings and attitudes of patients and caregivers following the decision. Ten of the eleven articles reviewed reported experiences about the outcome following decision-making. [23, 25-33] Caregivers who had the final decision due to patient illness reported a sense a burden and uneasiness in terms of responsibility for making the right decision;[25,27,31] "*Wondering if I was doing the right thing …either way it turned out, I was the one that was going to take the brunt of everything, which was scary*"[25] (p145). For patients, there was low reported decision regret if the decision made was consistent with their values.[23] Decision regret was connected to continued illness following LVAD decision. There was a sense that the decision to proceed with LVAD was "just the beginning" and that life was not automatically easier once LVAD was in place. Indeed, the "Outcome" theme related to patients and caregivers needing to adjust expectations following decision-making. When searching for information, patients and caregivers reported that many of the stories online and in the media reported people "returning to normality". For example, Dick Cheyney was reported to be living well following LVAD implantation and subsequent heart transplant in 2012 which lead to the "Cheyney Effect" and a sense of security for accepting the device.[30]

Adjusting expectations included reframing what "good health" meant now the LVAD was implanted. Patients and caregivers expected to be feeling better following LVAD

implantation, *"no…um I expected to be better. I am not as better as I expected. It is not coming as fast as I want, but I'm told by the professionals that I am on target"* [29](p68).

Kitko and colleagues found that participants described "*an improved quality of life and decreased symptom burden in the post implantation*"[28] (p97) but did not feel that the LVAD had met their expectations. Optimism, a positive attitude and dedicated caregiver aided patients post-LVAD implant; Ottenberg and colleagues reported "*daily frustrations were tempered by an optimistic spirit and a willingness to be patient with the recovery process*"[33] (p371). Adapting to the changes brought by the LVAD required resilience.

There was a sense that patients hoped that the LVAD would lead to being symptom free however there were setbacks and barriers in recovery and "good health" such as infections and continuing symptoms.[33] These barriers were disheartening for patients and caregivers. Patients could sometimes remember being told there were risks to the LVAD but this had not been taken on board at the time, "*I have had as many admissions with my heart failure. I remember them telling me risks but not sure I was listening"*[28] (p97*)*. Although disheartened by their experience, there was a sense that, for those who had accepted the device, they were "*happy to be alive*"[28] (p97). Caregivers reflected on their experience of living with an LVAD recipient. Although there was some disappointment at the outcome even those who were involved in the decision-making process appeared pragmatic:

> "not that I would change my decision but I had to make it without him. He was so sick, he was out of it. The times he is not doing well [with the LVAD], I feel guilty, I wonder if he would have made the same decision"[27] (p198).

For those who felt "well" and had not had a number of complications there was a sense that feeling well might not last. Articles also reported patients starting to outlive the expectancy of the device. For those where LVAD was destination therapy, uncertainty was

related to no further treatment options. For those hoping for transplant there was uncertainty as to whether they would be eligible:

> "I received the LVAD as a bridge to transplant…I am medically stable and that is good, but now I am not moving on the transplant list … the LVAD is really a double-edge sword because I feel like it is me keeping from getting a heart"[28] (p97).

For those who declined LVAD, adjusting expectations included revisiting the initial decision to decline the LVAD: "*These candidates explained that, although they made their initial decision reflexively, they were willing to revisit their decision once medical management no longer provided relief*"[24] (p837).

Discussion

The current synthesis describes three themes involved with decision-making surrounding LVAD. The themes "Context" and "Mechanism" feed into the decision-making process and the theme "Outcome" refers to the thoughts and feelings following decision. It is important for healthcare professionals to understand the "Outcome" described by patients and caregivers as this can aid the professionals in supporting patients and caregivers in the most suitable ways. In this way, "Outcome" feeds back into the understanding of "Context" and "Mechanism".

McIlvennan, and colleagues[42] interviewed mechanical circulatory support (MCS) coordinators regarding the preimplantation decision process. These healthcare professionals spoke of the complicated decision that patients make and believed that for optimal decision-making to occur three central components were required:

> "1) decision support with early introduction of [destination therapy] LVAD therapy and alternative options, 2) an iterative process and multidisciplinary team and 3) a

careful approach balancing tension between conveying enough detail about the process yet not overwhelming patients"[42] (p222).

Sagin and colleagues[43] describe the involvement of palliative care specialists in the decision-making phases of LVAD and the increased acknowledgement for the need of advanced care planning from the beginning. In line with this synthesis and studies with healthcare professionals, the timing of information regarding LVAD needs to happen sooner in the heart failure journey. Participants often reported being too sick or overwhelmed to fully comprehend information they were given about the LVAD. By not fully understanding the consequences of information this could lead to decision regret and the need to adjust expectations of life with an LVAD. If information was provided sooner it would enable a more collaborative, balanced decision. During this process, it would be important to include clear discussions regarding end of life care. Although in the UK, LVAD is used as a bridge to transplant, not all patients will recover sufficiently or reach candidacy for transplant.

Edlund and colleagues[44] conducted a questionnaire study to investigate patient's understandings of the LVAD. They reported that patients struggled to understand the procedure and device that they are consenting to which may be heightened for those with lower levels of verbal ability. Information needs to be provided in a range of formats with a balanced view regarding risks and benefits. As discussed in the synthesis, the role of peers would be highly beneficial to the process and enable patients and caregivers to have a clear understanding of the life adjustments that might take place.

Within the perspective piece by Boothroyd and colleagues[45] they propose a model of key elements of informed decision-making. Within this they suggest that informed decision-making should include the following: 1) the timing of discussions should occur prior to implantation and be revisited as situations change, 2) discussions should include multi-

disciplinary healthcare professionals, family/caregivers and peer mentors as well as the patient, 3) information should include risks and benefits in both physical and quality of life aspects for patients and caregivers, 4) information should be clear, up to date and patient preferences respected.

The meta-synthesis regarding adaptation and coping for patients with LVAD[19] highlighted the use of emotion-focused and problem-focused coping. Emotion-focused coping included intentionally having a positive attitude, sense of humour and passing on knowledge and support to others going through LVAD implantation. Problem-focused coping related to building skills and routines to live as independently as possible. Both of these styles of coping can be challenged by unexpected complications such as infections or over-protection from caregivers and the impact on the patients' sense of control and autonomy. These different coping strategies are part of the context and mechanism of the decision-making process as discussed above. Healthcare professionals need to understand the context and mechanism as it applies to the individual patient and in understanding the differences in adjusting expectations which could be supported by person-centred healthcare from the outset.

Strengths and limitations of the review

This study incorporated the experiences of decision-making surrounding LVAD support, the choice particularly whether or not to have the device implanted, and used rigorous methods for systematic review that included a comprehensive search of published studies using predetermined criteria. Study reporting was assessed according to the CASP framework which allowed readers to judge for themselves the quality of included studies and generalisability to their own context. This study combined eligible studies of experiences in treatment decision-making from patients' and caregivers' perspectives in an attempt to achieve the higher level analytical abstraction that is aimed for in thematic synthesis.[21]

Reviewer one was from a clinical psychology background and reviewer two was an experienced reviewer from a general medical background. Although there was discord between the initial scores given by the reviewers both reviewers provided similar positive ratings for all the papers. There was a tendency for reviewer one to be more positive overall. These minor differences were resolved through discussion and consensus scores agreed for all papers. This may have been due to different application of the scoring system. The need for discussion ensured that the incision of some papers that might otherwise be excluded.

Ben Gal and Jaarsma[12] reported that there may be differences in how patients and families from a range of cultures might perceive the LVAD and the withdrawal process. This could reflect the value related to bodily integrity. As such, it would be beneficial for future research that looks specifically at the views of culturally and linguistically diverse people regarding decision-making about LVAD support. The way that the data has been aggregated by papers in this synthesis means that it is not possible to establish and comment on the cultural homogeneity of the sample.

As the majority of papers in the review originated from the USA broad claims about the generalisability of the results to the worldwide LVAD population should be avoided. The licensing of LVAD across countries is different. The majority of the LVAD decision-making studies highlight the licensing protocols within territories that allow LVAD as destination therapy. This does not mean that decision-making and LVAD information should not be shared in early stages. As in those countries that do not currently employ LVAD as destination therapy, there is still the chance that patients will live with LVAD in situ until the end of their life.

Conclusions

This thematic synthesis of qualitative studies on decision-making surrounding LVAD support shows that there are a number of factors involved in decision-making which may not be fully supported by healthcare professionals at this time. Factors influencing decisions included the emotive and stressful timing of decision which can inhibit the understanding of information which may lead later to decisional regret. This synthesis highlights the need for optimal timing for information and education regarding the LVAD and the need for peer mentors to be included in the education process.

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What's New?

- LVAD decision-making was understood by the Context (including illness and quality of life) and Mechanism (including patient's understanding of information).
- People are less likely to regret their decision if it is made in line with their values.
- Healthcare professionals should support patients and caregivers along the decision-making journey.

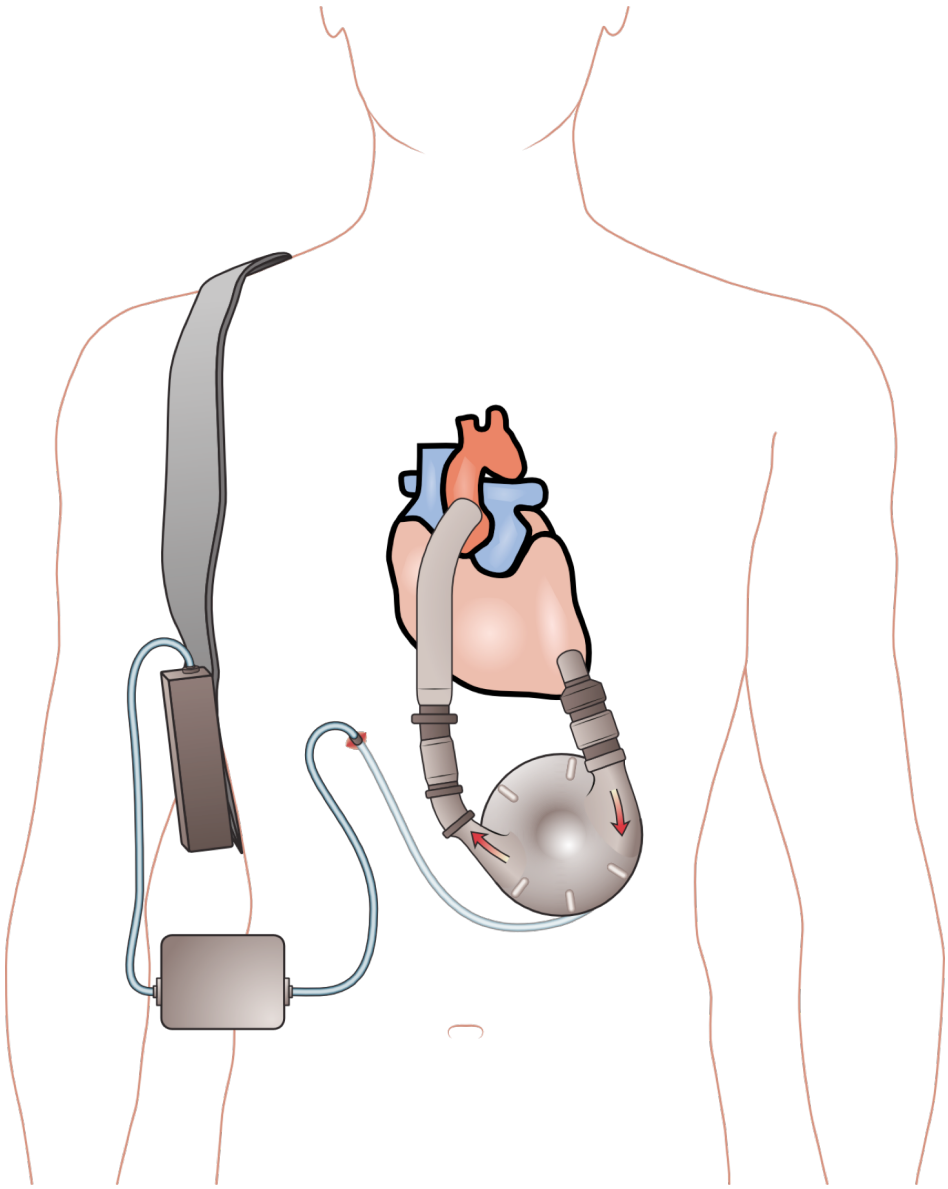

Figure 1. The left ventricular assist device (LVAD).
Ventricular Assist Device. Unmodified from Madhero88 (https://en.wikipedia.org/wiki/Ventricular_assist_device#/media/File:Ventricular_assist_device.png) , reproduced under the conditions Creative Commons Licence (https://creativecommons.org/licenses/by-sa/3.0/).
A more detailed but copyrighted picture is available from Rizzieri AG, Verheijde JL, Rady MY, McGregor JL. Ethical challenges with the left ventricular assist device as a destination therapy. Philos Ethics Humanit Med. 2008; 3(20): 1-15. https://doi.org/10.1186/1747-5341-3-20

Figure 2. Decision tree illustrating patient options and potential outcomes.

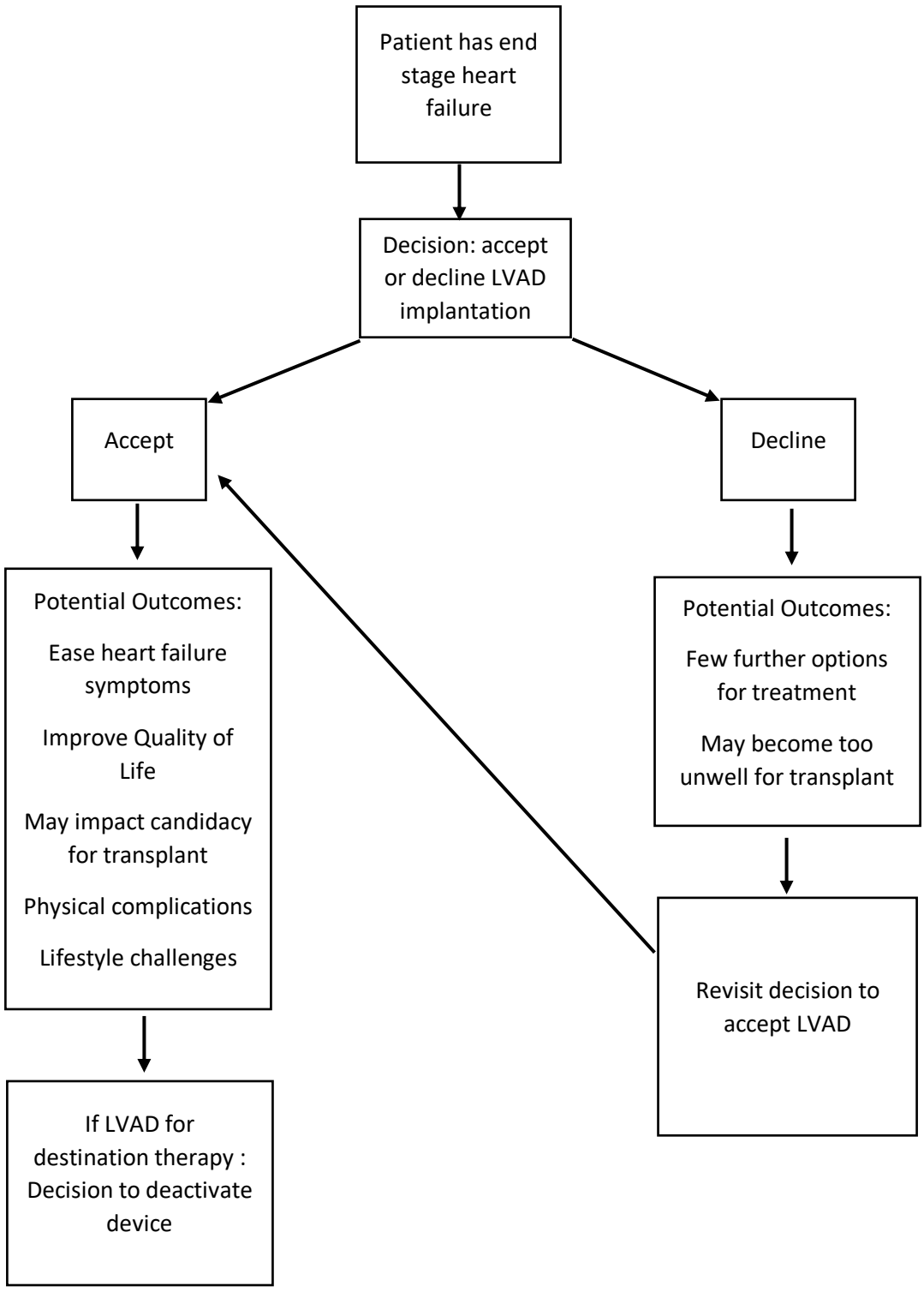

Table 1. Systematic Review Search Terms

	Heart Assist Device (…OR…)		Decision Making (…OR…)		Qualitative Research (…OR…)
Search terms (combined with Boolean terms 'OR' was used within columns and 'AND' was used across columns)	"heart-assist devices" (MeSH) VAD LVAD "Ventricular assist device" "Left ventricular assist device" "mechanical assist device" "heart assist device" "heart assist pump" "mechanical circulatory support" "bridge to transplant" "destination therapy"	AND	"Decision making" (MeSH) "Informed consent" (MeSH) Decision Consent "advanced care planning" "advanced directive" Choice	AND	"Qualitative Research" (MeSH) Qualitative Exploratory Descriptive "grounded theory" "thematic analysis" "content analysis" "interpretative phenomenological analysis" phenomenolog* narrative interview* "focus group" Questionnaire "lived experience" "life experience" Experience

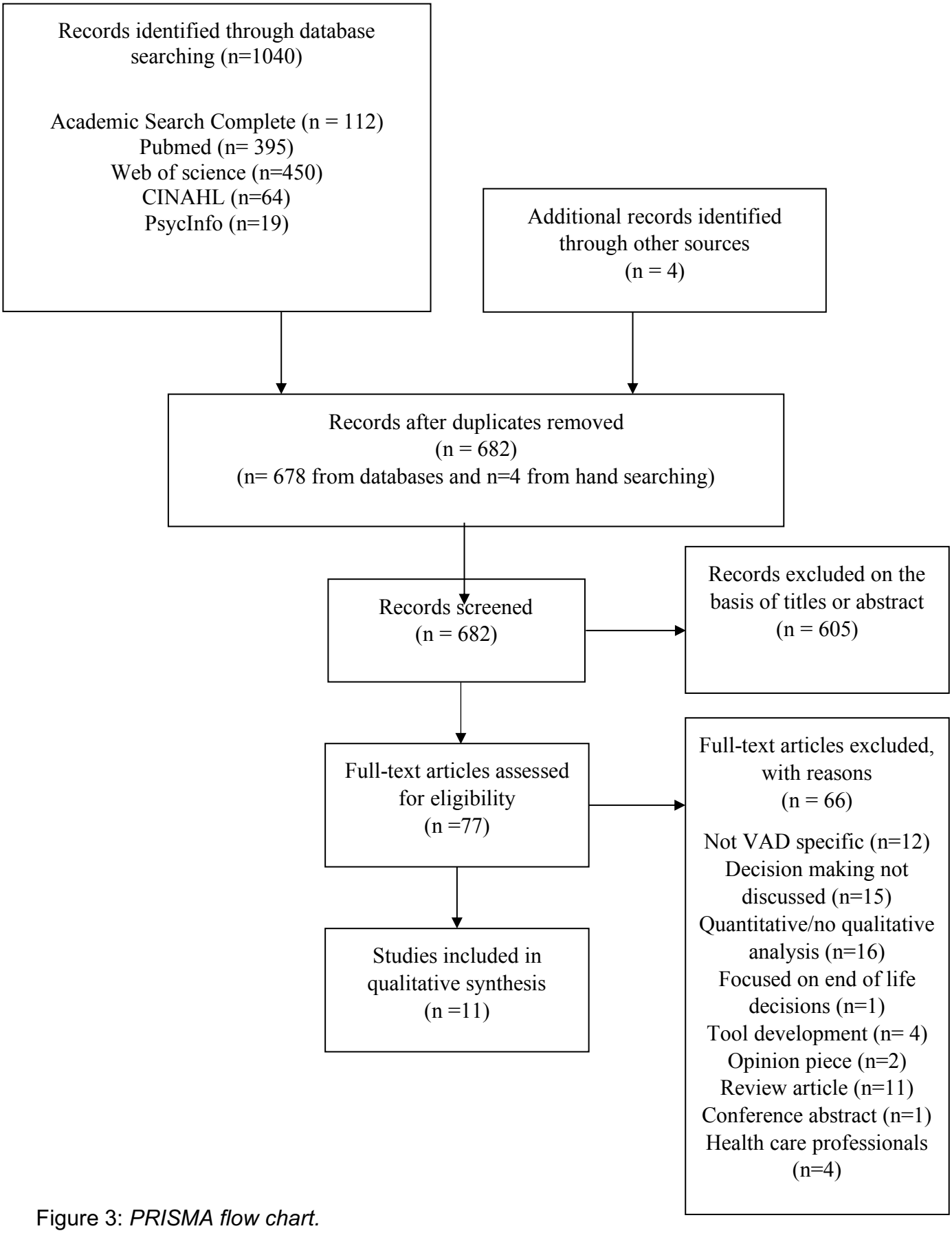

Figure 3: *PRISMA flow chart.*

Table 2. A Summary of the Included Articles in the Thematic Synthesis

Author, Date, Country	Aim of Study	Study design	Methods	Participants	Summary of Main Findings
Blumenthal-Barby et al, 2015, [23] USA	To investigate the decision-making process and informational and decisional needs of patients and their caregivers regarding LVAD placement.	Mixed methods, Interviews analysed using Grounded Theory; Decisional Regret Scale completed	Structured interviews, 40 in person, 5 by telephone, lasted between 12 to 87 minutes, digitally tape-recorded, transcribed verbatim	45 Candidates for treatment (15), patients currently with LVAD (15), caregivers (spouse, family member) of patients with LVAD (15), Included four pairs of patient-caregiver interviews	Theme 1: There was no decision to make Theme 2: Decisions were reflexive, made without deliberation Theme 3: Decisions were based on trust in physician Theme 4: Optimistic expectations regarding transplant Theme 5: Values are clear, include life extension, family and mobility Theme 6: A need to hear from other patients and caregivers Theme 7: A need for an involved and supportive clinical team and caregiver
Bruce et al, 2015 [24] USA	To understand how underlying perceptions inform the decision to decline LVAD	Qualitative	Structured interviews, audio recorded, transcribed verbatim	21 candidates who declined LVAD (8 BTT, 6 DT, 7 without designation), 11 of whom were identified prospectively and 10 identified retrospectively; 11 candidates persistently declined LVAD placement, with a median time of 175 days time	*Decision-Making Processes* Without deliberation and limited information Declination changes take many forms *Declination Factors* Perceiving negative effects of an LVAD on mobility Perceiving the LVAD as experimental

				from LVAD offered to interview; 10 candidates declined for an average of 224 days before agreeing to LVAD placement	Perceiving the LVAD as affecting transplantation Perceptions about illness severity Importance of bodily integrity
Kaan et al, 2010, [25] Canada	To describe the lived experience of caregivers of patients who were discharged home with a ventricular assist device.	Qualitative, grounded theory	Semi-structured interviews within focus groups.	13 caregivers of 9 patients discharged home with a ventricular assist device. 1 patient died on VAD, 2 explanted and 6 went on to transplant (2 went on to die following transplant)	Fear and Anxiety (including decision-making) Loss Burden (including decision-making) Coping (including decision-making)
Kirkpatrick et al, 2015, [26] USA	To characterise quality of life of caregivers and identify burdens and stressors with caregiving	Mixed methods, modified grounded theory, Caregiver QOL survey	Telephone interviews	42 caregivers interviews, 39 patients consented, 27 providers interviewed	Provider themes: Prerequisite for an LVAD: a competent caregiver to handle a "heavy burden" Specific requirements Emotional bind: caregivers during the decision-making process Extent of preparation Post-implantation social and psychologic burdens The value of psychological and social support
Kitko et al, 2013, [27] USA	To describe experiences of spousal caregivers of	Qualitative, Inductive methodology	Semi-structured interviews, phone interviews	10 caregivers (LVAD DT)	Adaptation within the role as a caregiver Caring for a spouse with heart failure

	patients with stage D heart failure from Pre-LVAD to Post-LVAD				Decision for LVAD implantation made Caring for a spouse with an LVAD-DT
Kitko et al, 2016, [28] USA	To examine patients' pre-implantation decision-making and pre and post-implantation expectations of LVAD	Longitudinal qualitative design, Descriptive thematic analysis	Semi-structured interviews, Participants were interviewed individually monthly for up to two years or until the patient's death	15 participants who received an LVAD, 5 implantation for DT, 10 implantation as BTT	Three consistent themes in both DT and BTT participants. Pre-implantation: No choice Post-implantation: I thought I would be doing better Post-implantation: I feel good, but now what?
Magid et al, 2016, [29] USA	To explore the influence of cognitive bias on the LVAD decision-making process	Qualitative, Framework analysis, inductive/deductive approach, reanalysed interview data from previous study (McIlvennan et al, 2014)	Semi-structured interviews	22 patients, 15 accepted, 7 declined	State dependence (high current state of suffering) Acceptors: • Anchoring • Availability • Optimism bias/affective forecasting • Halo effect Decliners: • Affective forecasting • Reflective reasoning

McIlvennan et al, 2014, [30] USA	To understand the decision-making processes of patients who accept or decline LVAD	Qualitative, Mixed inductive/deductive approach	Semi-structured interviews	22 patients, 15 accepted, 7 declined	Dominant decision processes: "there was no choice" versus "I thought about it an awful lot" Secondary influences: Severe illness Relationships Spirituality Finances Clinician Bias Media
McIlvennan et al, 2015, [31] USA	To understand the caregivers' experiences and identify their needs related to decision-making surrounding DT LVAD	Qualitative, Mixed inductive/deductive approach	Semi-structured interviews	17 caregivers, 16 caregivers of accepters of LVAD, 1 caregiver of LVAD decliner	Decision Context • Tension: hope and reality • Years of Poor Health • Sense of Urgency • Ineligibility for Transplant Decision Process • Tension: Wanting loved one to live and wanting to respect their wishes • Influences of relationships with the clinicians • Making the decision Decision Outcome • Tension: gratitude and a feeling of burden • Reflecting on the decision
Modica et al, 2015, [32] Italy	Investigate quality of life, psychological	Mixed methods	Quantitative questionnaires,	28 patients with an LVAD, 22 implantation	Concepts influencing LVAD acceptance: The characteristics of the device

	symptoms in conjunction with the emotional and cognitive reactions to LVAD implantation, and device acceptance and acceptability in the early period after implant.		Qualitative in-depth unstructured interviews	as BTT, 6 implantation as destination therapy.	The experience the disease The peculiar nature of the heart as diseased organ Doctor-patient communication The opportunity to share the experience Psychological characteristics of the patient
Ottenberg et al, 2014, [33] USA	To better understand the perceptions of patients about their care from before to after LVAD implant as DT	Qualitative, thematic analysis	In person semi-structured interviews, lasting 45 minutes, audio-recorded,	12 patients, median time from DT implantation to interview was 1.37 years, caregivers welcomed but not formally enrolled in the study	Theme 1: Preparedness planning Theme 2: new lease on life Theme 3: optimizing support networks Theme 4: systemic limitations Theme 5: reflections on time Theme 6: communication matters

Table 3. Researcher's Critical appraisal of study quality using the CASP qualitative appraisal tool.

Study	Research design	Sampling	Data collection	Reflexivity	Ethical issues	Data analysis	Findings	Value of research
Blumenthal-Barby et al, 2015	B	A	A	A	A	A	A	A
Bruce et al, 2015	B	A	B	B	A	B	B	A
Kaan et al 2010	A	A	B	B	C	B	A	A
Kirkpatrick et al, 2015	A	A	A	A	B	A	A	A
Kitko et al, 2013	A	A	A	A	B	A	A	A
Kitko et al, 2016	A	A	A	B	A	A	A	A
Magid et al, 2016	A	A	A	A	A	A	A	A
McIlvennan et al, 2014	A	A	A	A	A	A	A	A

McIlvennan et al, 2015	A	A	A	A	A	A	A	A
Modica et al 2014	B	B	B	C	B	B	B	B
Ottenberg et al, 2014	A	A	A	A	A	A	A	A

Quality rating: A- No or few flaws, high credibility, transferability, dependability and confirmability, B- some flaws unlikely to affect the quality, C- some flaws which may affect quality and D- significant flaws which are likely to affect credibility, transferability, dependability and confirmability of the study

Table 4: Consensus CASP Quality Scores

	Reviewer 1	Reviewer 2	Consensus
Blumenthal-Barby 2015	A	B	B
Bruce 2015	B-	A	A
Kaan, 2010	B	A	A
Kirkpatrick 2015	A	B-C	B
Kitko 2013	A	A-B	A
Kitko 2016	A	A-B	A
Magid 2016	AA	B	A
McIlvennan 2014	AA	B	A
McIlvennan 2015	AA	A-B	A
Modica 2014	B	B	B
Ottenberg 2014	AA	A-B	A

Quality rating: A- No or few flaws, high credibility, transferability, dependability and confirmability, B- some flaws unlikely to affect the quality, C- some flaws which may affect quality and D- significant flaws which are likely to affect credibility, transferability, dependability and confirmability of the study

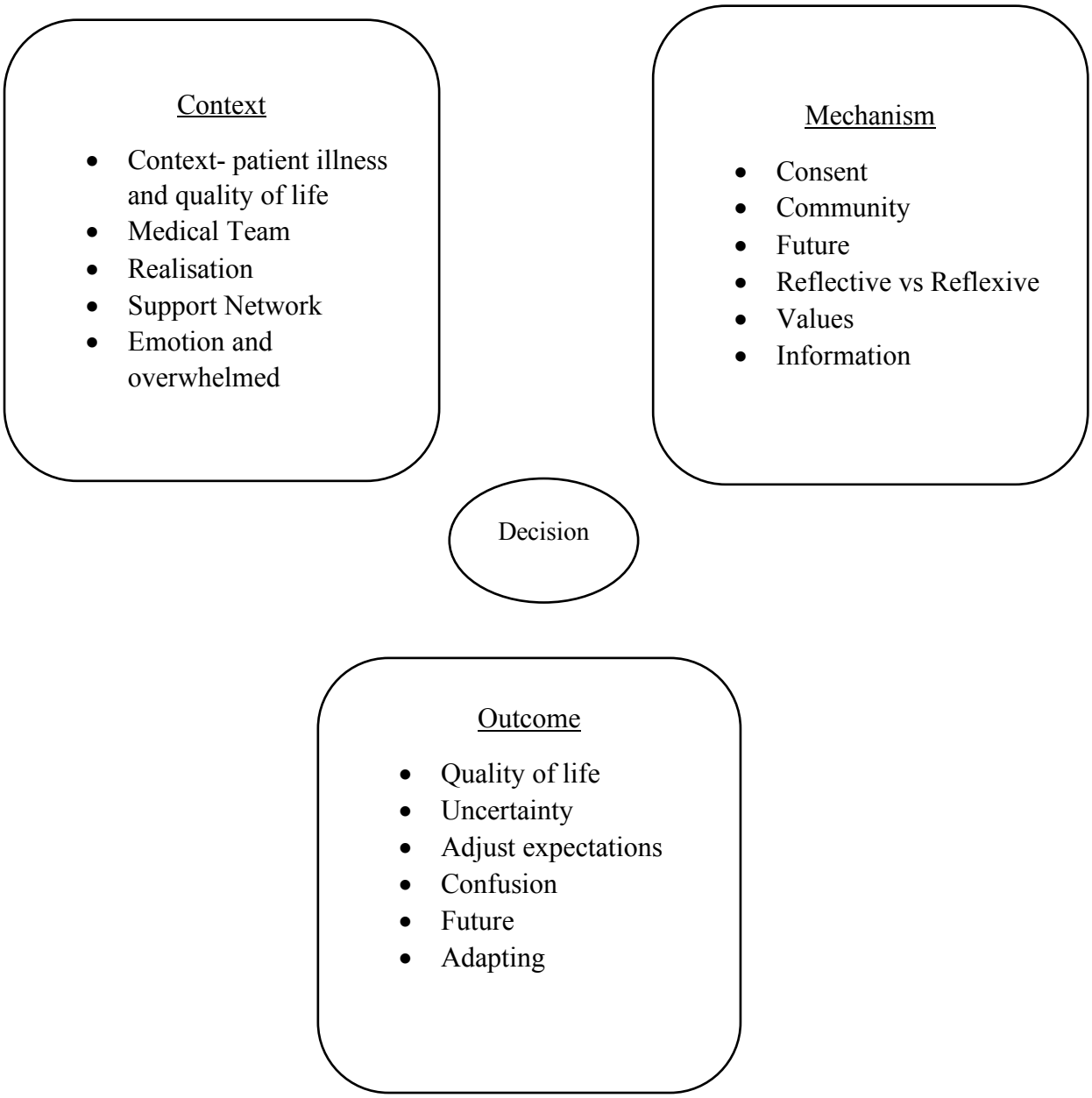

Figure 4. *Descriptive themes and how they relate to final analytical themes. Descriptive themes marked by bullet points*

Table 5: Theme Translational Table of Main Themes and Sub-themes and the related papers

	Theme one: Context			Theme two: Mechanism		Theme three: Outcome	
	Illness and quality of life	Medical professionals	Emotion	Information and understanding	Values	Adjusting expectations/ optimism	Decision Regret
Blumenthal-Barby 2015	X	X		X	X	X	X
Bruce 2015	X			X	X		
Kaan, 2010	X	X	X				X
Kirkpatrick 2015	X		X	X		X	X
Kitko 2013	X	X			X	X	X
Kitko 2016	X	X	X	X	X	X	
Magid 2016	X	X	X	X		X	
McIlvennan 2014	X	X	X		X		
McIlvennan 2015	X	X	X		X	X	X
Modica 2014	X	X	X		X	X	
Ottenberg 2014	X	X	X	X	X	X	

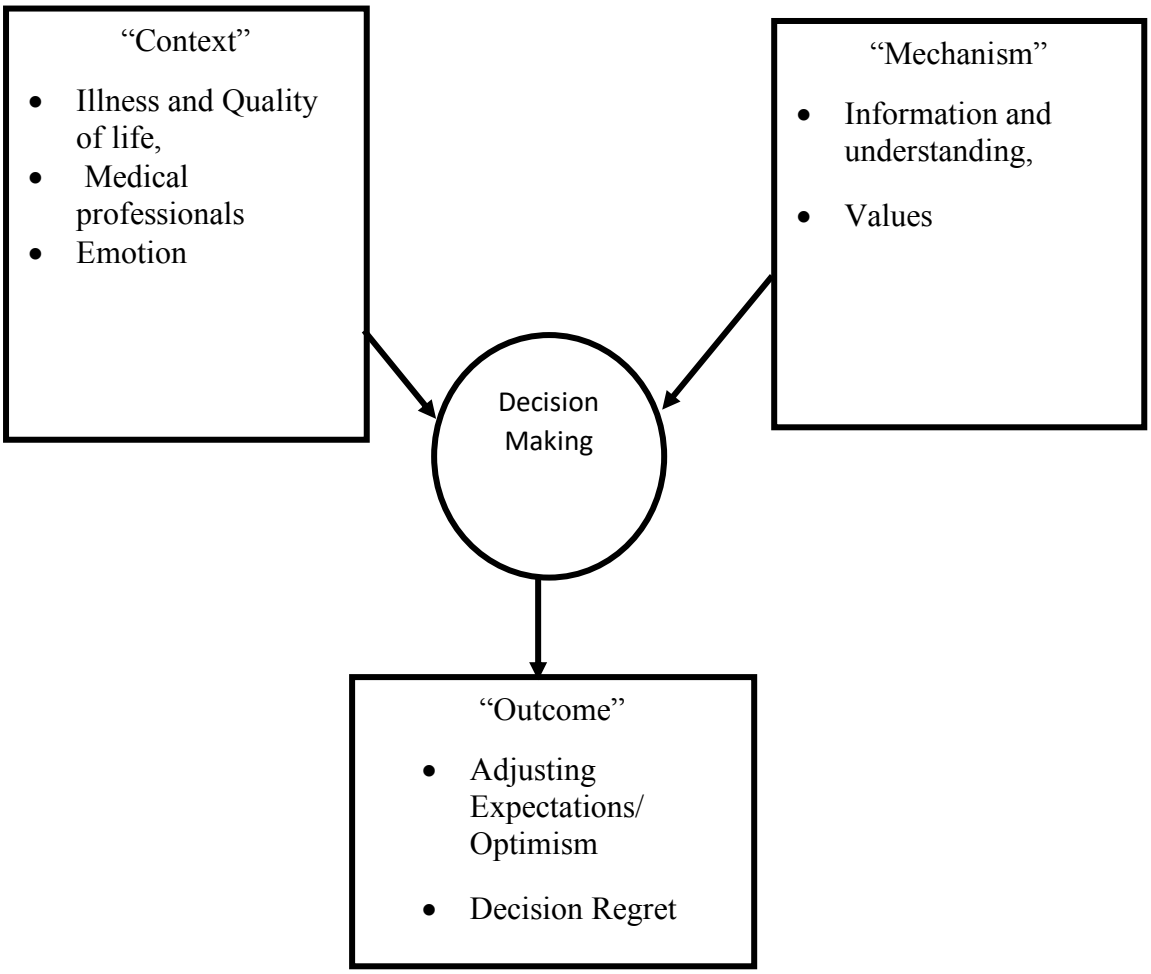

Figure 5. *Thematic Diagram Providing Themes with Accompanying Sub-themes.*

Appendix 1-A Journal Guidelines for The Journal of Cardiovascular Nursing

The primary objective of *The Journal of Cardiovascular Nursing* (JCN) is to foster expert, evidence-based clinical practice of cardiovascular nurses by publishing outstanding clinically relevant cardiovascular research, and state-of-the art, systematic reviews of the cardiovascular research literature. Issues address the physiological, psychological, and social responses of cardiovascular patients and families in a variety of environments.

Publication Policy

JCN publishes unsolicited articles (research reports, brief reports, systematic reviews of the literature, instrument development papers, and articles on innovations in practice) on any cardiovascular topic. We also publish Brief Reports, which are shorter versions of research articles and which can include pilot or preliminary results, negative findings, descriptions of study designs (and which can include baseline participant characteristics), validation of an existing instrument, and descriptions of unique clinical trial or intervention study methods. We do not publish quality improvement projects because the knowledge gained is not generalizable beyond the local setting.

Authors are encouraged to submit (1) original research articles and brief reports; (2) analytical, systematic reviews that codify existing knowledge; (3) instrument development papers and testing of the psychometric properties of new instruments; (4) clinical articles that synthesize information in a specific area or guide the practice of specialists in the field; and (5) articles describing innovations in practice that are evidence-based. The decision to accept or reject an article will be based on the judgment of the editors and of peer reviewers.

Manuscript Submission

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Doe JS, Lister FG, Lise JK, Kellert JL. Allied medical education. *JAMA*. 1975; 23(3):170–184.

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Doe JS, Justin MN, Gum KL, et al. Drug use during high school. *Am J Public Health*. 1976;64(1):12–22.

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Farber SD, Ball WD. *Neurorehabilitation: A Multisensory Approach.* Philadelphia, Pa: Saunders; 1982.

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Section Two: Research Paper

The Experiences of People Who Have Undergone Short-Term Ventricular Assist Device Support as an Emergency Procedure

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Word Count: 8,159

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Prepared for Journal of Cardiovascular Nursing[1]

[1] See Appendix 1-A (Section 1: Literature Review) for Journal of Cardiovascular Nursing manuscript guidelines

Abstract

Background: The short-term ventricular assist device (ST-VAD) can be used to stabilise patients following a cardiac event or deteriorating heart failure to enable recovery or understanding of the most effective next intervention. There are very few studies exploring the experience of having a ST-VAD implanted as an emergency procedure.

Objectives: The aim of this study was to explore the lived experiences of people following implant of a ST-VAD as an emergency procedure.

Methods: This qualitative study included eight participants (5 men and 3 women) who were interviewed and transcripts analysed using Interpretative Phenomenological Analysis.

Results: Participants described four superordinate themes regarding their journey with ST-VAD support: (1) Crisis and the fragile nature of life, (2) "You adapt, you've got no choice", (3) Moving on, and (4) The change in me.

Conclusions: The ST-VAD had a considerable effect on participants, but following the initial shock and crisis participants learned to adapt to the restrictions of the ST-VAD. Participants described moving on from the hospital to which they had become attached. Participants also reflected on positive changes and their changed priorities following the emergency procedure. This suggests strong links with existing posttraumatic growth literature.

Key words: Short-term ventricular assist device, heart-assist devices, posttraumatic growth, critical care

EXPERIENCE OF SHORT-TERM VENTRICULAR ASSIST DEVICE SUPPORT

A ventricular assist device (VAD) is a mechanical pump that is used to support heart function and blood flow for people who have heart failure. The device takes blood from a lower chamber of the heart (ventricle) and helps pump it to the body and vital organs, just as a healthy heart would.[1] Left ventricular assist devices (LVAD) support the left ventricle and hence pump blood around the body. Right ventricular assist devices (RVAD) support the right ventricle and pump blood to the lungs for oxygenation. The device assists the heart and differs from total artificial hearts.

In addition to the distinction between left and right VAD, there are further distinctions relating to short-term or longer-term use. Long-term VADs (LT-VAD) enable patients to be discharged from hospital as part of the device is implanted within the body (with a cable that connects the pump to a controller and power source which is worn outside the body).[2] The short-term VAD (ST-VAD) is an external cardiac device for people supported in intensive care. Short-term devices offer temporary circulatory support to stabilise patients with acute cardiogenic shock and to rest the heart;[3] this provides time to determine the most effective intervention. ST-VADs therefore offer a *bridge to decision* regarding the most useful intervention, which can include later removal, exchange to implantable LVAD, or heart transplant.[4] Between 1 April 2004 and 31 March 2014 179 patients received ST-VAD in the UK . 134 subsequent to critical cardiogenic shock and 42 were in progressive cardiovascular decline and the reasons for three patients were not reported.[5] There is no universal definition of “short-term VAD”; however, in line with Takayama and colleagues,[6] the current research will define ST-VAD as “mechanical circulatory support devices used only in the in-patient treatment setting” (p2). This study focuses on the experiences of people who have undergone ST-VAD support as an emergency procedure.

Although there is little research on ST-VAD, several studies have been conducted on LT-VAD and patients' experiences and perspectives of the device. These studies have reported that patients who temporarily or permanently rely on LT-VADs for end stage heart failure may face complex psychological, emotional and relational problems.[7] A literature review regarding quality of life for individuals with VAD[7] reported improvements in quality of life from 1-3 months post-implant as measured by health-related quality of life scales. However, they point out that emotional distress is often unexplored within these trials and further qualitative research could aid a better understanding of emotional health and the use of support.[8]

Qualitative research has explored the impact of LT-VADs on patients and their lives, including quality of life during and after VAD support, perceptions and concerns of patients and caregivers, and psychosocial and sexual concerns.[9] These studies report themes of adjustment,[9] mechanical dependence,[11,12] and perceived control.[13, 14] In a meta-synthesis, Abshire and colleagues[15] reported four distinct stages of adaptation of LVAD patients: 1) pre-LVAD, 2) implant and hospitalisation, 3) early home adaptation and 4) late home adaptation. Each stage included physical, psychological and social domain tasks to aid coping.

One of the studies included in the meta-synthesis conducted an interpretative phenomenological analysis (IPA) pilot study[9] with LT-VAD patients (N=4) and ST-VAD patients (N=2); those with LT-VAD all went on to have a transplant whereas those with ST-VAD went on to recovery. Two themes were reported: "Body and Self" and "Trust". Within the "body and self" theme there were sub-themes of shock, restrictions, scarring and infection. There were similarities in the journeys of each of their patients in that they experienced a physical decline and had to come to terms with an intrusive mechanical device keeping them alive but being constantly aware of vibration and noise.

The theme of "Trust" had two elements, the initial element of trusting the device and then the post-VAD period trusting either their own or donated heart. There had also been a lack of time to prepare family members who were shocked by the device when they first saw it. Due to the small sample size, it cannot be said whether the emergency nature of ST-VAD had a greater impact on patients' experiences than planned LT-VAD. Those who received the VAD device as an emergency procedure had no recollection of this period and needed to process their lack of control both cognitively and emotionally. This suggests that the emergency aspect of treatment may need to be better understood. During the implantation and hospitalisation phase participants reflected on their high dependency on others; this phase may be particularly pertinent for those in the current study.

ST-VAD shares similarities with Extracorporeal Membrane Oxygenation (ECMO). ECMO is a rescue intervention for patients who are at significant risk of dying from acute lung or heart failure where blood is actively pumped through an artificial lung that is external to the body and provides gas exchange and blood pressure support for hours to weeks until the underlying condition has resolved. The similarities with ST-VAD is that they are both short-term interventions that aim to *bridge* patients to the next intervention or recovery. Both interventions can be used in emergency situations and require the support of an intensive care unit. Tramm and colleagues[16] conducted a thematic analysis of experiences of ECMO survivors. Themes reported from this study included: (1) dealing with crisis, (2) being in ICU, (3) good and bad experiences, (4) ICU memory, (5) significant others and (6) existence today and tomorrow. Two themes are of relevance to the current study: "dealing with crisis" and "existence today and tomorrow". Within the "dealing with crisis" theme the authors described that most participants had experienced a crisis due to rapid symptom deterioration and emergency use of ECMO treatment. Within the "existence today and tomorrow" theme, all participants recognised and articulated their acute care as a matter of life and death.

Consequently, all participants expressed happiness about survival and thanked staff and helpers. Participants reported gaining new life perspectives and priorities such as living in the here and now or focusing on the future possibilities.

In summary, current research tends to focus on the impact for people with LT-VAD which may be a different experience from those who have a ST-VAD. ST-VADs have external pumps, the patient's mobility is severely limited and patients have intensive nursing support within a critical care environment. The ST-VAD offers critically "ill" patients a bridge to decision. Research has been conducted into the quality of life and experiences of people who have a LT-VAD often as a bridge to transplant, bridge to recovery or destination therapy, but little research has focused on the experience and psychological impact of ST-VAD implant.

Aim

The current study aims to examine the lived experiences of people following ST-VAD implant as an emergency procedure in transition to either heart transplant or LVAD. This will help to inform whether there might be a need for improved psychological care.

Methodology

Study Design

This study used an interpretative phenomenological analysis (IPA) approach to the collection, analysis and interpretation of the data.[17] One of the aims of IPA is to "explore in detail individual personal and lived experiences and to examine how participants are making sense of their personal and social worlds"[18] (p36); this encourages the researcher to focus on contexts and perspectives of individuals as well as a group. IPA provides a systematic and reflective way of the researcher working through five stages of learning.[19] Transcribing the

data corresponds to stage 1 (noticing), initial coding corresponds to stage 2 (making sense) and the forming of the superordinate themes corresponds to stage 3 (meaning making). The analytic process continues with stage 4 (working with meaning) as the individual participant responses are compared and contrasted and the final stage of the analysis is stage 5 (transformative learning). The role of the researcher in IPA is to make sense and make meaning rather than simply collecting and collating data.[20] The study did not aim to generate a theoretical-level account as in grounded theory.[17] Furthermore, grounded theory was not designed to discover theory related to people living outside their normal lives (p 106).[21] This study aimed to "add depth and purpose" which may not be offered by thematic analysis (p22).[20] At the point of data collection, the interview schedule and research approach had been informed by an IPA framework.

In accordance with the principles of IPA, the interview schedule was kept fairly open to allow participants to discuss their own personal experiences in relation to their journey through the emergency procedure to further intervention.

Participants

One of the main facets of IPA is that the sample recruited to be interviewed should be homogenous and closely defined to ensure similarity of experience being investigated and to allow for a detailed interpretative account of each of the participants interviewed. To conduct an in depth phenomenological analysis it is necessary to focus on a small sample to allow a rich analysis and interpretation to be performed (Figure 1).[22] Eight participants were recruited from one cardiothoracic transplant unit in the UK. Table 1 provides details of each participant including pseudonym, age, reason for ST-VAD, time on ST-VAD, time since ST-VAD and further intervention. Diagnosis was that reported by participants, it was not verified with the medical team to maintain confidentiality. Inclusion criteria were:

1) People who have undergone ST-VAD as an emergency procedure
2) People discharged from ICU and therefore outpatients
3) People who have capacity to give consent.

Potential participants were excluded from the study if they did not speak English or had special communication needs. A timeframe since discharge from hospital was not specified within the inclusion/exclusion criteria. At the time of the interviews, participants had been off ST-VAD for between one and 36 months. The bias of retrospective reporting is recognised but considered to be outweighed by the opportunity to interview patients who had managed the various challenges of post ST-VAD support.

Insert Figure 1

Insert Table 1

Recruitment

Recruitment took place in one of six specialised NHS sites providing multidisciplinary services to heart and lung transplant patients in the UK. Posters detailing the nature of the study were displayed in the hospital waiting room and participants were recruited by members of the cardiothoracic team. Potential participants were either given participant information packs while attending outpatient appointments, or they were posted if they were not due in for an appointment within a three-month timeframe. Potential participants were also telephoned by known clinicians to be informed of the study. This was the most reliable source of recruitment as all participants were recruited this way.

Participants were asked to complete an expression of interest form if they were interested in taking part in the study. Alternatively, participants could contact the chief investigator directly or consent for a member of the transplant team to pass on their contact

number. Following this, the chief investigator contacted those participants who had expressed an interest to determine whether they still wanted to engage in the study and to answer any questions they had. Interviews were arranged at times convenient to each participant and took place in the participants' homes or at the hospital site.

Data Collection

Semi-structured interviews were used to gain an insight into patient experiences. This method was chosen to establish rapport with participants and to allow the researcher flexibility in exploring areas of interest. In this way it was hoped that interviews would follow participants' interests or concerns rather than pre-determined topics of interest highlighted by the interviewer.[17] The semi-structured interview schedule included topics relating to the chronology of the illness trajectory, transition to and time on ST-VAD, further intervention and hopes for the future (Section Four, Appendix A).

Confidentiality, the right to withdraw data and the debriefing process were explained before each interview began and patients were then asked to sign a consent form (Section Four, Appendix D). All interviews were audio recorded and the first interview completed was analysed by the chief investigator and discussed with the academic supervisor to determine whether the questions used were appropriate to the research question as well as to the nature of the interview (i.e. open and non-leading). Interviews lasted between 35 minutes and 2 hours 50 minutes; the average across eight interviews was around one and a half hours. Participant's chose or were assigned a pseudonym following the interview.

Data analysis

The interviews were transcribed by the chief investigator and were read through several times to gain a full understanding of the data. They were input into and analysed in NVivo.[23] For

each of the transcripts, notes were initially made. These notes were both descriptive and interpretative and were designed to capture key words, ideas, or emerging interpretations. Once this initial note making stage had been completed, higher level, interpretative comments were made and these formed the basis of the emerging themes. A set of main themes was produced for each transcript and then the sets of themes from each participant were translated into a set of superordinate themes for the whole dataset.[17] Themes were discussed with the research and field supervisors and a reflective diary was kept to document thought processes and focus on the participant's interpretations. This process is illustrated in Appendix 2-B for Theme 2 to maintain the transparent analytic process.

Reflexive positioning

IPA is underpinned by an epistemological understanding that the researcher plays a key role in the analysis of the participants' data. This is because the researcher brings to the analysis their own beliefs, values and assumptions which may impact on how the data is viewed. In line with this is the assumption that researchers will make the analysis more transparent and robust. The chief investigator checked the transcripts with her academic supervisor who could highlight when her own assumptions may have been influencing the data. This was potentially the case later in the series of interviews when a pattern of responses was emerging. The early transcription and the iterative nature of the analysis mitigates this.

Ethics

Ethical approval was sought from the Health Research Authority and granted in November 2016. Application to the appropriate Research and Development (R&D) office was also made as the project was being conducted on NHS trust sites. R&D approval was granted in December 2016 (See Section Four: Ethics). Members of the local transplant forum group, including patients who have received ST-VAD as an emergency procedure, provided

feedback on the study design and participant information documents. They felt that the interview schedule and information documents were appropriate, however they specifically highlighted that they would rather get support from psychologists from the unit rather than being provided with contact numbers of support charities.

Results

Four superordinate themes were identified during the qualitative exploration of participants experiences of ST-VAD. The descriptions from participants highlighted the nature of the journey they had all been on since the emergency procedure. The superordinate themes were: Crisis and the fragile nature of life, "You adapt quite quickly, you've got no choice", Moving on, and The Change in Me. The themes, and sub-themes are summarised below and accompanied by quotations from participants. Figure 2 shows the journey that became apparent from the interviews and emergent themes.

Insert Figure 2.

Theme 1: Crisis and the fragile nature of life – "it was totally unexpected" (Andy)

Participants reflected on living well prior to a sudden decline in their health. Their sudden decline in cardiac function was emphasised by the transfer to a specialist Heart Centre and a stay within the cardiothoracic critical care unit (CTCCU). Five participants received medication for pre-existing heart conditions and reflected on the rapid and unexpected decline in their health . For example: "*I was still active, going away on holiday…doing all the sorts of normal things, still in the garden, the dancing and what have you" (John)*. For the three participants without a pre-existing heart condition, they had no previous difficulties regarding their hearts and described "living well" prior to the emergency procedure; for example: "*I was quite healthy, what I thought of as health…just, normal everyday life*

…taking [son] swimming, having a shower and stuff like that" (Rose). These participants spoke about being "blue lighted" to their local hospital and transfer to the specialist centre. For all participants, even those with managed long-term conditions, the sense of "living well" highlighted the enormity of the situation of needing the emergency procedure. The following account by Bob illustrates the emergency scenario faced by participants:

> "I had … an episode at home and we called an ambulance and I was taken through, first to [local hospital], then to [regional centre] and at some point, which I can't remember because I was unconscious most of the time, I had a heart attack, heart failure… most of me wasn't working" (Bob).

Emergency procedure/last resort: "I don't think there was much choice" (Daisy)

The ST-VAD was often the last of several interventions that people had received during this crisis period before either heart transplant or LT-VAD intervention. Participants spoke about the ST-VAD being the last option to keep them alive; Andy highlights the lack of alternatives: "*the only alternative was the [ST-VAD], it wasn't discussed with me what it was, cos obviously, I wasn't in any position to even respond, erm, and I just, slipped away and then woke up*" (Andy).

Participants demonstrated a range of understanding in terms of how critically ill each had been which appeared to be linked to how long they had been treated with the device. The range of time spent on the ST-VAD ranged from one week to three months. For those participants who were on the ST-VAD for a long time, there was an awareness of the life and death nature of their situation while in hospital. Those who were on the ST-VAD for a few weeks were not always aware of how critically ill they had been. Violet, who had been on ST-VAD for one week provided the following account of her experience:

> "there was one time that got a bit scary, one of [the doctors] told me that actually had I not had the [ST-VAD] fitted I wasn't going to live past that week and then at that point I hadn't known that … I remember feeling emotional after that thinking oh my gosh at that point I didn't even know I was critical" (Violet).

Participants reflected on the short-term nature of the ST-VAD which provided them with only a stop-gap until the next intervention. Participants spoke about the interventions they expected, Tom explained:

> "I was having problems with my kidneys, liver, bowel problems and whatever else…it kind of got to the point where it was I needed the [ST-VAD] to kind of keep alive until I could have the transplant really" (Tom).

Ongoing fear of death

The initial crisis period and the ongoing complications during treatment led to feelings of uncertainty for the future for participants. This fear and uncertainty was further added to by concerns regarding the length of ST-VAD use. Patient's supported by ST-VAD need to have the tubes changed after 30 days which can be a high-risk procedure. The longer participants were on the device, the more likely they would need the tubes changed. Those who were on the ST-VAD within the licensing period were concerned that the clock was ticking and what would happen if they reached the 30-day limit. As Violet described:

> "it was healing things erm but I also was aware that I only had 30 days on it …And that kind of scared me as well, and I didn't know what it meant when this licence expired what would happen to me, whether I was still allowed to be on them, whether the tubes would get infected, or, whether they would change them, whether after 30 days that was it, but I kind of didn't to want ask" (Violet)

Five of the participants were sustained by ST-VAD for a time that exceeded the licensing period which meant that tubes needed changing. This was a daunting procedure for participants who were fearful of the outcome. This highlights the sense of fragility of life felt, and the threat of death present, for those on the ST-VAD waiting to be well enough for further intervention. Bob reflected, *"only time I got concerned was when they changed the [tubes], ..., the anticipation of it was worse than the event, erm, but yeah that got me quite nervous"* (Bob).

Andy spoke about the physical and emotional side of having tubes changed:

> "It's horrendous, there's more people round you, telling you not to worry it's unbelievable, and then what they do is they take the pump out … for that five or six seconds, a quarter of your heart doesn't work so in some cases you get numbness down your face and shortness of breath in others there's pain elsewhere, so it's an awful experience and, as I said, the worst thing was the amount of people around me… it had to be done, so, erm, yeah, just if you want to know what the emotions were like, it's quite scary having that amount of people round you" (Andy).

Geoff relayed in detail the process of the tube changes and his fears during this. However, he felt the authority of the hospital staff helped:

> "… they put me under the sheet, you know because I was going to be bloody spurting around when they changed these tubes. And I thought this is horrendous, and I was really, really worried, but with [surgeon], I was under that sheet and I listened to him, and he was saying right, you're doing this you're doing that and you're doing the other, and I thought, that's fantastic that, what an air of authority, and [snaps fingers 3 times]and it was over" (Geoff).

There was a range of reactions to the tube changes, from an engineer who understood the changes to others visualising blood spurting everywhere. Participants were generally calmed

by the confidence of the surgeon although the number of people in the room increased anxiety.

Theme 2: "You adapt quite quickly, you've got no choice" (Bob)

This theme encompasses the time that participants were sustained on the ST-VAD. There was a sense of moving from a place of shock when first understanding what the machine was, to learning to live despite the ST-VAD. Participants described a love-hate relationship with the ST-VAD: the machine was seen as a life saver but also noisey, causing panic and limiting independence and mobility. They also described complications which would knock confidence, and concern regarding the licensing of the machine and what impact this might have on them.

Shock

Participants reflected on the first time they saw and understood the ST-VAD. They could not always remember being informed about the machine due to the critical physical state they were in when the decision was made. Shock and disbelief were common reactions for participants when noticing the ST-VAD. For example:

> "…the moment I woke up, the first thing I thought was Jesus Christ, this is like something out of a film, what's going on" (Andy).

> "I guess I was just a bit maybe in shock …. It was only when I started to have physio and things and when I got a bit better that it really bothered me, that I was on the [ST-VAD], at first I didn't really, just didn't really have a concept of how, how like important it was, like I understood what it was but the fact that it was like surgically put into my body wasn't really something that I thought about a lot" (Daisy).

Participants spoke about the physical impact of being on the ST-VAD and being reminded of what the machine was doing when realising that they did not have a pulse: *"I remember them saying, there's no point taking her blood pressure because you won't get anything, so I kind of felt like 'Death Becomes Her'"* (Violet). This highlighted the disbelief or unreal nature of being sustained by the ST-VAD in referencing film and fiction rather than real life.

Love/hate relationship: "it was kind of my best mate, it kept me alive" (Geoff)

Participants moved from the initial sense of shock and disbelief to a love-hate relationship with the ST-VAD. This shift suggested a process of adjustment. The machine was seen as life giving but also very restrictive causing participants to be dependent on others. They often reflected on the role of physiotherapy and their relationship with the ST-VAD. Participants spoke of being determined and physiotherapy allowed them to take control to work towards becoming fit enough for the next intervention. However, physiotherapy also highlighted the dependence on others, the enormity of the situation and made the ST-VAD more real. Participants were not able to avoid the situation they found themselves in when needing to take part in tasks to allow them to get fit for the next intervention. Daisy described:

> "I suppose [physiotherapy] just made me more conscious that I was stuck to this machine. And it didn't feel like, oh I'm so glad this machine's here, I just felt like, this is not fun, you know, I really don't like this" (Daisy).

Adapting

There was a sense that participants adapted to the ST-VAD. John reflected his change in perception, *"how big and impressive, well not impressive, intimidating it looked the first time when you see it, but you soon get used to it"* (John). Participants spoke strongly of being

determined to get to the next intervention. Adapting to the ST-VAD was a step towards leaving the hospital. Some participants noticed feeling physically better while on the ST-VAD which helped the adaptation, however others struggled with intense pain where the machine entered their bodies or constant complications such as infections which made adapting more difficult. Although physiotherapy was a reminder of the enormity of the situation, it was also a way to adapt to life with the ST-VAD and a necessity for moving on:

> "for the first five to seven days I was very trepid, I was scared of moving, emotionally etc. and then when I got used to it and I started moving, other than the effect that I couldn't move it was good, and feeling as good as I did, made it better, and you know after a week you know I was determined I'm going to beat this so right get the physios in" (Andy).

Participants spoke of life despite the ST-VAD "*I just felt a bit of a fraud being there [in CTCCU] cos everybody else was in comas and I wasn't*" (Violet). They noted that they would be able to sit and talk to friends and family and have jokes with staff members which felt different from those in CTCCU who were unconscious. They also spoke about the shock of friends and family when first seeing the machine and then that they appeared quite well. One participant commented on feeling powerful in that he was living despite the ST-VAD and felt proud in front of his friends.

However, participants struggled with feeling that their illness and treatment was the cause of unhappiness and pressure for friends and family. Participants felt further pressure due to the impact the treatment was having on friends and family. One participant noted:

> "I desperately wanted everyone to be happy, I didn't want to be the one in the middle of it all, causing all the fuss, because there was nothing I could do about it, so, that was a really hard feeling, I didn't want anyone else to be upset, in a way I would have felt better if they just

> stayed at home, and just got on with their lives, which they obviously wouldn't but it was hard knowing that I was causing all this" (Daisy).

Theme 3: Moving On

Moving on referred to future interventions with the awareness that transplant was the only long-term solution. It was on leaving the hospital that participants started to process the seriousness of their critical illness, with memory blanks being filled by hospital staff, friends, family and ICU diaries. Participants also spoke about doing their own research once leaving the hospital.

They saved my life

Participants reflected on the lifesaving nature of the interventions they had received and were grateful for the expertise and support of staff, for example: *"I wouldn't be here today if it wasn't for [the hospital]"* (Tom). Throughout the interviews there was a strong sense that friends and family were a source of practical and emotional support, Bob said "*friends and family … they went above and beyond"* (Bob). Participants said that staff were kind and helpful but they felt that their family and friends needed more information and emotional support. Once the ST-VAD was fitted, the support for participants from friends and family was bolstered by the hospital staff and support systems such as transplant buddies. Hospital staff offered emotional support and information, encouraging participants to stay positive and focus on the next intervention. They enabled participants to voice their fears without burdening family or friends. As John described:

> "[staff] tend to fill you in and tell you why things are being done and what this is for and what the other's for so you pick up a lot of information about that… the big difference is they take the time to listen to you, to answer your questions and just interact with you as a person" (John).

Although participants had been determined and striving towards discharge from hospital, there was also a sense of loss and grieving as their outpatient appointments became less frequent and there was more emphasis on the new heart or LVAD working for itself. There was a fine line between those who were still attending the hospital regularly, that this was a chore, compared to those who were moving towards six monthly reviews. The hospital and staff became like friends and family for many of the participants. The participant (Daisy) who was three years post discharge felt that she had moved on from that period of her life and the sense of loss was not as great. From this position, participants reflected on the changes they had noticed in themselves and that others had noticed in them since the ST-VAD and future plans.

Limbo vs moving on

Participants were very aware that the ST-VAD was only a short-term solution. Two participants moved on to have an LVAD whereas six had a transplant as the further intervention. None of the participants had recovered sufficient heart function for explantation while being on the ST-VAD. Participants spoke about the need for further intervention to enable them to leave hospital. For example:

> "I was begging for an [LVAD] so I could get out, but it wasn't worth it for me … yeah you're out of hospital earlier but for me again it would be a stop gap, you know some time in the next 2 years I need a heart transplant" (Andy).

Those on the LVAD had been placed on the transplant list but did not know how long they would need to wait,

> "cos I'm doing well, I'm less of a priority than those that are still in hospital or have come home but have kind of stayed the same as they were really, I'm less of a priority but still, can't help think, I should be next" (Rose).

For some participants, the complications they faced while on the ST-VAD led to a sense of relief when they knew they were moving on to a further intervention:

> "… when I knew I was finally getting a transplant, I was just grateful that I wouldn't have the [ST-VAD] in me rather than that I was getting a heart transplant and that was going to save my life" (Daisy).

Moving on from hospital

Participants spoke about the frequency of outpatient visits to the centre. This reduced as time passed: *"Every week we was there, yeah and then it went to every month, once a month and now it's every two months"* (Rose). The hospital appeared to act as a secure base for participants who developed a greater sense of autonomy and independence as they had less contact with the hospital.

> "I don't dread going cos there are a bunch of nice people that I'm going to see and stuff and you walk down the corridor and there's always somebody that you know, that I saw when I was in the hospital that always says hello and stuff" (Rose).

Participants who were having less regular contact with the hospital reflected on the attachment they had made with the building and the staff. Violet and Geoff described:

> "it's weird to say, but I actually miss the hospital sometimes. When I come here I sometimes feel I'm coming home and I know that sounds really strange… I feel like I'm going home because to me this was home for so long erm, so I always feel safe coming here … everything's just really nice so I feel like I'm getting support from [psychologist] … and I get a lot of support from the nurses" (Violet).

> "it's almost like a little grieving procedure when they take the [ST-VAD] off you, I've got one biopsy left and if it goes well, that's it unless something goes wrong … I'm out there and I get on with life, and I think, what do you mean I'm not going back to [hospital], and they

> said no, no, we will call you in occasionally, once a year for a check-up…but like that little sense of where's my washing machine [ST-VAD] gone, it'll be like, where's my visits to the hospital gone, it will be a bit of a wrench you know, although I'll find a way to get back up here" (Geoff).

The participant who was three years post intervention described less attachment to the hospital having achieved more autonomy and independence over her health and body,

> "At first I was there every week or even more cos I kept getting ill and I had a couple of rejections and stuff but now it's rare that I go in to [centre],… it's not a big part of my life" (Daisy).

Theme 4: The Change in Me: "I think my outlook on life has changed, whether anybody knows that I don't know" (Bob).

Participants reflected on how their outlook on life had changed following the emergency intervention, including noticing an inner strength that may not have been evident before. This was the case for those with and without pre-existing heart conditions prior to emergency implant. Participants re-evaluated their work-life balance, for example:

> "I was known for going in at six o'clock in the morning, going home 10 o'clock at night and then have my tea and back on the laptop again, where now I can get to work at, I'll get to work at 8 o'clock in the morning, I'll go home at 6, it's still a reasonably long day for most people, … but I go and do that but it's not kind of working all weekend preparing for meetings and travelling down south and here there and everywhere, … , I've got more time at home, …now we can kind of do more things together and it's a lot, lot better so, so in that respect yeah it has kind of changed but that isn't a bad thing really" (Tom).

Participants also spoke about gaining a different perspective on life and about what was really important to them. Priorities included family and giving back to the hospital either via fundraising or being a buddy for future patients, for example:

> "I think I've realised I'm stronger than I thought I was….and a lot more resilient… I've got more confidence in my ability to deal with things" (Daisy)

> "I feel a lot calmer I don't know whether that's going through everything I have, that I have a big perspective on life now… one of my work friends has actually said she can see that I have changed erm, that I'm a lot calmer, things don't phase me as much but I also have changed a bit in personality" (Violet).

They also reflected that the journey had brought family close together, *"it's brought [me and my wife] closer together, cos she was the only one who was here all the time, for better or worse"* (Bob).

Participants noticed that the way other people treated them had changed following the emergency procedure. It was often described that their closest family were worried about losing them, "*The kids all think I'm great, I'm brave, which I'm not. ...my wife's scared of losing me"* (Andy).

They reported that sometimes friends and family would be protective over them, *"In many ways, they still treat you...like a victim of something, you know, they still, they can still be ever so careful with you. As if you cannot cope with something"* (Geoff). However, participants would remind those closest to them that they were capable. They also spoke about their friends and family seeing a new strength, *"I think they just see me as, just that I can get on with things more than maybe it seemed beforehand"* (Daisy).

Discussion

This is the first qualitative study to explore the experiences of ST-VAD patients. Four superordinate themes were identified that focused on participants' journeys from crisis to moving on from hospital. The findings of this study revealed that the initial crisis leading to ST-VAD placement continued to impact on participants' ongoing fear of death, however while being sustained by ST-VAD participants learnt to adapt and live despite the device. The later themes followed participants as they went on to further intervention and started to notice a change in themselves and their priorities following discharge.

In Abshire and colleagues meta-synthesis regarding adaptation and coping,[15] the "implantation and hospitalisation" phase highlighted participants high dependency on others. In the current study a similar experience was reported while participants were in hospital. Participants spoke about their lack of independence while the ST-VAD was implanted. This often related to activities of daily living such as washing and going to the toilet. Physiotherapists may be well placed to highlight areas of independence when thinking about exercises and emphasising the aspects of daily living they are able and will be able to do as they get stronger. Johnston[24] concluded that support was a complex issue when surviving critical illness as more support was correlated with increased anxiety. The key factor that was identified was psychological agency and this highlighted better coping.

Similarly to the Chapman[9] study with two ST-VAD participants, the participants in the current study reflected on the shock and impact of the ST-VAD experience. The current participants also spoke of the intrusion of the device but this moved to a sense of learning to adapt to the device. Equally, as in Chapman's "trust" theme, the participants also described needing to trust the machinery that was keeping them alive and then to trust their new heart or LVAD.

In the current study, participants were not always fully aware of the life-saving nature of the ST-VAD and this understanding and adjustment was something that happened over time and sometimes once discharged. Chapman[9] described those patients who had received ST-VAD as an emergency procedure struggling to process what had happened to them. Waight and colleagues[25] described the "shock" that patients had on learning they needed coronary artery bypass graft surgery was the most traumatic part, either due to being faced with mortality and identity crises or learning that they were more ill than they had considered themselves. This is similar to the experience of participants in the current study who were faced with the ST-VAD which highlighted their own mortality. This was further emphasised for the participants by the 30-day licensing period of ST-VAD. This study has highlighted a potential communication issue for staff, that they should consider the psychological impact of licensing issues and how best to communicate this with patients and family. An approach similar to that employed by Dithole[26] might be successful. This would involve "the application of augmentative and alternative communication strategies" aimed at helping healthcare professionals to make sense and make meaning of the journey on which the patient is engaged. Communication training should also focus on healthcare professionals' knowledge, attitudes and raise self-awareness.[27] The training should also help nurses and carers to understand the implications of the licensing of the ST-VAD and the reality of facing death. Further to training, healthcare professionals may benefit from ongoing clinical supervision regarding communication[28] which could be provided by Clinical Psychologists attached to cardiothoracic units. Further research is needed to gain a better understanding of the informational and support needs of ST-VAD patients in line with the licensing period.

Participants spoke of feeling in good hands within the specialist cardiothoracic centre. Similarly, Overgaard and colleagues[12] described the relief of LVAD participants when they arrived at a unit with expert knowledge with it being their "safe haven". In the current study,

participants described attachments to the hospital and staff which changed over the period of time since intervention. As in the qualitative exploration of experiences of ECMO survivors,[16] the participants in the current study expressed their thanks to all that had aided their recovery and reported gaining new life perspectives.

Johnston's[24] study regarding surviving critical illness highlighted that participants benefited from telling their story which helped to develop a coherent illness narrative for what had happened to them. Indeed, in the current study, participants spoke about making sense and "filling in the blanks"; they described gaining information and some brought their ICU diaries with them. Johnston[24] proposed that a coherent illness narrative is a necessary step for building psychological agency, posttraumatic growth and increased coping. Following an understanding of mechanical dependence, participants spoke of adaptation to the ST-VAD within hospital. Participants then moved on to further intervention and with this came an awareness of a change in priorities which could be understood as posttraumatic growth. Posttraumatic growth has been defined as "the subjective experience of positive psychological change reported by individuals as a result of coping with trauma or highly challenging life crises"[29] (p1). These perceived changes include more meaningful relationships and changes in personal strength and changed priorities.[30] Hefferon and colleagues[31] reported findings from a systematic review of qualitative studies reporting posttraumatic growth and life threatening physical illness. Along with reappraisal of life and priorities, changes in personal strength and more meaningful relationships, there was a unique element of posttraumatic growth related to physical illness, that of a new awareness of the body which could lead to a better understanding of their body, and changes in health-related behaviours. As in the current study, Hefferon[31] described that people report benefits from illness while acknowledging the distressing side of the illness.

Clinical Implications

Participants spoke about struggling with anxiety at times and reference was made to feeling overwhelmed at times of transition. This reflected the emergency procedure and subsequent treatment as traumatic, being faced with their own mortality, and uncertainty for the future. In the present study, these issues were mostly managed by active problem solving and determination to get better or dependence on others for support. Participants referred to receiving information during and post intervention however healthcare professionals may need to provide additional emotional support when providing this information and be aware that this may need to be discussed during outpatient appointments. Participants spoke about meeting with buddies and felt that this was most effective when they were similar to the buddy. Buddies with experience of the ST-VAD may be well placed to provide normalising information and peer support for patients currently being maintained by ST-VAD.

Although there is little evidence regarding the efficacy of psychological therapies and ST-VAD use, Acceptance and Commitment Therapy (ACT) might be appropriate in supporting patients during and following ST-VAD implantation.[32] The ACT model encourages acceptance of a range of experiences, including those which are distressing. In relation to the practice of ACT, clinical interventions focus on the functions of problematic thoughts rather than on their content. This would be particularly relevant to anxious thoughts of death in this situation; cognitive approaches would have encouraged challenging such thoughts but they would be realistic fears given the need for intensive life support. ACT encourages the use of exercises which aid the identification of personal values which are in turn used to identify specific behavioural goals, along with the design and implementation of behaviour change strategies to achieve those goals.[32] This values-based work can be conducted in acute medical settings and would enable a greater sense of control and more

embodied sense of self. ACT along with other acceptance based approaches such as mindfulness[33] and Compassion Focused Therapy[34] may complement the areas of posttraumatic growth that have been apparent in the current research.

Understanding psychological processes of ST-VAD as an emergency procedure helps us to better understand the psychological needs of participants. From the experiences described by participants there are potentially key time points when participants would have benefitted from more psychologically informed practice such as transition points, discussing licensing issues, living with ST-VAD and trying to have as normal a life as possible. Although not the focus of the current research, participants spoke about the emotional support needs of friends and family which they felt were limited. Some participants stated that family and friends received psychological support from outside of the unit, however others felt that this should be provided by the unit at the most distressing points, for example while the patient was unconscious or around the time of transition to transplant or LT-VAD. Further research could include gaining an understanding of the needs of family and friends in this situation.

Participants described an attachment to the hospital and staff members during their ST-VAD support and further intervention. Healthcare staff may benefit from education and understanding around the natural attachment process for patients who have survived ST-VAD as an emergency procedure. Specialist units should plan to gradually increase the time between appointments not only due to the reducing need for medical intervention but also to highlight the psychological benefits of maintaining a safe base whilst patients gain psychological agency and confidence in their new heart or LVAD.

Limitations

The research used a self-selecting sample based on inclusion criteria and a very limited sample and as such it may be that these participants had a more positive view of ST-VAD implantation or life since intervention. The retrospective nature of participants' accounts might have been influenced by subsequent experiences or outcomes. This could be addressed in future research by following patients through their journey in real time, rather than a retrospective study.

The sample in the study was necessarily small and heterogenous in terms of differences in age, gender, previous heart condition, interventions prior to ST-VAD, further intervention and place of interview. Although the common experience was that of ST-VAD placement in an emergency it must be acknowledged that the differences between participants may have impacted on the experiences. Further qualitative research may benefit from a more defined sampling pool.

In line with IPA, this study is relatively exploratory and bound by the ST-VAD population studied. Theoretical generalisability can be understood in context with existing professional and experiential knowledge.[17] Similar investigations with ST-VAD samples would be beneficial and contribute to the existing literature.

Conclusion

Analysis of interviews identified the importance of navigating a journey from ST-VAD implantation to further interventions. Participants acknowledged the distressing aspects of the emergency procedure and ST-VAD support; however they also described the positive aspects and changed priorities, in line with posttraumatic growth literature. It is hoped that the experiences shared by these ST-VAD survivors will help professionals to support adults

to live in line with their values in the context of the opportunities and challenges that further intervention can bring.

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What's New?

- ST-VAD patients described a journey from the ST-VAD emergency procedure, learning to adapt to the machine and moving on to further intervention.
- Healthcare professionals would benefit from understanding the journey that patients travel to further intervention and the attachment they may form with the hospital and staff.
- Participants reflected on positive changes following the emergency procedure which may be suggestive of links to post traumatic growth.

Figure 1: Flowchart detailing the number of potential participants and final number of participants from recruitment centre. Participants were generally approached at their next outpatient appointment when this fell during the recruitment period and as such this had an impact on the number of potential participants that were available.

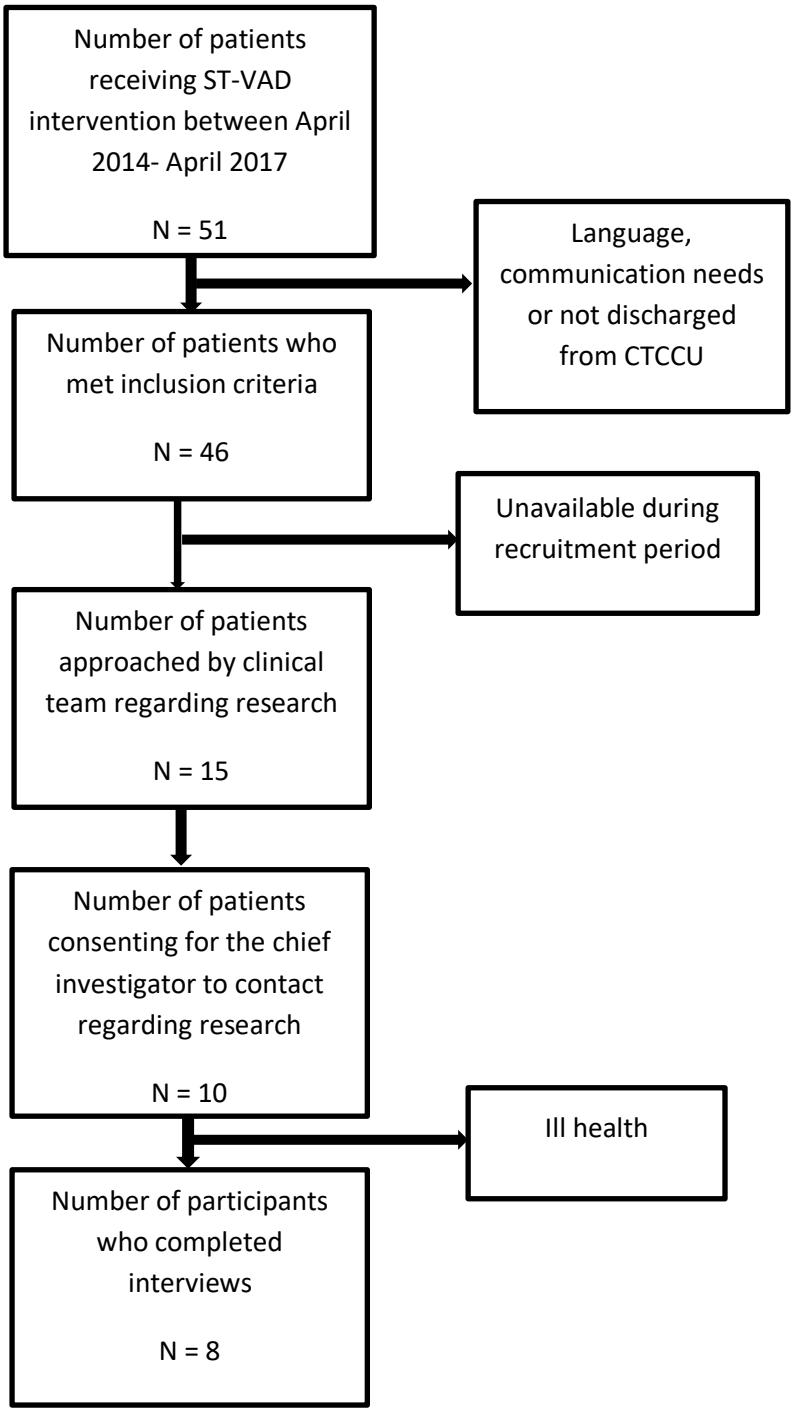


Table 1: Participant Characteristics

Participant Pseudonym (male/female)	**Age**	**Reason for emergency procedure**	**Time on ST-VAD**	**Time since ST-VAD**	**Further intervention**
Andy (M)	52	Deterioration of heart failure	2 months	4 months	Heart Transplant
Bob (M)	57	Heart failure following heart attack	3 months	5 months	LVAD
Daisy (F)	30	Decline following surgery for mitrovalve regurge	2 months	36 months	Heart transplant
Geoff (M)	57	Myocarditis	3 months	19 months	Heart Transplant
John (M)	51	Deterioration of heart failure	3 weeks	1 month	Heart transplant
Rose (F)	38	Spontaneous coronary artery dissection	3 weeks	12 months	LVAD
Tom (M)	38	Deterioration of heart failure	2 months	12 months	Heart transplant
Violet (F)	31	Deterioration of heart failure	1 week	6 months	Heart transplant

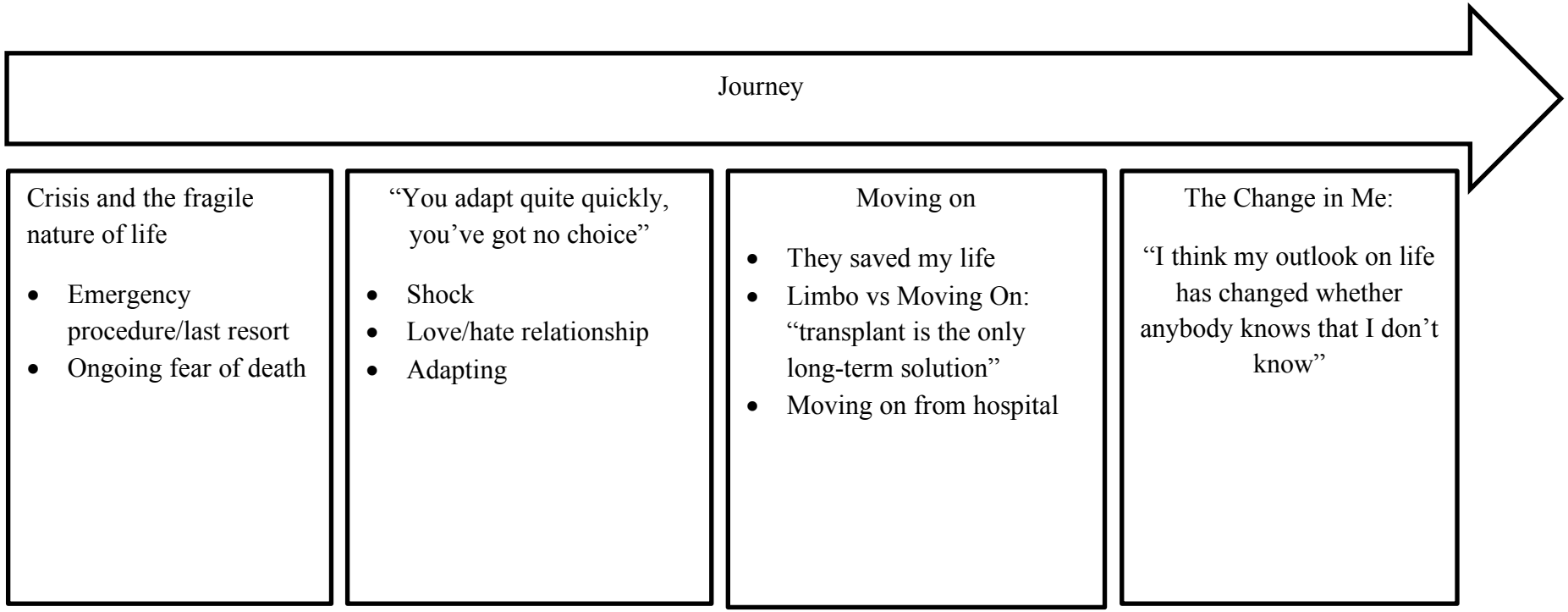
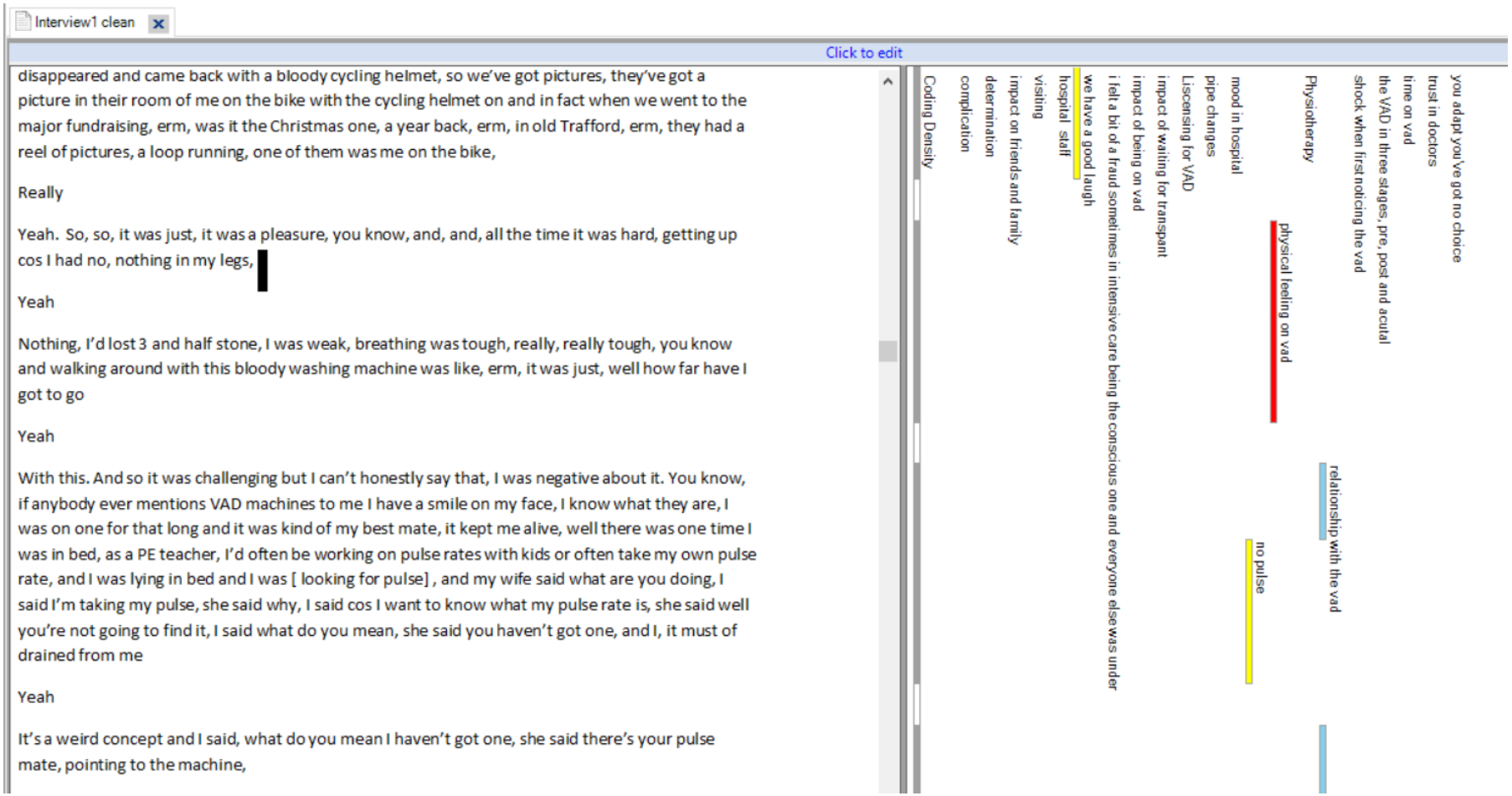


Figure 2. Experiencing ST-VAD: A Journey. *Four superordinate themes and their subthemes related to the short-term ventricular assist device journey.*

Appendix 2-A

Extract from Geoff's transcript showing coding for Theme 2 in NVivo.



Section Three: Critical Appraisal

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See Appendix 1-A (Section one: Literature Review) for Journal of Cardiovascular Nursing manuscript guidelines

CRITICAL APPRAISAL

This thesis comprises two main pieces of research, a literature review and an empirical study. The literature review addressed the experience of decision-making for patients and caregivers regarding the LVAD implant where thematic synthesis of the papers identified three main themes of "context", "mechanism" and "outcome". The research paper, an interpretative phenomenological analysis (IPA) study, reported the experiences of having a short-term ventricular assist device implanted as an emergency procedure. The participants' experiences were developed into four themes of (1) crisis and the fragile nature of life, (2) "you adapt, you've got no choice", (3) moving on, and (4) the change in me. Conventional reporting of research required for the format of this thesis and for publication, limit the depth to which these issues can be discussed. Therefore, this critical appraisal will provide an opportunity for further reflection of five areas related to the research. I will start by discussing the critical care environment and existential aspects of VAD followed by my reflections on VADS and the research process. Further to this I describe my professional development and implications of working in physical health settings. Finally, I argue aspects of patient centred care and the ethical and legal implications of VAD placement.

Critical Care Environments and the Existential Aspects of VAD

The participants who were interviewed in the research paper were cared for in a cardiothoracic critical care unit (CTCCU). Participants in the current study spoke of experiences following their CTCCU stay, however the research paper did not focus on the Intensive Care Unit (ICU) experiences that are common across conditions or ICU experiences such as hallucinations and memory gaps which have been observed in other studies.[1-3] Those typical ICU experiences were reported by participants and were in line with those often spoken about in general ICU research. There is an awareness of the psychological impact of an intensive care stay, such as post-traumatic stress disorder (PTSD), depression and anxiety.[1] It is believed that these consequences may impact negatively on a patient's ability

to engage with rehabilitation.[2] Although there is an increasing awareness of the psychological impact of an ICU stay, this is often a medicalised view of PTSD and delirium and the causes of these.[3]

The Core Standards for ICU[4] highlight the need for a psychological and emotional understanding of patients' needs, however, this is not clearly defined. It is suggested that psychologists should be part of the multi-professional team that conduct delirium assessments and provide strategies and interventions. Within the more recent Guidelines for the Provision of Intensive Care Services[5] it is recommended that psychological input is offered both within and following ICU stay.

With a better understanding of the need for psychological support during and after ICU stay, thought needs be given to the role that a clinical psychologist might have. It has been suggested that the role of clinical psychology is to give patients space for discussing and sharing their experiences.[6] Characteristic themes that can be discussed are survival, lost time and ICU experiences. Survival can be understood in two ways: 1) survival from death, and 2) survival for life.[6] The factors that lead people to an ICU stay mean that patients have often been close to death and therefore confronted with their own mortality. Participants in the research paper reflected that "it was not my time" and "there was a reason why I didn't go then". Clinical psychologists are well placed to speak about death, beliefs, experiences and assumptions.

Confrontation with mortality can change an individual's world view, how they see themselves and how they see others.[7] In the situation of VAD support, the patient realises the existential threat to themselves and that a machine controls his/her life. For those who have VAD implanted as a bridge to transplant, they describe themes of dependence on a mechanical device for life but also feelings of guilt waiting for a suitable donor heart and

therefore waiting for someone else to die.[7] With this in mind, people maintained by VAD need psychological support as they can experience psychosocial and emotional stress as severe as those following heart transplant. It has been suggested that social support is a key element for positive outcomes. In discussion with my field supervisor, a Clinical Psychologist within a Cardiothoracic Unit, it was pointed out that LVAD placement can affect transplant in that the LVAD can stabilise a patient and they would not be classed as high priority. This was highlighted in the research paper by participants supported by the LVAD and also in the thematic synthesis. My field supervisor described that there have been cases in the UK where people have sabotaged their LVAD so that they can be admitted to CTCCU and urgently listed for heart transplant. This emphasises the need for clear information regarding the impact of the decision to have LVAD implantation. Furthermore, as the complexity of distressing factors increases for individuals so does the emotional burden, which highlights the need for healthcare teams to understand the background and future treatment plans for each patient.

Research has described an often raised question by ICU survivors of "why me?".[6] This uncertainty could be understood for all participants in the research paper, those who had no previous heart conditions but also for those who had been taking care of themselves in light of heart failure. Uncertainty in illness happens when "*a person is unable to structure meaning in illness-related events*"[8] (p72). Understandably, patients may struggle with questions such as "will there be a complication?" or "how quickly will I deteriorate?". It has been suggested that for patients considering long-term mechanical circulatory support (LVAD) "*perhaps one of the most important elements in clinical encounters is helping the patient to recognise that uncertainty persists in modern medicine*"[9] (p185).

As described in the research paper, a coherent illness narrative is necessary after surviving critical illness.[10] One way that this can be achieved is through the use of an ICU

diary. During the interviews in the research study, participants gave varied responses regarding the helpfulness of their ICU diary. Some participants had brought their diaries to show me whereas others had not yet received theirs. For those waiting to receive their dairy, there was a sense of uneasiness as to what it would say and they felt that they had to rely on information from family, friends and the medical team for "filling in the blanks". One participant spoke about going through their medical notes with the clinical psychologist as they felt that the diary was more about what the inpatient stay was like for her family, she felt that she missed chunks of real world news and what had happened to her. This suggests that she was searching to build a coherent illness narrative. The theme of "time had got lost" has been reported elsewhere.[6] As participants did not receive their diaries until they were attending outpatient clinics, it was sometimes difficult for them to piece together what had happened to them. One participant spoke about a telephone call with a friend who imparted some important world news, and she thought her friend was joking as she was not aware of this news due to being unconscious; this highlighted to her the time that she had missed from the world. A clear illness narrative has been linked to posttraumatic growth and effective coping[10] and therefore it is important to understand how best to collect and deliver "the missing blanks". Healthcare professionals need to keep in mind that not all patients will want all of the information and that this discussion needs to be had so that information can be tailored to what the individual wants.

My Reflections on VADs and the Research Process

As I have written this thesis, and as I write this, it is apparent to me that as a healthy woman with no first-hand experience of what the participants have gone through I have been made more conscious of the total 'otherness' of their experience. In terms of my position on heart failure and the use of ventricular assist devices I would describe myself as somewhat naive as I am not associated with the Cardiothoracic Unit nor am I a medical professional. I feel this

led to participants providing rich descriptions, explanations and information about their experiences. However, as a young female asking questions of older men this may have impacted on the topics that were discussed in this study. My closeness in age to the female participants highlighted to me the critical nature of the situations that led to their emergency procedures. It was further highlighted to me that this experience could happen to anyone, including myself. I find this very humbling and feel that I am a more empathic listener within the interviews and my day to day work.

While arranging and conducting the interviews, I was often struck by the realities of living with an LVAD or life following transplant. One participant let me hold her VAD bag, which contained the power source and controller and I became more aware of the intrusion this had on her life. There was also a strong narrative throughout the interviews of the on-going ups and downs and complications that were evident once people had been discharged from the CTCCU. At times I felt a tension between the research role I was in and my everyday clinical role. When participants became upset it was difficult not to be drawn towards a more clinical role. This highlighted the sometimes challenging nature of conducting research as a clinician and the need for clear protocols. During the research process, I was able to balance this by reminding myself of my role at that time and ensuring I debriefed each participant fully, reminding them of the support available to them.

Further, the majority of interviews were conducted within the specialist unit, and this context may have given emphasis to certain issues such as healthcare professionals practice. This environment may also have had an impact on how participants saw themselves in terms of health and illness. Responses may have been different in environments where they were not labelled “patients”. During the research process I kept a reflective diary, which was useful during the analysis using my notes on initial hunches and my thought process throughout the interviews with some of the above reflections evident in my writings. The

diary provided a space for my reflections, which is required in interpretative phenomenological analysis to prevent preconceptions from unduly influencing the analysis process.

Professional Development and implications for working in physical health settings

My interest in health psychology started prior to clinical training. My first memory of the impact of critical illness was the death of my sister's best friend following kidney transplant aged 10. I was 7 years old at the time. My recollection was of how ill she was leading up to transplant and the hope that those around her had when a match was found. She died shortly after the surgery. Subsequently, I felt the impact of the psychological needs of the people with acute and chronic illness and the impact on their parents, carers and those around them. I have often been drawn to the phrase "extraordinary things happening to ordinary people". I feel this is often the case within a physical health field where traumatic and life changing events can happen to anyone. I completed a Masters degree in Health Psychology prior to clinical training and learnt about the models related to health psychology and developed my understanding of how we understand the experiences of health and illness. During clinical training, I have sought placements within healthcare settings with both adults and children and have completed research into healthcare professionals' understandings of clinical psychology within the ICU as part of a small-scale research project. During my specialist placement I worked on a paediatric oncology unit and was further struck by the fragile nature of life and the benefits of hearing people's stories and enabling people to tell their stories. These experiences have reinforced the value of clinical health psychology that I had developed and have promoted a wish to support people coping with the challenging and sometimes traumatic aspects of health care.

CRITICAL APPRAISAL

A recognition of the importance of psychosocial outcomes has begun to filter into different specialties within the physical health field. The Faculty of Clinical Health Psychology within the British Psychological Society[11] produced a briefing paper to provide information regarding the role of clinical health psychologists and how such professionals can fit into current health systems. This role can include: direct work, working with teams, providing support and supervision to staff and involvement with research and evaluation.[11] It is suggested that clinical psychologists within a health setting are well placed to integrate physiological, emotional, cognitive, behavioural, interpersonal and socio-cultural factors and understand the impact that these factors may have on an individual and how they might influence adjustment or recovery.[12] Furthermore, clinical psychologists are well placed to communicate this information to teams.

Patient-Centred Care

In a medically dominated field, I have often witnessed the physical aspects of healthcare being given priority and patient experiences being overlooked. However, in the thematic synthesis there were signs that the patient and caregivers' voices were given volume by healthcare professionals. Supporting the voices of patients to be heard through qualitative research, as well as synthesising the findings of such research, aids in giving more dominance to the patients' voice. Over the last two decades there has been a move towards a more patient/person centred health service. As reported by The King's Fund[13] patients need to be engaged and involved in decisions about their care, which can be facilitated by ensuring they are given the opportunity, information and support to do this. It is also stated that services are to reflect the needs of their patients. For this to be achieved, patients and caregivers need to be involved in all aspects of health care services including, commissioning, planning, design and improvement.

CRITICAL APPRAISAL

In terms of patient-centred decision-making, it has been highlighted that there is a need for healthcare professionals to contribute their expertise and support patients to use that expertise to inform their decision.[14] Furthermore, it has been reported that patient involvement with decisions improves outcomes.[14] Schwartz and colleagues[15] described that in their experience of decision-making they felt emotionally and cognitively overwhelmed when faced with a new reality. It was reported that this impacted on taking in and processing the information regarding healthcare related decisions. This provides strength to the argument of tailoring communication to the individual and re-visiting information throughout the timeline of decision-making.

The empirical study was developed during discussions with the field supervisor for the project, a clinician working within the Cardiothoracic Unit. This helped to ground the research in the clinical setting. Furthermore, it highlighted the under researched area of the ST-VAD. During the design of the research project, Transplant Buddies were involved by providing feedback regarding the design, practicalities and recruitment documentation. This was an invaluable perspective for me as someone new to the area of VADs. Following interviews, participants were offered a copy of the transcript to comment on. The aim was to ensure that I had understood what had been described. However, only two participants accepted this and although copies were sent I did not receive any feedback. On reflection I wonder if the participants who agreed to a copy of the transcript have used this as a way to develop a coherent illness narrative. In the future I would consider other ways to facilitate this feedback. Schwartz and colleagues[15] discussed the importance of involving patients in research from the design to analysis and write up. It is believed that this enables research to be more clinically relevant, genuine and in the interest of patients and services rather than academics. I would have liked to have had further involvement from patients, however, this

was difficult due to the small numbers of patients who experience the ST-VAD and the impact this would then have had on those I was able to recruit for the study.

Ethical and Legal Implications of VAD placement

From the research paper there is evidence that posttraumatic growth was present for participants. However, research has stated that partners/caregivers may be more likely to struggle with post-traumatic stress disorder type symptoms following VAD.[16] This was described by some participants in the research paper. Services need to consider how best to support families within the confines of commissioning structures.

For those caregivers of patients with LVAD who are bereaved, research describes high levels of confusion at the end of life.[17] More research and understanding is needed regarding the educational processes, timing and reiteration of information. Confusion at the end of life for an LVAD patient includes lack of knowledge about the nature of death, about the medical decisions to be made and about the palliative care and hospice services provided. The ethical and legal issues of LVAD deactivation can be a source of contention.[18-20] Commentaries from the USA suggest that VAD discontinuation can be seen as ethically permissible if this treatment is no longer consistent with the patient's goal, often increased quality of life, however, clinicians may have differing attitudes towards this and view deactivation as euthanasia.[20] In discussion with my field supervisor she has described that the legal advice provided to the Cardiothoracic Unit depends upon whether the device is mostly external or internal to the body as to whether deactivation is classed as euthanasia or allowing a patient to die from advanced heart failure. Published work from the USA argues that other percutaneous interventions are understood as distinct from the body.[18,19] Further difficulties arise when questions of an individual's capacity or inconsistency in preferences

arise.[18,19] The inclusion of ethics panels and palliative care teams can support deactivation decisions.[17,21]

Within emergency situations, consideration needs to be given to presumed and surrogate consent.[22] This begs the question of whether it is ethical to implant a mechanical device such as a VAD. This highlights the need for advanced directives or preparedness planning,[20] especially in understanding the wishes of those with heart failure. Advanced directives need to be revisited over time to allow for changes. Presumed or surrogate consent can lead to distress and regret, as seen in the thematic synthesis with thoughts such as "did I do the right thing?" This is more difficult for those who are supported by VAD where the heart condition came "out of the blue". The ethical and legal aspects of VAD placement need to be further understood and perspectives from other countries taken into account.

Summary

In summary, this critical appraisal has focused on the critical care environment, existential aspects of VAD, my reflections on VAD and the research process. I went on to describe my professional development, the role of clinical psychologists in physical health settings and the importance of patient centred care. Finally, I suggested further clinical implications following on from these discussions, research paper and thematic synthesis.

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Section Four: Ethics

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Section Four: Ethics

Letter of HRA approval

Health Research Authority

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07 November 2016

Dear Ms Taylor

Letter of HRA Approval

Study title:	**What are the experiences of people following short term VAD implant as an emergency procedure**
IRAS project ID:	**205179**
REC reference:	**16/NW/0631**
Sponsor	**Lancaster University**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England
The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section

also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.

- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The document *"After Ethical Review – guidance for sponsors and investigators",* issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback
The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please email the HRA at hra.approval@nhs.net. Additionally, one of our staff would be happy to call and discuss your experience of HRA Approval.

HRA Training
We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Your IRAS project ID is **205179**. Please quote this on all correspondence.

Yours sincerely

Rekha Keshvara
Assessor
Email: hra.approval@nhs.net

Copy to: *Dr Diane Hopkins- Sponsor contact*
[redacted]
– R&D contact

Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

Document	*Version*	*Date*
Copies of advertisement materials for research participants	2	27 September
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance Document]		
Interview schedules or topic guides for participants [interview schedule]	1	01 June 2016
IRAS Application Form [IRAS_Form_04082016]		04 August 2016
IRAS Application Form XML file [IRAS_Form_04082016]		04 August 2016
Letter from sponsor [IRAS sponsorship letter]		
Other [Staff information sheet]	1	01 June 2016
Other [Participant expression of interest form]	1	01 June 2016
Other [Participant debrief sheet]	1	01 June 2016
Other [Insurance Document professional negligence]		
Other [Participant Follow up letter]	1	27 September
Other [HRA SoE]	1	25 October 2016
Other [HRA SoA]	1	25 October 2016
Participant consent form [Consent form]	3	03 November
Participant information sheet (PIS) [PIS]	3	03 November
Research protocol or project proposal [STVAD protocol]	1	01 June 2016
Summary CV for Chief Investigator (CI) [Chief investigator CV]	1	01 June 2016
Summary CV for supervisor (student research) [supervisor CV]		

Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the *participating NHS organisations, capacity and capability* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Name: Dr Diane Hopkins
Tel: 01524592838
Email: ethics@lancaster.ac.uk

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	No comments
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	Statement of activities will act as an agreement of an NHS organisation to participate.

Section	HRA Assessment Criteria	Compliant with Standards	Comments
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this research study
4.3	Financial arrangements assessed	Yes	No application for external funding has been made.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	No comments
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.

This is a single NHS site study. The study activities will be undertaken by the research team once the eligible participants have been identified by the clinical care team.

The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website.

If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.

Participating NHS organisations in England **will be expected to formally confirm their capacity and capability to host this research**.

- Following issue of this letter, participating NHS organisations in England may now confirm to the sponsor their capacity and capability to host this research, when ready to do so. How capacity and capacity will be confirmed is detailed in the *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* section of this appendix.
- The Assessing, Arranging, and Confirming document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability.

- Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).
A Local Collaborator to be allocated at the participating NHS Trust. GCP training is not a generic training expectation, in line with the HRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken
Use of identifiable patient records held by an NHS organisation to identify potential participants should be undertaken by a member of the direct care team for the patient, so it would not normally be acceptable for this to be done by staff not employed by that organisation. A Letter of Access would be expected for any external NHS/HEI staff undertaking all of the other activities for the study once consent from the participant is in place. The pre-engagement checks should include an enhanced DBS check and Occupational Health Clearance.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.
• The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.

Research Protocol

What are the experiences of people following short term VAD implant as an emergency procedure

Eleanor Taylor
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[redacted]
Field Supervisor - Chartered Clinical Psychologist
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A ventricular assist device (V) is a mechanical pump that is used to support heart function and blood flow for people who have weakened hearts. The device takes blood from a lower chamber of the heart and helps pump it to the body and vital organs, just as a healthy heart would (The National Heart, Lung and Blood Institute, n.d.). It does not completely replace the heart but the VAD works with the heart to help it pump more blood with less work.

The VAD may be used to support and stabilise the heart until a suitable donor heart can be found for transplantation; this is called bridging to transplantation (BTT). The VAD can also be used to support a heart to allow it to return to strength after an acute illness; this is called bridging to recovery (BTR). The NHS currently commissions the use of VADs as a Bridge to Transplant or a Bridge to Recovery (NHS England, 2013). Specific VADs may also be used as a Bridge to Decision (BTD) which can act as a temporary measure to stabilise the heart prior to decisions regarding transplant or a similar intervention.

There are broadly two types of VAD, “short term VAD” and “durable/long term VAD” depending on the nature of the device. Durable/long term VAD enable patients to be discharged from hospital as some of the device is implanted within the body. There is a cable that shows outside the body which connects the pump to a controller and power source which is worn outside the body. Previous research has focused on the experiences of patients with a durable/long term VAD implanted. These studies have reported that patients who temporarily or permanently rely on VADs for end stage heart failure may face complex psychological, emotional and relational problems (Modica, Ferrantini, Torri, Oliva, Martinelli, De Maria & Frigerio, 2014).

A literature review was conducted by MacIver and Ross (2012) regarding quality of life for individuals with VAD. Durable/long term VAD clinical trials suggest improvements in quality of life are seen from 1-3 months post implant; however emotional distress is often unexplored within these trials (McIver & Ross, 2012). Furthermore, qualitative research has explored the impact of VADs on patients and their lives, quality of life during and after VAD support, perceptions and concerns of patients and care givers and psychosocial and sexual concerns (e.g. Chapman, Parameshwar, Jenkins,

Large & Tsui, 2007). These studies report themes of the journey of adjusting to the device (Casida, Marcuccilli, Peters & Wright, 2011), mechanical dependence for life (Marcuccilli, Casida & Peters, 2013; Overgaard, Kjeldgaard & Egerod, 2012) and perceived control over their lives (Hallas, Banner & Wray, 2009; Zambrowski, Combs, Cronin & Pfeffer, 2009).

The short term VAD is an external cardiac device that means people are maintained in intensive care; long term devices are internal and thus patients can be discharged home. Short term devices offer temporary circulatory support with the aim to temporarily stabilise patients with acute cardiogenic shock, with the aim to rest the heart (Subramaniam, 2015); this allows time to understand what intervention a person would benefit from. Short-term VADs (ST-VAD) therefore offer a bridge to decision (BTD) regarding the most useful intervention, which can include a later exchange to implantable/durable VAD, or removal for myocardial recovery and heart transplant (Takayama, Takeda, Doshi & Jorde, 2014). Takayama, Truby, Takeda and Naka (2014) point out that there is no clear definition of "short-term VAD", however, in line with the definition used by them, the current research will define "short-term VAD as mechanical circulatory support devices used only in the in-patient treatment setting" (p.2). This study will be focussing on the experiences of people who have undergone ST-VAD as an emergency procedure.

The research above focused on those with durable/ long term VAD, however a study by Chapman, Parameshwar, Jenkins, Large and Tsui (2007) conducted an interpretative phenomenological analysis pilot study with both durable/ long term VAD (4 patients) and ST-VAD (2 patients) patients. The two ST-VAD patients had received VAD as an emergency procedure. Chapman et al (2007) commented on the intrusion and adverse effects of the device, the impact of implanting the VAD as an emergency procedure, the difficulty to adapt after surgery and the lack of time to prepare family members who were shocked by the device when they first saw it. Furthermore, Chapman et al (2007) highlighted that different devices, durable/ long term or short term, may produce different experiences but due to the small sample size of ST-VAD within the Chapman et al (2007) it cannot be said whether the external VAD had a greater impact. As described, research tends

to focus on the impact for people with durable/long term VAD which may be a different experience from those who have a short-term VAD. ST-VADs are different to durable VADs. Short term VADs have external pumps and the patients mobility is severely limited and patients have intensive nursing support within a critical care environment. The ST-VAD offers critically "ill" patients a bridge to decision. Research has been conducted into the quality of life and experiences of people who have a durable/long term VAD often as a bridge to transplant, bridge to recovery or destination therapy however, little research has focused on the experience and psychological impact of short term VAD implant.

Service requirements for centres providing VAD allow centres to configure teams in a flexible manner to best serve the patients, however it is highlighted that social and psychological support should be available to patients and their families (NHS England, 2013). A deeper understanding of the experiences of people who undergo short term VAD treatment as an emergency procedure would be beneficial for all working with this group of people. Due to the training and knowledge of clinical psychologists, they are well placed to disseminate such knowledge and aid other multidisciplinary teams and individuals around the psychological reactions to such interventions.

Aim

The current research aims examine the lived experiences of people following ST-VAD implant as an emergency procedure. Therefore, this research will obtain subjective accounts of the experience of adults who have undergone ST-VAD implant and through their transition to further intervention to inform the potential role of clinical psychologists in their post-treatment care.

Method

Design

A qualitative approach to data collection and analysis will be adopted, employing face-to-face interviews. Telephone or Skype interviews may be used to enable participants to be included in the study. A semi-structured interview schedule (Appendix A) will be used to promote discussion on the subject of the research aims including basic demographic information , details of treatment, the journey to receiving ST-VAD, experiences during ST-VAD support, transition to further intervention and expectations for the future. This schedule will also allow flexibility and be responsive in order to facilitate participants in sharing their individual experiences and views. Following the first interview, the academic supervisor will read the transcript and will discuss this with the chief investigator in order to consider changes to interview style or order of questions.

Data will be analysed using Interpretative Phenomenological Analysis (IPA) as this approach aims to "explore in detail individual personal and lived experiences and to examine how participants are making sense of their personal and social worlds" (Smith & Eatough, 2007, p.36). Rather than applying predefined categories, this approach allows for expression of the lived experience through analysis which encourages the researcher to focus on contexts and perspectives of individuals as well as a group. Furthermore, this approach recognises the role of the researcher as an interpretative resource and the sense-making of people's accounts by the researcher during the analysis (Smith, Flowers & Larkin, 2009).

Materials

Potential participants will be provided with a participant information pack (Appendix B). This will include a participant information sheet and an expression of interest form including information on how to contact the researcher to obtain further information or to register interest in taking part in the study. A staff information sheet (Appendix C) will be provided for staff who will be handing out the information regarding the project to potential participants. Participants will be asked to complete a consent form (Appendix D) prior to the interview commencing. A semi-structured

interview schedule (Appendix A) will be used as a flexible guide for the interview. The interviews will be recorded using a digital recording device.

Participants

Participants will be recruited from the Cardiothoracic transplant unit of a hospital in the North West of England with the potential for further participants to be recruited from fellow cardiothoracic units within the UK. Between eight to twelve participants will be interviewed. Participants will be people who have had a short term VAD (ST-VAD) as an emergency procedure and been discharged from ICU to outpatient treatment. The study aims to gather people's experience across the timeline following ST-VAD. Tentative figures from the unit suggest that approximately 10-15 people per year fit these criteria at [redacted] and numbers are increasing each year. Inclusion criteria are:

1) People who have undergone ST-VAD as an emergency procedure
2) People discharged from ICU and therefore outpatients.
3) People who have capacity to give consent.

Participants who do not speak English or have special communication needs will be excluded from the study because there are no financial resources to allow for the use of interpreters. In addition, the method of analysis relies on the accurate use of words by participants and therefore would be likely to become more unreliable when based on interpreted accounts.

It is hoped that between 8-12 participants who meet the inclusion criteria will be recruited to the study, which would provide enough data to allow for the development of similarities between the accounts without the individuality and differences being lost (Smith, Flowers & Larkin, 2009).

Recruitment

Participants will be recruited by members of the cardiothoracic team (e.g. specialist nurse/consultant cardiologist/psychologist). Clinicians will distribute information packs to those patients who fit the criteria and who express an interest. Participant information packs will be either given to potential participants when attending for regular outpatient appointments, or posted to

potential participants if they are not due in outpatient appointments during the next 3 months. Furthermore, potential participants will be informed of the research via telephone calls made by known health care workers. Participants can contact the chief investigator directly to ask questions about the research. Alternatively those patients who opt in to the research via the clinician responsible will be informed that they can request to be contacted directly by the chief investigator so as to retain anonymity. Posters will also be displayed in the cardiothoracic department (Appendix E).

The research will be outlined to the team members, with opportunity for them to ask questions regarding the study. They will also be given a staff information sheet regarding the process of sharing the participant information packs, to ensure that this will be conducted in a facilitative rather than coercive manner (Appendix C). The participant information packs will be provided to members of staff for example, specialist nurse/consultant cardiologist/psychologist, to distribute to potential participants. The staff member will ask the participant whether they would agree to sign an expression of interest/consent to contact form, providing a contact telephone number, to allow the chief investigator to contact the potential participant to provide further information regarding the study. The expression of interest form (Appendix F) can be collected by the healthcare professional to pass on the researcher. The potential participant will also be provided with a stamped addressed envelope in which to request further information or to register their wish to take part in the study which can be used to maintain their anonymity of participation.

The participant information sheet will state that participation in the study is voluntary and that confidentiality will be maintained, unless there is indication of either risk to self or others. It may be possible for the chief investigator to attend follow up clinics when it is known that ex short-term VAD patients will be attending. Participants who have registered interest in taking part in the study will be contacted to arrange a time and location that is mutually convenient for the interview to take place.

Procedure

Interviews will be able to take place in a room at the transplant unit or at the participants' home. If a room at the transplant unit is used then it will be booked in the chief investigator's name so as to ensure anonymity for the participant. The chief investigator will remain aware of personal

safety and follow lone worker policies when conducting interviews in line with Lancaster University guidance.

At the outset of the interview, the nature and purpose of the research will be outlined to the participant. The chief investigator will also clarify their role in relation to the transplant team and the research and confidentiality and its limits will be reiterated. Subsequently, the participant will be asked to sign the consent form (Appendix D). Interviews will last approximately one hour, which could be split across two sessions if the participant wishes. The interview will be recorded using a digital recorder.

At the end of the interview, the participants will be asked whether they wish to be contacted at the conclusion of the research in order to receive an outline of the results, on which they will be invited to comment. These comments will not be used to alter the interpretation of the data, but will be included in the final report where relevant. They will also be asked whether they would like to choose a pseudonym, to be used to refer to their quotations, in the write up on the research. If the participant does not wish to do so, they will be informed that the chief investigator will assign a pseudonym. The recorded interviews will be transcribed and all identifying information (eg names and places) will be removed from the transcriptions. The digital recordings will be deleted after transcription.

Practical Issues

It will be important that participants are able to contact the chief investigator to ask any questions they may have about taking part in the research. The university will be able to furnish the chief investigator with a mobile telephone in order to receive texts and calls from participants.

Where travel expenses are incurred by participants, these will be reimbursed, up to £20, by the university.

Other financial implications of the research will include printing, photocopying and postage of materials, including participant and staff information sheets and consent forms. These costs will be met by the university.

Ethical considerations

There are two principle ethical concerns regarding potential participants: ensuring anonymity of participants and the potential for distress amongst participants. Furthermore, the procedure for lone working for the chief investigator.

Lone worker

Interviews may take place in participants' homes. If this occurs, a buddy system will be in place. A peer clinical psychology trainee will have information regarding when and where the interview will take place. If the interview runs over a specified time the peer will attempt to contact the interviewer (direction taken from Lancaster University Guidance on Safety in Fieldwork (Lone Worker) http://www.lancs.ac.uk/depts/safety/files/Fieldwork.pdf.).

Anonymity

Participants may be concerned that information will be identifiable. All identifiable information will be anonymised with the agreement of the participant. Participants' names will be anonymised using pseudonyms. This will also be discussed prior to the interview starting and participants will be informed that the field supervisor, clinical psychologist at the hospital, will not hear the interview or see the transcript and will only have access to the emerging themes. It will also be highlighted to participants that their care will not be affected by taking part in the study and that their participation is voluntary. Participants will be informed that the results of the study will be fed back to the participants if they request it and to the transplant units. The study will also be written up for publication.

Informed consent will be managed by the provision of clear information, on the participant information sheet and through discussion of the process with the chief investigator both prior to registering interest and prior to signing a consent form. Participants will be informed that their confidentiality will be maintained, unless risk to either self or other is indicated. The chief

investigator will be aware of the appropriate staff to contact and inform, and the relevant complaints procedure.

Distress

It is not anticipated that the nature of the questions will be experienced as intrusive or distressing. Participants will be aware that the interview will involve talking about their experiences of VAD before they provide consent to take part in the study. However, these interviews may still result in some distress as participants will be talking about difficult experiences. If a participant was to become distressed during the interview, the interview would be stopped and the participant given some time. All participants will be made aware that they are able two withdraw their data at any time during the interview and up to two weeks after this date.

Procedure if a participant becomes distressed

- Should the participant become distressed during the interview they would be informed that they can meet with a clinical psychologist from the unit, for support. Should the participant wish to meet with a clinical psychologist this would be arranged by the chief investigator. A phone call with a clinical psychologist will be provided 24 hours following the request during the working week and meeting with a clinical psychologist could be provided within one week of the request for support.
- Should the participant become distressed following the interview the debrief sheet (Appendix G) includes the contact details for a clinical psychologist, to allow them to arrange a session themselves.
- As an additional precaution, participants will not be interviewed on a Friday afternoon to ensure that staff at the unit would be available to provide support if needed immediately following the interview.

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Appendix A

Study Title: **The experiences of people following short term VAD implant as an emergency procedure**

Version number: 1

Date: June 2016

Semi-structured interview schedule

The following schedule will be used as a guide for the researcher, in order to facilitate participants to discuss their experiences. However the questions may be adapted or changed depending on individuals' responses.

- Background to research; purpose of interview; any questions

- Introduction: Thank you for meeting with me today. My name is Ellie. You might remember from the information sheet that I have a few questions I would like to ask you. It should take about an hour. You do not have to answer any questions if you do not want to. If you want to stop at any time, let me know and we will stop. What we talk about will be kept annonymised. However, if you tell me that you or someone else is being harmed then I will have to report this to a relevant member of staff to keep you or someone else safe.

- I have a digital recorder here to record our interview. This will make sure I have got what you said right.

- Before we start we'll go through the information sheet, to see if you have any questions. After that I will ask you to sign a consent form, which asks whether you understand what is involved in taking part and whether you agree to take part in the project.

Establishing rapport and general information

To help me to understand your experiences I wonder if it would be ok for me to ask you a few short questions about your ST VAD

- The factors that led to ST-VAD
- What was the diagnosis that led to the emergency procedure
- How old were you when you the emergency procedure occurred

- How long did you have to wait to be taken of ST-VAD and what was the next treatment/intervention
- How long were you in hospital
- How long has it been since you came off ST-VAD

Experiences:

Would it be ok for me to ask you about your experience in order starting with life before the emergency procedure?

- What was life like before you needed the STVAD
    - *Relationships, interests, work, health*
- Had you had any experience of ST VAD or heart conditions? Did you know anyone who had STVAD

During

- What was it like when you needed the STVAD
    - Any changes noticed
- How did you feel/what did you think about
- What were your expectations
- What actually happened
- What support did you need during this time

After

Transition to further intervention

- Aftermath/experience of being on STVAD
- Personal impact – has ST VAD/emergency procedure made a difference to how you see yourself?
- How would you say you have changed?
- What about the way other people see you?
- Impact of hospital admission, discharge, later interventions.
- Impact on others: Impact of hospital admission, discharge, later interventions.
- What support do you need now

Future

- What are your expectations about the future?
- What are your hopes for the future?
- What support do you think you might need in the future?

Is there anything that you feel you have not had chance to say about your experience?

Do you have any questions?

Additional questions

1. In the information sheet, that we went through before we started the interview, it mentioned that you would be given the opportunity to choose an alternative name for yourself that I can use in writing up this project. Do you want to choose an alternative name?
2. The information sheet also mentioned that I would ask whether you would like to comment on a summary of your interview? Your comments may be used in the write up.
3. I also want to ask you whether you would like to receive a summary of the research that I am doing. This would be posted to you and would be in May or June 2017.

Remind participants about reimbursement of travel expenses.

Thank participant for their involvement in the project.

Appendix B

Health & Medicine | Lancaster University

Participant Information Sheet

The experiences of people following short term VAD implant as an emergency procedure.

Why are we interested in talking to you?

You are someone who has had a Short Term VAD as an emergency procedure. Talking to you about your experiences will help us learn what it is like to have this procedure and life afterwards. It is hoped that this will help services to support similar people better in the future.

Do I have to take part?

No. It's completely up to you to decide whether or not you take part. If you decide to take part you can change your mind at anytime. You will not have to give a reason for changing your mind. Taking part or not taking part will not change the care you would receive from the hospital. I am not part of the hospital. I am a trainee clinical psychologist at Lancaster University and I am doing this project as part of my training.

What would I have to do?

If you decide to take part, I will meet with you either in a room at the Transplant Unit or at your home if you prefer. Your travel expenses, including parking, can be refunded up to £20. If you are travelling by car all that will be needed is the number of miles you will travel for the interview. If you are parking you will need to provide a receipt from the car park. If you are using public transport you will need to bring your receipts. If it is not possible for us to meet at your home or at the Transplant Unit, then interviews could be conducted via telephone or Skype.

The interview will involve talking about your experience of being on Short Term VAD. This will last about 1 hour. You could choose to split this time over two sessions if you prefer. The interview will be audio recorded. This is so I can record everything you said correctly. The recordings will be deleted when they have been typed up.

At the end of the interview I will ask you three things. First, whether you would like to choose an alternative name that can be used to refer to your words and phrases. Second, whether you would like the opportunity to comment on a summary of your interview. These comments may be included in the write up of the research. Thirdly, whether you would like a summary of the results after the research is completed; this could be provided by telephone or by post.

Will my data be confidential?

The information you provide will be annonymised. Personal data will be confidential. The data collected for this study will be stored securely and only the researchers conducting this study will have access to this data:

- Audio recordings will be deleted after the project has been submitted and marked.
- Your audio recording or typed up interview may be listened to or read by my supervisor at the university.
- The data files will be encrypted (that is, no-one other than the researcher will be able to access them) and the computer itself password protected.
- The typed version of your interview will be made anonymous by removing any identifying information including your name. Anonymised direct quotations from your interview may be used in the reports or publications from the study
- A written transcript of the interview will be kept for 10 years after the study has finished.

There are some limits to confidentiality: if what is said in the interview makes me think that you, or someone else, are at significant risk of harm, I will have to break confidentiality and speak to someone involved with your care. If possible, I will tell you if I have to do this.

What will happen to the results?

The results will be summarised in a report and may be submitted for publication in an academic or professional journal.

What will happen if I get upset?

I will not be asking any questions which are intended to upset you. But sometimes talking about our experiences can be upsetting. If you become upset in the interview we would stop. I would ask you whether you thought you needed any additional support and we could talk about what this might be. I would remind you of your right to decide not to take part in the research, this would be your decision and would not affect the support that would be offered to you. You can also change your mind up to two weeks after meeting with me, and decide that you do not want your interview to be part of the research. You will be given contact details of people in the hospital that would be able to provide you with support after the interview.

Are there any benefits to taking part?

Although you may find participating interesting, there are no direct benefits of taking part. It is hoped that the information gathered by the research may help to shape the service for people who are supported with a short term VAD.

What do I do now?

There are two ways you can get more information about the research or register your interest to take part:

1. You can complete the enclosed expression of interest form and give it to a member of staff during outpatient appointment. They might ask you about this when they

first tell you about the research. If you prefer, you can also post this form to me in the stamped addressed envelope enclosed.

2. You can telephone, text or email me, and I will get back to you
   Telephone: [redacted]
   Email: e.taylor@lancaster.ac.uk

I will interview up to 12 people for this research. Participants will be selected on a first come first served basis.

Thank you for reading this.
Ellie Taylor (Chief investigator & Trainee Clinical Psychologist)

Research Supervisor: Pete Greasley Clinical Psychology, Div. Of Health Research, Lancaster University, Lancaster, LA1 4YG Phone: 01524 592754 Email: p.greasley@lancaster.ac.uk	Field Supervisor: [redacted]

This study has been reviewed by the Faculty of Health and Medicine Research Ethics Committee and approved by the Local NHS Ethics committee.

Complaints
If you wish to make a complaint or raise concerns about any aspect of this study and do not want to speak to the researcher, you can contact:

Bill Sellwood
Research Director
Tel: (01524) 593998
Email: b.sellwood@lancaster.ac.uk
Clinical Psychology, Div. Of Health Research,
Lancaster University, Lancaster, LA1 4YG

Appendix C

Staff information Sheet

The experiences of people following short term VAD implant as an emergency procedure

This information sheet is for staff who are sharing information about this research project with service users they are working with. If you have any questions please contact me at the phone/email below or speak to [redacted]

Who can take part in the research?

Anyone who has had an external short term VAD. They need to have been discharged. Potential participants also need to be able to speak English. Potential participants need to be able to consent to taking part in the research.

When should information about the research project be shared with service users?

When you have identified people who could take part, information about the research project could be shared with services users in their next outpatient appointment. If this is not possible then the same information packs could be posted to the service user identified or information given verbally over the phone. If people express an interest over the phone and want more information then packs can be posted to them.

How to introduce the research project?

You might introduce the project by saying:

I have been asked to tell you about some research that is going to be happening. Ellie Taylor, from Lancaster University, is interested in talking to you about what it was like to be on a short term ventricular assist device and what happened after being on the device. The idea is that the experiences people share with Ellie can be used to improve services and support for people who have had short term VAD.

If this is something that you think you'd like to be involved in, Ellie has given me some further information that I can give to you. In this pack it tells you a bit more about the project and how to contact Ellie if you have any questions or want to take part.

If you would like Ellie to contact you with more information or about taking part in the research there is a form (expression of interest form) you can fill in.

Details for contacting Ellie

Ellie Taylor
Telephone: [redacted]
Email: e.taylor@lancaster.ac.uk

Thank you very much for your time and your assistance in helping with recruitment for this project, it is very much appreciated.

Appendix D

Consent Form

Study Title: **The experiences of people following short term VAD implant as an emergency procedure**

We are asking if you would like to take part in a research project which aims to explore the experiences of people following short term VAD implant as an emergency procedure.

Before you consent to participating in the study we ask that you read the participant information sheet and mark each box below with your initials if you agree. If you have any questions or queries before signing the consent form please speak to the Chief investigator, Ellie Taylor.

1. I confirm that I have read the participant information sheet (version 3) and fully understand what is expected of me within this study	
2. I confirm that I have had the opportunity to ask any questions and to have them answered.	
3. I know what I will be asked to do	
4. I understand that my interview will be audio recorded and then made into an anonymised written transcript.	
5. I understand that digital audio recordings will be kept until the research project has been examined.	
6. The interview will be typed out. I know that the typed out copies of my interview will only be read by Ellie and her supervisor.	
7. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected.	
8. I understand that once my data have been anonymised and incorporated into themes it might not be possible for it to be withdrawn, though every attempt will be made to extract my data, up to the point of publication.	
9. I understand that the information from my interview will be pooled with other participants' responses, anonymised and may be published.	

10. I understand that data collected from the study may be seen by regulatory authorities or by persons from the Trust where it is relevant to my taking part in this study. I agree to these persons having access to this information.	
11. I know that Ellie will use some of my words and phrases in her write up of the project. These will also be used in presentations and if the study is published. I consent to anonymised information and quotations from my interview being used in reports, conferences and training events.	
12. I understand that any information I give will remain strictly confidential and anonymous unless it is thought that there is a risk of harm to myself or others, in which case the chief investigator may need to share this information with her research supervisor	
13. I consent to Lancaster University keeping a written transcript of the interview for 10 years after the study has finished.	
14. I will be given the opportunity to comment on a summary of my interview. I know that Ellie may use some of my comments in her writing up.	
15. I know that taking part is my choice and I can change my mind at any time, including up to 2 weeks after the meeting.	
16. I have read the above and I agree to take part.	

Name of Participant_____Signature_____Date_____

Name of Chief Investigator_____Signature_____Date_____

Appendix E

Version 2 September 2016

Health & Medicine | Lancaster University

Appendix E

The experiences of people following short term Ventricular Assist Device implant as an emergency procedure

Were you on short term Ventricular Assist Device?

Would you like to talk about your experiences of being on short term Ventricular Assist Device?

If you answered yes to these questions please ask at reception for an information pack. This will tell you about the research that Ellie Taylor, from Lancaster University, is conducting and how you could get involved.

Appendix F

The experiences of people following short term VAD implant as an emergency procedure

Expression of Interest Form

I have been told about this research and have been given the information sheet.

I would:

(please tick)

	have some questions I would like to ask about the research to help me to decide whether I would like to take part
	would like to register my interest in taking part

I give my permission for Ellie Taylor to contact me directly on:

Telephone number	
Email address	

A convenient time to contact me by telephone is:

Signature

Date

Appendix G

The experiences of people following short term VAD implant as an emergency procedure

Debrief sheet

Thank you for taking part in this research

What happens next?

As we discussed, Ellie will contact you with a summary of your interview. Ellie will ask you to provide your comments on this summary.

Following this, a summary which captures all of the interviews will be produced. Ellie will post or email a copy of this to you.

What happens with my travel expenses?

If you travelled by car all that is needed to claim your travel expenses back is your mileage, which Ellie will ask you about either before or during the interview.

If you travelled by public transport you will need to provide receipts of your travel. You may need your receipt for your return journey. You will be given a travel expenses form to complete and a freepost envelope to return the expenses form with your receipts.

What happens if I feel I need support after the interview?

If you would like to talk to a member of the Transplant Team then please ask to speak to Dr [redacted], Consultant Clinical Psychologist for transplant. You can speak to her by telephoning the transplant Unit on [redacted].

Thank you again for your invaluable contribution to this research. Please do not hesitate to contact me if you require further information

Ellie Taylor

Telephone: [redacted] Email: e.taylor@lancaster.ac.uk

Appendix H

The experiences of people following short term Ventricular Assist Device (VAD) implant as an emergency procedure

Dear Sir or Madam

Re: The experiences of people following short term VAD implant as an emergency procedure

My name is Ellie Taylor. I am a Trainee Clinical Psychologist at Lancaster University. As part of my training I am going to do some research on what it is like to have a short term VAD as an emergency procedure.

You were recently informed about the research by someone at the hospital. I am interested in talking to you about your experience of having a short term VAD and hearing about what this was like for you.

If you think you would like to talk to me about these things, please read the information sheet enclosed. It provides you with more information about what would be involved in taking part in this research. It also tells you how to contact me if you want to ask questions or choose to take part.

Thank you for your time.

Ellie Taylor
Chief Investigator
Lancaster University

Appendix I

IRAS Form | Reference: 16/NW/0631 | IRAS Version 5.3.2

Welcome to the Integrated Research Application System

IRAS Project Filter

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

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

Please enter a short title for this project (maximum 70 characters)
Experiences of short-term VAD

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product

( ) Clinical investigation or other study of a medical device

( ) Combined trial of an investigational medicinal product and an investigational medical device

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

( ) Basic science study involving procedures with human participants

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

(●) Study involving qualitative methods only

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

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

( ) Research tissue bank

( ) Research database

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

( ) Other study

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

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

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

[x] England
[ ] Scotland

☐ Wales
☐ Northern Ireland

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

◉ England
◯ Scotland
◯ Wales
◯ Northern Ireland
◯ This study does not involve the NHS

4. Which applications do you require?

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

☑ IRAS Form
☐ Confidentiality Advisory Group (CAG)
☐ National Offender Management Service (NOMS) (Prisons & Probation)

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

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

Most research projects require review by a REC within the UK Health Departments' Research Ethics Service. Is your study exempt from REC review?

◯ Yes ◉ No

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

◉ Yes ◯ No

5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out research e.g. NHS Support costs) for this study provided by a NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or a Diagnostic Evidence Co-operative in all study sites?

Please see information button for further details.

◯ Yes ◉ No

Please see information button for further details.

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) Support and inclusion in the NIHR Clinical Research Network Portfolio?

Please see information button for further details.

◯ Yes ◉ No

The NIHR Clinical Research Network provides researchers with the practical support they need to make clinical studies happen in the NHS e.g. by providing access to the people and facilities needed to carry out research "on the ground".

If you select yes to this question, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form (PAF) immediately after completing this project filter question and before submitting other applications. Failing to complete the PAF ahead of other applications e.g. HRA Approval, may mean that you will be unable to access NIHR CRN Support for your study.

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

◯ Yes ◉ No

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

◯ Yes ◉ No

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

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

◯ Yes ◉ No

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

◉ Yes ◯ No

Please describe briefly the involvement of the student(s):
The project is being undertaken as part of the Chief Investigator's Doctorate in Clinical Psychology.

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

◉ Yes ◯ No

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

◯ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

◯ Yes ◉ No

Integrated Research Application System
Application Form for Research involving qualitative methods only

IRAS Form (project information)

Please refer to the E-Submission and Checklist tabs for instructions on submitting this application.

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Experiences of short-term VAD

Please complete these details after you have booked the REC application for review.

REC Name:
Lancaster

REC Reference Number:
16/NW/0631

Submission date:
04/08/2016

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

What are the experiences of people following short term VAD implant as an emergency procedure

A2-1. Educational projects

Name and contact details of student(s):

Name and contact details of academic supervisor(s):

Academic supervisor 1

	Title	Forename/Initials	Surname
	Dr	Pete	Greasley
Address	Lancaster University		
	Division of Health Research		
	Furness Building, Lancaster		
Post Code	LA1 4YG		
E-mail	p.greasley@lancaster.ac.uk		
Telephone	01524 593535		
Fax			

Please state which academic supervisor(s) has responsibility for which student(s):
Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

Student(s)	Academic supervisor(s)

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

- (•) Student
- ( ) Academic supervisor
- ( ) Other

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Ms	Eleanor	Taylor

Post	Trainee Clinical Psychologist
Qualifications	BSc Hons Psychology MSc Health Psychology
Employer	Lancashire Care NHS Foundation Trust
Work Address	Division of Health Research Furness Building Lancaster University
Post Code	LA1 4YG
Work E-mail	e.taylor@lancaster.ac.uk
* Personal E-mail	
Work Telephone	
* Personal Telephone/Mobile	
Fax	

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
	Dr	Diane	Hopkins

Address	Research Services B14 Furness College Lancaster University
Post Code	LA1 4YT
E-mail	ethics@lancaster.ac.uk
Telephone	01524592838
Fax	

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):

Sponsor's/protocol number:

Protocol Version:

Protocol Date:

Funder's reference number:

Project website:

Additional reference number(s):

Ref.Number Description	Reference Number

Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

A5-2. Is this application linked to a previous study or another current application?

◯ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments' Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.*

A Short Term Ventricular Assist Device (ST-VAD) is a form of mechanical circulatory support that offers temporary circulatory support with the aim to temporarily stabilise patients with acute carcinogenic shock with the aim to rest the heart. The ST-VAD works a bridge to decision regarding the most useful intervention for the person which can include exchange to durable/long-term VAD, explants for myocardial recovery and heart transplant (Takayama, Takeda, Doshi & Jorde, 2014).

Previous research has focused on the psychosocial impact of durable VADs however the durable VAD enables patients to be discharged from hospital. ST-VAD support is offered in critical care settings and patients are in hospital for the length of treatment. Chapman, Parameshwar, Jenkins, Large and Tsui (2007) conducted a qualitative study with both ST-VAD and durable VAD patients and discovered a difference between the experiences of these participants.

Due to the lack of research regarding solely the experiences of those who have undergone STVAD, the current research aims to explore the experience of people who have a short term VAD implant as an emergency procedure. A qualitative research design involving semi-structured interviews will be used to explore individuals' experiences of short-term VAD as an emergency procedure. Participants will be recruited from University Hospital of South Manchester NHS Foundation Trust and invited to take part in an interview which will last approximately one hour.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, HRA, or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

Ethical approval for the study will initially be sought from a North West Ethics Committee, after which R&D approval will be sought from the [redacted] The main ethical issues identified include informed consent and risk of distress to participants.

There is no direct benefit of participating in the current research however the themes that emerge may help the understanding of those who experience ST-VAD and the ways in which health care professionals work with patients.

Participants may be concerned that information will be identifiable. All identifiable information will be anonymised with the agreement of the participant. Participants' names will be anonymised using pseudonyms. This will also be discussed prior to the interview starting and participants will be informed that the field supervisor will not hear the interview or see the transcript and will only have access to the emerging themes. It will also be highlighted to participants that their care will not be affected by taking part in the study and that their participation is voluntary.

Informed consent will be managed by the provision of clear information, on the participant information sheet and through discussion of the process with the chief investigator both prior to registering interest and prior to signing a consent form. Participants will be informed that their confidentiality will be maintained, unless risk to either self or other is indicated. The chief investigator will be aware of the appropriate staff to contact and inform, and the relevant complaints procedure.

A further ethical issue relates to dissemination of the findings of the research. The results of the study will be fed back to the participants if they request it and to the transplant units. The study will also be written up for publication.
It is not anticipated that the nature of the questions will be experienced as intrusive or distressing. Participants will be aware that the interview will involve talking about their experiences of VAD before they provide consent to take part in the study. However, these interviews may still result in some distress as participants will be talking about difficult experiences. If a participant was to become distressed during the interview, the interview would be stopped and the participant given some time. All participants will be made aware that they are able two withdraw their data at any time during the interview and up to two weeks after this date.

In addition to the above, interviews may take place in participants homes. If this occurs, a buddy system will be in place. A peer will have information regarding when and where the interview will take place. If the interview runs over a specified time the peer will attempt to contact the interviewer. Direction taken from Lancaster University Guidance on Safety in Fieldwork (Lone Worker) http://www.lancs.ac.uk/depts/safety/files/Fieldwork.pdf.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply:*

- ☐ Case series/ case note review
- ☐ Case control
- ☐ Cohort observation
- ☐ Controlled trial without randomisation
- ☐ Cross-sectional study
- ☐ Database analysis
- ☐ Epidemiology
- ☐ Feasibility/ pilot study
- ☐ Laboratory study
- ☐ Metanalysis
- ☑ Qualitative research
- ☐ Questionnaire, interview or observation study
- ☐ Randomised controlled trial

☐ Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

The present study aims to explore the lived experience of people following short term ventricular assist device implant as an emergency procedure.

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

A ventricular assist device (VAD) is a mechanical pump that is used to support heart function and blood flow for people who have weakened hearts. The device takes blood from a lower chamber of the heart and helps pump it to the body and vital organs, just as a healthy heart would (The National Heart, Lung and Blood Institute, n.d.). It does not completely replace the heart but the VAD works with the heart to help it pump more blood with less work.

The VAD may be used to support and stabilise the heart until a suitable donor heart can be found for transplantation; this is called bridging to transplantation (BTT). The VAD can also be used to support a heart to allow it to return to strength after an acute illness; this is called bridging to recovery (BTR). The NHS currently commissions the use of VADs as a Bridge to Transplant or a Bridge to Recovery (NHS England, 2013). Specific VADs may also be used as a Bridge to Decision (BTD) which can act as a temporary measure to stabilise the heart prior to decisions regarding transplant or a similar intervention.

There are broadly two types of VAD, "short term VAD" and "durable/long term VAD" depending on the nature of the device. Durable/long term VAD enable patients to be discharged from hospital as some of the device is implanted within the body. There is a cable that shows outside the body which connects the pump to a controller and power source which is worn outside the body. Previous research has focused on the experiences of patients with a durable/long term VAD implanted. These studies have reported that patients who temporarily or permanently rely on VADs for end stage heart failure may face complex psychological, emotional and relational problems (Modica, Ferrantini, Torri, Oliva, Martinelli, De Maria & Frigerio, 2014).
A literature review was conducted by MacIver and Ross (2012) regarding quality of life for individuals with VAD. Durable/long term VAD clinical trials suggest improvements in quality of life are seen from 1-3 months post implant; however emotional distress is often unexplored within these trials (MacIver & Ross, 2012). Furthermore, qualitative research has explored the impact of VADs on patients and their lives, quality of life during and after VAD support, perceptions and concerns of patients and care givers and psychosocial and sexual concerns (e.g. Chapman, Parameshwar, Jenkins, Large & Tsui, 2007). These studies report themes of the journey of adjusting to the device (Casida, Marcuccilli, Peters & Wright, 2011), mechanical dependence for life (Marcuccilli, Casida & Peters, 2013; Overgaard, Kjeldgaard & Egerod, 2012) and perceived control over their lives (Hallas, Banner & Wray, 2009; Zambrowski, Combs, Cronin & Pfeffer, 2009).

The short term VAD is an external cardiac device that means people are maintained in intensive care; long term devices are internal and thus patients can be discharged home. Short term devices offer temporary circulatory support with the aim to temporarily stabilise patients with acute cardiogenic shock, with the aim to rest the heart (Subramaniam, 2015); this allows time to understand what intervention a person would benefit from. Short-term VADs (ST-VAD) therefore offer a bridge to decision (BTD) regarding the most useful intervention, which can include a later exchange to implantable/durable VAD, or removal for myocardial recovery and heart transplant (Takayama, Takeda, Doshi & Jorde, 2014). Takayama, Truby, Takeda and Naka (2014) point out that there is no clear definition of "short-term VAD", however, in line with the definition used by them, the current research will define "short-term VAD as mechanical circulatory support devices used only in the in-patient treatment setting" (p.2). This study will be focussing on the experiences of people who have undergone ST-VAD as an emergency procedure.

The research above focused on those with durable/ long term VAD, however a study by Chapman, Parameshwar, Jenkins, Large and Tsui (2007) conducted an interpretative phenomenological analysis pilot study with both durable/ long term VAD (4 patients) and ST-VAD (2 patients) patients. The two ST-VAD patients had received VAD as an emergency procedure. Chapman et al (2007) commented on the intrusion and adverse effects of the device, the impact of implanting the VAD as an emergency procedure, the difficulty to adapt after surgery and the lack of time to prepare family members who were shocked by the device when they first saw it. Furthermore, Chapman et al (2007) highlighted that different devices, durable/ long term or short term, may produce different experiences but due to the small sample size of ST-VAD within the Chapman et al (2007) it cannot be said whether the external VAD had a greater impact. As described, research tends to focus on the impact for people with durable/long term VAD which may be a

different experience from those who have a short-term VAD. ST-VADs are different to durable VADs. Short term VADs have external pumps and the patients mobility is severely limited and patients have intensive nursing support within a critical care environment. The ST-VAD offers critically "ill" patients a bridge to decision. Research has been conducted into the quality of life and experiences of people who have a durable/long term VAD often as a bridge to transplant, bridge to recovery or destination therapy however, little research has focused on the experience and psychological impact of short term VAD implant.

Service requirements for centres providing VAD allow centres to configure teams in a flexible manner to best serve the patients, however it is highlighted that social and psychological support should be available to patients and their families (NHS England, 2013). A deeper understanding of the experiences of people who undergo short term VAD treatment as an emergency procedure would be beneficial for all working with this group of people. Due to the training and knowledge of clinical psychologists, they are well placed to disseminate such knowledge and aid other multidisciplinary teams and individuals around the psychological reactions to such interventions.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

A qualitative research design is identified as being the most appropriate method of inquiry for the present study as it will allow the Chief Investigator to explore the experiences of individuals who have undergone ST-VAD as an emergency procedure. Semi-structured interviews will be conducted as these provide a flexible source of data collection to develop insights into the individuals lived experiences. Participants who express and interest to take part in the study will be invited to take part in an interview which will last approximately one hour and informed that they can be interviewed in a location most convenient to them, whether that be at their home or in a clinic room at the cardiothorasic department at a time and date which is most suitable for them.

The information collected from the participants interviews will be analysed using Interpretative Phenomenological Analysis (IPA). This model of analysis is favoured as it offers a flexible approach to exploring and analysing qualitative data and will allow the Chief Investigator to examine the lived experiences of individuals who have undergone ST-VAD as an emergency procedure, in terms of how they make sense of this and what meanings this holds for the individuals concerned (Smith & Osborn, 2008).

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- [x] Design of the research
- [ ] Management of the research
- [ ] Undertaking the research
- [ ] Analysis of results
- [ ] Dissemination of findings
- [ ] None of the above

Give details of involvement, or if none please justify the absence of involvement.
The information packs to be handed out to potential participants were viewed and commented on by service users from the transplant unit with regards to wording and content.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A15. What is the sample group or cohort to be studied in this research?

Select all that apply:

- [ ] Blood
- [ ] Cancer

- [x] Cardiovascular
- [ ] Congenital Disorders
- [ ] Dementias and Neurodegenerative Diseases
- [ ] Diabetes
- [ ] Ear
- [ ] Eye
- [ ] Generic Health Relevance
- [ ] Infection
- [ ] Inflammatory and Immune System
- [ ] Injuries and Accidents
- [ ] Mental Health
- [ ] Metabolic and Endocrine
- [ ] Musculoskeletal
- [ ] Neurological
- [ ] Oral and Gastrointestinal
- [ ] Paediatrics
- [ ] Renal and Urogenital
- [ ] Reproductive Health and Childbirth
- [ ] Respiratory
- [ ] Skin
- [ ] Stroke

Gender:	Male and female participants
Lower age limit: 18	Years
Upper age limit:	Years

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

Inclusion criteria include;
People who have had a short term VAD as an emergency procedure, including those who were fit and well and living a "normal" life until cardiac arrest, sudden viral infection etc.
Participants will have been discharged from ICU.
This study will include people who have gone on to have further intervention as STVAD is often used as a bridge to decision. It will also be open to people who have not had further intervention.
They will have capacity to give consent.

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

Participants who do not speak English or have special communication needs will be excluded from the study because there are no financial resources to allow for the use of interpreters. In addition, the method of analysis relies on the accurate use of words by participants and therefore would be likely to become more unreliable when based on interpreted accounts.

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Receiving information regarding the study	1		5-10 minutes	Information packs will be handed to the potential participants during outpatient appointments. This will be done by members of the team or by the chief investigator. During this the participants' will be asked to complete an expression of interest form. Team members may also provide this information over the phone to potential participants.
Arranging interview time and place	1		10-15 minutes	It will be the responsibility of the Chief Investigator to have contact with participants to arrange a time and location for interview that is convenient for the participants
Seeing informed consent	1		10-15 minutes	It is the responsibility of the Chief Investigator to gain informed consent. This will take place prior to the commencement of the interviews.
Interviews	1		approximately 60 min	The Chief Investigator will conduct the interviews and these will take place at a location most convenient for the participants.

A21. How long do you expect each participant to be in the study in total?

The maximum duration of participation is calculated at approximately 12 months. This is calculated from when participants opt in to being contacted regarding the research until their last contact with the research team at the proposed dissemination process of the project.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

It is not anticipated that the nature of the questions will be experienced as intrusive or distressing. Participants will be aware that the interview will involve talking about their experiences of VAD before they provide consent to take part in the study. However, these interviews may still result in some distress as participants will be talking about difficult experiences. If a participant was to become distressed during the interview, the interview would be stopped and the participant given some time. All participants will be made aware that they are able two withdraw their data at any time during the interview and up to two weeks after this date.

Procedure if a participant becomes distressed

- Should the participant become distressed during the interview they would be informed that they can meet with a clinical psychologist from the unit, for support. Should the participant wish to meet with a clinical psychologist this would be arranged by the chief investigator. A phone call with a clinical psychologist will be provided 24 hours following the request during the working week and meeting with a clinical psychologist could be provided within one week of the request for support.
- Should the participant become distressed following the interview the debrief sheet (Appendix G) includes the contact details for a clinical psychologist, to allow them to arrange a session themselves.
- As an additional precaution, participants will not be interviewed on a Friday afternoon to ensure that staff at the unit would be available to provide support if needed immediately following the interview.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

(●) Yes ( ) No

If Yes, please give details of procedures in place to deal with these issues:

It is not anticipated that the nature of the questions will be experienced as intrusive or distressing. Participants will be aware that the interview will involve talking about their experiences of VAD before they provide consent to take part in the study. However, these interviews may still result in some distress as participants will be talking about difficult experiences. If a participant was to become distressed during the interview, the interview would be stopped and the participant given some time. All participants will be made aware that they are able two withdraw their data at any time during the interview and up to two weeks after this date.
Procedure if a participant becomes distressed
• Should the participant become distressed during the interview they would be informed that they can meet with a clinical psychologist for support. Should the participant wish to meet with a clinical psychologist this would be arranged by the chief investigator. A phone call with a clinical psychologist will be provided 24 hours following the request during the working week and meeting with a clinical psychologist could be provided within one week of the request for support.
• Should the participant become distressed following the interview the debrief sheet (appendix) includes the contact details for a clinical psychologist, to allow them to arrange a session themselves. The debrief sheet (appendix) also provides contact details for other staff at their cardiothoracic unit who are willing to provide support to participants of this study.
• As an additional precaution, participants will not be interviewed on a Friday afternoon to ensure that staff at the unit would be available to provide support if needed immediately following the interview.

A24. What is the potential for benefit to research participants?

There is no direct benefit from participation in this study.

A26. What are the potential risks for the researchers themselves? *(if any)*

Interviews may take place in participants homes which may place the Chief Investigator at some risk. If this occurs, a buddy system will be in place. A peer will have information regarding when and where the interview will take place. If the interview runs over a specified time the peer will attempt to contact the interviewer. Direction taken from Lancaster University Guidance on Safety in Fieldwork (Lone Worker) http://www.lancs.ac.uk/depts/safety/files/Fieldwork.pdf.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used?*For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

The Chief Investigator will not have access to the names and contact details of potential participants. Participants will be required to 'opt in' to the research; by completing an expression of interest form or by contacting the Chief Investigator directly to express an interest in taking part in the study, at which point they would need to sign an expression of interest/consent to contact form, providing a contact telephone number to allow the Chief Investigator to contact the potential participant. The only exception to this is if participants 'opt in' to the research via the clinician responsible for their care and request to be contacted by the Chief Investigator directly. In these circumstances, the clinician would seek verbal consent from the participant for their contact details to be shared with the Chief Investigator.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

◯ Yes ◉ No

Please give details below:

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

◉ Yes ◯ No

If Yes, please give details of how and where publicity will be conducted, and enclose copy of all advertising material (with version numbers and dates).

A poster (Appendix E) advertising the research and providing information about the study will be placed in the waiting room. Contact details of the Chief Investigator will also be distributed to staff members and placed at the reception area and in the waiting room.
In addition to the above, information packs including a copy of the participant information sheet (Appendix B) and a copy of the consent form (Appendix D) for the study will be able to requested from the reception staff or the clinician who is responsible for their care.
Clinicians will also distribute information packs to individuals who fall within the inclusion criteria for the study and who express an interest to take part in the research.

A29. How and by whom will potential participants first be approached?

As noted previously, participants will be required to 'opt in' to the research. This may happen by potential participants contacting the Chief Investigator directly to express an interest in taking part in the study.
Participants may 'opt in' to the research via the clinician responsible for their care and request to be contacted by the Chief Investigator directly. In these circumstances, the clinician would seek verbal consent from the participant for their contact details to be shared with the Chief Investigator.
In addition to the above, information packs may be posted to suitable participants as identified by clinicians involved in their care. Potential participants will be informed of the research via telephone calls made by known health care workers.
All participants who decide that they would like to take part in the study will be informed, prior to the commencement of the interviews, that their participation is voluntary and reminded that they have the right to withdraw from the research at any point during the interview and up to two weeks after the interview, at which point data analysis will begin.
Participants will be informed that any information collected during this period will be deleted and/or destroyed if they do choose to withdraw from the study.

A30-1. Will you obtain informed consent from or on behalf of research participants?

◉ Yes ○ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

Prior to the commencement of the interviews, participants will initially be provided with a participant information sheet (Appendix B) and given the opportunity to ask any questions they may have. If participants express that they would like to take part in the study, they will be required to provide their informed consent and asked to sign a consent form (Appendix D) confirming their wish to participate in the research.

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

◉ Yes ○ No

A31. How long will you allow potential participants to decide whether or not to take part?

If participants have expressed an interest in participation via their clinician then the Chief Investigator will phone the potential participant at the next convenient time up to one week.

Potential participants will be given two weeks to decide whether or not to take part in the study from receiving the information pack.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? *(e.g. translation, use of interpreters)*

Due to monetary and time restraints of the present study, individuals who are not fluent in English will be excluded from the study.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

- ○ The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.
- ◉ The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
- ○ The participant would continue to be included in the study.
- ○ Not applicable – informed consent will not be sought from any participants in this research.
- ○ Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

If you plan to retain and make further use of identifiable data/tissue following loss of capacity, you should inform participants about this when seeking their consent initially.

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)? *(Tick as appropriate)*

- ☐ Access to medical records by those outside the direct healthcare team
- ☐ Access to social care records by those outside the direct social care team
- ☑ Electronic transfer by magnetic or optical media, email or computer networks
- ☐ Sharing of personal data with other organisations
- ☐ Export of personal data outside the EEA
- ☐ Use of personal addresses, postcodes, faxes, emails or telephone numbers
- ☑ Publication of direct quotations from respondents
- ☐ Publication of data that might allow identification of individuals
- ☑ Use of audio/visual recording devices
- ☑ Storage of personal data on any of the following:
  - ☑ Manual files (includes paper or film)
  - ☐ NHS computers
  - ☐ Social Care Service computers
  - ☐ Home or other personal computers
  - ☑ University computers
  - ☐ Private company computers

☐ Laptop computers

Further details:
The use of personal telephone numbers will be required.
Personal addresses will also be required for those participants who choose to be interviewed at their home.
In addition to the above, as outlined in both the participant information sheet (Appendix B) and consent form (Appendix D), participants interviews will be audio recorded on a digital audio recording device and anonymised direct quotations from participants may be used in the reports or publications from the study. As the digital audio recording device cannot be encrypted, the audio recordings of the interviews will be uploaded from the device onto the Chief Investigator's personal file space on the University's secure server, after which point they will be immediately deleted from the recording device. In the meantime, the audio recording device will be stored securely with the Chief Investigator. The audio recordings will be kept for a maximum of six months following the interview itself in order to allow time for the interview to be transcribed and checked, after which point they will be destroyed.
Audio recordings and transcripts used by the Chief Investigator will be stored on the Chief Investigator's personal file space on the University's secure server. Any paper files (e.g. consent forms) used by the Chief Investigator during the study will be scanned and stored securely by the university in a password protected file for a maximum of 10 years. After this point, they will be destroyed by a staff member responsible in the Lancaster Doctorate in Clinical Psychology(DClinPsy) Programme.
The above information is outlined in the participant information sheet (Appendix B) and/or consent form (Appendix D).

A37. Please describe the physical security arrangements for storage of personal data during the study?

Digital audio recordings will be kept in a password protected space on the university server. The digital recordings will be destroyed 10 years after the completion of the research by the DClinPsy Research Coordinator

A38. How will you ensure the confidentiality of personal data? *Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

In order to ensure that participants' information remains confidential, a number of steps will be taken throughout the research process.

Initially, participants will be informed that their participation in the study will remain confidential. That is, any identifying information e.g. participants' names will only be known to the Chief Investigator after they have expressed an interest to, or decided to, take part in the study, and that these will be anonymised when the interviews are transcribed by assigning each participant with a pseudonym of their choice.
Participants will be informed that the only exception to ensuring confidentiality is if I, the Chief Investigator thought that what the participants said in the interview indicates that they or someone else is at significant risk of harm. At this point, confidentiality would be breached and another person or persons would be informed, primarily the field supervisor (a clinical psychologist) and/or the clinician involved in the participants care if applicable.
This is outlined to participants in both the participant information sheet (Appendix B) and consent form (Appendix D) and participants will be reminded of the limits of confidentiality prior to the commencement of the interviews.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

Participants will be informed that their participation in the study will remain confidential in that personal information will only be known to the Chief Investigator.

The research supervisor and field supervisor involved in the project will be given access to anonymised transcripts for supervisory support.

Storage and use of data after the end of the study

A41. Where will the data generated by the study be analysed and by whom?

Data will be analysed by the Chief Investigator with input from the research supervisor.

A42. Who will have control of and act as the custodian for the data generated by the study?

	Title	Forename/Initials	Surname
	Dr	Bill	Sellwood
Post	Chair in Clinical Psychology		
Qualifications			
Work Address	Clinical Psychology, Furness Building Lancaster University Lancaster		
Post Code	LA1 4YW		
Work Email	b.sellwood.lancaster.ac.uk		
Work Telephone	01524593998		
Fax			

A43. How long will personal data be stored or accessed after the study has ended?

- ○ Less than 3 months
- ○ 3 – 6 months
- ○ 6 – 12 months
- ○ 12 months – 3 years
- ◉ Over 3 years

If longer than 12 months, please justify:
Consent forms will be scanned and kept electronically. At the end of the study, the electronic consent forms will be stored by the DClinPsy Research Coordinator in password protected file space on the university server. This data will then be deleted by the Research Coordinator 10 years after submission. In accordance with the DClinPsy programme policy. Paper copies will be destroyed. Personal details will be kept if the participant requests feedback of results following completion of the study.

A44. For how long will you store research data generated by the study?

Years: 10
Months:

A45. Please give details of the long term arrangements for storage of research data after the study has ended. *Say where data will be stored, who will have access and the arrangements to ensure security.*

At the end of the study, the electronic consent forms will be stored by the DClinPsy Research Coordinator in password protected file space on the university server. This data will then be deleted by the Research Coordinator 10 years after submission. In accordance with the DClinPsy programme policy.

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

◉ Yes ○ No

If Yes, please give details. For monetary payments, indicate how much and on what basis this has been determined.
Participants will be informed that they will be reimbursed for travel expenses up to the value of £20 should they wish to travel to meet the Chief Investigator for the interview.

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

◯ Yes ◉ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

◯ Yes ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

◯ Yes ◉ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

◯ Yes ◉ No

Please give details, or justify if not registering the research.
No suitable register exists for research conducted as part of the Doctorate of Clinical Psychology (DClinPsy) programme as a Trainee Clinical Psychologist.

Registration of research studies is encouraged wherever possible.
You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

- ☑ Peer reviewed scientific journals
- ☑ Internal report
- ☑ Conference presentation
- ☐ Publication on website
- ☐ Other publication
- ☐ Submission to regulatory authorities
- ☐ Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- ☐ No plans to report or disseminate the results
- ☐ Other (please specify)

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

Identifiable personal data will not be used and pseudonyms will be used to ensure anonymity for participants.

A53. Will you inform participants of the results?

(●) Yes ( ) No

Please give details of how you will inform participants or justify if not doing so.
At the end of each interview, participants will be informed of the proposed dissemination process for the research. That is, participants will have the option of receiving a shortened report outlining the results of the study.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed? *Tick as appropriate:*

- [ ] Independent external review
- [ ] Review within a company
- [ ] Review within a multi−centre research group
- [x] Review within the Chief Investigator's institution or host organisation
- [ ] Review within the research team
- [ ] Review by educational supervisor
- [ ] Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
The scientific quality of the proposed research has been reviewed within the Doctorate in Clinical Psychology programme team, by the research supervisor and research support office at Lancaster University.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size: 12
Total international sample size (including UK):
Total in European Economic Area:

Further details:
A total of up to 12 participants will be recruited. Purposive sampling will be used in order to recruit a more closely defined and homogenous group of participants which is in line with the proposed method of analysis, Interpretative Phenomenological Analysis (IPA).

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

A sample size of up to 12 was considered sufficient in order to offer a detailed insight into the experiences of individuals. However, it is acknowledged that the proposed method of analysis, IPA can be conducted on smaller sample sizes (Smith & Osborn, 2008).

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

IPA will be used to analyse the data collected from the participants' interviews. This model of analysis is favoured as it

offers a flexible approach to exploring and analysing qualitative data and can potentially produce a richer account of the data set (Smith & Osborn, 2008).
As the research is concerned with exploring the experiences of individuals a critical realist stance will be adopted to the collection and analysis of the data. This will allow the Chief Investigator to examine the individual lived experiences of the participants, specifically in terms of how they make sense of these experiences and what meanings these hold for the individuals concerned (Smith & Osborn, 2008).
This will involve an indepth engagement with, and detailed analysis of, the individual transcripts from which themes will emerge and be explored in relation to the topic areas identified in the interview schedule (Appendix A). The connections between the themes will be explored in terms of similarity and difference, convergence and divergence (Smith & Osborn, 2008) and then eventually grouped under broader themes known as 'superordinate themes'.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co-applicants, protocol co-authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

Title Forename/Initials Surname

[redacted]

Post
Qualifications
Employer
Work Address

Post Code
Telephone
Fax
Mobile
Work Email

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
- ◯ NHS or HSC care organisation
- ◉ Academic
- ◯ Pharmaceutical industry
- ◯ Medical device industry
- ◯ Local Authority
- ◯ Other social care provider (including voluntary sector or private organisation)
- ◯ Other

Commercial status:

If Other, please specify:

Contact person

Name of organisation	Lancaster University
Given name	Diane
Family name	Hopkins
Address	Research Services, B14 Furness College
Town/city	Lancaster
Post code	LA1 4YT
Country	UNITED KINGDOM
Telephone	01524592838
Fax	
E-mail	ethics@lancaster.ac.uk

Is the sponsor based outside the UK?

◯ Yes ◉ No

Under the Research Governance Framework for Health and Social Care, a sponsor outside the UK must appoint a legal representative established in the UK. Please consult the guidance notes.

A65. Has external funding for the research been secured?

☐ Funding secured from one or more funders

☐ External funding application to one or more funders in progress

☑ No application for external funding will be made

What type of research project is this?

◉ Standalone project

◯ Project that is part of a programme grant

◯ Project that is part of a Centre grant

◯ Project that is part of a fellowship/ personal award/ research training award

◯ Other

Other – please state:

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? *Please give details of subcontractors if applicable.*

◯ Yes ◉ No

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

◯ Yes ◉ No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

Title Forename/Initials Surname

[redacted]

Organisation
Address

Post Code
Work Email
Telephone
Fax
Mobile

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A69-1. How long do you expect the study to last in the UK?

Planned start date: 01/09/2016
Planned end date: 31/03/2017
Total duration:
Years: 0 Months: 6 Days: 31

A71-1. Is this study?

- (•) Single centre
- ( ) Multicentre

A71-2. Where will the research take place? *(Tick as appropriate)*

- [x] England
- [ ] Scotland
- [ ] Wales
- [ ] Northern Ireland
- [ ] Other countries in European Economic Area

Total UK sites in study 1

Does this trial involve countries outside the EU?

( ) Yes (•) No

A72. Which organisations in the UK will host the research? *Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

- [x] NHS organisations in England 1
- [ ] NHS organisations in Wales
- [ ] NHS organisations in Scotland
- [ ] HSC organisations in Northern Ireland
- [ ] GP practices in England

☐ GP practices in Wales
☐ GP practices in Scotland
☐ GP practices in Northern Ireland
☐ Joint health and social care agencies (eg community mental health teams)
☐ Local authorities
☐ Phase 1 trial units
☐ Prison establishments
☐ Probation areas
☐ Independent (private or voluntary sector) organisations
☐ Educational establishments
☐ Independent research units
☐ Other (give details)

Total UK sites in study: 1

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

◯ Yes ◉ No

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

The study will be monitored in line with [redacted] R&DI Standard Operating Procedures.

A76. Insurance/ indemnity to meet potential legal liabilities

***Note:** in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland*

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (NHS sponsors only)
☑ Other insurance or indemnity arrangements will apply (give details below)

Lancaster University legal liability cover will apply.

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol

authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (protocol authors with NHS contracts only)

☑ Other insurance or indemnity arrangements will apply (give details below)

Lancaster University legal liability cover will apply.

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

☑ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)

☐ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Please enclose a copy of relevant documents.

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

○ Yes ◉ No ○ Not sure

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the Institution row and insert the research site (e.g. GP practice) in the Department row.*

Investigator identifier	Research site	Investigator Name
IN1	(●) NHS site ( ) Non-NHS site Country: England Organisation name Address Post Code [redacted]	Forename Eleanor Middle name Family name Taylor Email e.taylor@lancaster.ac.uk Qualification (MD...) BSc Psychology MSc Health Psychology Country UNITED KINGDOM

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.
3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.
4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.
5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.
6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.
7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.
8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.
9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:
    - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
    - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
    - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
    - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
    - May be sent by email to REC members.
10. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.
11. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication *(Not applicable for R&D Forms)*

NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

◉ Chief Investigator

◯ Sponsor
◯ Study co-ordinator
◯ Student
◯ Other – please give details
◯ None

Access to application for training purposes *(Not applicable for R&D Forms)*
Optional – please tick as appropriate:

☐ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by Miss Eleanor Taylor on 03/08/2016 13:30.

Job Title/Post:	Trainee Clinical Psychologist
Organisation:	Lancaster University
Email:	e.taylor@lancs.ac.uk

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co-sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.
2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.
3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.
4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.
5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.
6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.

   Please note: *The declarations below do not form part of the application for approval above. They will not be considered by the Research Ethics Committee.*
7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.
8. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publically accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

This section was signed electronically by An authorised approver at ethics@lancaster.ac.uk on 03/08/2016 17:32.

Job Title/Post:	Head of Research Services
Organisation:	Lancaster University
Email:	y.fox@lancaster.ac.uk

D3. Declaration for student projects by academic supervisor(s)

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.

2. I undertake to fulfil the responsibilities of the supervisor for this study as set out in the Research Governance Framework for Health and Social Care.

3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.

4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Academic supervisor 1

This section was signed electronically by Peter Greasley on 03/08/2016 13:45.

Job Title/Post:	Teaching Fellow
Organisation:	Lancaster University
Email:	p.greasley@lancaster.ac.uk

Appendix J

HRA Statement of Activities

Health Research Authority

for Participating NHS Organisations in England (template version 4.1)

For non-commercial studies, one Statement of Activities should be completed as a template for each site-type in the study. Each Statement of Activities should be accompanied by a completed HRA Schedule of Events, as part of the submission via IRAS for HRA Approval.

Blue shaded fields (also marked with an asterisk) should be completed by the sponsor/applicant prior to submission to the HRA.*
Where appropriate, for the purpose of confirming capacity and capability, green shaded fields (also marked with a caret^) should be completed by the participating organisation before returning the document to the sponsor.
Other questions may be completed either by the sponsor/applicant or participating organisation (or collaboratively between both parties), as appropriate.

For participating organisations in Northern Ireland, Scotland or Wales, the sponsor should transfer a Site Specific Information Form to each local research team for completion and submission to their research management support function.

To provide an answer in the form, click in a box with the blue text and over-write this text, or select the relevant option if presented with drop-down text. A separate guidance document is provided and should be consulted prior to completion of this template. Please also read the question specific guidance where present.

IRAS ID*	205179
Short Study Title*	Experiences of short-term VAD
Full Study Title*	What are the experiences of people following short-term VAD implant as an emergency procedure
Contact details of sponsor, or sponsor's delegated point of contact (e.g. Study Manager), for questions relating to study set-up*	Dr Diane Hopkins ethics@lancaster.ac.uk 01524592838
Site Type*	Recruiting Site *Select one option. If 'Other', give details.* If 'Other', insert details here

Name of Participating Organisation	*Where this statement is to be used as the agreement between sponsor and participating organisation, the name of the participating organisation should be entered here prior to agreement. If this Statement is being agreed to cover multiple separate entities (e.g. multiple GP practices within a single LCRN geography) please make this clear here.* [redacted]
Location/s within Participating Organisation	*Where the research is planned to take place only at specified hospitals or other locations within the participating organisation (as may be the case in an NHS Trust comprised of more than one hospital) please name those hospitals/locations here.* [redacted]

Date *HRA Office Use Only*	*Date template assessed by HRA* 25/10/2016
Version Number	Applicant version assessed by HRA

HRA Office Use Only	1.0

1. Does the sponsor intend that this document forms the agreement between itself and the participating organisation/s in England?*

For non-commercial studies other than clinical trials and clinical investigations, the HRA encourages use of the Statement of Activities as the only form of agreement between sponsor and an English participating organisation, in place of bespoke agreements created by sponsors. For research in primary care settings, the Statement may be used for a geographical area, e.g. at the LCRN level, although agreement should be between the sponsor and independent legal entity (e.g. GP Practice). For clinical trials and clinical investigations the HRA expects that sponsors will use the relevant model agreement, where one exists.

Yes

2. Date this Statement of Activities confirmed by participating organisation, if applicable.^

Enter date confirmed

3. Confirmation on behalf of participating organisation provided by (insert name and job title), if applicable.^

Enter name and job title

It is not intended that this confirmation requires wet-ink signatures, or a passing of hard copies between the sponsor and participating organisation. Instead, sponsors are expected to accept confirmation by email from an individual empowered by the participating organisation to agree to the commencement of research (including any budgetary responsibility, where the study involves the transfer of funds).

4. If this Statement is not intended to form the agreement with the participating organisation/s in England, will the sponsor be using an unmodified model non-commercial agreement?*

No

5. If no, please provide details of the modifications made to the model agreement and the reasons for them. If the sponsor intends to use an agreement not based on the model agreement, please provide detailed justification for this (templates of all 'site agreements' to be used, including for sites in the devolved administrations (where applicable) should be provided as part of the submission for HRA Approval).*

Provide details of modification made to model agreement and the reasons for them

6. Predicted Participant Recruitment, if applicable.

This is recruitment or identification at participating organisation, not overall for the study. Please clarify if this refers to participants, samples or data. Please clearly state if this is per month, per year, overall etc. Leave blank if not applicable to this site type.

Between 8 and 12 participants will be recruited from the participating organisation. This number of participants is the overall number of participants for the study required.

7. Proposed start date of research/participant identification activity at participating organisation.

Where it might otherwise be open to interpretation, please specify whether this date refers to the commencement of screening, the recruitment of the first participant, etc.

The proposed start date for this study is 01/09/16. Specifically, this will be the start of the recruitment process ie providing potential participants with information about the study

8. Predicted end date of research/participant identification activity at participating organisation.

Where it might otherwise be open to interpretation, please specify whether this date refers to the recruitment of the final participant, the final visit of the final participant, database lock, etc.

The predicted end date for this study is 31/03/17, this will be the final meeting with participants.

9. Person responsible for research activities at site.*

Local Principal Investigator

The HRA expects Principal investigators to be in place at participating organisations where locally employed staff take responsibility for research procedures. Where this is not the case, the HRA expects Local Collaborators to be in place where central study staff will be present at site to undertake research procedures (the role of the Local Collaborator is to support practical arrangements for the presence of research staff under Letters of Access or Honorary Research Contracts). Where existing data is being provided for research purposes without additional research procedures and without the presence of central research team members at site, the HRA does not expect that a Principal Investigator or Local Collaborator is appointed and you should select Chief Investigator.

10. Are you requesting support to identify a Principal Investigator or Local Collaborator?*

Please indicate whether support from the host organisation is being requested to identify a Principal Investigator/Local Collaborator and provide further information on expectations below. Where a Principal Investigator or Local Collaborator has already been identified, their details appear on Part C of the IRAS Form.

No

11. Further Information (where applicable).*

Please provide further information on sponsor expectations for a Principal Investigator/Local Collaborator, to help participating organisations identify an appropriate individual if required (e.g. Profession, specialty, seniority etc.)

The sponsor would expect that the principal investigator (Eleanor Taylor, Trainee Clinical Psychologist at Lancaster University) would be supported by a supervisor within the host organisation [redacted]

12. The following capabilities and capacity are needed locally in order to deliver the study, e.g. specific equipment, patient/participant groups, service support nursing time, excess treatment costs, etc.*

Any funding or support from the sponsor/funder to the participating organisation is set out in the Finance Schedule.

The sponsor would expect that the principal investigator (Eleanor Taylor) could work with members of the transplant team [redacted] to recruit participants who have undergone impant of short-term VAD as an emergency procedure. However, the recruitment information may be given out at the end of clinic sessions or arranged contact with potential participants which would not require additional resourcse rom the host organisation.

13. Projected NHS Treatment Cost savings at this site type, if applicable.*

Although many studies incur Excess Treatment Costs (see AcoRD for information on cost attribution) many studies also give rise to treatment cost savings during the study (e.g. a two armed study comparing standard care to a less intensive, and less expensive, alternative treatment). Please describe below any projected treatment cost savings, so your participating organisations may include this information when considering the overall treatment costs/cost savings of their portfolio of research. Any funding or support from the sponsor/funder to the participating organisation is set out in the Finance Schedule. Excess Treatment Costs will be indicated above (question 12) and in the HRA Schedule of Events.

Provide information on projected treatment cost savings (or leave blank if not applicable)

14. The following training for local staff will be provided by the sponsor. Where only specific team members (e.g. the Principal Investigator) will receive this training, this is described below.*

No additional training will be required.

15. In addition to the above training, to be provided by the sponsor, the sponsor also expects that the following local research team members will undertake or have already undertaken the following training.*

It would not be usual for the sponsor to expect study specific training additional to that which it will provide, this section does however allow sponsors to state that they will accept, for example, NIHR CRN training in Good Clinical Practice where the study is a Clinical Trial of an Investigational Medicinal Product etc.

No additional training required, as only the principle investigator will be collating data.

Schedule 1 (Finance) (template version 4.1)

Please select one of the following*	
There are no funds/resources/equipment, etc. being provided to this/these organisation/s by the sponsor. *This schedule should be left blank.**	☒
The following funding/resources/equipment, etc. is to be provided to this/these local participating organisation/s. However, the finance schedule to cover such transfer is detailed in a separate agreement. *Please complete the information below but leave the schedule blank and submit your separate agreement to the HRA.**	☐
Enter information on funding, resource and/or equipment etc. to be provided to the site by the sponsor but do not complete the schedule below	
The following funding/resource/equipment, etc. is to be provided to this local participating organisation. This Statement of Activities is intended by the sponsor to form the agreement between them and the participating organisation. The finance schedule below details the funds to be provided to the site by the sponsor. *Please complete the information and the schedule below.**[1]	☐
Enter information on funding, resource and/or equipment etc. to be provided to the site by the sponsor and also complete the schedule below	

1 Payment Schedule (i.e. frequency or trigger for payments)*
Enter details of payment schedule
2 Area of Cost (e.g. set-up, procedure, overall cost, etc.)*
Enter details on area of cost

Payment Details:

If VAT is payable, then the Sponsor shall pay the VAT in addition to the payment on presentation of a VAT invoice. If VAT is not payable, then the Sponsor shall issue a VAT exemption certificate.

3 Invoices to be submitted to (insert job title, name of body and address)*
Enter address details

4 Payment to be made by cheque to^
Enter cheque payable details
4.1 AND remitted to (insert job title/position and address)
Enter job title/position and address
OR
5 Arrange BACS transfer to: Bank Name
Enter bank name

[1] The Statement of Activities is not intended for use with participating organisations in Northern Ireland, Scotland or Wales

5.1 Sort Code

Enter sort code

5.2 Account Number

Enter account number

5.3 And send the relevant paper work to the following address

Enter address details

Invoices should be presented promptly. No payment shall be made in the case where invoices are not presented in a complete, accurate and timely fashion and funding from an external funding body has been irrecoverably reclaimed by such external funding body as a result of such delay or inadequacy.

Schedule 2 (Material Transfer Provisions)

(template version 4.1)

These provisions do not remove the responsibility for a sponsor to clearly lay out in their protocol (and to potential participants in the patient information sheet/s) at a minimum the following information for all human biological material taken: 1) The nature of the materials, 2) The reason that the material is being taken, 3) where the material is to be sent, 4) what will happen to any remaining material once it has been processed/analysed, etc. for the purposes of this study (e.g. return, retention or destruction).

Detailed guidance on what information should be included in a protocol may be found on the HRA website http://www.hra.nhs.uk

Please select one of the following*	
This study does not involve the transfer of human biological material from this participating organisation to the sponsor or its agents. ***This schedule does not form part of this agreement.****	☒
The Sponsor has separately provided to the HRA and participating organisation an agreement for the transfer of human biological material. ***This schedule does not form part of this agreement.****	☐
These provisions form part of the agreement between the sponsor and this participating organisation. ***Select this option if no other agreement is provided, and the terms below constitute the arrangements for this study.**[2]	☐

1 Where the protocol requires the participating organisation to supply material to the sponsor/joint sponsor(s)/either of the co-sponsors, these provisions shall apply if stated above.

2 In accordance with the protocol, the participating organisation shall send material to the sponsor/joint sponsor(s)/a co-sponsor or, in accordance with provision 8 below, a third party nominated by the sponsor/joint sponsor(s)/either of the co-sponsors.

3 The participating organisation warrants that all material has been collected with appropriate informed consent and has been collected and handled in accordance with applicable law (including, without limitation, the Human Tissue Act 2004 or the Human Tissue (Scotland) Act 2006[3] (as the case may be)) and as required by the protocol.

4 Subject to provision 3 above, the materials are supplied without any warranty, expressed or implied including as to their properties, merchantable quality, fitness for any particular purpose, or that the materials are free of extraneous or biologically active contaminants which may be present in the Materials.

5 The sponsor/joint sponsor(s)/one of the co-sponsors shall ensure, or procure through an agreement with the sponsor/joint sponsor(s)/co-sponsors nominee as stated in provision 2 above that.

5.1 the material is used in accordance with the protocol, the consent of the participant, and the HRA Approval for the Study,

[2] The HRA Statement of Activities is not intended for use with participating organisations in Northern Ireland, Scotland or Wales.

[3] Although the HRA Statement of Activities is not intended for use with participating organisations in Scotland, studies taking place in England might involve transfer of Human Tissue to Scotland for (for example) analysis in a central technical facility.

5.2 the material is handled and stored in accordance with applicable law,

5.3 the material shall not be redistributed or released to any person other than in accordance with the protocol or for the purpose of undertaking other studies approved by an appropriate ethics committee and in accordance with the participant's consent, and

5.4 no alteration shall be made to the title, coding or acronym of the material.

6 The parties shall comply with all relevant laws, regulations and codes of practice governing the research use of human biological material.

7 The participating organisation and the sponsor/joint sponsors(s)/a co-sponsor shall each be responsible for keeping a record of the material that has been transferred according to these provisions.

8 To the extent permitted by law the participating organisation and its staff shall not be liable for any consequences of the supply to or the use by the sponsor/joint sponsors//co-sponsor of the material or of the supply to or the use by any third party to whom the sponsor/joint sponsors/co-sponsor subsequently provides the material or the Sponsor's/Joint Sponsors/Co-Sponsor's nominee as stated in provision 2 above, save to the extent that any liability which arises is a result of the negligence of the participating organisation.

9 The sponsor/joint sponsors/co-sponsor undertake(s) that, in the even that material is provided to a third party in accordance with provision 2 above, it/they shall require that such third party shall undertake to handle any data and Material related to the Study in accordance with all applicable statutory requirements and codes of practice and under terms no less onerous than those set out in these provisions.

10 Any surplus material that is not returned to the participating organisation or retained for future research (in line with participant consent) shall be destroyed in accordance with applicable law (including, without limitation, the Human Tissue Act 2004).

Schedule 3 (Confidentiality, Data Protection and Freedom of Information) (template version 4.1)

Please select one of the following*	
This study does not involve the transfer of Personal Data from this participating organisation to the sponsor or its agents, nor is there transfer of confidential information between the parties. ***This schedule does not form part of this agreement.****	☒
The Sponsor has separately provided to the HRA and participating organisation another agreement for the transfer of data. ***This schedule does not form part of this agreement.****	☐
These provisions form part of the agreement between the sponsor and this participating organisation. ***Select this option if no other agreement is provided, and the terms below constitute the arrangements for this study.**[4]	☐

1. Participant Confidentiality
   1.1. The parties agree to adhere to all applicable statutory requirements and mandatory codes of practice in respect of confidentiality (including medical confidentiality) in relation to participants
   1.2. Personal Data shall not be disclosed to the sponsor by the participating organisation, save where this is required directly or indirectly to satisfy the requirements of the Protocol, or for the purpose of monitoring or reporting adverse events, or in relation to a claim or proceeding brought by a participant in connection with the study.
   1.3. Neither the sponsor nor the participating organisation shall disclose the identity of participants to third parties without the prior written consent of the participant except in accordance with applicable statutory requirements and codes of practice, including HSCIC Code of Practice on Confidential Information.
   1.4. The sponsor agrees to act as Data Controller in relation to any processing of Personal Data under this agreement. This extends to all processing that would not have taken place but for this agreement regardless where that processing takes places. In particular, it extends to processing by the participating organisation where that processing is undertaken solely for the purposes of the study.
   1.5. The sponsor agrees to comply with the obligations placed on a Data Controller by the Data Protection Act 1998. This is not limited to, but includes, ensuring that:
      1.5.1. Personal Data shall be obtained only for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or those purposes
      1.5.2. Personal Data are adequate, relevant and not excessive in relation to the purpose or purposes described within the protocol.
      1.5.3. Personal Data shall be accurate and, where necessary, kept up to date.
      1.5.4. Personal Data shall be processed in accordance with the rights of data subjects under the Data Protection Act 1998.
   1.6. The Sponsor agrees to ensure appropriate training. In particular:
      1.6.1. To ensure that any persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the Participating Site) processing

[4] The HRA Statement of Activities is not intended for use with participating organisations in Northern Ireland, Scotland or Wales.

Personal Data are subject to annual mandatory training in the information governance responsibilities and have appropriate contracts including sanctions, including for breach of confidence or misuse of data;

1.6.2. To ensure that the Senior Information Risk Owners, e.g. Caldicott Guardians, senior partners and board members of the sponsor (or organisational equivalent of each of these) complete additional data security training annually.

1.7. The participating organisation agrees to ensure that its employees, honorary employees, students, researchers, consultants and subcontractors processing Personal Data are subject to annual mandatory training in the information governance responsibilities and have appropriate contracts including sanctions, including for breach of confidence or misuse of data;

1.8. The sponsor agrees to use Personal Data solely in connection with the operation of this agreement and the study and not otherwise. In particular;

1.8.1. Not to disclose Personal Data in whole or in part to any person without the participating organisation's prior written consent;

1.8.2. Not to disclose other than pursuant to a data sharing agreement that conforms to the requirements set out in the Information Commissioner's data sharing code of practice.

1.9. The participating organisation agrees to act as Data Processor on behalf of the sponsor as Data Controller for processing undertaken under this agreement solely for the purposes of the study. The participating organisation agrees to comply with the obligations placed on it as the data controller by the seventh data protection principle ("the Seventh Principle") set out in the Data Protection Act 1998, namely:

1.9.3. to maintain technical and organisational security measures sufficient to comply at least with the obligations imposed on the Data Controller by the Seventh Principle;

1.9.4. only to process Personal Data for and on behalf of the Data Controller, in accordance with the instructions of the Data Controller and for the purpose of the study and to ensure the Data Controller's compliance with the Data Protection Act 1998;

1.9.5. to allow the sponsor to audit the participating organisation's compliance with the requirements of this clause on reasonable notice and/or to provide the Data Controller with evidence of its compliance with the obligations set out in this clause;

1.9.6. the participating organisation shall obtain prior agreement of the sponsor to store or process Personal Data at sites outside the European Economic Area (comprising the countries of the European Community, Norway, Iceland and Liechtenstein).

2. Freedom of Information

2.1. Parties to this agreement which are subject to the Environmental Information Regulations 2004 (EIR) and the Freedom of Information Act 2000 (FOIA) or the Freedom of Information (Scotland) Act 2002 (FOI(S)A) and which receive a request under EIR, FOIA or FOI(S)A to disclose any information that belongs to another party shall notify and consult that party, as soon as reasonably practicable, and in any event, not later than seven (7) calendar days after receiving the request.

2.2. The parties acknowledge and agree that the decision on whether any exemption applies to a request for disclosure of recorded information under EIR, FOIA or FOI(S)A is a decision solely for the party responding to the request.

2.3. Where the party responding to an EIR, FOIA or FOI(S)A request determines that it will disclose information it will notify the other party in writing, giving at least four (4) calendar days' notice of its intended disclosure.

3. Confidential information

3.1. The receiving party agrees to take all reasonable steps to protect the confidentiality of the confidential information and to prevent it from being disclosed otherwise than in accordance with this agreement.

3.2. Subject to clause 3.4 below, the participating organisation agrees to treat the results, excluding any clinical data of the study, as confidential information disclosed by the sponsor and the sponsor agrees to treat Personal Data as confidential information disclosed by the participating organisation.

3.3. The receiving party agrees:

- 3.3.1. To ensure that any of its employees, students, researchers, consultants or sub-contractors who participate in the operation of the study are made aware of, and abide by, the requirement of this clause 3 and, where relevant, clause 2.
- 3.3.2. To use confidential information solely in connection with the operation of the agreement and not otherwise.
- 3.3.3. Not to disclose confidential information in whole or in part to any person without the disclosing party's prior written consent.

3.4. The provision of clause 3 shall not apply to the whole or any part of the confidential information that is:

- 3.4.1. lawfully obtained by the receiving party free of any duty of confidentiality;
- 3.4.2. already in the possession of the receiving party and which the receiving party can show from written records was already in its possession (other than as a result of a breach of clause 3.1 or 3.2);
- 3.4.3. in the public domain (other than as a result of a breach of clause 3.1 or 3.2);
- 3.4.4. independently discovered by employees of the receiving party without access to or use of confidential information;
- 3.4.5. necessarily disclosed by the receiving party pursuant to a statutory obligation;
- 3.4.6. disclosed with prior written consent of the disclosing party;
- 3.4.7. necessarily disclosed by the receiving party by virtue of its status as a public authority in terms of the Freedom of Information Act 2000;
- 3.4.8. published in accordance with HRA expectations on research transparency.

3.5. The restrictions contained in clauses 2 and 3 shall remain in force without limit in time in respect of Personal Data or which relates to a patient, his or her treatment and/or medical records. Save as aforesaid and unless otherwise expressly set out in this Agreement, these clauses shall remain in force for a period of 10 years after the termination or expiry of this Agreement.

Appendix K HRA provisional opinion letter

Health Research Authority

North West - Lancaster Research Ethics Committee
Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ
Telephone: 020 71048008

14 September 2016

Ms Eleanor Taylor
Trainee Clinical Psychologist
Lancashire Care NHS Foundation Trust
Division of Health Research
Furness Building
Lancaster University
LA1 4YG

Dear Ms Taylor

Study Title:	**What are the experiences of people following short term VAD implant as an emergency procedure**
REC reference:	**16/NW/0631**
IRAS project ID:	**205179**

The Research Ethics Committee reviewed the above application at the meeting held on 08 September 2016. Thank you for attending to discuss the application.

Provisional opinion

The Committee is unable to give an ethical opinion on the basis of the information and documentation received so far. Before confirming its opinion, the Committee requests that you provide the further information set out below.

Authority to consider your response and to confirm the Committee's final opinion has been delegated to the Chair.

Further information or clarification required

a. The Committee would like to see a follow up letter for recruitment to replace the

telephone call

b. The Committee would like to see the Participant Information Sheet revised to
   i) State that only 12 participants are needed and that if more volunteer they will be selected on a first come first served basis
   ii) State whether parking expenses will be paid

c. The Committee would like to see the Poster revised to
   i) State Ventricular Assist Device rather than VAD

d. The Committee would like to see the Consent Form revised to
   i) include the version number of the Participant Information Sheet which has been read at point 1
   ii) Include the regulatory clause "I understand that data collected from the study may be seen by regulatory authorities or by persons from the Trust where it is relevant to my taking part in this study. I agree to these persons having access to this information"
   iii) line up the boxes with the statements
   iv) omit points 13 and 14

If you would find it helpful to discuss any of the matters raised above or seek further clarification from a member of the Committee, you are welcome to contact Carol Ebenezer whose contact details are on this letter.

When submitting a response to the Committee, the requested information should be electronically submitted from IRAS. A step-by-step guide on submitting your response to the REC provisional opinion is available on the HRA website using the following link: http://www.hra.nhs.uk/nhs-research-ethics-committee-rec-submitting-response-provisional-opinion/

Please submit revised documentation where appropriate underlining or otherwise highlighting the changes which have been made and giving revised version numbers and dates. You do not have to make any changes to the REC application form unless you have been specifically requested to do so by the REC.

The Committee will confirm the final ethical opinion within a maximum of 60 days from the date of initial receipt of the application, excluding the time taken by you to respond fully to the above points. A response should be submitted by no later than 14 October 2016.

Summary of the discussion at the meeting
The Chair welcomed you to the REC and thanked you for attending to discuss the study.

Social or scientific value; scientific design and conduct of the study
The Committee asked whether there had been any service user involvement in the design of the study.

You said that the information pack had been seen by a group of buddies at the transplant unit.

The Committee asked for a definition of short term VAD.

You said that this would usually be used in the ICU whereas the long term version can be used by patients being discharged.

The Committee asked whether the patients would know that they had had short term VAD.
You confirmed that they would.

Recruitment arrangements and access to health information, and fair participant selection
The Committee noted that 12 participants would be required and as how regularly the intervention was performed.

You said that it was quite specialised and that you saw 10 – 15 patients per year so there would be 45 potential candidates.

The Committee asked what would happen if more than 12 volunteered.

You said you would use a first come first served basis.

The Committee noted the intention to follow up with a telephone call and commented that this could be considered coercive. The Committee requested a letter instead of a telephone call.

You agreed to this.

Care and protection of research participants; respect for potential and enrolled participants' welfare and dignity
The Committee asked who would transcribe the interviews.

You said you would do this yourself.

The Committee queried the arrangements for getting support if a participant became distressed and asked whether they could see someone earlier than within a week.

You said that you had thought about this and had considered including a number for the Samaritans. However, the buddies rejected this idea.

The Committee asked whether any other support was available, e.g. any other psychologists in the area.

You said you would ask about this. You told the Committee you thought they would be seen as soon as possible depending on the severity of the problem.

The Committee asked whether it was possible that some patients would still be in the hospital where more support would be on hand.

You said that it was possible that some participants would have been discharged from the ICU but still a patient on another ward.

The Committee asked how often the patients came back as outpatients.

You said that as some would have been seen three years previously, you would be able to see them in the outpatients department.

The Committee asked how participants would be able to distinguish between the long term and short term VAD memories.

You said that it might be difficult but that the short term one would have been when they were in patients.

The Committee suggested it might be better to focus on recovered patients and it was agreed that wherever possible the interviews would be carried out in the hospital and that you would look for additional psychologists who would be able to see any distressed participants quicker.

The Committee asked whether car parking expenses would be paid.

You said you did not know.

Informed consent process and the adequacy and completeness of participant information The Committee advised that they would require changes to the Participant Information Sheet and Consent Form (as above) and that these would be in the decision letter.

Suitability of supporting information
The Committee told you that the Poster did not stand out and suggested you might like to make some changes, e.g. adding colour, to attract attention. Should such changes be made they should come to the Committee as part of the response to the REC's decision. The Committee asked that Ventricular Assist Device be stated in full rather than using the abbreviation.

You asked the Committee whether you should put additional telephone numbers in the Information Sheet. The Committee told you to go along with the buddies' recommendations and leave this out.

You had no further questions for the REC.

Documents reviewed

The documents reviewed at the meeting were:

Document	*Version*	*Date*
Copies of advertisement materials for research participants	1	01 June 2016
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance Document]		
Interview schedules or topic guides for participants [interview schedule]	1	01 June 2016
IRAS Application Form [IRAS_Form_04082016]		04 August 2016
IRAS Application Form XML file [IRAS_Form_04082016]		04 August 2016
Letter from sponsor [IRAS sponsorship letter]		
Other [Staff information sheet]	1	01 June 2016
Other [Participant expression of interest form]	1	01 June 2016
Other [Participant debrief sheet]	1	01 June 2016
Other [Insurance Document professional negligence]		
Participant consent form [Consent form]	1	01 June 2016
Participant information sheet (PIS) [PIS]	1	01 June 2016
Research protocol or project proposal [STVAD protocol]	1	01 June 2016
Summary CV for Chief Investigator (CI) [Chief investigator CV]	1	01 June 2016
Summary CV for supervisor (student research) [supervisor CV]		

Membership of the Committee

The members of the Committee who were present at the meeting are listed on the attached sheet

Statement of compliance

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

16/NW/0631	**Please quote this number on all correspondence**

Yours sincerely

Dr Lisa Booth Chair

Email: nrescommittee.northwest-lancaster@nhs.net

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments.*

Copy to: *Dr Diane Hopkins*

[redacted]

North West - Lancaster Research Ethics Committee Attendance at Committee meeting on 08 September 2016

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Brenda Ashcroft	Retired Lecturer	Yes	
Mr David Barber	Pharmacist	Yes	
Dr Lisa Booth	Senior Lecturer / Chair	Yes	
Ms Debbie Foord	Retired community psychiatric nurse	Yes	
Dr Grace Hurford	Senior Lecturer, public services leadership	Yes	
Dr Brenda Leese	Retired Health Researcher	Yes	
Dr Laura Machin	Lecturer in Medical Ethics	Yes	
Dr Anas Olabi	Consultant Paediatrician	No	
Mrs Susan Page	Senior Clinical Tutor	Yes	
Mrs Gillian Rimington	Paralegal	No	
Mrs Valerie Skinner	Nurse (Retired)	No	
Professor Jois Stansfield	Professor of Speech Pathology	Yes	
Dr Gary Whittle	Consultant in Dental Public Health (retired)	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mrs Carol Ebenezer	REC Manager

Appendix L HRA favourable opinion letter

NHS
Health Research Authority

North West - Lancaster Research Ethics Committee

Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ
Telephone: 020 71048008

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

30 September 2016

Ms Eleanor Taylor
Trainee Clinical Psychologist
Lancashire Care NHS Foundation Trust
Division of Health Research
Furness Building
Lancaster University
LA1 4YG

Dear Ms Taylor

Study title:	**What are the experiences of people following short term VAD implant as an emergency procedure**
REC reference:	**16/NW/0631**
IRAS project ID:	**205179**

Thank you for responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.
We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require

further information, or wish to make a request to postpone publication, please contact the REC Manager, Mrs Carol Ebenezer, nrescommittee.northwest-lancaster@nhs.net.

Confirmation of ethical opinion

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

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Copies of advertisement materials for research participants	2	27 September
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance Document]		
Interview schedules or topic guides for participants [interview schedule]	1	01 June 2016
IRAS Application Form [IRAS_Form_04082016]		04 August 2016
IRAS Application Form XML file [IRAS_Form_04082016]		04 August 2016
Letter from sponsor [IRAS sponsorship letter]		
Other [Staff information sheet]	1	01 June 2016
Other [Participant expression of interest form]	1	01 June 2016
Other [Participant debrief sheet]	1	01 June 2016
Other [Insurance Document professional negligence]		
Other [Participant Follow up letter]	1	27 September
Other [HRA schedule of activities]	1	27 September
Other [HRA statement of activities]	1	27 September
Participant consent form [Consent form]	2	27 September
Participant information sheet (PIS) [PIS]	2	27 September
Research protocol or project proposal [STVAD protocol]	1	01 June 2016
Summary CV for Chief Investigator (CI) [Chief investigator CV]	1	01 June 2016
Summary CV for supervisor (student research) [supervisor CV]		

Statement of compliance

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

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments

- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality- assurance/

HRA Training

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

16/NW/0631	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project. Yours sincerely

Dr Lisa Booth
Chair

Email:nrescommittee.northwest-lancaster@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: *Dr Diane Hopkins*
[redacted]

Appendix M IRAS sponsorship letter

Applicant name: Eleanor Taylor
Division: DHR

2 August 2016

Dear Eleanor

Re: What are the experiences of people following short term VAD implant as an emergency procedure

The University of Lancaster undertakes to perform the role of sponsor in the matter of the work described in the accompanying grant application. As sponsor we assume responsibility for monitoring and enforcement of research governance. As principal investigator you will confirm that the institution's obligations are met by ensuring that, before the research commences and during the full term of the grant, all the necessary legal and regulatory requirements are met in order to conduct the research, and all the necessary licenses and approvals have been obtained. The Institution has in place formal procedures for managing the process for obtaining any necessary or appropriate ethical approval for this grant. Full ethical approval must be in place before the research commences and should be reviewed at all relevant times during the grant.

Yours sincerely,

PP Professor Roger Pickup
Associate Dean for Research
Chair Faculty of Health and Medicine Research Ethics Committee.

CC Dr Diane Hopkins, Secretary to FHMREC

Appendix N Insurance Document 1

ZURICH
MUNICIPAL

To Whom It May Concern

Our ref: MD/FEHE 1 August, 2016

Zurich Municipal Customer: Lancaster University

This is to confirm that Lancaster University has with this company until the policy expiry on 31st July 2017 Professional Negligence Insurance incorporating the following essential features:

Policy Number: NHE-07CA04-0013

Services covered: Training, Research and Consultancy

Limit of Indemnity: £5,000,000 any one claim and ***in the aggregate for all claims*** first made against the Insured and notified to Zurich Municipal during the period of insurance

Excess : Research & Consultancy: £5,000 any one claim
Training: £500 any one claim

Retroactive Date: 01 August 2008

Exclusions
Standard insurance market exclusions apply, notably exclusion of Pollution other than sudden and accidental; punitive or exemplary damages; express warranties or guarantees; claims the cause of which occurred prior to the Retroactive Date.

This is a brief summary and the full policy should always be referred to for exact details of cover.

Yours faithfully

Martin Docis
Underwriting Services
Zurich Municipal
Farnborough

Zurich Municipal
Southwood Crescent
Farnborough
Hampshire
GU14 0NJ

Telephone 0870 2416050

Direct Phone 01252 387796
Direct Fax 01252 375244
E-mail Martin.Docis@uk.zurich.com

Appendix O Insurance Document 2

ZURICH®
MUNICIPAL

To Whom It May Concern

Our ref: MDO/LGE 20 July, 2016

Zurich Municipal Customer: Lancaster University

This is to confirm that Lancaster University has with this company until the policy expiry on 31st July 2017 Insurance incorporating the following essential features:

Policy Number: NHE-07CA04-0013

Limit of Indemnity:

Public Liability:	£	25,000,000	any one event
Products Liability:)	£	25,000,000	for all claims in the
Pollution:)		aggregate during any one period of insurance	
Employers' Liability:	£	25,000,000	any one event inclusive of costs

Excess :

Public Liability/Products Liability/Pollution:	£Nil any one event
Employers' Liability:	£Nil any one claim

Indemnity to Principals :
Covers include a standard Indemnity to Principals Clause in respect of contractual obligations.

Full Policy :
The policy documents should be referred to for details of full cover.

Yours faithfully

Martin Docis
Underwriting Services
Zurich Municipal
Farnborough

Zurich Municipal
Southwood Crescent
Farnborough
Hampshire
GU14 0NJ

Telephone 0870 2418050

Direct Phone 01252 387796
Direct Fax 01252 375244
E-mail Martin.Docis@uk.zurich.com

Appendix P [NHS Trust]- Letter of access for research

[redacted]

22nd November 2016

Ms Eleanor Taylor
Trainee Clinical Psychologist
Doctorate in Clinical Psycology
Furness Building
Lancaster University
LA1 4YG

Dear Ms Taylor

Letter of access for research

We have received copies of:

- *Your CV*
- *GCP Training Certificate*
- *Validated Research passport*
- *DBS*
- *Occupational Health*

I am pleased to offer you a Letter of Access for [redacted] based on the documents mentioned above.

In accepting this letter, [redacted] confirms your right of access to conduct research through their organisation for the purpose and on the terms and conditions set out below. This right of access commences on 22nd November 2016 and ends on 31st August 2017 unless terminated earlier in accordance with the clauses below.

Your right of access is for the following research projects:

- *What are the experiences of people following short term VAD implant as an emergency procedure*

Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving confirmation from the individual organisation(s) of their agreement to conduct the research.

The information supplied about your role in research at the organisation(s) has been reviewed and you do not require an honorary research contract with the organisation(s). We are satisfied that such pre-engagement checks as we consider necessary have been carried out. Evidence of checks should be available on request to the organisation(s).

[redacted]

You are considered to be a legal visitor to the [redacted] premises. You are not entitled to any form of payment or access to other benefits provided by the organisation(s) or this organisation to employees and this letter does not give rise to any other relationship between you and the organisation(s), in particular that of an employee.

While undertaking research through at [redacted] you will remain accountable to your substantive employer but you are required to follow the reasonable instructions of the organisation(s) or those instructions given on their behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by the organisation(s) in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with the [redacted]rust policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with the organisation(s) in discharging its/their duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on the organisations premises. You must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of any other contract holder and you must act appropriately, responsibly and professionally at all times.

If you have a physical or mental health condition or disability which may affect your research role and which might require special adjustments to your role, if you have not already done so, you must notify your employer and each organisation prior to commencing your research role at that organisation.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the organisations premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that the organisation(s) do not accept responsibility for damage to or loss of personal property.

This organisation may revoke this letter and any organisation(s) may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of the organisation(s) or if you are convicted of any criminal offence. You must not undertake regulated activity if you are barred from such work. If you are barred from working with adults or children this letter of access is immediately terminated. Your employer will immediately withdraw you from undertaking this or any other regulated activity and you MUST stop undertaking any regulated activity immediately.

[redacted]

[redacted]

Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

No organisation will indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

If your current role or involvement in research changes, or any of the information provided in your Research Passport changes, you must inform your employer through their normal procedures. You must also inform your nominated manager in each participating organisation and [the R&D office] in this organisation.

Yours sincerely

[redacted]
Research Governance Officer
[redacted]

Cc
s.heard@lancaster.ac.uk substantive employer
[redacted]

[redacted]

[redacted]

Appendix Q NHS to NHS confirmation of pre-engagement checks

[redacted]

NHS to NHS Confirmation of Pre-Engagement Checks Proforma.

For NHS researchers who have a substantive NHS contract of employment or clinical academics with an honorary clinical contract with an NHS organisation, who need an NHS to NHS Letter of Access (LoA) from an NHS organisation hosting their research.

CONFIRMATION OF PRE-ENGAGEMENT CHECKS

To: Research & Development Department [redacted]

Re: **Researcher's name: Eleanor Taylor**

Job title: Trainee Clinical Psychologist

Contract end-date: November 2016

Workplace and postal address: Clinical Psychology
Division of Health Research
Furness College
Lancaster University
Lancaster, UK
LA1 4YG

Electronic Staff Record number: 24057212

As the representative of the NHS employer[1] of the above-named person, I can confirm that s/he is employed by this organisation. I understand that the responsibility for ensuring that the appropriate pre-engagement checks have been undertaken rests with us as the individual's substantive employer. I can confirm that the appropriate pre-engagement checks have been completed, commensurate with her/his job description and proposed research role in your NHS organisation, and in line with NHS employment checks standards.

Name of employer's representative: Dr Anna Daiches

Job Title: Clinical Director

Workplace address: Lancaster University

Tel: 01524 594406

[1] *For clinical academics, this would be a representative from their HEI employer*

[redacted]

[redacted]

[redacted]

Email: a.daiches@lancaster.ac.uk

Signature: