

Submitted in partial fulfilment of the Lancaster Doctorate in Clinical Psychology

Doctoral Thesis:

The experience of body image for people with a left ventricular assist device

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Ethics Section	4241	5580	9821
Total	24222	19884	44107

Thesis Abstract

This thesis is comprised of a systematic literature review, an empirical paper and a critical appraisal. Firstly, a systematic review and metasynthesis of qualitative studies exploring psychological experiences of adult heart transplant recipients was conducted. A meta-ethnographic approach was used to synthesise the findings of 12 papers. The results demonstrated that recipients underwent a process of making sense of their identity following transplantation. Recipients perceived that their psychological adjustment was impacted by the expectations of medical professionals, friends, family and wider society. They experienced fluctuating positive and negative emotions such as anxiety, grief and gratitude. Physical, social and psychological factors influenced coping and adaptation, contributing to better psychological wellbeing. Clinical implications are discussed.

Secondly, the empirical paper explores experiences of body image for adults implanted with a left ventricular assist device (LVAD). Nine participants were interviewed, and the data were analysed using interpretative phenomenological analysis. The findings highlighted the importance of social, functional and appearance-related aspects of body image for LVAD-users. Participants re-evaluated their body with the LVAD and perceived that it, and themselves were “different”. They perceived their body as restricted and had a constant awareness of their body and device, which led to feelings of anxiety. LVAD-users used practical and psychological strategies to adjust to their changed body and perceive themselves as more “normal”. Clinical implications and limitations of the study are discussed, and further research is recommended.

Finally, the critical appraisal offers a reflection on the process of conducting LVAD research including strengths and limitations. It also compares the findings of the review and empirical papers and recommends further areas for research.

Declaration

This thesis records work undertaken for the Doctorate in Clinical Psychology at the Division of Health Research at Lancaster University between January 2018 and October 2019.

The work presented here is the author's own, except where due reference is made. The work has not been submitted for the award of a higher degree elsewhere.

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Date:

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I would like to express a sincere thank you to the nine participants who generously volunteered their time to share their experiences with me, as well as the rest of the LVAD community who showed a keen interest in this research along the way. A big thank you to the transplant teams who have been extremely helpful and supportive, especially my field supervisor whose enthusiasm inspired and made this research possible.

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Section One: Literature Review

A qualitative metasynthesis of the psychological experiences of adult heart transplant recipients

Word count: 7996 words

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ABSTRACT

Aims and objectives: This study aimed to systematically review and synthesise primary studies on the psychological experience of adult heart transplant (HTX) recipients.

Background: Individuals with long term physical health problems are at increased risk of developing psychological distress. Quantitative research has identified numerous physical and psychosocial factors which increase the risk of psychological distress for HTX recipients. Synthesised knowledge from qualitative data can provide increased understanding of the complexity of the psychological experience of transplant recipients and an evidence base to guide health professionals supporting these individuals.

Design: Qualitative metasynthesis.

Methods: Using the PRISMA guidelines, four electronic databases were utilised to search for qualitative articles published between 2013 and March 2019. 12 papers were included and appraised using the Critical Appraisal Skills Program assessment tool. A metasynthesis was undertaken guided by the meta-ethnographic methodology described by Noblit and Hare (1988).

Results: Four main concepts were identified: ‘Identity: making sense of the self after HTX’, ‘Bearing others’ expectations’, ‘The overwhelming emotional impact of HTX’ and ‘Developing coping skills’.

Conclusions: The HTX experience can impact an individual’s identity. Making sense of the self is proven to be more challenging due to the expectations of family, professionals and wider society on recovery following transplantation. HTX recipients experience fluctuating, contradicting emotions and high levels of anxiety at times. Yet, despite this, they utilise a variety of coping skills to overcome the challenges they face and support adjustment to “normality”. More research is needed regarding psychological experiences at different time points post-HTX.

Relevance to clinical practice: Knowledge of the psychological experiences of adult HTX recipients can increase healthcare professionals' understanding of the distress and challenges they face and guide them in their efforts to provide support and facilitate adjustment.

KEYWORDS

anxiety, cardiology, emotional adjustment, heart transplantation, organ transplantation, qualitative research, quality of life, transplant recipients

1 | INTRODUCTION

Long-term physical health conditions can have a detrimental effect on an individual's mental health; those with long-term health conditions are two to three more times more likely to experience psychological distress such as anxiety or low mood (Naylor et al., 2012). In a study of health-related quality-of-life (QoL), Mujica-Mota et al. (2015) found that experiencing a mental health difficulty alongside a long-term physical health problem had a greater negative impact on people's QoL than any single co-existing physical health difficulty. Mental health difficulties can also exacerbate the symptoms and effects of long-term physical health conditions and create poorer clinical outcomes (Naylor et al., 2016).

Organ transplantation is one such area of medicine associated with long-term physical illness. A heart transplant (HTX) is a surgical operation performed for individuals experiencing severe heart failure in which their heart is replaced with a healthier heart from a human donor (British Heart Foundation, 2015). During the financial year 2018/2019, 158 adults underwent HTX in the UK; this demonstrates an 86% increase from the number of transplants performed a decade earlier, in the period 2009/2010 (NHS Blood and Transplant [NHSBT], 2019). The aim of HTX is to extend the life expectancy of those experiencing heart failure, it also provides most recipients with an improved QoL (Grady, 2003).

As the number of HTXs increases it is imperative that professionals understand the impact of this surgery on those who undergo it in order that their emotional wellbeing can be

better supported. Due to the scarcity of organs, the journey to HTX can be a long one characterised by serious illness. After organ transplantation, recipients must establish considerable coping skills and are still considered to have a long-term physical illness (Schulz & Kroencke, 2015). In the UK, the National Institute for Health and Clinical Excellence (NICE, 2009) requires that healthcare professionals routinely assess individuals with long-term physical health problems for depression. A review of mental health outcomes reported that up to 63% of recipients experience depression and up to 26% experience anxiety following HTX (Dew & DiMartini, 2005). Research has demonstrated that HTX recipients who experience mild to severe depression are at increased risk of mortality independent of other physical health and lifestyle factors (Havik et al., 2007).

Current literature has highlighted many factors which can contribute to distress in HTX recipients. Psychosocial variables associated with poor psychological outcomes include; limited strong social support, avoidant coping styles, poor sense of control over one's life, low self-esteem and lack of optimism for future outcomes (Dew & DiMartini, 2005). Recent quantitative research reported that coping skills, sense of coherence and perceived control are significant predictors of QoL and depression in HTX recipients (Doering et al., 2018; Ruzyczka et al., 2011). Sense of coherence, self-efficacy and optimism are also significant predictors of both depression and stress (Milaniak et al., 2016). HTX recipients' physical health and functioning can also have a detrimental impact on psychological outcomes; sleep disturbance, concern about medications and physical symptoms, complications, and functional limitations which prevent recipients from carrying out a full range of activities of daily living all increase risk for distress (Dew & DiMartini, 2005).

Quantitative studies have demonstrated utility by identifying factors which contribute to distress in HTX recipients so that they may be screened for. However, they do not provide a detailed understanding of how such factors are experienced by recipients in day-to-day life

so that they might be better supported. Furthermore, qualitative and mixed-method research suggests that a greater number of HTX recipients experience distress (52-88%) than that captured by self-report questionnaires in quantitative research, but that distress is hidden (Abbey et al., 2011; Ross et al., 2010). Further qualitative investigation might gather additional information about how and why this is.

Current qualitative research has provided an in-depth exploration of the individual perceptions and psychological experiences of HTX recipients. Studies have explored the daily impact of HTX on recipients (Monemian, Abedi, & Naji, 2015; Vasconcelos, Pessoa, Menezes, Florêncio, & Frota, 2015), the process and challenges recipients face (Waldron, Malpus, Shearing, Sanchez, & Murray, 2017), and coping strategies (Sadala & Stolf, 2008). Qualitative research has also examined more specific psychological experiences of HTX recipients, such as grief (Poole et al., 2016), gratitude (O'Brien, Donaghue, Walker, & Wood, 2014) and self-efficacy (Almgren, Lennerling, Lundmark, & Forsberg, 2017a). Integrating these rich findings could provide greater knowledge about the psychological experiences of HTX recipients over and above individual studies.

2 | AIMS

Qualitative systematic reviews have been recognised as valuable to the evidence base in healthcare research (Dixon-Woods & Fitzpatrick, 2001). Conway et al. (2013) conducted a systematic review of qualitative research in order to integrate findings regarding adults' psychological experiences of HTX. However, they judged that qualitative findings at that time were 'summaries' of qualitative data rather than interpretative syntheses. Therefore, Conway et al. (2013) produced a meta-summary rather than a metasynthesis; in a meta-summary the frequency of qualitative findings is taken to indicate validity and is used to calculate effect sizes (Sandelowski & Barroso, 2005). This meta-summary found that recipient's perception of social support could either improve or hinder psychological

wellbeing, they had negative and positive psychological experiences post-HTX, and that faith and optimism were important in recovery (Conway et al., 2013).

Conway et al.'s (2013) meta-summary was an important first step in integrating qualitative findings regarding the psychological experiences of adult HTX recipients. The review provided support for quantitative research that optimism, sense of control, and social support are pertinent to psychological wellbeing. However, an interpretative synthesis of qualitative findings is yet to be conducted. Qualitative metasynthesis aims to provide more than a summary of findings by offering new information and a more comprehensive account of the phenomenon it examines (Sandelowski & Barroso, 2003; Sandelowski, Docherty, & Emden, 1997).

Since Conway et al.'s (2013) review, a greater number of qualitative, interpretative studies have been published. The aim of this review was to synthesise the recent primary studies exploring adult recipients' psychological experiences of HTX in order to achieve a greater understanding of how the numerous, complex factors identified in quantitative research might contribute to psychological distress. By gaining a more comprehensive understanding of the psychological experiences of HTX recipients, psychological theory and intervention can be developed to provide better psychological support to those experiencing distress. Many of the existing qualitative studies were conducted with small samples, in different countries, in specific contexts and addressed disparate aspects of post-HTX experience, meaning generalisability is restricted. Synthesising findings across countries, contexts and aspects of experience can not only offer novel findings and a more thorough understanding of a phenomenon but may also achieve greater generalisability (Sandelowski et al., 1997).

Conforming with Conway et al.'s (2013) meta-summary, for this metasynthesis "we defined qualitative findings, which included yet were not limited to emotions, perceptions

and attitudes, as ‘experiences.’” (pp.450). The main research question of this metasynthesis was: what are adults’ psychological experiences of heart transplantation?

3 | METHOD

3.1 | Data search

A ‘Context-How-Issues-Population’ ([CHIP]; Shaw, 2012) mind map was used to identify search terms, including terms used by Conway et al. (2013). Two key concepts were identified: ‘heart transplantation’ and ‘qualitative’. On the advice of the subject librarian, and in line with Conway et al.’s (2013) original search, concepts relating to population and issues were not included in the search terms as important papers may have been missed. Instead, concepts of ‘adult recipients’ and ‘psychological experiences’ were manually screened for.

Published articles using qualitative methodology to explore the psychological experiences of adult HTX recipients were identified through searches in March 2019 using four electronic databases: MEDLINE, Cumulative Index to Nursing and Allied Health Literature (CINAHL), PsycINFO and Web of Science. These key databases were selected as their individualism and degree of overlap increased the probability that all relevant papers would be captured. For each database, a free text search and, where possible, a search using relevant Medical Subject Headings (MeSH) or subject terms for the two concepts were completed separately. Then, the results were combined to identify relevant papers. In Conway et al.’s (2013) meta-summary, databases were searched for papers published in the period “1995-end 2012” (p.450). As the current metasynthesis was designed as an update of this meta-summary, date limiters were applied to exclude any papers published prior to 2013. The search was verified by an academic subject librarian at the University; see Appendix 1-A for the detailed search strategy.

3.2 | Inclusion and exclusion criteria

To be considered eligible for this review, papers were required to meet the following criteria: published in English; published in peer-reviewed journals; reported primary data; explored psychological experiences following HTX, using adult recipients as primary informants; used a predominantly qualitative approach to data collection and analysis, in line with Sandelowski et al.'s (1997) guidance that a metasynthesis should include the fullest range of qualitative methodologies. Mixed-method studies were included due to scarcity of research in this area.

Papers were excluded if they met any of the following criteria: used exclusively quantitative methodology; were not written or available in English; were published prior to 2013; reported on transplant experiences generally, where HTX recipients' data could not be separated from those who were transplanted with a different organ; reported exclusively on the pre-transplantation period. Studies which reported on experiences of children and adolescents were excluded in recognition of them being at a unique and contrasting life-stage. Studies were also excluded if the primary informant was not a HTX recipient, for example carers, spouses, family members. One study was included whose sample comprised of recipients alongside 10 spouses/family members (Palmar-Santos et al., 2019); in this instance, only findings applicable to the HTX recipients' experiences contributed to the synthesis and only quotations from the HTX recipients were used to evidence the meta-themes. Another study was included which involved participants from pre-HTX and post-HTX phases (Poole et al., 2016); only the data for the post-HTX participants were included. One mixed-method paper was included (Janelle, O'Connor, & Dupuis, 2016).

The PRISMA guidelines informed the strategy for screening studies for eligibility (Moher, Liberati, Tetzlaff, & Altman, 2009). In total, 5062 papers were identified from the combined search strategy (MEDLINE: 2294; CINAHL: 563; PsycInfo: 64; Web of Science:

2141); the use of Endnote software and manual screening identified 2771 duplicates which were removed. The preliminary screening of titles and abstracts against inclusion and exclusion criteria led to the exclusion of a further 2273 papers. The remaining 18 papers were reviewed in full against the inclusion criteria; 7 papers were excluded at this stage. Forward and backward searching of the remaining papers was conducted using the citation search capacity of Google Scholar and hand searching of reference lists. This identified one additional article which was not captured by the original database search. Therefore, a total of 12 papers met the inclusion criteria and were included in the review. See Figure 1 for the PRISMA diagram of the search process (Moher et al, 2009).

3.3 | Characteristics of the selected studies

The methodological and demographic characteristics of each the 12 papers included in this metasynthesis are detailed in Table 1. The 12 papers were published between 2014 and 2019 and represented data collected from 10 studies. These studies were conducted in seven countries; one in Sweden, three in Iran, two in Canada, one in Australia, one in Spain, one in Brazil and one in the UK. Across the 10 studies the total number of HTX recipients who participated was 146, with sample sizes varying between nine and 25 participants. Given that the majority of HTX recipients are male (Khush et al., 2018), this prevalence was reflected in the samples of the included studies. The data from two of the 10 studies were presented in two separate articles. Both papers from each of the studies were included as they differed in the focus of their analysis; uncertainty and self-efficacy (Almgren, Lennerling, Lundmark, & Forsberg, 2017a, 2017b), identity and experiences of grief (Mauthner et al., 2015; Poole et al., 2016). Data collection took place in the form of individual interviews with the exception of one study (Vasconcelos et al., 2015) which used focus group interviews.

Two papers, representing one study, used a qualitative visual methodology based on theory that body language offers additional insight which precedes speech in its

demonstration of meaning (Merleau-Ponty, 1973). Regarding the analytic approaches of the remaining papers, two papers used content analysis, two used the descriptive-phenomenological Colaizzi (1978) method, two used interpretative phenomenological analysis, and four used other phenomenological-hermeneutic methods. Although this was not part of the inclusion criteria, the final selected papers all used phenomenological methodologies. This is likely to lead to a more coherent theoretical interpretation, as formulating theory through metasynthesis can be challenging across different qualitative methodologies e.g. phenomenology, ethnography, and grounded theory (Estabrooks, Field, & Morse, 1994).

3.4 | Critical appraisal

The final 12 papers were quality-appraised across ten criteria considered important in qualitative research, in accordance with the Critical Appraisal Skills Programme (CASP, 2018). Sandelowski et al. (1997) suggested that studies should not be excluded from a metasynthesis based on quality given the absence of consensus regarding what constitutes ‘good’ qualitative research. Furthermore, considering the word limits of journals, a low score may be more representative of reporting quality rather than genuine research procedure (Atkins et al., 2008). Thus, papers were included regardless of quality appraisal scores in order to produce the most comprehensive and valuable synthesis and include as many experiences and possible. Remarkably, two of the papers derived from the same study (Mauthner et al., 2015; Poole et al., 2016) had drastically different CASP scores, demonstrating that excluding papers based on such tools would be inappropriate.

The papers were each rated using the CASP (2018) tool combined with a three-point rating scale created by Duggleby et al. (2010). The first two domains acted as a screening tool. The subsequent eight domains were given a score between one and three, contingent on whether the paper provided a weak (1), moderate (2), or strong (3) explanation in its report of

that domain. Appraisal of the included papers using the CASP (2018) tool merely aimed to contextualise the findings and raise awareness of the strengths and weaknesses of each study and the group of papers together. For example, half of the included papers presented weak evidence of adequate consideration of the relationship between the researcher and participant. Description of participant-researcher relationship is considered important in qualitative research (American Psychological Association, 2019). Only two papers were rated strongly in this domain, indicating that reflection on the relationship should be greater in future HTX research.

The scores of individual papers were considered throughout the analysis to check that the overall metasynthesis was supported by papers scoring across the range, rather than being reliant on weaker scoring papers. For instance, the core concept ‘developing coping skills.’ was contributed to by three of the lowest-scoring articles (Dehghan-Nayeri, Vareaei, & Azizi-Fini, 2017; Monemian et al., 2015; Vasconcelos et al., 2015) but also by the three articles that received the highest CASP scores (Almgren et al., 2017b; Peyrovi, Raiesdana, & Mehrdad, 2014; Waldron et al., 2017). See Table 2 for an overview of scores.

3.5 | Metasynthesis procedure

Metasynthesis is method of creating new meaning by systematically integrating the findings of qualitative studies (Harden & Thomas, 2005). Noblit and Hare’s (1988) seven-stage meta-ethnography method was used to guide the analysis; this interpretative method of synthesizing qualitative findings was adapted for health research by Britten et al. (2002).

The 12 selected papers were read numerous times, themes and subthemes were noted for each paper using text verbatim information. Participants’ language (‘first-order’ interpretations) and the authors’ interpretations following analysis (‘second-order’ interpretations) were both used in this metasynthesis. The themes and subthemes were examined for similarities and differences, then translated into each other by grouping similar

ideas into key themes so that the greatest number were represented by the final iteration. At times, the key theme/final iteration was represented using the language of one of the constituent papers.

Next, reciprocal translation was undertaken; recurring key themes were identified and further synthesised into overarching core concepts. The results and discussion sections of each paper were re-examined to ensure that: the papers were analysed in sufficient detail, the iterations were representative of the data and the integrity of each study was maintained (Sandelowski et al., 1997). As some of the papers explored different aspects of the psychological experiences of HTX, such as identity or the impact on HTX daily-living, line of argument synthesis (Malpass et al., 2009) followed. An argument was constructed about what the set of papers together told the reviewer, to create a fuller picture of psychological experiences of HTX and ensure that these different aspects were represented. Four third-order constructs/core concepts were developed; these offered conceptual development over and above that of the original, individual studies. See Appendix 1-B for details of the metasynthesis process.

3.6 | Reflexivity

The reviewer was a trainee clinical psychologist with no prior experience of working with HTX recipients. It is necessary to acknowledge that they approached the analysis from a social constructionist standpoint. As the findings represented the reviewer's own interpretations of the papers, an audit trail was kept documenting the synthesis process to ensure transparency of interpretation. The metasynthesis took place under the supervision of two researchers experienced in conducting qualitative metasyntheses.

4 | RESULTS

Three core concepts emerged from this metasynthesis: 'Identity: making sense of the self after HTX', 'The overwhelming emotional impact of HTX' and 'Developing coping skills'.

One superordinate concept also emerged: ‘Bearing others’ expectations’. The superordinate concept and three core concepts are distinct but interlinked (see Figure 2).

4.1 | Bearing others’ expectations

Individual psychological experiences of HTX occurred against a backdrop of wider societal discourse about transplantation, which impacted others’ abilities to support and understand recipients. This common narrative, and the perceived expectations of others, seemed to perpetuate and silence negative emotions that occurred for recipients post-implantation (Almgren et al., 2017a; Almgren et al., 2017b; Janelle et al., 2016; Mauthner et al., 2015; Monemian et al., 2015; O’Brien et al., 2014; Palmar-Santos et al., 2014; Peyrovi et al., 2014; Poole et al., 2016; Waldron et al., 2017).

The dominant societal discourse of HTX as the ‘gift of life’ led others to believe that the new heart would end recipients’ difficulties, disregarding that recovery might be a long process; “A lot of people just think everything just goes back to normal...But they don’t realise everything like biopsies and rejection and scans.” (Waldron et al., 2017, pp.1979). Recipients reported that their grief reactions were silenced; as the donor heart is perceived as the ultimate gift “recipients feel obligated to appear to be ‘happy,’ ‘grateful’ and ‘worthy’” (Poole et al., 2016, pp.196). Recipients also struggled with issues of deservingness, feelings of shame and anxiety (O’Brien et al., 2014; Palmar-Santos et al., 2014). The concept of the heart as an object to be exchanged or gifted led recipients to feel indebted and they sought reasons to justify that they were worthy of the new heart; “I’ve only got a few years. But there wasn’t anybody else who could have accepted it at that time” (O’Brien et al., 2014, pp.1639)

Recipients felt responsibility towards the donor, their family and the transplant community to care for and protect their gift (Palmar-Santos et al., 2014). As such, they sought ways to demonstrate their gratitude and repay their debt, including strict adherence to

their treatment regimens and giving forward to the transplant community; “We were heavily involved in a support group...I mean it’s a privilege to have it done. Why not tell other people about it?” (O’Brien et al., 2014, pp.1643). Repayment to donor families seemed harder to achieve, as recipients perceived that relatives of their donor would hold high expectations on their future life:

I don’t want to be a disappointment to [the donor family]...because you get that, someone has died that you love, and they’ve given the gift of life, the second chance, cos 90% of people think that way, and they put you up on a pedestal and think you’re going to have done something amazing with your life (Waldron et al., 2017, pp.1979).

Recipients described making great efforts to live according to the expectations of those around them post-HTX; “I do exactly as I am told without exception” (Almgren et al., 2017a, pp.3012). They felt anxiety and disappointment when they could not meet the recovery expectations of medical professionals. Some recipients expressed feelings of abandonment in relation to medical professionals and a lack of support which made adjustment even more overwhelming post-HTX (Almgren et al., 2017b).

The support offered to recipients by family and friends was reportedly limited; some noted an important role for family support in their recovery, but others reported a lack of support and understanding stemming from others’ high expectations (Almgren et al., 2017a, 2017b; Janelle et al., 2016; Monemian et al., 2015; Peyrovi et al., 2014). Many recipients explained that when family members offered support this created feelings of confinement and anxiety around being a burden: “...when family members visit, they bring love but they also create stress” (Janelle et al., 2016, pp.1856). Recipients’ family members expressed expectations that they would be feeling and functioning better post-HTX; “...it is a bit like it was before and that devastated both me and my partner” (Almgren et al., 2017b, pp.170).

Recipients felt pressured to meet these expectations to prevent disappointing others and hid their feelings of tiredness and illness due to shame.

4.2 | Identity: making sense of the self after HTX

A considerable aspect of the psychological experiences of HTX was the impact on recipients' sense of self. Recipients experienced identity disruption, they asked themselves 'who am I now?' and attempted to integrate the multiple identities of the new heart, the donor and the self (Almgren et al., 2017a; Janelle et al., 2016; Mauthner et al., 2015; Monemian et al., 2015; Palmar-Santos et al., 2014; Peyrovi et al., 2014; Vasconcelos et al., 2015; Waldron et al., 2017).

Despite continuing medication regimes and health constraints, some recipients described themselves as healed post-HTX and were reluctant to identify themselves as ill (Janelle et al., 2016; Waldron et al., 2017). HTX recipients attempted to separate themselves from their illness, reduce its impact on their identity and encourage coherence between themselves pre- and post-illness: "inside you're still who you were twelve months ago. You've not changed, you're not a different person; it's just that your body isn't quite what it used to be" (Waldron et al., 2017, p.1978). In line with dominant social discourse, recipients described their HTX experience as a miracle or second chance (Janelle et al., 2016; Monemian et al., 2015; Palmar-Santos et al., 2014; Peyrovi et al., 2014; Vasconcelos et al., 2015; Waldron et al., 2017). For some recipients these narratives positively influenced their identity, they described themselves as fortunate survivors who had been gifted life; "It seems that I am born again, I should begin to live again, everything is new to me and I should get the most of this new beginning" (Monemian et al., 2015, p.7).

Alongside their 'miracle', HTX recipients experienced widespread disruption to their identity and a shattered worldview, underpinned by ontological unease (Almgren et al.,

2017a; Mauthner et al., 2015). They questioned who they were, had altered feelings towards important people in their lives and perceived changes in how others experienced them:

For a long time I felt really...almost like I wasn't me for a while...I don't know, I just felt like, who am I? You know, there were all these emotions I was going through. Like that wasn't me...like it was somebody else...and you couldn't control it...My heart is like its mine and somebody else (Mauthner et al., 2015, p.586).

Recipients found it challenging to achieve a coherent identity. They experienced interconnectedness with their new organ and a perceived changed body, which was difficult to understand and minimised by societal disregard of self-embodiment (Mauthner et al., 2015).

For recipients, integrating the new heart was an important part of making sense of the self after transplantation. Part of this involved acknowledging the heart's position with both life and death (Mauthner et al., 2015). Recipients' thoughts about their future self and aspirations were influenced by the knowledge of the shortened life expectancy of the organ: "I guess most people don't really question their mortality do they?...don't set a sort of date and time on how long they think they'll live" (Waldron et al., 2017, p.1979). Furthermore, recipients had to actively think about their new heart because, in contrast to their previous damaged heart, its activity was no longer felt:

Before, with my huge heart disease I might be lying around with a book, and the book would go up and down with each heartbeat...Now, afterwards, I don't notice it, and at first I noticed something strange as if [laughter]...as if I didn't have a heart, you see. But if I...if I remember the donor, then I say, "yes, it's his" (Palmar-Santos et al., 2019, p.52).

For recipients, this new heart was attached to the identity of its previous owner. For some the identity of the donor was intrusive; "I felt I had an alien thing in me, or somebody

else [heart]” (Mauthner et al., 2015, p.587). They were overwhelmed by their donor’s identity, fantasised about what the donor may have been like and wondered whether they were better than themselves. Recipients painted an image of their donor based on the information available to them and considered characteristics held by the donor as they integrated the heart into their new identity; “I have a good strong man’s heart...that must be the reason why I haven’t rejected it. It’s strong. It’s a strong heart” (Palmar-Santos et al., 2019, p.52). Even if the picture of the donor is created by guesswork, for some people knowing their donor supported their integration into identity.

4.3 | The overwhelming emotional impact of HTX

Following HTX, the recipients experienced a complex range of emotions which were challenging to tolerate at times due to their fluctuating nature; recipients had mixed feelings about their illness experience, their new heart, and the future (Almgren et al., 2017b; Almgren et al., 2017a; Dehghan-Nayeri et al., 2017; Janelle et al., 2016; Monemian et al., 2015; O’Brien et al., 2014; Palmar-Santos et al., 2014; Peyrovi et al., 2014; Poole et al., 2016; Vasconcelos et al., 2015). These overwhelming emotions and distress existed in the context of them making sense of their experience and identity, bearing others’ and their own expectations, and experiencing uncertainty about the future.

Many recipients experienced positive and negative emotions post-HTX which were often paradoxical and therefore difficult to tolerate. Recipients experienced satisfaction with their organ and regret about being transplanted (Monemian et al., 2015), some experienced relief and optimism alongside uncertainty and fear (Palmar-Santos et al., 2014), and many felt contentedness and gratitude alongside sadness and frustration (Janelle et al, 2016). Peyrovi et al. (2014) suggested that recipients moved along a continuum between these contradictory emotions. Although gratitude was felt positively by recipients post-HTX, it also created internal conflict in certain situations and was a source of shame, guilt and obligation;

No, the heart hasn't [made her feel like her "normal old self"]. Not at all. That's fine.

That's just the way my life's supposed to go I guess... I don't want to be cynical about it because I'm really very grateful. (O'Brien et al., 2014, pp.1642)

Some recipients were overwhelmed by distress after their HTX and described negative emotions like bewilderment, hopelessness and depression which they occasionally coped with by crying (Almgren et al., 2017a; Monemian et al., 2015). Recipients' emotional state changed rapidly and they became easily angered or upset; "...Lately I was stubborn and not emotional at all but now, I am a different man and even if I watch a film, I promptly influenced by it and become emotional and cry" (Monemian et al., 2015, pp.6). Recipients also experienced long-lasting grief and persistent thoughts about the donor (Almgren et al., 2017a; Monemian et al., 2015; Poole et al., 2016.); "somebody dies to make someone live, you know... You think about it all the time" (Poole et al., 2016, pp.196). Some recipients managed their grief by trying to contact the family of their donor whereas others tried to avoid thinking about the donor and their family altogether.

Although recipients previously perceived their HTX to be a 'cure', this was not the case; "Now I feel almost as bad as before the heart transplantation, it's all crap and it makes me very depressed" (Almgren et al., 2017a, pp.3011). For some, distress was caused by physical setbacks, ongoing illness, and the side-effects of medications which were all unexpected (Almgren et al., 2017a; Monemian et al.2015; Vasconcelos et al., 2015). Recipients lost autonomy and were limited in their social roles, which created feelings disappointment; "There is nothing we can do, everything we want we just can't" (Vasconcelos et al., 2015, pp.576).

The experience of HTX also created intrusive anxious thoughts and feelings of uncertainty which was difficult to bear and impacted on recipients' day to day lives;

Well afterwards, it's about whether the heart will stop beating and if you notice that something might be wrong you react very strongly. You're not used to what it's like or how it's supposed to be when you're transplanted...I was very anxious after the transplantation and that anxiety is still there. (Almgren et al., 2017a, pp.3012)

Recipients experienced overwhelming and frequent anxiety as they navigated new concerns following HTX (Almgren et al., 2017a; Dehghan-Nayeri et al., 2017; Peyrovi et al., 2014); they worried about their physical health and recovery, relationships, and the future. The participants of the included studies conducted in Iran reported financial distress caused by the high cost of their treatment, difficulties with medical insurance and inability to work (Dehghan-Nayeri et al., 2017; Monemian et al., 2015; Peyrovi et al., 2014).

4.4 | Developing coping skills

Recipients developed coping skills to manage the challenges they faced adjusting to their HTX; these included cognitive, physical and social strategies (Almgren et al., 2017a; Dehghan-Nayeri et al., 2017; Janelle et al., 2016; Monemian et al., 2015; Peyrovi et al., 2014; Vasconcelos et al., 2015; Waldron et al., 2017). Psychological coping skills helped recipients overcome some of the day-to-day obstacles they faced and supported them to avoid becoming overwhelmed by negative emotions. Striving for good health and “normality” gave recipients a focus, helped them to recognise improvements and improved their overall wellbeing.

Some recipients coped by accepting uncertainty which inspired them to evade making long term plans; “I just take it one day at a time, whatever happens next will happen next[...]And if things go well, that's great.” (Janelle et al., 2016, pp.1854). Recipients who experienced medical complications or illness had better self-efficacy when they recognised recovery achievements, perceived a sense of control and adjusted their expectations to avoid disappointment. Resilience was created by a belief in the possibility of recovery and a

fighting spirit; “Well it was me, I was the one fighting to survive. I want to survive, I want to live a little longer.” (Almgren et al., 2017a, pp.3010). Many recipients cited positivity/optimism as an important strategy in the achievement of accomplishments. Some used their HTX experience as a marker to put other problems into perspective;

The difference is amazing. Psychologically, I get upset when I feel myself getting worked up over nothing again. I try to tell myself, “Think about your heart! Make the most of this moment and don’t waste your time sweating the small stuff.” (Janelle et al., 2016, pp.1855)

Recipients experienced less disappointment and increased hope by being inspired by the recovery of other HTX recipients or by comparing themselves to others and concluding they were doing better (Almgren et al., 2017a).

Spirituality had an important role in achieving positive psychological experiences for some recipients post-HTX (Dehghan-Nayeri et al., 2017; Janelle et al., 2016; Monemian et al., 2015; Peyrovi et al., 2014; Vasconcelos et al., 2015). Spirituality provided recipients with the motivation to overcome the obstacles they faced in recovery and faith in God provided comfort, particularly in times of uncertainty;

Well, I mean everything of my sickness is in the hand of God...I say that even [a] tree will not shed a leaf unless God wants it to. We thank God. I say that life is in God’s hands. (Peyrovi et al., 2014, pp.239).

Recipients performed religious obligations, such as prayer, to manage feelings of grief and show gratitude to God, the donor and the donor’s family: “...I got my heart from a young boy...I say praying and Quran for him every morning because I owe my life to him” (Monemian et al., 2015, pp.6).

Physical and social accomplishments also improved recipients’ psychological wellbeing post-HTX (Almgren et al., 2017a; Vasconcelos et al., 2015; Waldron et al., 2017).

Physical activities, such as getting out of bed, acted as concrete indicators of improvement and increased recipients' confidence in recovery; "I haven't been able to ride a bike for many years. However, this summer I could and it simply makes me very happy." (Almgren et al., 2017a, pp.3010). Similarly, socialising with friends, living independently, travelling, and leisure activities, boosted recipients' self-esteem and acted as markers of "normality". Returning to employment was also important to some recipients in recovering their identity as an autonomous, healthy individual; "[I] was really keen on just being able to afford my own things. And my rent and, not only my rent ...everything... all the bills that go with all that independence" (Waldron et al., 2017, pp.1979).

Recipients reported an ongoing commitment and vigilance to their health after transplantation, including their diet, medication regimes and self-care activities (Almgren et al., 2017a; Dehghan-Nayeri et al., 2017; Janelle et al., 2016; Peyrovi et al., 2014); "I actively perform physical activities and adhere to dietary regimen as much as possible. I don't like to become ill again. I feel responsible toward this heart and should care for it properly" (Dehghan-Nayeri et al., 2017, pp.200). For some, these strict treatment regimens were tiring and a barrier to perceiving themselves as normal. However, other recipients found them beneficial to their health and a way to show gratitude for their 'gift' (Janelle et al., 2016).

5 | DISCUSSION

The aim of this review was to synthesise studies exploring the psychological experiences of adult HTX recipients. Existing quantitative studies have focused on simply identifying factors which impact on psychological outcomes (e.g. Dew & DiMartini, 2005). However, there was no known interpretative metasynthesis of qualitative findings. The current review was designed to address this gap in the literature and provide an update of Conway et al.'s (2013) meta-summary.

The first concept ‘Identity: making sense of the self after HTX’ indicated that HTX caused great disruption to a recipient’s identity and led them to reflect on who they were in relation to illness, death, their new heart and the donor. Recipients described themselves as survivors, fortunate to experience a miracle and/or starting a new life. Research of individuals who have experienced cancer demonstrated that “survivor identity” is correlated with superior psychological wellbeing and post-traumatic growth rather than “victim identity” (Park, Zlateva & Blank, 2009). The self-descriptions in the current metasynthesis could indicate positive psychological outcomes for HTX recipients consistent with the concept of post-traumatic growth; a positive psychological change experienced following difficulty related to highly challenging life events (Tedeschi & Calhoun, 1995). A qualitative review of post-traumatic growth in life threatening illness described themes of self-development, existential re-evaluation and new awareness of the body which contributed positive psychological outcomes (Hefferon, Grealy, & Mutrie, 2009). This draws parallels to the findings of the current review, indicating that the significant identity evaluation and adjustment experienced by HTX recipients could be considered as a necessary part of post-traumatic growth.

Within this review, the presence of the new heart created queries about the self and other; the donor was prominent in recipients’ thoughts and they felt unlike themselves at times. This concept relates to philosophical debates regarding embodiment and may act as a unique barrier to post-traumatic growth in transplant recipients, compared with other life-threatening illnesses. Western healthcare systems are dominated by Cartesian ideas that the self and the body are separate and ontologically distinct (Haddow, 2005). HTX recipients are encouraged by medical professionals to view the heart as a functional pump to be exchanged, despite socio-cultural attachments to attributes such as love, empathy and fear and representations as being of great personal significance (Shildrick, 2012). Within this review,

the mechanistic worldview conveyed by health professionals and wider social circles prolonged identity adjustment and silenced the distress experienced by recipients. Recipients' embodied experiences and difficulties incorporating multiple identities might be perceived as non-normative by society and therefore lead to anxiety about sharing them (Shildrick, 2012).

In contrast to Conway et al.'s (2013) findings, the role of support in psychological experiences was not the most prominent theme that emerged from the data in this review, but it created similarly mixed outcomes. Recipients perceived that family and medical professionals set high expectations for recovery and at times offered little in the way of support. This lack of support may be due to others' lack of knowledge of recipients' true physical and psychological condition; Ivarsson, Ekmeahag, and Sjoberg (2013) found that HTX candidates experience a lack of support and shrinking social network due to others not knowing how seriously unwell they were, partially due to ineffective communication of information on their part.

In the current review, recipients strived to meet the inherent responsibilities stemming from society's 'gift of life' narrative by expressing gratitude, hiding distress, strict medical adherence, and seeking to repay their debt. Difficulties with social accountability have been identified in other areas of transplant research; kidney transplant recipients were motivated to engage in self-management regimens to demonstrate gratitude to the medical team and show indebtedness to the donor, despite them being emotionally and physically exhausted (Jamieson et al., 2016). HTX recipients may find it hard to share their true feelings of distress because of the perceived expectation they should be grateful for the 'gift' that saved their life. This metasynthesis supports previous qualitative findings that recipients' distress may be hidden and therefore not captured by routine outcome measurement (Abbey et al., 2011; Ross et al., 2010). The complexity of the pressures perceived by HTX recipients from society, the donor, donor family, medical professionals, friends and family constitutes a novel finding.

Despite hiding distress from those around them, recipients shared their emotional experiences with researchers and they formed the third concept 'The overwhelming emotional impact of HTX'. This concept supports the findings of Conway et al. (2013) that positive and negative psychological experiences are prominent for recipients. The current review describes the intricacies of these emotional experiences in greater detail; recipients experienced paradoxical emotions which fluctuated swiftly and felt out of their control. Greater fluctuation in positive emotion and the simultaneous experience of lows and highs across time is associated with poor psychological wellbeing and life satisfaction, and increased depression and anxiety (Gruber, Kogan, Quoidbach, & Mauss, 2013). The powerful negative emotions in direct contrast with the positive emotions related to HTX might pose a barrier to psychological wellbeing for HTX recipients. This may, in turn, lead to poorer physical health outcomes (Havik et al., 2007). Thus, creating a vicious cycle of negative emotions as continued illness and medical complications were prominent causes of distress for recipients.

In the current metasynthesis, a large proportion of distress was associated with anxiety. HTX was successful at prolonging life but created countless new concerns. Recipients appeared unprepared for the reality of living with a new heart and had frequent anxious thoughts about the impact of their transplant on relationships, health, day-to-day functioning and future aspirations. HTX recipients have, retrospectively, reported gaps in their knowledge whilst on the waiting list for HTX and described that they did not actively seek information about HTX (Ivarsson et al., 2013). Recipients are largely reliant on medical professionals for their knowledge of HTX. As research has shown that information about transplant-related psychological distress is often hidden to make way for expressions of gratitude (O'Brien et al., 2014), medical professionals may have insufficient knowledge of

the realities of life after HTX and therefore cannot prepare people with adequate information about the challenges they might face.

Regardless of whether professionals share adequate information, uncertainty in the pre-HTX period could act as a barrier to better psychological wellbeing for recipients post-HTX. In the pre-HTX waiting period, candidates experience high levels of uncertainty about when or even if a donor heart will be found and are constantly reminded of their mortality (Haugh & Salyer, 2007). Kidney transplant candidates tolerated uncertainty by focusing on the present, but this prevented them from contemplating the future (Moran, Scott & Darbyshire, 2010). Avoidant coping styles have been evidenced in HTX candidates and are correlated with experiences of depression and poor health in the pre-HTX stage (Burker, Evon, Losielle, Finkel, & Mill, 2005). This review suggests that further poor psychological outcomes, in the form of unexpected new concerns and anxiety, might occur if HTX candidates are focused on the present in the pre-transplant waiting period and avoid thinking about the future realities of receiving a heart.

Findings of this metasynthesis demonstrated that recipients used coping strategies to help them to adjust and experience better psychological wellbeing post-HTX. Recipients felt increased happiness, self-esteem and self-efficacy when they accomplished greater numbers of physical and social activities as these indicated that they were “normal”, healthy and independent. Quantitative research has found that recipients who struggled to return to activities of daily living had poorer psychological outcomes (Dew & DiMartini, 2005). Lower levels of physical activity have also been shown to be associated with lower levels of perceived QoL in female HTX recipients (Evangelista, Dracup, Doering, Moser, & Kobashigawa, 2005). The findings of this review support existing quantitative research that increased activity levels are linked to better psychological outcomes but also expanded our

conceptual understanding of what increased activity represents for HTX recipients and their identity.

In line with Conway et al.'s (2013) review, faith and spirituality promoted psychological wellbeing and helped some recipients better understand their experience of HTX. Engagement in religious practices and belief in the will of God helped recipients to tolerate the uncertainty and grief that was so distressing for other recipients. Research indicates that spirituality provides hope for HTX recipients which in turn promotes fulfilment, wellbeing and emotional coping (Walton & Clair, 2000). This review found that recipients could also find hope in other places to improve their psychological wellbeing, for example by looking up to HTX peers. Having a fighting spirit and belief in their ability to recover was found to be a positive coping skill. It seems that, even for those who are not religious, hope and belief have a role in coping better post-HTX and may protect recipients from negative emotions such as disappointment. This review provided a more nuanced understanding of optimism in HTX recipients and provides further support for quantitative research findings that higher levels of optimism and hope reduce the risk of depression and stress (Evangelista, Doering, Dracup, Vassilakis, & Kobashigawa, 2003; Milaniak et al., 2016).

5.1 | Limitations and future research

All of the articles reviewed explored experiences of both male and female HTX recipients. Many of the samples had a greater number of male participants than female participants; in line with evidence that a greater proportion of transplant recipients are male (NHSBT, 2019). It could be argued that the findings of the current metasynthesis relied heavily on male HTX recipients' experiences and attempts to generalise these findings to female HTX recipients should be made cautiously. Indeed, and as noted by Conway et al. (2013), previous quantitative research has evidenced gender differences in psychological experiences. For

example, Dew et al. (2005) found HTX recipients who experienced persistent psychological distress were more likely to be female. More explicit qualitative exploration of differences in psychological experiences of HTX between male and female recipients is warranted.

In the current review, one included study's sample consisted of HTX recipients within 3 months post-HTX, another study's sample consisted of participants 12 months post-HTX, other studies did not recruit participants according to time post-HTX and their samples therefore included participants with a variety of lengths of time since HTX (10 weeks to 11 years). Evidence suggests distress decreases over time (Dew & DiMartini, 2005) and recipients' psychological QoL is like that of the general population 10 years post-HTX (Politi et al., 2004). As the research base increases, a synthesis of qualitative findings related to psychological experiences of HTX at different time points (e.g. early post-HTX versus a few years post-HTX) might be possible. This would increase understanding of the potentially different psychological experiences at these time points and how distress and coping change over time. The current study highlighted that some recipients perceived a lack of support from transplant services post-implantation; future qualitative research specifically focused on perceived experiences of support might be beneficial to service design and provision, including that of psychological interventions.

6 | CONCLUSIONS

The current review is the first to synthesise qualitative findings of the psychological experience of HTX recipients. Bringing together qualitative findings in this way deepens understanding and allows a rich exploration of recipients' thoughts, feelings and experiences post-HTX. Undergoing HTX can be an emotionally challenging experience for recipients, who are somewhat isolated in their experiences by the expectations of others around them. Despite this, many participants attempt to integrate transplant into their identity and employ strategies to cope and adapt to their situation leading to positive experiences of acceptance

and “normality”. Ultimately, HTX recipients should have access to psychological support at times of distress aimed at helping them to accomplish adaptation and integration related to their perceived “normal”.

7 | RELEVANCE TO CLINICAL PRACTICE

Understanding the psychological experiences of HTX recipients is essential for tailoring support to help manage the physical and emotional demands faced in the adaptation period post-transplant. In the current review, participants experienced fluctuating positive and negative emotions related to their transplant, including high levels of anxiety and uncertainty. A paucity of literature means it is not yet possible to draw any conclusions regarding the effectiveness of psychological interventions for HTX recipients (Dornelas & Sears, 2018). Cognitive-Behavioural Therapy (CBT) could be considered for individuals experiencing high levels of anxiety post-transplantation as CBT has demonstrated some success at reducing overall distress, anxiety and low mood in other cardiac populations (e.g. Dickens et al., 2013; Tully, Selkow, Bengel, & Rafanelli, 2015). Alternatively, Acceptance-based psychological support approaches such as Acceptance and Commitment Therapy (Hayes, Luoma, Bond, Masuda, & Lillis, 2006), mindfulness (Grossman, Niemann, Schmidt, & Walach, 2004) and Compassion Focused Therapy (Gilbert, 2014) might be beneficial to support recipients to tolerate uncertainty and distress as it arises and promote adaptation and post-traumatic growth. The findings that recipients might hide psychological distress from professionals indicate that questionnaires should not be used in isolation to screen for distress post-HTX but alongside observations and qualitative interviews in which chance to build rapport and ask open questions are maximised.

This study indicated that physical accomplishments and social activities improved psychological wellbeing and helped recipients regain their sense of self-identity. HTX recipients should receive person-centred support to engage in such activities following

transplant, in line with what is meaningful to them. The current findings indicated that participants experience distress and disruption to their identity which is challenging for them to talk about and for family and professionals to understand. Recipients may benefit from peer support groups in which they can express psychological experiences related to HTX, such as disruption to embodied self, to reduce feelings of isolation, acknowledge distress and promote the development of a more coherent sense of self. Emotional expression, rather than avoidant styles of emotion regulation, led to decreased distress, mood improvement and reduced intrusions in a review of psychological adjustment to chronic illness (De Ridder, Geenen, Kuijer, & van Middendorp, 2008).

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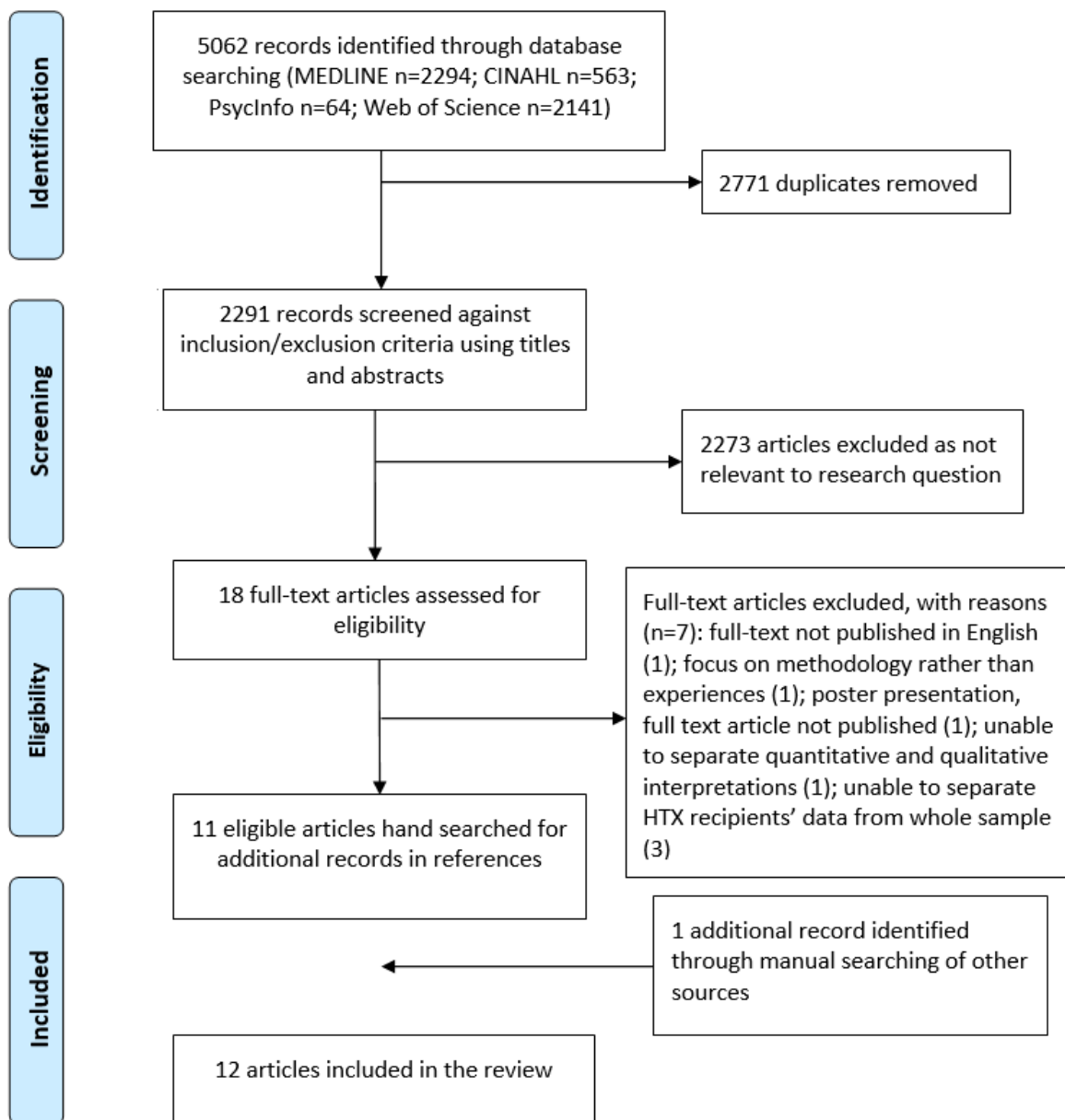


FIGURE 1 PRISMA diagram of search strategy

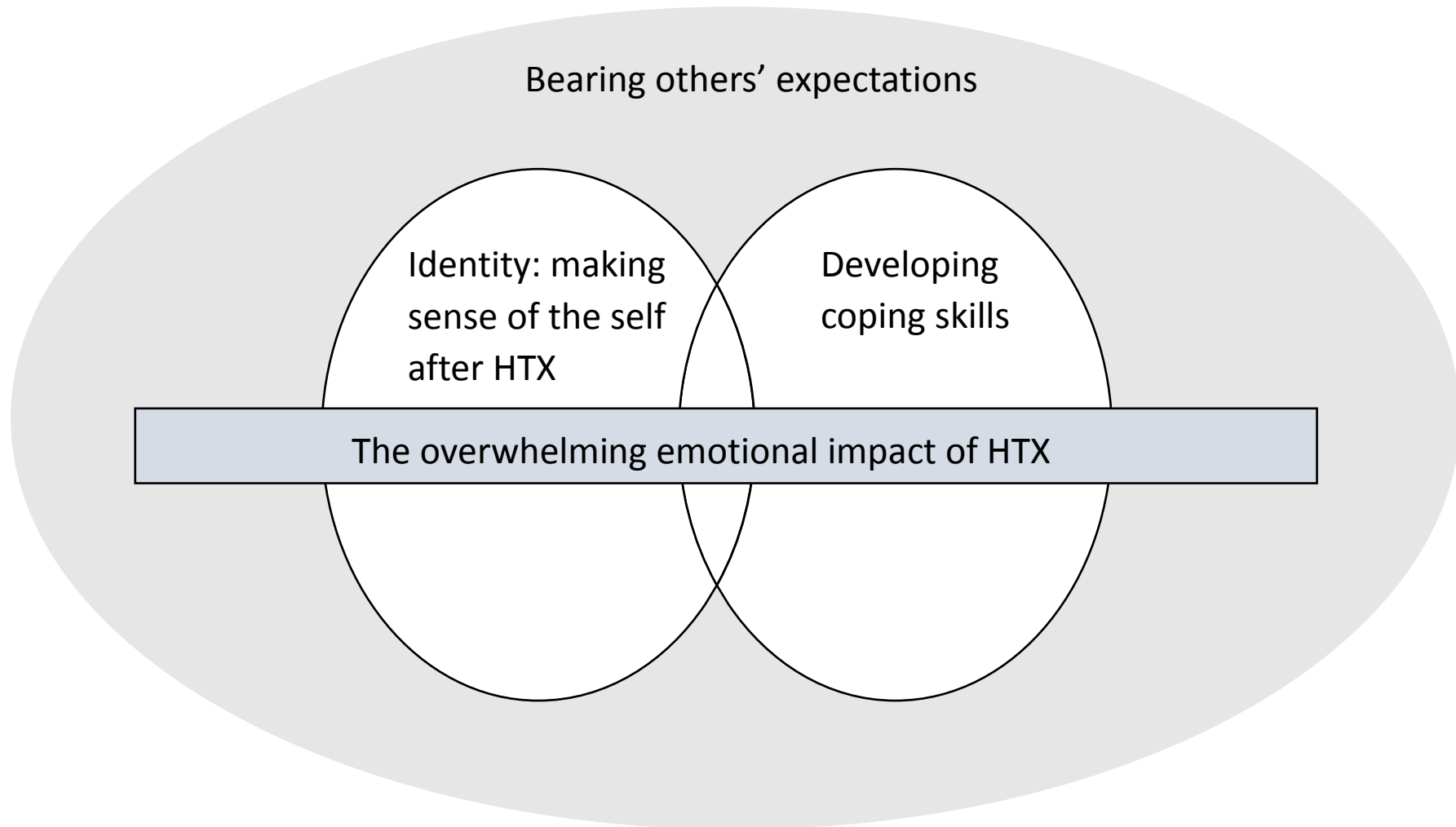


FIGURE 2 Diagrammatic representation of concepts

TABLE 1 Characteristics of included studies

No.	Author(s)/ Year	Country	Aim(s) of study	Stated methodology – data analysis	Method of data collection	Participants	Themes
1.	Almgren, Lennerling, Lundmark, & Forsberg (2017a)	Sweden	Detailed exploration of self-efficacy in HTX recipients using Bandura's (1977) self-efficacy theory.	Directed content analysis (Hsieh & Shannon, 2005)	Open-ended individual interviews.	14 HTX recipients; 4 women, 10 men, mean age 51 years (range: 28-67 years). 12 months post-transplantation.	Findings presented according to the areas of Bandura's (1997) self-efficacy theory: efficacy expectation; outcome expectation; performance accomplishment; vicarious experience; verbal persuasion; emotional arousal; contextual factors.
2.	Almgren, Lennerling, Lundmark, & Forsberg (2017b) ^a	Sweden	Detailed exploration of the meaning of uncertainty for people during their first-year post-heart-transplant.	Phenomenological – hermeneutic	Open-ended individual interviews.	14 HTX recipients; 4 women, 10 men, mean age 51 years (range: 28-67 years). 12 months post-transplantation.	Six main themes: doubting survival; doubting the recovery process; doubting one's performance; struggling with close relationships; feeling abandoned; doubting the future.
3.	Dehghan-Nayeri, Varaei, & Azizi- Fini (2017)	Iran	To explore the physical and psychosocial outcomes for HTX recipients.	Qualitative content analysis (Graneheim & Lundman, 2004)	Individual semi-structured interviews.	15 HTX recipients; 2 women, 13 men, mean age 43.4 years. Mean time post-transplantation: 19.49 months.	Main theme: "Living under the perfect storm of problems". Subcategories: financial distress; perceived physical and psychosocial changes; greater commitment to one's own health; tendency to spirituality.
4.	Janelle, O'Connor, & Dupuis (2016)	Canada	To explore illness perception after HTX; evaluating whether qualitative analysis improved quantitative measurement.	Mixed-methods; qualitative data analysed using phenomenological reduction	'Non-directive' individual interviews.	15 HTX recipients; 2 women, 6 men, age range: 22-66 years. All within 3 months post-transplantation.	Findings presented according to the subscales of the quantitative measure used: identity; causes; timeline; consequences; personal control; treatment; emotional representations; illness coherence. Additional qualitative theme: social support.
5.	Mauthner et al. (2015)	Canada	To explore HTX recipients' experiences of incorporating their new heart into their identity.	Qualitative visual methodology (Heath, 1997).	Video-taped individual semi-structured interviews.	25 HTX recipients; '70%' male, mean age 53 years (range: 18-72 years). Mean time post-transplantation: 4.1 years.	Three main themes: identity disruption and bodily integrity; interconnectedness of recipient with donor; imagining and speculating about the donor

Abbreviations: HTX, heart transplant; IPA, Interpretative phenomenological analysis.

^a Derived from the same study as the paper immediately above it.

6.	Monemian, Abedi, & Najj (2015)	Iran	To understand the life experiences of HTX recipients.	Phenomenology (Colaizzi method)	Unstructured, individual interviews	9 HTX recipients; 5 women, 4 men, mean age 47.6 years. Mean time post-transplantation: 19.4 months (3months-8 years).	Eleven main concepts: belief; tendencies of the recipient and family of donor; bewilderment; moment of facing with transplantation; satisfaction; vital organ; support; temperament; physical effects of transplantation; mental changes; paradox of life and death.
7.	O'Brien, Donaghue, Walker, & Wood (2014)	Australia	To explore the lived experience of HTX recipients; focusing on how they experience and manage the moral and personal elements of gratitude.	IPA	Individual semi-structured interviews	13 HTX recipients; 5 women, 8 men, mean age 56.2 years (range: 35-72 years). Time post-transplantation ranged from 10 weeks–11 years.	Three themes identified: deservingness; nuances of gratitude; giving forward.
8.	Palmar-Santos et al. (2019)	Spain	To explore the subjective experiences of HTX recipients, particularly their constructs of life and death.	Phenomenology (Colaizzi method)	Individual semi-structured interviews	12 HTX recipients; 6 women, 6 men, mean age 49.3 years (range: 27-70 years). Mean time post-transplantation: 4.2 years (3months-17 years).10 family members were also interviewed about their relative's experiences.	Three themes identified: towards death; the frontier between life and death; towards life.
9.	Peyrovi, Raiesdana, & Mehrdad (2014)	Iran	To gain further insight into the lived experience of HTX recipients in Iran.	Hermeneutic analysis (Diekelmann method)	Individual semi-structured interviews	11 HTX recipients; 2 women, 9 men, median age 30 years (range: 21-55 years). Time post-transplantation: median 48 months, range (7-216 months).	Six major themes: having a new life; living with new concerns; living with vigilance; paradoxical emotions bearing others' behaviours; the prominent role of God in life.
10.	Poole et al. (2016) ^b	Canada	To understand experiences of loss and grief for those waiting for and living with HTX.	Qualitative visual methodology	Video-taped individual semi-structured interviews	15 HTX recipients and 15 people on waiting list for HTX. Sample taken from larger sample of participants, specific demographics for this smaller sample unavailable.	Four central themes total. Two relevant themes from the post-transplant group; complicated grief; disenfranchised grief.

^b Derived from the same study as the paper by Mauthner et al. (2015).

11.	Vasconcelos, Pessoa, Menezes, Florêncio, & Frota (2015)	Brazil	To understand the impact of HTX on the daily living of recipients.	Hermeneutics	Focus groups (all participants meeting 4 times)	9 HTX recipients; 2 women, 7 men, mean age 40.8 years. Time post-transplantation: between 6 and 12 months.	Two thematic categories: being a heart transplantation patient - before and after; and feelings and perceptions on heart transplantation.
12.	Waldron, Malpus, Shearing, Sanchez, & Murray (2017)	UK	To explore the process and challenges of HTX for young adults.	IPA	Individual semi-structured interviews	9 HTX recipients; 4 women, 5 men, age range 19-29 years. Mean time post-transplantation: 3.6 years (7 months-9.5 years).	Three themes: separating from illness; working toward normality; and integrating transplant into identity.

TABLE 2 Quality appraisal scores

CASP question	Study number											
	1	2	3	4	5	6	7	8	9	10	11	12
Was there a clear statement of the aims of the research?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Is a qualitative methodology appropriate?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Was the research design appropriate to address the aims of the research?	2	2	1	2	3	2	2	2	3	2	1	3
Was the recruitment strategy appropriate to the aims of the research?	2	3	1	2	3	1	2	2	3	2	3	3
Was the data collected in a way that addressed the research issue?	2	2	2	2	3	2	3	2	3	1	3	3
Has the relationship between researcher and participants been adequately considered?	2	3	1	1	1	1	2	2	2	1	1	3
Have ethical issues been taken into consideration?	3	2	3	2	2	1	3	2	2	1	1	3
Was the data analysis sufficiently rigorous?	2	3	3	2	1	1	1	2	2	1	1	2
Is there a clear statement of findings?	3	2	2	2	3	2	3	2	3	2	2	3
How valuable is the research?	2	2	1	3	3	1	2	2	2	1	1	3
Total score	18	19	14	16	19	11	18	16	20	11	13	23

CASP, Critical Appraisal Skills Programme.

APPENDIX 1-A

DETAILED SEARCH STRATEGY

MEDLINE	
Free text search terms (applied to title/abstract)	"heart transplant*" OR "cardi* transplant*" OR "cardi* allo*" OR "heart allo*" AND "interview*" OR "focus group*" OR "case study" OR "view*" OR "experience*" OR "opinion*" OR "attitude*" OR "perce*" OR "perspective*" OR "belie*" OR "feel*" OR "know*" OR "understand*" OR "qualitative" OR ethnog* OR phenomenolog* OR "grounded theory" OR narrative OR thematic OR theme*
MeSH terms	"Heart Transplantation"
Additional limiters	Date of publication: 20130101-20190331
CINAHL	
Free text search terms (applied to title/abstract)	"heart transplant*" OR "cardi* transplant*" OR "cardi* allo*" OR "heart allo*" AND "interview*" OR "focus group*" OR "case study" OR "view*" OR "experience*" OR "opinion*" OR "attitude*" OR "perce*" OR "perspective*" OR "belie*" OR "feel*" OR "know*" OR "understand*" OR "qualitative" OR ethnog* OR phenomenolog* OR "grounded theory" OR narrative OR thematic OR theme*
Subject terms	"Heart Transplantation"
Additional limiters	Date of publication: 20130101-20190331
PsycINFO	
Free text search terms (applied to title/abstract)	"heart transplant*" OR "cardi* transplant*" OR "cardi* allo*" OR "heart allo*" AND "interview*" OR "focus group*" OR "case study" OR "view*" OR "experience*" OR "opinion*" OR "attitude*" OR "perce*" OR "perspective*" OR "belie*" OR "feel*" OR "know*" OR "understand*" OR "qualitative" OR ethnog* OR phenomenolog* OR "grounded theory" OR narrative OR thematic OR theme*
Additional limiters	Date of publication: 20130101-20190331
Web of Science	
Free text search terms (applied to title/abstract)	"heart transplant*" OR "cardi* transplant*" OR "cardi* allo*" OR "heart allo*" AND "interview*" OR "focus group*" OR "case study" OR "view*" OR "experience*" OR "opinion*" OR "attitude*" OR "perce*" OR "perspective*" OR "belie*" OR "feel*" OR "know*" OR "understand*" OR "qualitative" OR ethnog* OR phenomenolog* OR "grounded theory" OR narrative OR thematic OR theme*
Additional limiters	Date of publication: years 2013-2019 (date of search 01.04.19)

APPENDIX 1-B

METASYNTHESIS PROCESS

Key themes, first iterations	Key themes, final iterations (second-order constructs)	Core concept, first iteration	Core concept, final iteration (third-order constructs)	Relevant papers
A new life begins/ A new life, a new chance for survival/ HTX as a second life or miracle/ Paradox of death and life, risking HTX and choosing life/ Gratitude and satisfaction with a new life/ Gift of life and second chance/ Identity disruption and bodily integrity – ‘who am I?’, ontological unease/ Distress caused by difficulty creating a new worldview/ Restricted from separating illness from identity/ ‘No longer being sick’/ Feeling/not feeling – the new organ must be thought about because it’s not felt/ Integrating transplant into identity/ The frontier between life and death - rebirth, the return to life with a dead organ/ Interconnectedness of recipient with donor - distress and identity disruption/ Incorporating the image of the donor with the self/ Kinship with donor, donor family and other recipients/ Imagining and speculating about the donor - the struggle of combining self and other	A new life, a second chance. Who am I? Separating illness from identity. Life with a new organ. Making sense of self-identity in relation to the donor.	Who am I now? Integrating the new heart, the donor, and the self.	Identity: making sense of the self after HTX.	Almgren et al. (2017a) Janelle et al. (2016) Mauthner et al. (2015) Monemian et al. (2015) Palmar-Santos et al. (2014) Peyrovi et al. (2014) Vasconcelos et al. (2015) Waldron et al. (2017)
Anxiety, disappointment, and uncertainty caused by not meeting others’ expectations for recovery/ Striving to be better than normal due to perceived expectations of the donor family/ Playing a role and hiding negative emotions: meeting others’ expectations that they should feel better/ Bearing others’ behaviours: recommendations, questions and myths of HTX/ Hiding negative feelings associated with post-HTX illness/ Deservingness - responsibility to the donor, donor family and the transplant community to look after their gift/ The 'gift of life' narrative means others expect a quick return to normality/ Disenfranchised grief/ Identity disruption - normative and sociocultural expectations of the integrity of the embodied self	Living up to others’ high standards. Limited support and understanding. Society’s ‘gift of life’ discourse creates emotional challenges. Deservingness, gratitude and repayment: new roles	Others’ high standards silence difficult feelings. Limited support and understanding. The ‘gift of life’ discourse imposes expectations.	Bearing others’ expectations	Almgren et al. (2017a) Almgren et al. (2017b) Janelle et al. (2016) Mauthner et al. (2015) Monemian et al. (2015) O’Brien et al. (2014)

contrasts with personal perceptions and experiences of a changed body/ The gift: acceptance, gratitude and repayment/ Deservingness – showing your worth/ Giving forward to solve the reciprocity dilemma/ Feeling abandoned/ Struggling with close relationships – lack of support and understanding/ Support – limited availability and utility/ Social support has advantages and disadvantages

Emotional representations – positive and negative/ Satisfied with the organ, unsatisfied with life post-HTX/ Paradoxical emotions/ Vital organ – accepting the difficulties to cherish the new beginning/ Nuances of gratitude – a highly complex interplay of emotions/ Overwhelmed by feelings/ Changes to temperament/ Living with new concerns/ Distress caused by inability to perform familial, professional, and social roles, worries about the future/ Doubting the future – what will it look like?/ Physical effects of HTX – medications create problems and reviewing pre-HTX experiences is hurtful/ Disappointment from physical complications/ The ‘cure to all ills’ comes with challenges to keep well/ Doubting the recovery process/ Nuances of gratitude – disappointment brings guilt/ Negative emotions caused by disappointment, intrusive thoughts, grief for the donor, uncertainty, and making sense of HTX/ Doubting survival/ Doubting one’s performance in recovery/ Bewilderment/ Mental changes – hopelessness, grief for the lost heart, depression and disappointment/ Complicated, long-lasting grief/ Financial distress.

created from receiving ‘the gift’.

Complex paradoxical emotions.
New concerns and unmet expectations.
Distress, grief and bewilderment.

Complex paradoxical emotions.
Emotional distress; grief, uncertainty, disappointment and guilt.

The overwhelming emotional impact of HTX.

Palmar-Santos et al. (2014)
Peyrovi et al. (2014)
Poole et al. (2016)
Waldron et al. (2017)

Almgren et al. (2017a)
Almgren et al. (2017b)
Dehghan-Nayeri et al. (2017)
Janelle et al. (2016)
Monemian et al. (2015)
O’Brien et al. (2014)
Palmar-Santos et al. (2014)
Peyrovi et al. (2014)
Poole et al. (2016)
Vasconcelos et al. (2015)

Mental accomplishments - adjusting expectations, feeling optimistic, perceiving a sense of control, and being resilient/ Positive physical, cognitive and emotional outcomes/ Developing coping strategies to overcome obstacles/ Vicarious experience/ Tendency to spirituality – God, gratitude and giving back/ Belief – sense of being grateful, spiritual dimension/ Prominent role of god in life/Spirituality is motivating/ Uncertainty inspires taking each day as it comes/ Improving self-efficacy by being positive and setting reasonable expectations to avoid disappointment/ Performance adjustment is tough but improves satisfaction/ Physical accomplishments signify recovery towards health, boosting self-confidence/ Overcoming post-HTX difficulties to resume activities of daily living/ Social accomplishments – independence boosts self-esteem/ Working towards normality/ Living with vigilance/ Greater commitment to one’s own health/ Importance of treatment regimen/ Striving to follow professional advice.

Positive coping strategies.
Spirituality.
Accepting uncertainty and adjusting expectations.
Physical and social accomplishments improve wellbeing.
Being vigilant to physical health.

Psychological strategies overcome obstacles.
Striving for good health and normality.

Developing coping skills.

Almgren et al. (2017b)
Dehghan-Nayeri et al. (2017)
Janelle et al. (2016)
Monemian et al. (2015)
Peyrovi et al. (2014)
Vasconcelos et al. (2015)
Waldron et al. (2017)

APPENDIX 1-C

SUMMARY OF AUTHOR GUIDELINES IN JOURNAL OF CLINICAL NURSING

The Journal of Clinical Nursing (JCN) is an international, peer reviewed, scientific journal that seeks to promote the development and exchange of knowledge that is directly relevant to all spheres of nursing practice. The primary aim is to promote a high standard of clinically related scholarship which advances and supports the practice and discipline of nursing. The Journal also aims to promote the international exchange of ideas and experience that draws from the different cultures in which practice takes place. Further, JCN seeks to enrich insight into clinical need and the implications for nursing intervention and models of service delivery. Emphasis is placed on promoting critical debate on the art and science of nursing practice.

JCN is essential reading for anyone involved in nursing practice, whether clinicians, researchers, educators, managers, policy makers, or students. The development of clinical practice and the changing patterns of inter-professional working are also central to JCN's scope of interest. Contributions are welcomed from other health professionals on issues that have a direct impact on nursing practice.

We publish high quality papers from across the methodological spectrum that make an important and novel contribution to the field of clinical nursing (regardless of where care is provided), and which demonstrate clinical application and international relevance.

Topics include but are not limited to:

Development of clinical research, evaluation, evidence-based practice and scientific enquiry;
Patient and family experiences of health and health care; illness and recovery;
Nursing research to enhance patient safety and reduce harm to patients;
The nature of nursing need, intervention, social interaction and models of service delivery;
Clinical nursing leadership;
Examination of clinical decision-making;
Exploration of organisational or systemic factors that enhance or impede the provision of effective, high-quality nursing care;
Application and dissemination of clinical knowledge and theory;
Role development and inter-disciplinary working, exploring the scope and changing boundaries of clinical nursing; and
Cultural comparisons and evaluations of nursing practice in different health sectors, social and geographical settings.

MANUSCRIPT CATEGORIES AND REQUIREMENTS

i. Original Articles

Pilot studies are not suitable for publication as original articles.

Word limit: 8,000 words maximum (quotations are included in the overall word count of articles, and abstract, references, tables and figures are excluded).

Abstract: 300 words maximum, and structured under the sub-headings: Aims and objectives; Background (stating what is already known about this topic); Design; Methods (for both qualitative and quantitative studies state n); Results (do not report p values, confidence intervals and other statistical parameters); Conclusions (stating what this study adds to the topic); Relevance to clinical practice.

Main text structure: Introduction (putting the paper in context - policy, practice or research); Background (literature); Methods (design, data collection and analysis); Results; Discussion; Conclusion; Relevance to clinical practice.

References: 50 maximum; all references must be available in English

Impact Statement: should contain 2-3 bullet points under the heading 'What does this paper contribute to the wider global clinical community?'

ii. Review Articles

Literature reviews on any area of research relevant to clinical nursing are welcomed.

Word limit: 8,000 words maximum (quotations are included in the overall word count of articles, and abstract, references, tables and figures are excluded).

Main text structure: Review Articles should be structured, under the sub-headings: Introduction, Aims, Methods, Results, Discussion, Conclusion, and Relevance to Clinical Practice.

References: 50 maximum; all references must be available in English.

Main Text File and Figures

The main text file should be presented in the following order:

Title, abstract and key words;

Main text;

References;

Tables (each table complete with title and footnotes);

Figure legends;

Appendices (if relevant).

Figures and supporting information should be supplied as separate files.

Title

The title must contain both a descriptive and concise title of the paper. Country names are only to be included in titles where it is made clear the content is being compared and contrasted to the International arena.

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Please provide up to 10 keywords. When selecting keywords, Authors should consider how readers will search for their articles. Keywords should be taken from those recommended by the US National Library of Medicine's Medical Subject Headings (MeSH) browser list at <https://www.nlm.nih.gov/mesh/>.

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As papers are double-blind peer reviewed, the main text file should not include any information that might identify the authors.

All articles must be relevant to an international audience. Authors should explain policies, practices and terms that are specific to a particular country or region; outline the relevance of the paper to the subject field internationally and also its transferability into other care settings, cultures or nursing specialities; placed discussions within an international context any papers exploring focussed cultural or other specific issues, and that clinical issues are put into context to other geographical regions and cultural settings.

The journal uses British/US spelling; however, authors may submit using either option, as spelling of accepted papers is converted during the production process. Footnotes to the text are not allowed and any such material should be incorporated into the text as parenthetical matter.

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Legends should be concise but comprehensive – the figure and its legend must be understandable without reference to the text. Include definitions of any symbols used and define/explain all abbreviations and units of measurement.

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Appendices will be published after the references. For submission they should be supplied as separate files but referred to in the text.

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Abbreviations: In general, terms should not be abbreviated unless they are used repeatedly and the abbreviation is helpful to the reader. Initially, use the word in full, followed by the abbreviation in parentheses. Thereafter use the abbreviation only.

Units of measurement: Measurements should be given in SI or SI-derived units. Visit the Bureau International des Poids et Mesures (BIPM) website at www.bipm.fr for more information about SI units.

Numbers: numbers under 10 are spelt out, except for: measurements with a unit (8mmol/l); age (6 weeks old), or lists with other numbers (11 dogs, 9 cats, 4 gerbils).

Trade Names: Chemical substances should be referred to by the generic name only. Trade names should not be used. Drugs should be referred to by their generic names. If proprietary drugs have been used in the study, refer to these by their generic name, mentioning the proprietary name and the name and location of the manufacturer in parentheses.

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In recognition of the significance of data as an output of research effort, Wiley has endorsed the FORCE11 Data Citation Principles, and is implementing a mandatory data citation policy. Journal policies should require data to be cited in the same way as article, book, and web citations and authors are required to include data citations as part of their reference list. Data citation is appropriate for data held within institutional, subject focused, or more general data repositories. It is not intended to take the place of community standards such as in-line citation of GenBank accession codes.

When citing or making claims based on data, authors must refer to the data at the relevant place in the manuscript text and in addition provide a formal citation in the reference list. We recommend the format proposed by the Joint Declaration of Data Citation Principles:

Authors; Year; Dataset title; Data repository or archive; Version (if any); Persistent identifier (e.g. DOI)

Research Reporting Guidelines

Accurate and complete reporting enables readers to fully appraise research, replicate it, and use it. For Original Articles, Review Articles and Special Issue submissions, we require authors to adhere to the relevant EQUATOR research reporting checklist.

For each item in the checklist, please state the manuscript page number on which this aspect of the guidelines has been addressed. Should your manuscript be accepted for publication, your completed checklist will be published alongside the manuscript as a supporting information file; when preparing your manuscript draft please therefore include the checklist as a “supporting file for review and online publication”. Please state in your manuscript abstract which checklist you have used using the short title (e.g. CONSORT), where available, and cite the checklist as a supporting file in the Methods section using the full title (e.g. Guidelines for reporting parallel group randomised trials (Supplementary File 1)).

EQUATOR checklists include:

CONSORT checklist for reports of randomised trials and cluster randomised trials

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PRISMA guidelines for systematic reviews and meta-analyses

STROBE checklist for observational research

COREQ checklist for qualitative studies

SQUIRE checklist for quality improvement

TRIPOD checklist for prediction model development and/or validation

CHEERS guidelines for economic evaluations

SPIRIT checklist for study protocols

AGREE checklist for clinical practice guidelines

Section Two: Empirical Paper

The experience of body image for people with a left ventricular assist device

Word count: 7999 words

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Prepared for: Journal of Clinical Nursing³

³ See Appendix 1-C (Section 1: Literature Review) for Journal of Clinical Nursing author guidelines

ABSTRACT

Aims and objectives: To explore the lived experiences of body image for adults with a left ventricular assist device (LVAD).

Background: Medical equipment or devices used for the treatment of chronic illnesses can cause disruption to an individuals' body image and compromise psychological wellbeing. The LVAD, a mechanical heart pump for individuals with end stage heart failure, has considerable external components. Current research indicates the potential influence of the changed body and LVAD on adaptation and coping following LVAD implantation.

Design: An exploratory qualitative phenomenological design was used.

Methods: Nine adults using an LVAD were recruited and participated in individual semi-structured interviews. Transcribed interviews were analysed using interpretative phenomenological analysis.

Results: Three themes regarding the experience of body image were identified: (1) Making Sense of the Changed Body: "When I came to everything was different", (2) Constant Awareness and Restriction: "There is no sort of mental escape from it or physical escape because it's there", and (3) "Get on and Live".

Conclusions: LVAD-users experience disruption to their body image, which leads them to see themselves as "different" from their previous self and others. They are required to have a constant awareness of their body and learn to become accustomed to restrictions in their everyday life. Individuals use behavioural and psychological strategies to overcome perceived restrictions to physical functioning and appearance including: concealing their device to appear "normal", finding alternative ways to carry their device and do the things they enjoy, and having a positive attitude towards their changed body and LVAD.

Relevance to clinical practice: The findings provide medical professionals with a greater understanding the impact of the LVAD on body image and recommendations to guide provision of support following implantation.

KEYWORDS body image, cardiology, cardiovascular nursing, electronics medical, emotional adjustment, hermeneutics, psychological adaptation, qualitative research

1 | INTRODUCTION

The National Heart Failure Audit (McDonagh et al., 2019) demonstrates that approximately 900,000 people in the United Kingdom are living with heart failure. The most common type of heart failure causes impaired left ventricular functioning, in which the left ventricle contracts or fills poorly leading to symptoms of breathlessness, fatigue and swollen ankles (McDonagh et al., 2019). Heart transplantation may be considered if other medical treatments are not successful for individuals with advanced, end-stage heart failure. Improvements in quality of life are demonstrated following heart transplantation (Tackmann & Dettmer, 2018) however, there is a scarcity of donor hearts available.

The development of Ventricular Assist Devices (VADs) mean that some people with end-stage heart failure can be mechanically supported and achieve prolonged survival until a suitable donor heart is found (Drakos, Charitos, Nanas, & Nanas, 2007). In these cases, the VAD is life-sustaining and used as a ‘bridge to transplant’ (BTT). In other cases, the VAD is a ‘bridge to recovery’ by improving myocardial functioning so that a donor heart is no longer needed (Drakos et al., 2007). This study focuses on the Left Ventricular Assist Device (LVAD); a long-term, durable VAD. The LVAD pump, which sits next to the heart, is connected to an external controller by a fine cable called a driveline, which exits through the skin of the abdomen. The controller connects to two external rechargeable battery packs which are carried on the person (Prinzing et al., 2016) (see Figure 1). The external LVAD components are bulky and heavy and are typically carried in a bag or harness worn over the

shoulders (British Heart Foundation, n.d). Individuals with an LVAD are usually discharged from hospital and some even return to work (Prinzing et al., 2016).

Six hospitals in the UK offer adult LVAD implantation: 842 long-term VADs were implanted in the 10-year period April 1, 2008 to March 31, 2018 (NHS Blood and Transplant [NHSBT], 2019). Support from an LVAD can lead to improvements in an individual's functional capacity, daily physical activity levels, and perceived quality of life (QoL) (Grady et al., 2004; Jakovljevic et al., 2014; Kugler et al., 2011; Rogers et al., 2010).

As the number of people using an LVAD increases, research on the impact of LVAD-use on psychosocial wellbeing has emerged. People with long-term physical health difficulties are two to three times more likely to experience mental health difficulties than the general population (Naylor et al., 2012). It is estimated that 12-18 percent of NHS expenditure on long-term physical illness is related to difficulties with mental health, in part because such difficulties may exacerbate physical illness (Naylor et al., 2012). For example, mortality rates after coronary bypass surgery are significantly increased for people experiencing depression (Blumenthal et al., 2003). In order to provide better, integrated psychological support for individuals with long-term physical illnesses, it is imperative to understand the types of difficulties that they face (Naylor et al., 2016).

2 | BACKGROUND

Research suggests that QoL and psychological functioning may be poorer in individuals using an LVAD, compared with individuals whose LVAD has been explanted due to heart transplantation or myocardial recovery (Wray, Hallas, & Banner, 2007). Despite perceived improvements in QoL early after LVAD implantation, emotional distress remains high (Modica et al., 2014). Much of the current literature on the impact of the LVAD on psychosocial wellbeing focuses broadly on QoL and 'adjustment' or 'coping' post-

implantation (e.g. Casida, Marcuccilli, Peters, & Wright, 2011; Chapman, Parameshwar, Jenkins, Large, & Tsui, 2007; Hallas, Banner, & Wray, 2009).

A qualitative metasynthesis of coping and adaptation identified that LVAD patients undertake a variety of tasks in physical, psychological and social domains, across four distinct stages of adaptation: pre-LVAD, implant hospitalization, early home adaptation and late home adaptation (Abshire, Prichard, Cajita, DiGiacomo & Dennison-Himmelfarb, 2016). The metasynthesis concluded that interventions focused on body image recovery might be beneficial and reduce poor psychological outcomes for those living with an LVAD. In line with this, a qualitative conceptualisation of QoL for LVAD-users found that attainment of a positive self-image formed part of the social QoL domain (Sandau, Hogle, Weaver, Boisjolie, & Feldman, 2014). Yet, despite the findings of these studies, there remains a paucity of knowledge around the specific impact of LVAD use on body image.

Cash (2004) explains that “body image refers to the multifaceted psychological experience of embodiment, especially but not exclusively one’s physical appearance... It encompasses one’s body-related self-perceptions and self-attitudes, including thoughts, beliefs, feelings, and behaviors” (p.1-2). Physical health difficulties and their treatment may cause substantial changes to the appearance and functioning of an individual’s body, positively or negatively altering their body image, psychological wellbeing and quality of life as a result (Cash, 2004).

Poor body image has been identified as a factor contributing to psychological distress for people experiencing a range of physical health difficulties (e.g. Friedman, Reichmann, Costanzo & Musante, 2002; Khalid, Malik, Musharraf, 2018; Przedziecki et al., 2013). Visible differences, such as scarring, can have a negative impact on body image, self-concept and adjustment, leading to social anxiety, isolation and low mood (Bessell & Moss, 2007). When bodily impairment negatively affects an individual’s psychological experiences, it can

take time for gradual adjustment and acceptance of their different body (Taleporos & McCabe, 2002). It is important to understand perceptions of body image for those experiencing physical illnesses, so that the potentially harmful impact of changes to body image on psychological wellbeing might be prevented/addressed.

Research of other health conditions where external medical equipment is a necessary part of treatment may inform understanding of the possible impact of the LVAD on body image. Manderson (2005) found that the use of a stoma bag compromised individuals' body image and self-esteem as they struggled to re-establish a sense of identity separate from their impaired body. At times, individuals are prevented from presenting a preferred "normal" self and they engage in strategies to conceal their medical device (Gately, Rogers, Kirk, & McNally, 2008). A qualitative metasynthesis found that the use of a medical device made illness more tangible and visible to others; this, along with potential for stigma, shame, and loss of dignity, impacted on body image and identity (Gately et al., 2008). As the LVAD equipment includes substantial external components, one might hypothesise a similarly significant, potentially negative impact on body image.

Factors relating to the changed body and external LVAD components which may cause difficulties adjusting to life post-implantation, e.g. scarring, difficulty showering, buying clothing, are briefly but frequently mentioned in the literature (e.g. Casida et al., 2011, Chapman et al., 2007). In a study of self-concept, of which body image is a component of, individuals perceived that their appearance was shocking to others and changed the way they dressed to hide the external components of the device and appear "normal" (Marcuccilli, Casida & Peters, 2013). A single case study aimed to address the lack of knowledge around clothing issues relating to body image for people with LVADs. It found that appropriate choice of clothing was necessary to preserve function of the device and the individual's satisfaction with her body image (Marcuccilli & Casida, 2012). Another case study reported

that an LVAD-user experienced considerable psychological distress due to incidents during which strangers incorrectly perceived the external components of his LVAD as an explosive device, and he a security threat (Sharp, Miller, & Al-Attar, 2018).

Retrospective reflections on the psychosocial challenges of an LVAD by those who went on to receive a heart transplant suggest that the device dramatically changed their body and sense of self (Chapman et al., 2007); for some the incorporation of the LVAD into their body image occurred without much difficulty, for others restriction to their everyday functioning and perceived physical and psychological scars from the experience of LVAD implantation led to difficulties adapting. Marcuccilli & Casida (2012) suggest that perception of body image is a key factor in the success of adapting to an LVAD. However, experiences of body image in those currently using an LVAD are yet to be explored and understood in any detail.

3 | AIMS

The current study addresses the gap in the literature by exploring individuals' perceptions of their body and appearance and their perspectives on physical changes to their body and the need to wear the external components of the device. The main research question was: how do adults implanted with an LVAD make sense of their body image?

4 | METHOD

4.1 | Design

This qualitative study used an interpretative phenomenological analysis (IPA) approach to data collection, analysis and interpretation. The aim of this approach is to “explore in detail individual personal and lived experience and to examine how participants are making sense of their personal and social world” (Smith & Eatough, 2007, p.51). The meanings that experiences hold for individuals are the focus of IPA; this approach has demonstrated suitability to the fields of health and clinical psychology research where there is interest in

understanding how people make sense of significant life events (Smith, 2004; Smith, 2011; Smith & Eatough, 2007).

Three theoretical positions underpin IPA; phenomenology, hermeneutics, and idiography. The phenomenological nature of IPA allows lived experience to be expressed through the analysis, rather than relying on pre-defined categories. Hermeneutics allow for the interpretative role of the researcher to be recognised during the analysis process. The idiographic approach encourages the researcher to recognise and focus on the individual contexts and perspectives of each participant, as well as the generalised understanding of the sample (Smith, Flowers, & Larkin, 2009). The interview schedule (Appendix 4-A) remained fairly open, in line with IPA principles and due to the paucity of published studies which have involved interviewing LVAD patients in depth. This allowed participants to discuss their own personal, important experiences related to their body image as a result of LVAD implantation.

4.2 | Participants

A purposive sampling method was used to ensure homogeneity of participants, in accordance with the theoretical orientation of IPA. A small sample size was aimed for to ensure a rich phenomenological analysis with a detailed, interpretative account of the perceptions and understandings of each participant (Smith et al., 2009).

Inclusion criteria were that participants were: (a) aged 18 years or over, (b) currently using an LVAD and implanted at least 6 months ago, (c) an outpatient, (d) had capacity to consent. Potential participants were excluded if they did not speak English or if they had their LVAD for less than 6 months. Research demonstrates that some patients experience weight gain approximately 3 months post-implantation (e.g. Thomas, Hanson, Woscyna, & Lowes, 2016). Interviewing people at least 6 months post-implantation meant that weight changes were captured and participants had experienced living with their LVAD for some time. A

larger proportion of UK patients receiving an LVAD are male (e.g. Parameshwar et al., 2019), this was reflected in the final sample.

Nine participants (6 males, 3 females) were recruited to the study. Participants ranged in age from 40-66 years, with an average age of 52 years. All participants were using a Heartmate 3™ LVAD; the length of time since LVAD implantation ranged from 6 months to 3 years 6 months, the average time was 2 years. All participants were White British; in 2014, Clarke and colleagues reported 91% of UK LVAD-users were White. Individual participant characteristics are not reported due to concerns regarding possible identification of participants as the number of UK LVAD patients is small.

4.3 | Recruitment

Recruitment took place at two of the six specialist NHS heart and lung transplant sites which are responsible for LVAD implantation and care in the UK. Clinical psychologists and nurses in the LVAD teams were provided with staff information sheets detailing the study (Appendix 4-B). These staff distributed participant information packs (Appendix 4-D) to potential participants while they attended for outpatient appointments. Posters advertising the study were also displayed in outpatient waiting areas (Appendix 4-C). One month into the recruitment window the study was also advertised on a private Facebook page for UK-based LVAD-users; the group administrator shared a research poster (Appendix 4-G) which directed interested potential participants to contact the researcher for further information. The final sample included one participant recruited from Facebook.

All potential participants were invited to share their contact details via an expression of interest form in the information pack or to contact the researcher directly if they were interested in taking part. Subsequently, the researcher contacted individuals who had expressed an interest to answer any questions they had and establish whether they still wanted to participate. Interviews were arranged at a convenient time for each participant and took

place either in the participant's home (n=4), their transplant hospital (n=4), or over the telephone (n=1). Telephone interviews were offered due to the large geographical footprint being recruited from.

4.4 | Data collection

Semi-structured interviews were used to gain insight into experiences of body image for LVAD-users. This method permitted the researcher flexibility in exploring areas of interest as well as following the participants' interests or concerns, rather than adhering to pre-determined topics. The interview schedule (Appendix 4-A) was created according to IPA guidance that questions should be based around the broad range of topics being explored (e.g. Smith et al., 2009). The schedule, including topic prompts, was informed by suggestions from members of an LVAD participation group. For example, they suggested it was important to ask about others' perceptions of the body and the impact on relationships.

Prior to the commencement of the interview, participants were required to complete a consent form (Appendix 4-E). Confidentiality, the right to decline any questions and the right to withdraw data were also explained before the interview began. All interviews were audio-recorded; they ranged in length from 36 minutes to 1 hour 32 minutes, with an average length of 1 hour 3 minutes. During one of the interviews a technical malfunction meant that 25 minutes of the interview was not recorded. Detailed field notes were used to capture the missing data. The first interview was transcribed by the researcher and reviewed by an academic supervisor for guidance on the interview style and to ensure the questions were appropriate to the research question. Following the interview, participants were given a debrief sheet (Appendix 4-F). All participants chose their own pseudonyms to maintain confidentiality.

4.5 | Data analysis

Data analysis followed IPA's systematic and reflective approach of working through five stages of learning; noticing, making sense, meaning making, working with meaning, and transformative learning (Smith & Eatough, 2007). First, an interview was transcribed by the researcher and read several times to gain a thorough and full understanding of the data. Next, the researcher engaged in initial, exploratory commenting of the transcript; descriptive, linguistic, and conceptual comments were made related to the research question. From the exploratory comments, emergent themes were identified using statements which reflected both the participant's thoughts and words but also the researcher's interpretation (Smith et al., 2009) (see Appendix 2-A for a short section of coded transcript). Then, the researcher looked for connections across emergent themes to establish a set of super-ordinate themes for that participant (see Appendix 2-B for example development of a superordinate theme); emergent themes were noted and organised in an excel spreadsheet. This process was repeated for each of the participants' accounts. Finally, the researcher looked across the cases for patterns of higher order concepts and participant idiosyncrasies, which determined the final master themes (see Appendix 2-C for example development of a final theme).

4.6 | Reflexivity and credibility of analysis

IPA is underpinned by an epistemological understanding that the researcher brings their own beliefs, values and assumptions, which may impact their perception of participants' data. IPA necessitates that the researcher's assumptions and pre-conceptions are recognised and bracketed off in order that they are prevented from influencing the research process (Smith et al., 2009). The researcher kept a reflective journal to document her thoughts and experiences throughout the research. For example, prior to interviewing, the researcher expected that having an LVAD would influence participants' perceptions of their body as 'human', which was not the case for most participants. Identifying and bracketing such

preconceptions ensured that they did not influence the analysis disproportionately and ensured the focus on individual participant's interpretations.

The research team included two academic supervisors who were experienced in IPA. They reviewed the analysis across all five stages to ensure adherence to the theoretical principles of IPA. Furthermore, they could highlight if the researcher's assumptions were influencing the analysis. The merging of final themes was discussed in detail.

4.7 | Ethics

Ethical approval was granted following review by the Health Research Authority. Approval was also obtained from the two NHS Research and Development (R&D) offices relevant to the sites where the project was conducted. See 'Section Four: Ethics' for the letter of approval and other documents demonstrating ethical adherence for this study.

5 | RESULTS

Three themes were identified from the exploration of participants' experience of body image. The themes were: (1) Making Sense of the Changed Body: "When I came to everything was different", (2) Constant Awareness and Restriction: "There is no sort of mental escape from it or physical escape because it's there", and (3) "Get on and Live". Although distinct, the themes are interlinked as participants experienced changing perceptions of body image, not as a clearly linear journey, but as an ongoing process of re-adjustment and assimilation. See appendix 2-D for additional supporting quotes for each theme.

5.1 | Making sense of the changed body: "When I came to everything was different" (Bertie).

Participants described that their body image was informed by an ongoing process of appraising the function and appearance of the body. Individual, internal perceptions of bodily change alongside social aspects of body perception influenced participants' body image.

These sources of information led participants to see both their body and self as "different".

Participants reflected on the illness journey that led them to be implanted with an LVAD; some experienced years of declining cardiac function and illness whilst others had unexpected cardiac events which occurred whilst they perceived themselves as healthy. Despite these differences, all participants described that their LVAD was implanted urgently following a sudden awareness that they were close to death. Three participants talked about their focus on survival as a barrier to contemplating the impact of the device on their body image pre-implantation:

I wasn't even thinking about image I hadn't even thought that through at that point, it wasn't until you woke up with a bag permanently attached to you that you're like "oh shit, I've now got to live with this" (Daniel)

Other participants reflected that they were physically and psychologically disconnected from the reality of the LVAD's impact on their body whilst they were in hospital. They felt overwhelmed by the sudden realisation of their changed body once they returned home and responsibility for their health and LVAD was passed to them.

All participants reported that their body image was disrupted by their LVAD, they perceived their body as different/abnormal in terms of appearance and physical functioning. In part, participants noticed difference by drawing comparisons with their own body prior to LVAD-implantation; "I'm pretty confident that I looked OK before all of this, now I'm not so sure. So yeah, my confidence has been dented." (Dave). Participants also drew comparisons between themselves and others: "before I was just like everybody else, but now I'm not, but I wanna look like everybody else, but I'm never gonna look like anybody else while I've got this" (Chloe). Perceived differences in appearance were mainly caused by the external components of the LVAD, scarring and changes to weight/shape.

Social interactions reinforced participants' perceptions of their body and self as different/unique as others had an absence of knowledge about the LVAD: "...[people]

haven't got an idea what an LVAD is...you're constantly explaining yourself...not just to people in your street, to your friends, you're explaining yourself to other medical professionals" (Stephen). When others saw the LVAD they asked numerous personal questions. Participants perceived others as fascinated, astonished and even scared or sickened by their body. For some participants this questioning was objectifying, exposing and detrimental to their body and self-image. In contrast, Stephen and Garcia occasionally enjoyed interest in their body as it provided the opportunity to educate others and created feelings of pride:

...the novelty value is high and sometimes yes, I will if you like exploit that "Bet you haven't seen one of these before? or this is what they do..." you set the alarms off...you might as well make something of it because there isn't a lot else that's in your favour (Garcia).

All participants described significant emotional distress related to appearance and physical functioning in the early stages of recovery at home:

I was unconfident about what I looked like when I came out because I thought "what the hell am I going to wear? what do I wear now with this?" and I thought "I don't like what I look like, I don't like my body" (Anabelle).

For most this distress reduced with time but for some distress persisted. For example, Chloe described herself as "fat and ugly", continued weight-gain post-LVAD implantation perpetuated her negative body image.

A few participants described that aspects of their body image were experienced positively following the initial, difficult disruption. For participants who had long periods of illness pre-implantation, the opportunity for better physical functioning led them to see their body as increasingly fitter and healthier over time: "my body is in better physical shape now than it's been for at least 10 years, my legs have regained their strength, their muscle...I can

do things that I couldn't contemplate doing, actually even 6 months ago" (Garcia). Five participants explained that significant weight loss led to improvements in physical functioning and appearance post-implantation. However, Bertie and Daniel described that the external LVAD equipment made it harder to incorporate their weight loss into their body image:

I've lost 27 kilos, so I'm a lot trimmer than I used to be. So, it's kind of odd, people go "you look really good and thin" and I'm like thinking "actually I don't feel thin" because I've got these huge [batteries] on my side (Daniel).

Occasionally, participants' body image was positively informed by social interaction. Many described that their friends and family appeared not to notice their visible differences. Some complimented participants' appearance but most were amazed at participants' survival of life-threatening illness and instead commented on bodily strength and psychological resilience. Family members' acceptance of the changes to their body helped some participants believe that they were perceived as "normal". Tommy described that his family made jokes about his body which supported his own self-perception of no longer being ill: "I say 'it's only my dressing for my exit wound' 'exit wound?' they said, 'you've had a bit of an operation [Tommy] you've not been shot'."

5.2 | Constant awareness and restriction: "There is no sort of mental escape from it or physical escape because it's there" (Chloe).

Participants described ongoing physical restrictions and constant awareness of the changed body caused by their dependence on their device. They experienced distress related to the LVAD's physical presence on or next to their body and described feeling attached, stuck and tethered. These feelings were heightened in the early stages of adjustment, particularly when their LVAD was plugged into the mains electric at night: "mentally it's really hard to get

your head around that you're plugged into this machine at night and you can't, you just can't escape that quickly if there was somebody coming in the house or a fire" (Chloe).

Participants were always consciously or subconsciously aware of the LVAD and their body, particularly those who used a shoulder bag to carry their device. The bag was heavy, it had to be remembered and considered with every bodily movement:

...you can't put that bag down. If you sit on a chair, you have to pull a chair next to you to put it on. If you're eating dinner in a restaurant, you only get one chair, what do you do with your bag? It's on your shoulder...you're constantly afraid of the bag dropping (Stephen).

Participants described that their heightened bodily awareness created anxiety, fear and thoughts of mortality. They were hypervigilant to their surroundings and experienced catastrophic thoughts of danger related to theoretical or anecdotal adverse events. Participants took steps to protect their body from imagined and realistic threats including holding their bag and avoiding crowds: "when I'm walking past people in the street I tend to hold onto that [driveline] and walk near the wall, so nobody can walk past that side of me, just in case." (Tommy)

Some participants described frequent thoughts about how others perceived them based on their appearance, which led them to feel self-conscious and fearful: "I don't want to look like a goon like I say or any kind of freak or anything" (Dave). A few participants who used an LVAD vest, which holds the external equipment in pockets close to the torso, believed that the vest made them look "like a suicide bomber" (Daniel). They feared that, if visible, it might lead someone to perceive them as dangerous. All participants described a preference for clothing that concealed their device and gave them a more "normal" appearance, consistent with their previous body image. However, this created its own anxieties about others' perceptions. Participants told stories of being challenged or criticised by others who

weren't aware of their invisible disability: "I am conscious that it does work the other way, that almost looking too well or being too able can have, well, other people make assumptions about you all the time" (Garcia).

Participants described an ongoing journey of physical improvement and adjustment to bodily restriction. Routines and rules were important to keep the body and LVAD working effectively but led some participants to reflect that their life revolved around their device. The LVAD's presence forced them to make adaptations during many activities of daily living such as washing, dressing, toileting and eating. These activities took longer to achieve and required thinking about:

I can wash the bottom half of me in the shower which makes life a bit easier and then I just wash the top half over the sink really and then dry myself off and wash my hair over the bath...so it takes me like 3 times as long (Lucy).

Keeping the LVAD equipment dry was a concern to all participants, some described becoming "obsessed" with protecting their driveline site from moisture which could cause infection. Many reported a heightened awareness of unpredictable weather as they perceived rain as life-threatening and their body as vulnerable. Participants were restricted from activities that they had previously enjoyed, such as swimming, theme park rides, cycling, shopping: "Obviously I will never get into the bath until it's removed. I won't go swimming again, I used to love going swimming." (Bertie). Two participants described that the LVAD pump limited their physical exertion as it could not respond like a heart by working harder when needed. Awareness of the limitations of the changed body increased at certain times, for example when planning holidays.

Participants reflected that the LVAD also created clothing restrictions, particularly difficulties balancing practicality and image. Many described having a limited selection of casual, loose-fitting clothes that they now felt comfortable wearing. Formal occasions were

particularly challenging to presenting a preferred “normal” appearance due to the LVAD’s external components. Male participants talked of difficulties wearing suits and shirts: “A couple of times I turned down events, I’ve been invited to certain events where a suit had to be worn. I did one but a suit with a bag didn’t feel comfortable, didn’t feel right” (Stephen). Female participants highlighted difficulties wearing dresses and high waisted trousers/skirts. For all participants, clothing restrictions were more distressing early after implantation: “I went shopping and I thought ‘I like that dress’ and then I just burst out crying in the shop because I thought ‘I can’t have that dress, I can’t wear dresses anymore and I love dresses’” (Chloe).

Overall, restrictions meant that participants felt they had limited control over their body. This feeling was perpetuated by their views of the LVAD team as experts of their changed body and LVAD. Participants described striving to precisely follow the team’s rules, they asked permission to do activities and were “told off” at times: “I’ve asked if I can go race cars and they said no” (Stephen). Some described a fear of being perceived as ungrateful if they shared their body image concerns. Many experienced conflicting feelings of gratitude and resentment towards their body and LVAD; “you’re glad you’ve got the machine but then you also don’t want it” (Chloe).

5.3 | “Get on and live” (Garcia).

Participants described a process of adjustment in which they developed strategies to reduce the impact of their LVAD on their body image and in turn on their wellbeing. Although day-to-day adaptations felt forced onto participants by their LVAD, they perceived that some bodily restriction and awareness was essential for survival. They reflected on their committed action to re-gaining a “normal” body image which included improved physical functioning and appearance. Flexibility, creativity and problem-solving helped participants to achieve a greater sense of “normal”:

I'm trying to find clothes and things to wear that at the end of the day make me look as normal as I possibly can, and I would compromise with things that look OK...I don't expect to look the best of the best you know I've had a lifesaving operation (Dave).

Participants were supported with problem-solving by family, friends and medical professionals. They also sought solutions from LVAD peers online or at networking events.

Some participants described that the bag and harness provided by LVAD manufacturers to carry the LVAD equipment were not fit for purpose and had a detrimental effect on appearance and physical functioning e.g. posture. Participants trialled alternative garments to carry their LVAD including different bags and tactical/fishing jackets. Two participants developed a t-shirt/"vest" which had pockets to hold the batteries and controller close to the body: "I thought right I can solve this problem, I can make my life better, so I made the vest...I remember dancing round the kitchen, and I thought 'this is a game changer'" (Stephen). The positive psychological impact of finding a better way to carry the LVAD was evident for many participants. For some, the LVAD vest alleviated the barriers to physical improvement caused by the bag and reduced their need to think about the device.

With time, participants found ways to feel more in control of their body, appearance and even mortality. Some achieved this through reaching fitness/weight goals suggested by their LVAD team: "The fitter you are, the more chance you've got to survive and it's simple isn't it, it's simple maths" (Stephen). Others talked about "not letting the LVAD control me" (Daniel) and finding alternative ways to do the things they enjoyed. Some participants found a sense of freedom by occasionally breaking/stretching the rules imposed on them as they perceived bodily risk-taking as "normal":

“You mustn’t go up ladders”, well I do go up ladders and I do cut hedges and I do wield power tools and things...it’s got to be about fun as well, you’ve got to feel good...it’s not just about doing everything right by the book in life” (Garcia).

The female participants reflected that finding solutions to the clothing difficulties which had created distress about their appearance led to a similar liberation and reduced awareness of their device. Lucy described that finding a different style of shoulder bag to hold her equipment meant she could get rid of the “ugly hospital bag”:

I’m one of these people who like wears matching socks and everything’s gotta be matching type thing...So I’ve got like a pink one, a beige one y’know for like different occasions really, and I’ve got a blue and yellow spotty one.

Chloe described that her friend helped her to wear dresses again by altering them so that her equipment could be passed through a side-seam/pocket. Similarly, Anabelle wore black leggings, so she was less conscious of the LVAD wires picking up the hem of dresses. By achieving flexibility in their clothing choices participants felt more like themselves.

Alongside making physical adaptations, participants used psychological strategies to reduce the impact of body image concerns. One group of participants demonstrated mentally distancing or disconnecting from the reality of the impact of the LVAD on their body. They avoided anxious thoughts relating to their perception of appearance, bodily safety and strangers’ stares: “there’s something in your mind saying you should be worried about that, that’s keeping you alive that and you should, but I don’t and don’t know why I don’t” (Tommy). They used strategies such as making jokes, avoiding discussing their LVAD, or using externalising language: “I call it ‘the machine’...I deliberately mentally distance myself from it...don’t give it any kind of meaning but it has value to me if that makes sense” (Daniel). Some used fantasy to temporarily escape from their body image concerns; Anabelle held on to hope of transplant and fantasised about her body without the LVAD:

At first, I used to think “oh look at my stomach, I’ve had this done” I used to think that but now I don’t...I think “well when I get this heart this won’t be here, I won’t have this” and then I’ll let it go.

Many participants described that over time they accepted their changed body and the necessity to do things differently and normalised difference: “everybody’s a bit strange but they’re all strange in different ways aren’t they” (Tommy). They accepted their physical limitations and visible differences by reminding themselves of the life-saving purpose of the LVAD. Numerous participants cited positivity or a “get on with it” attitude which helped them to reduce the impact of body image concerns on their QoL:

I try not to let it become all-consuming and I try not to let that dictate my life because I suppose, overall, I work on the basis that the life that you have has got to be worth living in whatever way you define that, otherwise what’s the point of just extending your life? (Garcia)

6 | DISCUSSION

The current study aimed to offer an initial exploration of the experiences of body image for adult LVAD-users. Through IPA, three main themes were generated from the data. The findings illustrated that body image is disrupted by the LVAD, in line with previous research that external medical devices undermine body image and confuse individuals’ perceptions of their body as “normal” (Gately et al., 2008; Manderson, 2005). Chapman and colleagues (2007) found that LVAD-users experienced shock by the sudden implantation of the LVAD and family members had little time to prepare for the sight of their loved-one’s changed body. This study indicated that LVAD-users themselves are unable to psychologically prepare for the reality of the impact of the LVAD on their body image due to a focus on survival.

In this study, participants’ concerns about their changed body reflected a recognition of the body and self as different; both as a distinct human being, and as different from one’s

previous self and others. Participants made sense of their bodily changes by looking inwards and by considering the perceptions of others. This is consistent with Cash's (1990) theory that physical appearance comprises of perspectives of self-image, or "the inside view", and social image, namely the knowledge that human beings make assumptions and hold attitudes about a person based on physical appearance. For example, in the current study, participants who had perceived themselves as overweight prior to LVAD implantation experienced weight loss positively; these changes may benefit the body image of LVAD patients as they reduce the risk of appearance stereotyping and stigma associated with obesity (Cash, 1990; Puhl & Heuer, 2012).

The current findings are consistent with those of Marcuccilli and colleagues (2013) that LVAD-users have a heightened awareness of the public eye and aim to conceal their device to be perceived as "normal" and avoid scrutiny. Marcuccilli and colleagues (2013) described that LVAD-users unanimously accepted the curious nature of others and continued to flourish in social relationships. This study offered novel findings that some individuals experienced this scrutiny as intrusive and distressing, it led them to avoid social interaction at times and was damaging to their body image.

In the current study, participants aimed to conceal their device to be perceived as "normal", believing that if strangers saw it they might be perceived as "different", "stupid", a "freak". However, concealment created concerns related to the stigma of invisible disability. Individuals with chronic conditions which are invisible or can be hidden have a difficult decision regarding disclosure of their condition to others; non-disclosure may mean individuals pass as normal and avoid disability-related stigma, but this causes stress as they risk being "caught in a lie" and discredited (Joachim & Acorn, 2001). In this study, participants who were told by family and friends that they looked "better" or "healthy" incorporated this into their perceptions of their appearance as "normal". Two participants

chose to disclose their device at times when it had social value; this may be considered a form of preventative disclosure, which assists with managing stigma if individuals believe they can influence the social judgement of others and prevent negative perceptions of themselves (Joachim & Acorn, 2001).

Participants perceived their body to be limited by restrictions imposed on them by the LVAD, which led to modifications in their day-to-day activities. Themes of physical restriction and dependence on the LVAD have been highlighted in previous research (Chapman et al., 2007; Sandau et al., 2014; van Manen, 2017). Sandau and colleagues (2014) suggested that the LVAD's presence leads to a changed balance, which requires continual awareness of needing to move slowly. The current study expanded further on LVAD-users' experience of constant awareness of the body and their device and suggested a link with perceived vulnerability. Findings indicated that constant awareness of the LVAD may be underpinned by feelings of anxiety and thoughts of possible danger and bodily harm.

Helman (1995) described that treatment of chronic illnesses which involve major body changes such as the creation of new orifices and appendages, of which the LVAD does both, invert the normal relation of "inner" to "outer", "public" to "private". Regarding the current study, participants may perceive the LVAD as representative of a body part that is usually invisible and not thought about (the heart). As a functioning heart is required for human life, the presence of the LVAD as representative of the heart crossing the internal-external bodily boundary is indicated by participants' consciousness of being dependant or "tethered" to the device. Awareness of dependence increased participants' perceived threat to life and a need to protect the device, which was distressing. Participants employed a pragmatic approach to managing this distress by reminding themselves the alternative was death. For some, using a vest to carry the device closer to their body seemed to mitigate concerns and perceived vulnerability. Anticipatory fears associated with death have been

identified in heart failure patients (Selman et al., 2007), the findings of this study suggest that receiving this life-saving device does not remove such fears.

In this study, participants experienced distress related to the impact of physical restriction and the LVAD's presence on perceived control of their body. Participants felt that their body was, in part, controlled by the technological elements of the LVAD and by the LVAD team who imposed rules on them. Hallas and colleagues (2009) identified that perceived control was the core category in the cognitive construction of QoL for VAD patients; perceived control was a dynamic cognition that fluctuated according to patient circumstances. Like Hallas and colleagues (2009), this study found that seeking and maintaining control were important to LVAD patients and were achieved by engaging in activities. The findings of this study also indicated that participants achieved greater satisfaction with the functional and aesthetic dimensions of body image through finding solutions to difficulties with clothing and the garments which carried their device, which increased their perception of control. Cash (1990) explains that clothing is "a universal tool of aesthetic self-management" (p.70) used to construct physical self-representations for audiences of others. This offers support to the findings of the case study by Marcuccilli and Casida (2012) which suggested that the LVAD, in relation to the body, becomes a major focus of dressed appearance and that, by taking steps to accommodate and conceal the device, individuals improve their perception of body image.

In their metasynthesis of adaptation and coping, Abshire and colleagues (2016) reported emotional coping mechanisms which supported LVAD-users through difficult times including keeping a positive attitude, having a sense of humour, and religious involvement/prayer. In the current study, positivity and humour were also perceived as important to cope with body image disruption. However, no participants described religious involvement. Like the current study, Abshire and colleagues (2016) found that some

participants intentionally tested the limits of the device and ignored professional advice regarding activities that should be avoided. They posited that this was due to difficulties accepting the restrictions imposed by the LVAD. The current findings offer an alternative explanation for risk-taking behaviours, related to body image, that choosing to risk-take is perceived to signify a “normal” body and self and helps LVAD-users feel greater control.

Findings from this study suggested that increased familiarity with and perceived control over the body, LVAD and appearance lessened LVAD-users’ awareness of their body and LVAD, facilitating adaptation and self-acceptance. Numerous models of coping with illness (e.g., Morse & Johnson, 1991) highlight acceptance of illness and its consequences as a form of adaptive emotion-focused coping important to restoration of wellbeing (Bostock, Sheikh, & Barton, 2009). Optimism has also been documented as being central to recovery and adjustment in health settings, with some research suggesting that it is associated with reduced risk of heart failure (Kim, Smith & Kubzansky, 2014). In the current study some participants described “being positive” as a strategy which promoted adaptation and overcoming body image concerns. Research of post-traumatic growth suggests dispositional optimism, having a favourable outlook on the world, as a specific personality characteristic that is adaptive for those with physical health conditions (Bostock et al., 2009). This research offers initial findings that such a characteristic could positively impact an LVAD-users adjustment to their disrupted body image.

6.1 | Limitations and future research

Despite attempts to recruit participants via two UK LVAD centres and a UK-wide Facebook group, the final sample were from a relatively limited geographical area. This study is exploratory in nature and bound by the LVAD population studied. Similar investigations recruiting LVAD-users across a greater number of LVAD sites would be beneficial to further develop theoretical understandings of body image for LVAD-users.

A main limitation of this research is that the researchers were unable to report individual demographic information due to concerns about ensuring anonymity. It is recognised that information concerning the demographic variation across participants would have been useful to fully contextualise the research findings. As this study provided an initial exploration of body image experiences, the sample was necessarily heterogenous in terms of differences in age, gender, time since implantation, illness history and medical interventions. Therefore, the differences between participants may have impacted on experiences. A more defined sampling pool might be beneficial for future qualitative research.

Further, considering individual differences, this research provided initial evidence that LVAD-users' experience of body image is a dynamic one and adjustment does not follow a clearly linear trajectory with time since implantation. Future quantitative research could examine whether other individual factors might also impact the experience of body image for LVAD patients. For example, self-esteem, self-efficacy and self-compassion have been found to mediate the relationship between body image and emotional wellbeing in breast cancer patients (Pintado, 2017; Przedziecki et al., 2013). The findings of the current study also indicated that LVAD-users might experience disruption to their embodied self, particularly early after implantation. Future qualitative research could further examine LVAD-users' experiences of embodiment.

7 | CONCLUSIONS

The current study explored how nine adults perceived their body image following LVAD-implantation. The findings indicated that the LVAD caused disruption to body image and led individuals to see their body and selves as "different". Physical restriction and constant awareness of the body and LVAD were difficult for LVAD-users to tolerate. The importance of functional and appearance-related adaptation and acceptance of the changed body was

highlighted. The findings indicated a need for more prolonged physical and psychological support for LVAD-users to adjust to their changed body.

8 | RELEVANCE TO CLINICAL PRACTICE

LVAD-users demonstrate improved physical activity and health-related QoL following implantation, but these are below that of heart transplant recipients and healthy subjects (Jakovljevic et al., 2014; Kugler et al., 2011). This study offered initial indications that increased physical activity may have a positive impact on body image for some adults using an LVAD. Positive relationships between activity and body image are evidenced in other areas of physical illness (Mehnert, et al., 2001; Wetterhahn, Hanson, & Levy, 2002). However, in the current study many participants reported perceived restriction from physical activity. These findings indicate that LVAD-users might benefit from long-term support with physical activity and bodily mastery post-implantation.

Healthcare research indicates that self-efficacy is an important factor in predicting the initiation of physical activity/exercise (Jones, Harris, Waller, & Coggins, 2005; Lee, Arthur, & Avis, 2008). Integrating self-efficacy strategies with exercise interventions has been shown to be beneficial to the initiation and short-term maintenance of exercise for heart-failure patients (Rajati et al., 2014). Research of LVAD patients suggests that higher self-efficacy and adherence to treatment regimens results in greater improvements in QoL following implantation (Casida, Wu, Senkiv, & Yang, 2016). Interventions to improve self-efficacy for LVAD clients could support the initiation and maintenance of physical activity, facilitate an increased confidence and knowledge of their bodily capabilities, and promote adjustment so that individuals feel less restricted. In turn, this may benefit individuals' body image, perceived control, and health outcomes, including suitability for transplant.

This study found that some LVAD-users used avoidant-coping strategies, such as humour, fantasy and “not thinking” to mentally distance/disconnect them from their changed

body and reduce the impact of body image concerns on their lives. Avoidant coping styles are significantly associated with anxiety and depression early after LVAD implantation (Modica et al., 2014) and predict poorer health-related QoL (Bose, Bjorling, Elfstrom, Persson, & Saboonchi, 2015) and mortality (Murberg, Furze, & Bru, 2004) in heart failure patients. Thus, psychological approaches to reduce avoidant-coping and body dissatisfaction should be considered. However, there is scarce evidence for the effectiveness of psychosocial interventions for body image in healthcare. Outside of the healthcare setting, cognitive-behavioural therapy (CBT) has demonstrated effectiveness at improving body image, particularly when behavioural exposure elements are employed (Jarry & Ip, 2005). Behavioural exposure strategies may reduce the avoidant-coping observed in LVAD-users. But, Norman and Moss' (2015) review found very limited support for the use of CBT either individually or combined with social skills training for adults with visible differences and appearance-related distress.

Acceptance and Commitment Therapy (ACT) offers an alternative approach to support LVAD-users who employ avoidant-coping strategies; the ACT model promotes acceptance of emotional distress and behaviour change based on what is meaningful for individuals to live a rich life (Pearson, Heffner, & Follette, 2010). Device acceptance is strongly correlated with QoL and psychological distress for LVAD-users (Tosto et al., 2019). Preliminary evidence shows improvements in emotional wellbeing and acceptance following ACT interventions in physical health settings (Brassington et al., 2016) and for individuals with body dissatisfaction (Pearson, Follette & Hayes, 2012). In line with research of posttraumatic growth, that acceptance is important to restoration of wellbeing for those with chronic illnesses (Bostock, et al., 2009), ACT may support LVAD-users to be accepting of their changed body and promote problem-solving behaviours leading to greater perceived

control. Future LVAD research should address the scarcity of evidence for the effectiveness of psychological interventions to improve body image.

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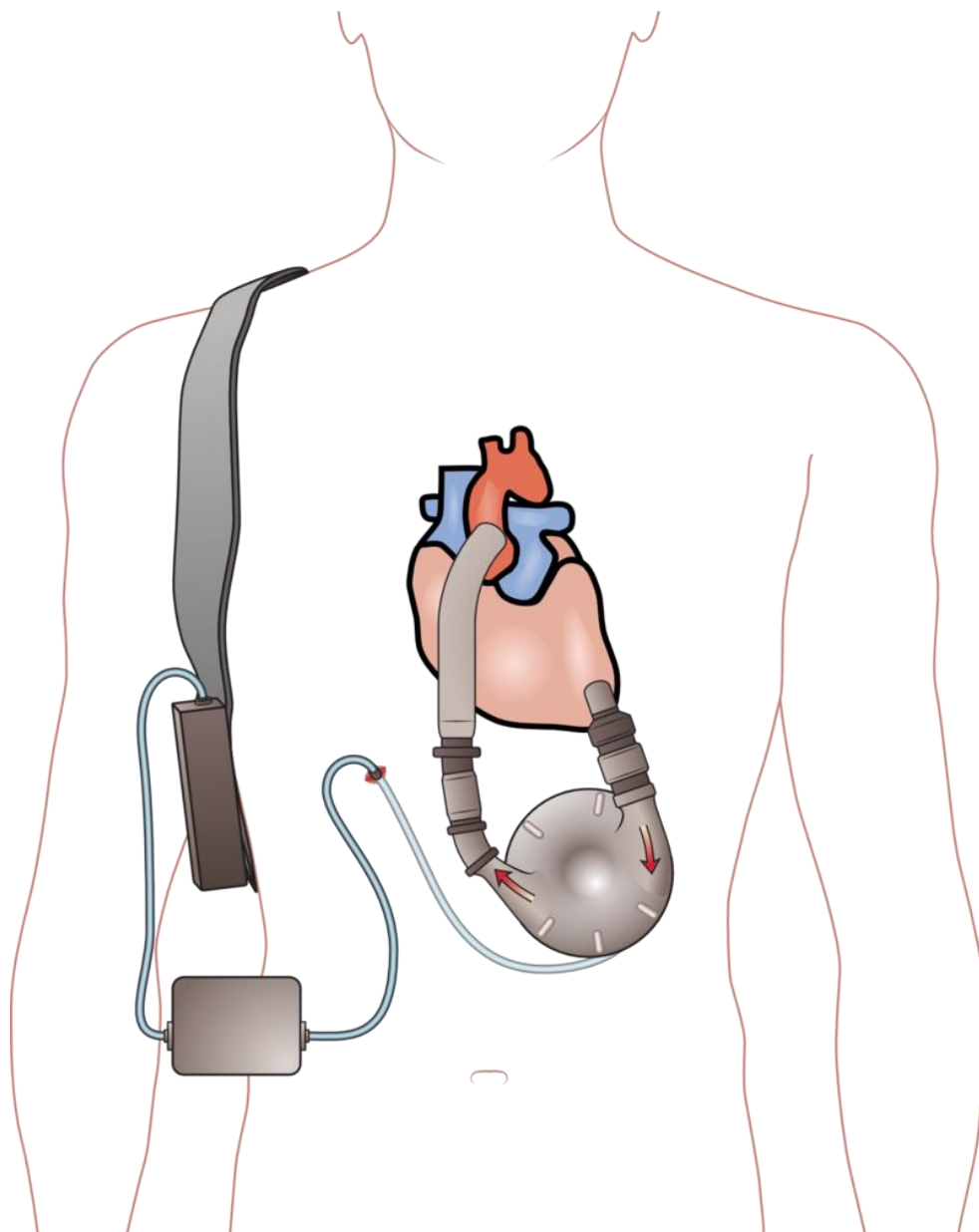


FIGURE 1 Example image of the left ventricular assist device (LVAD)

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/>).

For a more accurate, detailed but copyrighted image of an LVAD please see Zimpfer, D., Netuka, I., Schmitto, J. D., Pya, Y., Garbade, J., Morshuis, M., ... & Sood, P. (2016). Multicentre clinical trial experience with the HeartMate 3 left ventricular assist device: 30-day outcomes. *European Journal of Cardio-Thoracic Surgery*, 50(3), 548-554. <https://doi.org/10.1093/ejcts/ezw169>

APPENDIX 2-A

EXTRACT OF CODED TRANSCRIPT – CHLOE

Emergent themes	Transcript	Exploratory comments
<p>No self-confidence and constant self-doubt.</p> <p>Fantatising. Not normal.</p> <p>Gratitude vs animosity – LVAD means being alive but also being abnormal.</p>	<p><i>R: Do your beliefs or kind of what you think about your appearance affect your day to day life?</i></p> <p>P: Yeah, as I say because I've got no self-confidence, self-doubt myself all the time. I just wish sometimes I could just take that [pointing to the bag] and put it on the floor. I've forgot how it feels to be normal, I've forgotten what it's like not to have it, if that makes sense, and I can understand why some people get excited about the fact of having a transplant so to get rid of it and don't get me wrong, I'm so grateful that they've saved me and I'm still here but it does affect it yeah.</p>	<p>No self-confidence and constant self-doubt</p> <p>Fantatising about the body without the LVAD attached</p> <p>Forgotten how it feels to be normal <u>sees herself as not normal?</u> Forgotten what it's like to not have it <u>intruded by the LVAD being attached? a part of her/ separate from her old bodily identity?</u> Understand others excitement for transplant <u>can't wait to get rid of it?</u> <u>Switch to gratitude to LVAD team – anxiety about being perceived as ungrateful if talk about negative impact of LVAD or wanting it gone?</u> LVAD means being alive but affects day to day life. <u>existential dilemma?</u></p>
<p>The LVAD is intrusive – “it's always there”</p> <p>Managing risks day to day - aware of movement.</p> <p>The body is vulnerable from the environment.</p>	<p><i>R: And do you have any strategies or things that you do differently to overcome that?</i></p> <p>P: Umm, no not really, I just gotta get on with it haven't I. I mean it's there, its not going anywhere, I just, it's like when I'm in the kitchen if I'm doing tea I have to be careful cos this bit could get caught on handles [points to drive line] so I'm gonna have a new kitchen put in with handleless units in because yeah that obviously pulls on my driveline. Um but no, I don't know, I just, there's no point sitting and wallowing in self-pity, it's happened I just gotta deal with it and but it's there, it's always there, even when you sit down to</p>	<p>Gotta get on with it <u>coping strategy?</u> <i>It's not going anywhere – lvad fixed, attached</i></p> <p><u>Implied it's hard to 'get on with it' due to needing to be careful? thinking about the lvad?</u> Driveline could get caught on kitchen handles <u>imagining the risks in day-to-day life? home creates danger?</u> Changing the environment because of changed body. No point sitting and wallowing in self-pity – <u>implied acceptance is more psychologically beneficial?</u></p>

Trying to accept change
and adapt to avoid the
alternative.

have a brew and watch telly, it's there cos you've got
this [points to bag] by the side of you.

R: So the bag is a constant reminder?

Always physically
restricted by LVAD bag.

P: Yeah cos you can take it off, like now [indicating
strap isn't on her shoulders] but if I tried to get up I
couldn't go far anyway because I need to get this [bag].
In fact we laughed yesterday because I unclipped it [bag
strap] and I was talking to my daughter on the bed and
I just put that round me [loose strap, not fully clipped to
bag] like that, and I got up and I went "oh shit" and she
started laughing and I went "I better attach it to the bag
aint I" and yeah we started laughing but yeah.

Movements need to be
thought about.

Laughter as coping.

[40:00]

Always there – always physically and mentally aware of LVAD
implied separate? not integrated to body?
Thinking about being different/normal because the bag is a
reminder?

Momentary release from your shoulder relief from awareness of
physically touching your body? but body is still restricted by
presence of bag and LVAD?
Can't go far without having the machine on your body? limited
physical range from the bag?

The LVAD will remind you it's attached
Bag has to be thought about with every movement?
*Laughing to cope with the intrusion of the bag on body and
realisation of restriction?*

APPENDIX 2-B

EXAMPLE DEVELOPMENT OF A SUPERORDINATE THEME

The below table illustrates the development of one superordinate theme (‘no mental or physical escape’) for one participant (Chloe). This superordinate theme informed the final theme: Constant Awareness and Restriction: “There is no sort of mental escape from it or physical escape because it’s there”, which was illustrated with a quote from Chloe’s interview.

Transcript page marker	Emergent themes	Super-ordinate theme
P2.p15	No mental or physical escape.	No mental or physical escape.
P2.p15	The LVAD is thought about with every movement.	
P2.p27	The LVAD is a part of the body that must always be thought about.	
P2.p31	LVAD as a reminder of illness.	
P2.p35	LVAD as a barrier to intimacy.	
P2.p24	Managing the imagined risks as they come day to day.	Constant awareness: the bag and LVAD need to be thought about.
P2.p15	The bag is a permanent reminder of the LVAD.	
P2.p24	Movements need to be thought about.	
P2.p13	Catastrophic thoughts of theft.	
P2.p26	Looking out for potential damage to the LVAD.	
P2.p10	Bodily restriction leads to catastrophic thoughts of danger.	Always considering potential risks and danger.
P2.p10	Reliant on external power – the body cannot sustain itself.	
P2.p10	Fear of being stuck – death by restriction, lack of control.	
P2.p42	Stories about danger lead to feeling more vulnerable.	
P2.p24	The body is vulnerable from the environment.	
P2.p43	Strangers don’t know how easy it is to kill me.	Thoughts about mortality.
P2.p21	Others don’t know what the LVAD is.	
P2.p39	Mortality concerns continue.	
P2.p44	Awareness of the pump increases thoughts of mortality.	
P2.p10	Feeling unsafe and out of control.	

P2.p44	Lack of knowledge means lack of control.	
P2.p17	Feeling physically better increases appearance concerns.	
P2.p10	A huge mental challenge to accept bodily restriction. Gratitude vs animosity – LVAD means being alive but also being abnormal.	
P2.p24		
P2.p41	Excitement turns to disappointment.	
P2.p11	Emotionally challenging to be tied down by the LVAD at night.	
P2.p42	Psychological struggle occurs when using this body in the real world.	Psychological struggle from feeling restricted, unsafe and out of control.
P2.p21	Having no control/choice with this body.	
P2.p43	Hearing the machine-body connection creates fear and paranoia.	
P2.p24	The LVAD is intrusive – “it’s always there”	
P2.p9	LVAD is a burden to the body.	
P2.p25	The body is burdened by LVAD equipment.	
P2.p18	The LVAD takes away the ease at which you can manage your body.	
P2.p40	This body is better but still restricted.	The LVAD burdens a better body.
P2.p10	Machine and body become integrated due to restriction.	
P2.p24	Always physically restricted by LVAD	
P2.p41	The LVAD poses more restrictions in certain situations.	
P2.p9	The mains cable is in control of where I can go.	
P2.p9	Body is restricted to one area at night.	
P2.p41	Barrier to showering.	The body is restricted: the mind wants what the body cannot have.
P2.p41	Frustration at body limitations.	

APPENDIX 2-C

EXAMPLE DEVELOPMENT OF A FINAL THEME – “GET ON AND LIVE”

Bold text – Participant Superordinate Theme

Italic Text – Participant Emerging Theme

Dave	Chloe	Tommy	Stephen	Bertie	Lucy	Garcia	Daniel	Anabelle
Adjusting to this body is a process	Finding a way forward through improving appearance	Seeing the bright side of the body with an LVAD	Integrating the LVAD into the body and self	Freedom and control from finding solutions and adapting	A journey with the body and self	A journey to regain sense of self through health and physical fitness	Not letting the LVAD control me by finding a way to be me	Thinking differently about body image over time: letting go
<i>Creativity and flexibility</i>	<i>Challenge with clothing: always adapting</i>	<i>LVAD as a necessary evil</i>	<i>Change as an opportunity for choice and control</i>	<i>Acceptance</i>	<i>Flexibility and choice reduce clothing concerns</i>	<i>Ongoing journey of physical improvement:</i>	<i>Finding the best way to carry the equipment is a process</i>	<i>Time and acceptance reduce distress caused by body image concerns</i>
<i>Belief in positive future outcomes</i>	<i>Aiming to be discrete</i>	<i>Accepting difference: everybody's strange</i>	<i>Routine as a sense of control</i>	<i>Joking to cope with the difficult times</i>	<i>Finding the confidence to do things differently</i>	<i>Physical and cognitive liberation caused by the LVAD vest</i>	<i>Aiming for normal by concealing the LVAD</i>	<i>Thinking of the LVAD positive</i>
<i>Acceptance</i>	<i>Making an effort to manage appearance concerns</i>	<i>Positive beliefs about appearance</i>	<i>Self-confidence</i>	<i>Get on with it: positive motivation</i>	<i>Mentally disconnecting to cope</i>	<i>Positive impact of physical fitness improvements: exceeding my own expectations</i>	<i>Flexibility and freedom from finding a new way to do hobbies</i>	<i>Practicing self-care</i>
<i>Vicarious experience: a role for others</i>	<i>Finding a way to wear the LVAD has a positive impact on body esteem</i>	<i>Positive outlook for what this body can do</i>	<i>Accepting adapting</i>	<i>Tolerating the compromised body</i>		<i>A positive experience of body image: pride, strength, acceptance and confidence.</i>	<i>Deliberately distancing from the LVAD's impact on the body</i>	<i>Mentally disconnecting: avoidance, fantasy and hope</i>
<i>Taking risks to take back control</i>	<i>Positive identity change</i>	<i>Emotional detachment and joking as coping</i>	<i>Being active to fight for your life</i>	<i>Finding ways to feel in control of the body</i>		Resilience through positivity	<i>Taking risks and hoping</i>	<i>Finding a way forward through clothing</i>

<i>Striving for a 'normal' body</i>	<i>Regaining control of this body</i>	<i>Making adaptations</i>	<i>Positive outlook</i>	<i>Finding solutions from the LVAD community</i>	<i>Problem-solving to find a way that works</i>
<i>More learning to come</i>	Psychological coping strategies		<i>Positive vicarious experience</i>	<i>Finding a way to wear the LVAD is a process: LVAD vest is best</i>	<i>Learning to love your LVAD</i>
"A shadow on your quality of life": using avoidance to manage constant awareness	<i>Accepting and adapting to this body is a process that gets easier</i>		Life-changing clothing solutions		<i>Life's got to be worth living: seeing positives in a bad situation to have a better relationship with your body</i>
<i>Fantatising of an easier life with the body and LVAD</i>	<i>Fantatising Coping involves mentally disconnecting from the bodily reality of the LVAD</i>		<i>The vest creates a more natural body</i>		<i>Tolerating uncertainty by living day to day</i>
<i>Avoiding the reality of the LVAD's impact on the body</i>					<i>"It's not just about doing everything right by the book in life": taking risks and taking back control to have fun</i>
<i>It's a joke</i>					

APPENDIX 2-D

ADDITIONAL EXAMPLE SUPPORTING QUOTES

Theme 1 - Making Sense of the Changed Body: "When I came to everything was different"

"all of a sudden I'm being told that my life is threatened unless I have this [LVAD] so even after it was fitted, did I or didn't I know what I was aware of, I don't think I did to be quite honest. I don't even think I started realising that I had had this thing fitted and what the seriousness was until about three months after it was fitted. That's genuine that." (Dave)

"I am still massively learning. I get frustrated. From the simplest little thing like I am really tired".
(Dave)

"I've come to the conclusion that [my body] just looks a bit shit anyway because I've got batteries sticking out and it isn't ideal." (Dave)

"When you're in the hospital you're just catered for 24 hours a day, it's great, you don't have to do anything... so when you come out, the first thing I found difficult to get used to was the meds okay and obviously then there was the diet so that running in tandem with getting used to the equipment itself" (Bertie)

"Well I'm no oil painting so I don't need to worry about that [appearance] so I don't really worry about it. The only time I worried about the way I look was when I first started going to the football matches and I was thinking 'Do I look like a normal person?... I really don't want to broadcast the fact that I'm bionic.'" (Bertie)

"it's hard, it's not easy and you're just so grateful that you're alive and it's not until you actually get home because you know you've got big gowns on up there [hospital] and it's hidden underneath... it's not until your actually home and in normal everyday environment's that you realise." (Chloe)

"...I don't like my appearance at all... now I don't look at the scales because I just feel devastated when I look at them, cos to think how tiny I was and now, I think "oh shit", I've got clothes in my wardrobe that I bought when I came out and I just can't even get in them and it's just soul destroying..." (Chloe)

"I understand people's fascination because it's like "it's a what?" "what does it do? god that's amazing!" and it is amazing, however, I'm not a freak on show, please just have some self-respect for me because I just don't wanna keep flashing my belly out to you all the time or explaining it." (Chloe)

"my mates all say that I'm dead glam... I'm not one full of self-praise and all that shit because I have no confidence whatsoever but I think they're all in awe of what I've been through"
(Chloe).

“I’m much happier that I’m a lot lighter than what I used to be...I can wear things that there’s no way I could have worn that when I was 5 or 6 stone heavier” (Anabelle).

“I mean my eldest daughter... she views me as being attractive, I don’t view myself as being attractive I don’t think I am at all, it’s not that I don’t believe that she thinks that, I just don’t think I am” (Anabelle)

“we had friends round on Saturday, and they said and quite unprompted, ‘you look better than we have ever known you look’ so in that respect I know that the general feedback from people is that I look remarkably well” (Garcia)

“depending on what I am wearing, if I am just wearing a T-shirt, there is a bulk round there [abdomen] which I don’t feel the need to hide or disguise.” (Garcia)

“the fact that I’ve got to drink between 2 and 3 litres of water a day, has had an impact on me because I couldn’t do it at the beginning” (Lucy)

“Well, I was a size 10 and then I had me little boy which put me up to a size 12 and now I’ve gone up to a 14 which if you walk round with your label hanging out people know don’t they but only you know what size clothes you wear and stuff like that um, just, it’s... [becoming upset] just I’ve got this massive scar from there to there [indicates from top down chest] um and like the tube and stuff I don’t really like” (Lucy)

“So with my body image, I’ve always worked for a living and all that, I’ve always been handy so, externally I’m just like a normal fit fella” (Tommy)

“I’ve got hardly any muscle at all now y’know compared to what I used to be like” (Tommy)

“I hang it on me back, y’know nobody would notice...but you know you put it at the front of you and everybody asks ‘what’s that’, and y’know to save all the pallava of going through y’know, cos no offense but you keep answering the same questions over and over and over again” (Tommy)

“I don’t think they [sisters] look at me as ill now, I don’t think they do, well obviously they would do but y’know, at least they you’ve got the grace not for to show it” (Tommy)

“I was very ill at the time, I didn’t have long to live which was explained to me, y’know how I wouldn’t live without this LVAD. I said ‘Right, do what you want, crack on’” (Stephen)

“I couldn’t live with a bag. No way...Men don’t carry handbags, they’re not used to carrying handbags.” (Stephen)

“They’re gobsmacked. When you show them, they just can’t believe it. When you explain, you show them the wire coming out of your stomach they’re just like [opens mouth, shocked expression]...not long ago a guy’s showing his scar on his knee. I said that’s not a scar mate, this is a scar and he was the same, he was gobsmacked...They can’t think that’s keeping you alive. You’re walking around and that’s keeping you alive, your batteries and your controller is keeping you alive.” (Stephen)

“your on the ward for a couple of weeks or so and that’s quite rarefied because you’re surrounded by people, everyone’s doing everything for you” (Daniel)

“I am self-conscious you know...the batteries are quite visible and make you broader and an odd shape when somebody looks at you.” (Daniel)

“people notice and you look lumpy but they’ve no idea what’s going on they just know it doesn’t look quite, quite right. But your friends and your family they don’t even see it, so it’s like anything y’know, I’ve got a friend with a huge facial disfigurement and I don’t even notice that he’s disfigured in any way shape or form and then I look back at old photographs of us and you think ‘oh actually yeah that’s what he looks like’...I think it’s just strangers... I’m personally quite conscious of it yes, yeah cos they’re massive these batteries on the side” (Daniel)

Theme 2 - Constant Awareness and Restriction: “There is no sort of mental escape from it or physical escape because it’s there”

“I’m always literally tied to it and therefore there are quite a lot of things which I can’t do either at all or can’t do naturally” (Garcia)

“...the sense of physical vulnerability, because when you’re wearing a bag on your shoulder, which is basically your life system, and you can’t take it off, it’s connected to you and you know that any trauma, if it didn’t kill you it would be exceedingly damaging and dangerous.” (Garcia)

“so we went to the park, wandering around and then suddenly, it started raining...it just rained and rained and rained... I got a bit wet but managed to keep the batteries, the pump and my drive line dry so I wasn’t so bothered about the top and the bottom being soaking wet but it was an example of just how quick things that most people don’t think of ‘oh I’ve got a bit wet...I’ll dry out, it’s not cold’ whereas obviously for me it’s a significant extra dimension, it is potentially a matter of life and death.” (Garcia)

“I find myself making all sorts of adjustments. When I move around, even just if I am downtown walking around, I find I am constantly in almost like sort of defensive alert so I am constantly aware of other people and prepared, if needs be, I suppose basically to protect my vulnerable bit there with my arm” (Garcia)

“it does put a bit of shadow on your quality of life...there were times when I would turn round to my partner and I’ve said ‘honest to God, I’m going to rip that fucking thing, I’m that close to ripping this damn thing out me stomach.’ I’m not going to but I’ve been annoyed.” (Dave)

“I can just imagine the hedge trimmers going through my wire now as we’re speaking for example” (Dave).

“I would rather swim than walk. I absolutely love my water... spa, jacuzzi, sauna, steam room, I can't do any of that. Yeah, so simply because of that one reason and one reason alone, we are never going to be friends.” (Dave)

“For a guy that used to leave his coat in every pub going and not remember, I've had to completely change my attitude to life carrying spare batteries around... I am having to do a hell of a lot of other stuff with other things like making sure you remember your medication, making sure you clean your batteries and at times I've just become a complete paranoid person” (Dave)

“Obviously you want to try and tick all the right boxes with what you've been told by our LVAD team, they're the specialists. You've just been fitted with a fantastic life-saving opportunity, and all this business, course you don't want to be seen to be sticking your fingers up at the LVAD team.” (Dave)

“I'm constantly Googling is it going to rain today, praying and hoping that it's not.” (Dave).

“Getting up in the night, that's a lot of fun. The first time you're plugged in and you walk to the bathroom and you're dragging it along with you and then you'll get it caught under the door and you're thinking how much of this can I actually pull before it comes flying off the cupboard.” (Bertie)

“it's dangerous standing in water with all that power and you're thinking, you've got to be careful and don't move too quickly and all the rest of it because it will come off and it will pull the line that's into your stomach and things like that so you are really conscious about doing things very carefully” (Bertie)

“It's the perception that someone's going to see it and think that it's an IED... These things do go through your mind, what if somebody sees it, what if they pull it, what if they you know put you up against the wall and all the rest and you just think you're just letting your imagination run wild, just stop yourself, behave.” (Bertie)

“So I try to be discrete, it's hard when you have your bag around you all the time as well y'know cos if you're sat having a meal you wouldn't have your bag across you whereas we do, us VADers, or if I can if there's like a spare chair I'll stick it on the chair but I'm very wary like of people pinching it see.” (Chloe)

“it's not that easy because you've still got to carry the bag around with you, there's no sort of, the only sort of relief you get from it is when you're in bed, but then, when you turn over you've got to take [the LVAD] with ya and the lead and yeah it's hard, there is no sort of mental escape from it or physical escape because it's there, y'know it's there” (Chloe)

“it's that third person, it's [Victor], [Victor]'s in bed with us y'know, [Victor] goes everywhere with us” (Chloe).

“my mate started running a few years ago and he said “why don’t you come?” and I wasn’t sure about running with that but they said yeah you can but, you know be careful... but now they all come with dogs half of them so I stopped going... it’s a lead isn’t it [lifts drive line] you dangle and bit of thing and a dog will go for it won’t it, it’s just inbred” (Tommy)

“I don’t go out as much now as I used to” (Tommy)

“I still weigh myself everyday because that’s the one thing that worries me...it used to like creep up and like, I used to have to phone the [LVAD nurse] up, and she said ‘why what do you look like? stand in front of a mirror’” (Tommy)

“[My hair] gets trapped in it and I suppose some people might think, not that I’ve ever discussed that with anyone but... I suppose some people like well ‘at least you’re alive [Ana]’ and I must think ‘well yeah at least I am but it is frustrating’” (Anabelle)

[regarding wearing a dress for her daughter’s graduation] “I was anxious thinking oh god, because I don’t like showing me legs and I thought oh god they’re thin tights it’s gonna go right up and everyone’s gonna see everything” (Anabelle)

[Field notes] Daniel talked about being “meticulous” when he washes, he said “I’m very paranoid about infections...because 49% of LVAD patients die from a driveline infection” (Daniel)

[Field notes] Daniel described having to negotiate sex/intimacy, because “it’s always there”. “But you have to get around these things otherwise you’d be missing out on a really good part of your married relationship.” He said it’s not ‘normal’ because you’re always aware of the wires and where it is.

“The LVAD affects everything you do, everything, going to the toilet, you take it into the toilet with you. Shower, everything you do. Lovemaking, it’s in the bed with you. It’s there and you become very protective of it, very protective. It affects everything you do, everywhere you go, you think ‘what am I going to do with my bag? I’m going there, am I going to wear the vest, am I going to wear the bag?’” (Stephen)

“I knew I had to be very organised and you have to get yourself into a routine. Everything you do, no matter what you’re doing, if you’re doing something else and it’s time to do that, you have to do it. The only way to get better is do what the doctors tell you. If you don’t do what they tell you, you’re wasting their time, NHS money... Everything I’ve done, I’ve done what the doctors have told me. Some days you get a bit pissed off” (Stephen)

“they give you like a chest harness but you look like a suicide bomber in it and I went out with it once and I thought ‘no I can’t do this’” (Stephen)

“Plus, you go out with a bag, and I think it’s happened to a patient from [city], somebody thinks it looks a bit like a computer bag and somebody snatches it and they start running with it, you know they can kill you... I didn’t want to be one of the statistics so that’s in the back of your mind all the time” (Stephen)

“the only thing that I miss is having a shower, like a full, full shower y’know standing under the water and washing me hair and stuff like that and going swimming with my little boy”

(Lucy)

“it was like, not so much my physical appearance but it’s like... the mental side of it, like I explained to you getting out of bed and stuff like, unplugging from the mains to into my batteries and stuff like that and... just it’s really hard to explain it d’y’know what I mean it’s like... I did struggle a bit at first” (Lucy)

“tryna find something for Christmas, like my work’s do and stuff...like nice to go out in and I could wear again but it’s really really difficult because everything’s like dresses or top and a skirt and I’m not comfortable in wearing those now” (Lucy)

“when I’m out and about with having the LVAD in this bag it’s like making sure that nobody knocks me or anything and I was quite conscious of this right at the beginning... It looks like a camera case and I was frightened of anyone thinking that it was a really expensive camera and stealing it” (Lucy)

“well previous to me having the LVAD and the heart attack I used to wear like some skirts and dresses and things like that um, which I don’t wear now so um it’s mainly like jeans and a top and or, quite low-key things really... skirts and things don’t really suit me now because of the way that my body’s changed size-wise and stuff” (Lucy)

Theme 3 - “Get on and Live”.

“I didn’t hardly wear dresses but because y’know I had this life saving op I thought I’m gonna start wearing nice things, I am gonna start wearing dresses with leggings” (Anabelle)

“at first I thought ‘uh what are people going to think I look like? what do I look like?’ Then I thought after a few months ‘does it really matter it saved your life’. So, I’m not bothered” (Anabelle).

“there were times when I was going to hospital and I’ve thought ‘I look really fat in this, what are they gonna say? what are they gonna think before they weigh me?’ I have thought that in the past, I’m going back like months ago but I don’t think that now y’know...I just think now that really I shouldn’t have been like that about me appearance, me weight, whatever size I was because I was still the same person, to a certain extent, I feel like I’ve changed in some ways I mean y’know, y’know the same for anyone who’s struggling with their weight and I think it doesn’t matter what size you are you know you should be happy inside and out basically.” (Anabelle)

“...it felt at the time, incredibly liberating. When I first put the vest on, it was like wow this is amazing because it like restored a normal posture. ... I can remember going out...and getting out of the car with the LVAD vest on and having to stop and think ‘I’ve forgotten

something, I haven't got my equipment' and then I thought 'Oh yes I have because it's all there'" (Garcia)

"What's been really important in all that is the post-hospital physio and I suppose I would stress this quite strongly in terms of effects on body image... basically all they were doing was making sure that I had a degree of physical, I could do some physical exercise without killing myself... I am not bothered actually what people think of me but knowing that I am actually OK and I can move around in a way that no-one would think I wonder what's wrong with him is really significant." (Garcia)

"I've got to approach it in the most positive frame of mind..." (Garcia)

[regarding cycling with LVAD peers] "it's just this wonderful sensation of we can do things that we thought were completely finished for us... doing things with a small group of others who are obviously all in the same hole, we're all different but to an extent we're kind of like-minded as well and it's just a very exhilarating experience. They're not giving up either, they're doing this!" (Garcia)

"I'm just one of these people who don't sit and mope and think about stuff like that I just get on with it type thing... Even though... [begins crying] it does upset me a little bit um I just don't think about it really... my little boy keeps me busy" (Lucy)

"I do more or less everything really, within moderation at least anyway [laughs]" (Lucy)

"I always look after it because it looks after me... it's like an extra 5 or 10 minutes out of my day but what's 5 or 10 minutes when it's doing its job" (Lucy)

"Alright yes sometimes you're obviously taking risks, you take risks in life anyway and I must admit I'm getting used to that" (Dave)

"you can't look at 'well I've only got to put up with this until my transplant.' You don't look at it that way. That's me now, that's it for the rest of my life so I've got to find images that suit me, things that I can get away with" (Dave)

"I am at the very basic stage where I am making do and trying to do the best. I can do better than that, I can do more than that, I could start colour matching and y'know wearing things for suitable times of the year." (Dave)

"I am finding that different types of clothing are for different types of days depending on what you are doing, which I suppose in life in general is normal" (Dave)

"You see them who do look well, them who don't, they don't look well. It's positive attitude... I ain't sitting down me, no way. I'm not ready to go yet, I've got a few things I want to do" (Stephen).

"Yes, a couple of occasions I turned down going because the dress code and I didn't feel right with a suit and the bag and I just got on with life. I just had to get on with it and that's my way

of coping... That's what kept me going, do what I want to do not what anybody else tells me to do, do what's good for me. I can't do it any other way" (Stephen)

"I've only just started going back on the driving range recently and I've still not had a full round of golf, which is something I'm gonna do as soon as I can." (Tommy)

"I don't think that [LVAD] affects me as much as it should in a way... I think you should be worried about something that's like I say it's there, you can see it, there's a little wire, I know I said before about a space man but he must think when he steps out y'know without that there you're a dead man in space, if that line got damaged, and I think you should worry about it but... [I don't]" (Tommy)

"we do joke about it from time to time, the fact that there is absolutely no sexual contact now" (Bertie).

[regarding change in diet] "If you know there's a means to the end and it's a good one you just get on with it and that's what I did." (Bertie)

[Field notes] Daniel reported feeling "tethered" to the machine can impact mood but he has found a way to overcome it by "making myself do something I enjoy... play a video game, watch a movie, walk the dog." Daniel said that at the end of every day if he can look back and I can see that he's done one thing he enjoyed that's how he manages "Like said earlier, I try not to let it get to me or think too much about it". (Daniel)

"I try to consciously not project my insecurities into whatever [strangers] might be thinking, so try and be self-aware of y'know what are your own personal insecurities but just shut them off, I know they exist and they're there but I'm not gonna let them take control of me." (Daniel)

"I know now what I can and can't do. So I know now that if I find a dress that I like with pockets yay! great! And I know now that if I don't it's okay cos I've got my mate [who alters them]... it's just second nature now, it's not a big deal to us now and I think cos now I know what I can and do, where I can and can't shop y'know that it's not so hard." (Chloe)

"We played a game on the plane, how many times am I gonna be asked 'put your bag underneath your seat please?'... you have to find sometimes the fun side of it" (Chloe)

"I just gotta get on with it haven't I. I mean it's there, its not going anywhere.... there's no point sitting and wallowing in self-pity, it's happened I just gotta deal with it" (Chloe)

"I had the hospital bag for a bit but then [the Consultant Cardiologist]'s like 'you know some women do put them in normal bags'. So, that's like I say when I got my Mulberry bag. Um, and then obviously, I've tried to google it on websites and there was a girl in America that she'd got it all in a rucksack and was wearing it and I thought 'oh great idea'" (Chloe)

"if I'm cleaning the house I've got this rucksack, I have got like a Louis Vuitton bag that I tend to put my spares in... And then, on special occasions I'll get a bag to match me outfit, y'know to make it like it's part of it." (Chloe)

Section Three: Critical Appraisal

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1 | AIMS OF THE CRITICAL APPRAISAL

This thesis is comprised of two main pieces of research, a literature review and an empirical study. The literature review examined adults' psychological experiences of heart transplant (HTX) where a meta-ethnographic approach to synthesis identified four main concepts: 'Identity: making sense of the self after HTX', 'Bearing others' expectations', 'The overwhelming emotional impact of HTX' and 'Developing coping skills'. The research paper explored the experience of body image for adults implanted with a left ventricular assist device (LVAD). Using an interpretative phenomenological analysis (IPA) approach three themes were developed: (1) Making Sense of the Changed Body: "When I came to everything was different", (2) Constant Awareness and Restriction: "There is no sort of mental escape from it or physical escape because it's there", and (3) "Get on and Live".

The depth to which these issues can be discussed is limited by the format of this thesis and conventional reporting limits for publication. Therefore, this critical appraisal aims to offer further reflection of my journey through this research project. Firstly, I will draw attention to comparisons between the findings of the literature review and empirical study, including possible areas for future research. Secondly, I will explore my experience of the research journey including: deciding on a research project, research design, sampling and data collection. Thirdly, I will share some reflective insights for the purpose of reflexivity.

2 | COMPARISONS BETWEEN THE REVIEW AND EMPIRICAL PAPER

Recognising similarities between the literature review and the research paper was an interesting experience and one that I had not predicted as they felt rather distinct early in the thesis process. Upon reflection, I considered that participants across both papers will have experienced similar, distressing histories of heart failure prior to receiving their intervention: HTX or LVAD. The final interview I conducted was the first that highlighted this similarity to me in an obvious way; the participant described that two days prior to LVAD-implantation

she was woken in the night in hospital by a nurse telling her they had found her a donor heart, only a few hours later to be told that the surgeons had decided it was “too old” and unsuitable. The fact that both sets of participants had been end-stage-heart failure patients likely explains the similarity of findings across both papers that avoidance of emotions pre-intervention might cause difficulties to adjustment post-intervention. Both sets of participants experienced life-threatening illness that may have left them vulnerable to post-traumatic distress at a rate higher than the normal population (Tulloch, Greenman & Tassé, 2015). Therefore, similar acceptance-based psychological interventions were indicated to support adjustment and coping following LVAD and HTX.

An interesting commonality between the studies is that participants experienced contradictory feelings towards the intervention and demonstrated a stoic reluctance to share difficulties with medical professionals. Participants experienced gratitude for life and the professionals who saved them, alongside feelings of frustration, resentment or disappointment with their changed and limited body. There is scarce literature on gratitude and physical health, particularly life-saving treatment. Wood, Froh and Geraghty (2010) suggest a gratitude can be conceptualised as wider than an emotion and may be a disposition or “wider life-orientation towards noticing and appreciating the positive in the world” (pp.2). Research has demonstrated that gratitude is correlated with autonomy, personal growth, environmental mastery and self-acceptance (Wood, Joseph & Maltby, 2009); these factors were identified in the current papers as important to successful adjustment and coping following HTX and LVAD implantation. The field of healthcare research might benefit from research that explores experiences of gratitude following life-saving interventions. The experience of negative emotions, such as guilt, alongside gratitude, could also be examined to determine their impact on psychological wellbeing and quality of life.

Parallels between the two papers may be drawn regarding findings that the medical interventions changed the body, which impacted on participants' perceived sense of self. It is important to acknowledge the ongoing philosophical and theoretical debates regarding the relationship between the body and self. The Cartesian biomechanical model, prominent in western medicine, reduces the physical body into separate parts to be treated or fixed (Marcum, 2004); this sociocultural context created distress for participants in the review paper as others perceived the transplanted organ as a "spare part" and expected immediate recovery. Phenomenological philosophies offer an alternative perspective that the body represents a meeting point between the self and the world and that through engagement with the world our self can be known: "there is no inner man, man is in the world, and only in the world does he know himself" (Merleau-Ponty, 1962, p.xii). van Manen (2017) offers the first examination of how the ventricular assist device (VAD) might impact embodied existence in a paediatric sample and suggests that the presence of the VAD poses difficulties for a smooth sensory embodiment. Similarly, in the empirical paper, LVAD-users experienced distress caused by the permanent presence of the LVAD on or next to their body; their attempts to reduce their conscious awareness of the device might be an attempt to ease embodiment. Further examination of the imperfect embodiment of the device for adults is warranted, phenomenological theories may help understand the distress and disruption to self which was created by the changed body and LVAD.

The current research papers found that striving for "normality" of functioning and appearance with the changed body was important to participants, demonstrating a possible link between body image and identity. Daniels and Gillen (2015) argue that theories of body image such as objectification theory (Frederickson & Roberts, 1997) and the theory of social comparison (Festinger, 1954) indicate processes through which positive identity formation may be disrupted. Some research has indicated that the body is salient in individuals'

formation of identity (Kling, Wängqvist & Frisé, 2018) and body image, body esteem and identity are linked (Wängqvist & Frisé, 2013). However, research on the relationship between body image and identity needs significant development, particularly in the field of health research.

3 | THE RESEARCH JOURNEY

3.1 | Background to choosing a topic

My interest in health psychology started prior to clinical training. Growing up, my mother was a cardiac nurse. Myself and my brother inherited a blood condition which required biannual appointments with the haematologist at the hospital where my mother worked. I recall great excitement from visiting my mother's colleagues at the coronary care unit after these appointments and sitting behind the desk as a small child mesmerised by the ECG monitors. Even then, I was aware of how unwell and close to death people with "poorly hearts" could be, as I knew that sometimes my mother would have to leave home in the night to help care from them. I admired the care the medical professionals gave to their patients and knew I wanted to emulate caring for others in the future. Completing work experience in this same hospital as a teenager led me to clinical psychology as a profession.

During clinical training I have sought placements in healthcare settings. Working with children with complex neurological and endocrine conditions I was struck by the far-reaching impacts of illness on the lives of individuals and their families. My interest in the LVAD began when I was conducting small-scale research in a UK transplant unit as part of my training. I interviewed medical professionals about their experiences of discussing end-of-life care with transplant patients. Two of the staff described challenging ethical issues arising whilst caring for LVAD patients who did not receive a donor heart and could no longer be sustained on their LVAD due to severe illness. The staff described the distress experienced by family members and other professionals when it was decided that no further medical

intervention was possible and the LVAD must be switched off to allow the patient to die. The fragility of life with an LVAD was evident. I wondered how it must be living with a life-sustaining device in day-to-day life and how it might impact an individual's relationship with their body. During a meeting with the clinical psychologists at the transplant unit, one psychologist shared anecdotal evidence of the impact of the LVAD on appearance and highlighted that there was little research on the impact of the LVAD on body image. This gap alongside the psychologist's enthusiasm sparked my interest in the topic.

3.2 | Research design and positioning

Guba and Lincoln (1994) assert that it is essential for researchers to align themselves to a methodology that compliments their ontological and epistemological stance as well as addressing the aims of the research. My perception of what can be considered as 'truth' and how it may be discovered within the context of understanding the impact of the LVAD on body image was carefully considered whilst generating my research question. I believe that there is not one objective truth and that individuals' realities are developed through and given meaning by their knowledge and perceptions of the social environment. Thus, a social constructionist approach to the research was taken. Social constructionists posit that the findings of any research inquiry are co-constructed by the researcher and participant during the collection and analysis of the data (Finlay, 2002b; Finlay & Gough, 2003; Guba & Lincoln, 1994).

To date there are no known studies exploring body image amongst adults implanted with and LVAD therefore an absence of richness and exploratory research was identified. My epistemological position drew me to adopting a qualitative approach for the present study, specifically phenomenology. Interpretative phenomenological analysis (IPA) was chosen as it aims to understand how individuals' make sense of their unique lived experience (Smith, Flowers, & Larkin, 2009). IPA is concerned with obtaining rich, in-depth personal accounts

of the phenomenon that is being studied (Smith, 2004). Therefore, one-to-one semi-structured interviews were conducted to enable LVAD users to offer an in-depth account of their experience and perception of their body image.

3.3 | Sampling

The use of a self-selecting sample based on inclusion criteria may mean that participants generally had a more positive experience of the LVAD and body image as they felt comfortable to discuss it with a researcher, representing self-selection bias (Costigan & Cox, 2001). However, it appeared that this was not the case as a range of positive and negative perspectives on body image were shared by participants. It seemed that the motivation for most participants to take part was that they wanted to help inform the evidence base and encourage others to understand their experiences, as they perceived a lack of wider societal knowledge of the LVAD. Research of rare illnesses has demonstrated that patients value having a voice and making a positive contribution, particularly when they feel isolated in their experiences (Young et al., 2019).

Large delays in the research process meant that recruitment for the study commenced approximately seven months after initially planned and there was a sense of urgency to recruit participants. The final sample coming from a limited geographic area was partly due to differences in enthusiasm of recruitment to the research at the two sites and recruiting on a first-come-first-served basis. It seemed that one site was sharing information packs at a much quicker and greater rate and LVAD-users were keen to take part. The enthusiasm of LVAD users to participate in my research felt relieving due to the time pressure I faced; all interviews were organised and undertaken within a period of 8 weeks following commencement of recruitment.

Given the enthusiasm of the LVAD community to participate, future researchers could take a different approach to recruiting participants across multiple recruitment sites to

increase heterogeneity of the sample and improve generalisability of results. The use of a quota sampling approach, in which a set of categories such as geographical location is determined in advance and a minimum number of cases is allocated to each one, may broaden the sampling pool (Robinson, 2014). Similarly, the enthusiasm of LVAD-users to participate offers scope for researchers to recruit more homogenous LVAD samples in the future. In the findings of the current study, participants reported high levels of distress related to body image immediately following implantation and/or in the early stages of recovery at home. Now that these timepoints have been identified as particularly difficult regarding adjustment of body image, further qualitative research could examine LVAD-users' experiences during these stages.

3.4 | Data collection

I aimed for the interviews to feel conversational in style in order to build rapport and create a space where participants felt safe to share their experiences (Pezalla, Pettigrew, & Miller-Day, 2012). Smith and colleagues (2009) note that the "most important thing in this opening phase is to help the participant get used to talking" (pp.64). In order to do this, the interview schedule began with two broad questions including: 'can you briefly explain what led you to be implanted with an LVAD?' After the first two interviews I noted that this question could not elicit a brief answer; each participant had talked for between ten and fifteen minutes about their illness history, including specific dates, intricate details of medication regimes and decision-making processes. I wrote about this in my reflective journal:

Although I do not show it, I feel concerned when participants talk for a long time about their illness before the LVAD because this is not the focus of the research and I don't want to waste their time. I have tried to help move them along and remove focus on the details, but it seems like when people are telling the story of their illness they

can't help but tell the whole thing. Today, Chloe even showed me a photo. (Reflective journal entry, July 2019).

I discussed this reflection further with one of my research supervisors. I was reminded of the purpose of these opening questions and how they might help participants feel comfortable discussing body image later. Literature describes that the process of telling the history of illness can be therapeutic for individuals in helping them make sense of their experience and transforming it into a processed narrative (Adler, 1997). Reflecting on this following all nine interviews, I do believe this storytelling was important to the research as it may have helped participants feel understood and contextualised the findings, particularly of the changed body. Smith et al. (2009) note that additional data which contextualises the data can be useful for the development of an IPA analysis.

My clinical skills around maintaining confidentiality were repeatedly tested during interviews. The number of UK LVAD users is small, patient social groups are common in transplant units and many LVAD users are part of the online LVAD community on social media. It seemed that some participants assumed that I may know other patients from their LVAD site; they named them in interviews and on occasion asked if I had heard of or met them, to which I had to remind participants of our confidentiality agreement.

Similarly, when discussing choosing a pseudonym with one participant as part of the debriefing process, they told me to use their own name and said that they believed that it was overcautious to not allow them to do so as they were happy for others to know they participated. In this case I explained that I was bound by NHS ethical approval to anonymise the data to maintain his confidentiality, but he could choose to tell others if he wished. Research indicates that it is not easy to guarantee confidentiality to participants if they are part of small communities (e.g. Stein, 2010). Utilising supervision with field and research supervisors allowed my reflection on issues of anonymisation and ensured confidentiality

was maintained, in line with the NHS ethical approvals obtained for the research. Some researchers are beginning to take a more critical approach to the universalisation of anonymity principles: it is suggested that excessive anonymisation of the data may undermine the value of the results and that identification of participants may be empowering (Surmiak, 2018). It is not thought that anonymisation has greatly reduced the quality of the data in the current study, however bolder approaches to anonymisation might be considered in design of future LVAD research.

4 | REFLEXIVITY

Reflexivity has been defined as conscious or explicit self-awareness (Finlay, 2002a, 2002b). In qualitative research reflexivity is considered a valuable tool to recognise implicit biases in the researcher's approach and enable the integrity of the research to be scrutinised through keeping a log of research decisions (Finlay, 2002b). Reflexivity requires the researcher to engage in critical self-reflection of their positioning, assumptions, social background, and behaviour to examine how these intersubjective elements impinge on and even transform the research process (Finlay, 2002a; Finlay & Gough, 2003). By making the impact of these elements explicit, qualitative researchers attempt to increase the transparency, trustworthiness and accountability of their research (Finlay, 2002a).

Reflexivity is an important component of conducting IPA due to its strong hermeneutic influence which recognises that: "the researcher is making sense of the participant, who is making sense of *x*" (Smith et al., 2009, pp.35). In IPA a dynamic, cyclical approach is required to bracketing the researcher's preconceptions so that they do not unduly influence the research process (Smith et al., 2009). In the current study, this was achieved by keeping a reflective journal, as suggested by Morrow (2005). The journal allowed me to capture my thoughts, feelings and experiences as I became conscious of them during or immediately after interviews and throughout the research journey.

4.1 | The body as a machine and a parallel illness experience

Whilst designing the research I reflected that I was a healthy woman with no experience of hospital stays or illness like those which the prospective participants might have experienced prior to LVAD implantation. In some ways I felt naïve and, as I imagined what having an LVAD might be like, I recognised my assumption that the mechanical workings of the device might impact on participants' view of their body as human. By recognising my assumption, I was able to bracket it and remain open to the experiences of the participants. In doing so, at analysis I recognised that a few participants anthropomorphised their LVAD and the device became more human, rather than their body becoming less human: they likened it to an annoying sibling or unwanted friend in describing their gratitude and resentment towards its presence.

Throughout the research journey I revisited dominant social narratives of the human body as a machine. I became unwell and required urgent surgery prior to seeking ethical approval for the research. A few months later, following surgery, I continued to experience ongoing illness which led me to feel tired and limited my day-to-day functioning. When I struggled to meet my own expectations for achieving academic work, I noticed the dominant biomechanical model of the body reflected in my language:

From this work, I am realising how many phrases we use everyday which imply a mechanistic view of the body and mind. I just told my partner I was going to “power through” with work. When I felt unwell and struggled to concentrate, I told myself “you are not a machine” (Reflective journal entry, June 2019).

I reflected on the disappointment that I felt because surgery hadn't been a simple ‘fix,’ and a perceived lack of control over my body and symptoms. This ongoing illness was at its worst in the few weeks immediately prior to recruitment. I was aware of the potential impact of my illness experience on the research and managed to compartmentalise my own feelings of

frustration towards my body. I believe that these experiences, although they were unlike that of the participants in severity, allowed me to be empathic and understanding whilst my clinical skills supported me to remain objective.

4.2 | Body image and gender

There is no universally accepted definition of body image (Massidda, Bastianelli, & Vidotto, 2010). Therefore, to avoid my own assumptions regarding body image impacting data collection I avoided using the term and designed the interview schedule with broader questions about participants 'body', 'appearance' and 'the way you look'. During the third interview I noticed thoughts that the interview may not have been fruitful as the male participant told me that he did not shop for his own clothes and he was not concerned about what others perceived of his appearance. Following the interview, I wondered how the research would progress if other participants reported a lack of concern about appearance. By recognising my possible gender bias that men's body image may not be impacted by the LVAD as much as women's, I was able to consider that perhaps body image was broader than appearance for LVAD users. Moving forward, I reduced my use of the word 'appearance' in the interviews and replaced it with 'body'. Throughout, I focused on simply using prompts from the interview schedule to reduce the opportunity for my own values to influence the interviews. Due to this process, I was able to remain open to discovering new meanings for individual participants, to be sensitive to different aspects of how body image is constructed and ultimately to conceptualise body image as broader than appearance.

5 | CONCLUSIONS

The current thesis explored the broad psychological experiences of adult HTX recipients in a qualitative metasynthesis and experiences of body image for adults implanted with an LVAD in an IPA study. Conducting the research has enabled me to reflect on the influence of social and wider societal factors on psychological wellbeing and individual perceptions of body

image. I have developed a greater awareness of how dominant social narratives can be detrimental to coping and adaptation after trauma. Acknowledging my personal bias of appearance being central to body image has allowed me to broaden my perspectives and recognise the importance of physical functioning to how others might perceive their body. The functional aspects of body image may have been less prominent for me until this research, and my parallel illness journey, as I had perceived myself as healthy most of my life. The research process has also highlighted the importance of reflecting on my own beliefs and assumptions. In my first post as a qualified psychologist I will be working with individuals with eating difficulties, including those with chronic illnesses; it will be important for me to incorporate this learning, a broader conceptualisation of body image and heightened awareness of social narratives of the body, in my clinical work.

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Section Four: Ethics

Hannah Gordon

Doctorate in Clinical Psychology

Division of Health Research, Lancaster University

Word count (excluding references and appendices):

Correspondence:

Hannah Gordon, Doctorate in Clinical Psychology, Furness College, Lancaster University,
Lancaster, LA1 4YG.

Email: h.gordon@lancaster.ac.uk

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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)
The Experience of Body Image for People with an LVAD v1

1. Is your project research?

Yes No

2. Select one category from the list below:

- Clinical trial of an investigational medicinal product
- Clinical investigation or other study of a medical device
- Combined trial of an investigational medicinal product and an investigational medical device
- Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
- Basic science study involving procedures with human participants
- Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
- Study involving qualitative methods only
- Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
- Study limited to working with data (specific project only)
- Research tissue bank
- Research database

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

Other study

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

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

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

- England
- Scotland

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- 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?

- IRAS Form
 Confidentiality Advisory Group (CAG)
 Her Majesty's Prison and Probation Service (HMPPS)

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 Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or Medtech and In Vitro Diagnostic Cooperative 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?

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 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 study is being undertaken as part of a Doctorate in Clinical Psychology at Lancaster University. The student will be leading the research; co-designing the study, collecting the data, conducting qualitative analysis, and writing up the findings. This will be overseen by Dr Anna Daiches (Deputy Programme Director and Clinical Director, Lancaster University), Dr Clare Dixon (Clinical Tutor, Lancaster University), and [REDACTED]

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

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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 familiar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
The Experience of Body Image for People with an LVAD v1

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

REC Name:
North West - Preston

REC Reference Number:
19/NW/0104

Submission date:
01/02/2019

PART A: Core study information
1. ADMINISTRATIVE DETAILS
A1. Full title of the research:

The Experience of Body Image for People with a Left Ventricular Assist Device

A2-1. Educational projects

Name and contact details of student(s):

Student 1

	Title	Forename/Initials	Surname
	Miss	Hannah	Gordon
Address	Clinical Psychology, Div. Of Health Research, C-Floor, Furness College Lancaster University, Lancaster		
Post Code	LA1 4YG		
E-mail	h.gordon@lancaster.ac.uk		
Telephone			
Fax	n/a		

Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/ degree:
Doctorate in Clinical Psychology (DClinPsy)

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Reference:
19/NW/0104

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Name of educational establishment:
Lancaster University

Name and contact details of academic supervisor(s):

Academic supervisor 1

	Title Forename/Initials Surname
	Dr Anna Daiches
Address	Clinical Director, Doctorate in Clinical Psychology Division of Health Research, C-Floor, Furness College Lancaster University, Lancaster
Post Code	LA1 4YG
E-mail	a.daiches@lancaster.ac.uk
Telephone	01524594406
Fax	n/a

Academic supervisor 2

	Title Forename/Initials Surname
	Dr Clare Dixon
Address	Clinical Tutor, Doctorate in Clinical Psychology Division of Health Research, C-Floor, Furness College Lancaster University, Lancaster
Post Code	LA1 4YG
E-mail	c.dixon3@lancaster.ac.uk
Telephone	01524 593492
Fax	n/a

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)
Student 1 Miss Hannah Gordon	<input checked="" type="checkbox"/> Dr Anna Daiches <input checked="" type="checkbox"/> Dr Clare Dixon

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:

IRAS Form

Reference:
19/NW/0104

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	Title Forename/Initials Surname
	Miss Hannah Gordon
Post	Trainee Clinical Psychologist
Qualifications	2.1 BSc Psychology, University College London
ORCID ID	
Employer	Lancashire Care NHS Foundation Trust
Work Address	Clinical Psychology, Div. Of Health Research, C-Floor, Furness College Lancaster University, Lancaster
Post Code	LA1 4YG
Work E-mail	h.gordon@lancaster.ac.uk
* Personal E-mail	h.gordon@lancaster.ac.uk
Work Telephone	
* Personal Telephone/Mobile	
Fax	n/a

** 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
	n/a Becky Gordon
Address	Research Support and Systems Manager Research Services Lancaster University
Post Code	n/a
E-mail	ethics@lancaster.ac.uk
Telephone	01524 592981
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): n/a

Sponsor's/protocol number:

Protocol Version:

Protocol Date:

Funder's reference number (enter the reference number or state not applicable): N/A

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)"

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Reference:
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section.

A5-2. Is this application linked to a previous study or another current application?
 Yes No

Please give brief details and reference numbers.

n/a

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.

How do individuals with a left ventricular assist device (LVAD) experience their body image?

Individuals with visible differences due to illness or accident may experience poor body image, which impacts negatively on their self-esteem and mood. Some individuals who are required to wear external medical equipment, e.g. stoma bags, experience significant distress accepting/adapting to an altered body (e.g. Brown, 2007).

An LVAD is a mechanical circulatory pump which can be implanted in an individual's chest and attached to their left ventricle to push blood around the body. Individuals may be given an LVAD if their heart is failing and unable to sustain life without support until a suitable donor heart is found for transplantation. LVADs have significant external components which must be worn at all times to keep the wearer alive, including a controller, wires, and two large batteries.

Qualitative literature on the psychosocial aspects of LVAD implantation is sparse and focuses more broadly on how individuals adapt to living with an LVAD. Challenges around bodily changes, identity, and clothing have been mentioned in these studies (e.g. Marcuccilli, Casida & Peters, 2013). However, body image is yet to be explored in depth. This study aims to explore the impact of being implanted with an LVAD on individuals' perceptions of their body image. This is a valuable area of research as it will help further inform services as to the needs of people living with an LVAD.

Participants will be recruited by clinical psychologists and nurses from the LVAD teams at [REDACTED] and [REDACTED] hospitals. Participants will be adult outpatients implanted with an LVAD for at least six months. Semi-structured interviews will take approximately 1-hour either in a private room at the hospital, at the participant's home, or via telephone/skype. Interviews will be anonymised, transcribed and analysed using Interpretative Phenomenological Analysis (IPA).

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.

Design

As the number of people receiving an LVAD increases, this area of heart failure medicine is growing; LVAD devices are continually being re-designed and developed, as is the support for LVAD recipients. There is a small but growing body of literature on the impact of LVAD-implantation on psychosocial wellbeing. The majority of this literature uses quantitative or mixed-method approaches to measure change in psychosocial functioning post-implantation e.g. quality of life, mood. There is some qualitative research which takes a more exploratory approach in trying to understand adaptation and coping to life with an LVAD. This research highlights challenges that individuals' may face relating the

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device's external equipment, their body image and clothing. However, this is often captured only briefly.

There are other areas of medicine where external medical equipment is used (e.g. stoma bags, continuous glucose monitors). In these areas, qualitative research has been used to deepen understanding of the impact of such equipment on body image. For example, the use of a stoma bag can undermine self-esteem and body image, creating challenges to adjusting and day-to-day functioning (e.g. Manderson, 2005).

The purpose of this research is to explore and understand perspectives on body image of those who experience being implanted with a left ventricular assist device (LVAD), as this is yet to be explored in any detail. A qualitative approach will be used as it is the most appropriate design to develop an understanding of the experience of LVAD recipients. The research question is broad and as such there is not a specific hypothesis to be tested. Instead, starting to understand individual perspectives and the personal meanings of those implanted with an LVAD requires the more naturalistic, information gathering approach offered by qualitative methodology.

Review process

The project design has been informed by discussion with the supervisors involved in the research, two with an academic role and one with a clinical role with regard to the research. The design of this research was critiqued in a peer review process, involving peers and academic staff from the Doctorate in Clinical Psychology at Lancaster University.

Recruitment

The chief investigator aims to recruit between 6 and 12 participants in order to provide sufficient data for analysis. Potential participants will be identified by staff in the transplant units who work specifically with those people with an LVAD. Potential participants will be provided with information about the study by LVAD staff during routine outpatient appointments or via the post. The staff in the LVAD team will be briefed about the project and offered support to ensure that recruitment is undertaken in a facilitative, non-coercive manner. Posters will also be placed in waiting rooms at the transplant unit where LVAD-users attend appointments, in order that they may approach staff to request further information about the research.

In the event that this does not provide sufficient numbers of participants, the chief investigator will request for an adapted version of the research poster to be shared on an active, private facebook group for UK LVAD-users and their family called 'LVAD life UK'. This poster will be shared by the group's administrators and will inform potential participants to contact the chief investigator directly, using the research mobile phone number or email address provided, to request further information about the study.

Inclusion and exclusion criteria

Participants will currently be implanted with a left ventricular assist device. They will have had the device for at least 6 months. They will be outpatients. They will be over the age of 18. They will speak English.

Consent

Informed consent will be ensured by the provision of clear information on the participant information sheet and all other supporting documents e.g. expression of interest form, cover letter. Prior to taking part participants will be provided with at least two opportunities to ask questions about the research (following expression of interest in taking part, and before the interview commences). Participants will be required to sign and initial a consent form before the interview starts. A copy of this consent form will be provided to participants. Participants will be informed that they are able to withdraw their data from the study for up to two weeks after their interview, after which it will have been transcribed and anonymised.

Burdens, risks and benefits

It is not anticipated that the participants will experience the nature of the questions as distressing. Prior to the interview participants will be told that they can choose not to answer any of the questions they are asked. However, if a participant should become distressed the interview will be stopped and the participant will be offered a break or to not continue. Sources of further support will be discussed with the participant at this time, and with all participants at the end of their interview.

Confidentiality

The chief investigator will not have access to the personal information of any potential participants until they have expressed an interest in taking part in the research and have chosen for their details to be shared via the expression of interest form or by contacting the chief investigator directly.

From the participant information sheet and in discussion prior to the interview, participants will be informed that the information they share will be treated confidentially except in the event that they disclose that themselves or someone else may be at risk of harm or have been harmed previously. In this situation information will be shared with the appropriate people, such as their care team, GP, or police.

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Digital audio recordings will be stored as encrypted files and will be destroyed following transcription, within three months. Identifying information will be removed or changed during the transcription process (e.g. names, places, ages, dates). Transcripts will be stored as encrypted electronic files. If transcripts are printed during the analysis stage they will be stored in a locked filing cabinet at the chief investigators home before being securely destroyed as soon as possible after analysis. Electronic versions of the transcripts will be stored securely for up to ten years following the research and will then be destroyed.

Participants will be informed that their interview may be listened to and/or read by the academic supervisors (Dr Anna Daiches and/or Dr Clare Dixon) so that the interview schedule and interview style can be reflected on and adjusted if necessary. Participants will be informed of the academic supervisors' duty to maintain confidentiality. Any data (audio recording or transcription) that is shared with the academic supervisors prior to being anonymised will be transferred securely via box.com (Lancaster University academic folders) or using password protected files sent between university email addresses.

Participants will be informed that anonymous quotes and excerpts from their interviews will be used in the research report and dissemination, including presentations and publication.

Conflicts of interest

The research is being supervised by [REDACTED] As such it is important that no access to interview data, such as digital recordings, will be granted prior to it being anonymised.

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)

n/a

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

The project aims to explore experiences of body image for adults who are living with a left ventricular assist device (LVAD).

How do people perceive their body image whilst living with an LVAD? Do the external components of this life-saving device influence their body image? If so, how? And do they make any adjustments to manage this?

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

How do people living with an LVAD describe their body/appearance?

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This project aims to understand what factors might influence individuals' body image, including whether they perceive their image positively and/or negatively.

It will consider how individuals living with an LVAD think that other people perceive their body/appearance, and what impact this has on them.

It will also try to explore perceived changes to body image from pre-LVAD to living with an LVAD.

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

People who experience chronic heart failure may be offered a mechanical heart pump for several reasons; if they are not yet well enough for a heart transplant, if there is reduced chance of a suitable donor heart, if physical decline means implantation is necessary, or as a temporary measure if it's expected that the heart may recover. The left ventricular assist device (LVAD) is one such pump (British Heart Foundation, n.d); blood enters the pump via the left ventricle and the device pumps the blood via the aorta to the rest of the body. The LVAD is connected to an external controller by a fine cable which passes through the skin. The controller connects to two external rechargeable battery packs which are carried on the person.

The external LVAD components are bulky and heavy and are usually carried in a shoulder bag, or harness worn over the shoulders. This impacts users' self-care and day-to-day functioning, including the clothes they can wear, ease of showering etc. Research in other areas of medicine has shown that carrying external medical devices, particularly in public, can lead to feelings of shame and a perceived negative impact on identity (Gately, Rogers, Kirk, & McNally, 2008). Individuals who receive an LVAD may also gain weight, the reasons for this are complex. For example, LVAD improves health and increases appetite, however there is a reduced need for calories. In addition, individuals may have been inactive beforehand and inactivity continues.

Scarce qualitative research has been conducted on experiences of LVAD-use from a phenomenological perspective. Difficulties with body image, including clothing and weight gain, have been occasionally commented on during wider research on adapting to or coping with an LVAD. For example, in one study of people who received a heart transplant but had previously used an LVAD, participants described retrospective reflections that the LVAD dramatically changed their body and sense of self (Chapman, Parameshwar, Jenkins, Large, & Tsui, 2007). However, research is yet to look at the impact of having an LVAD on body image, namely the way people see themselves, in its own right.

This project aims to fill the gap in the research and look specifically at individuals' perspectives of their body image whilst living with the LVAD. This could deepen professionals' understanding of living with an LVAD and inform the support offered to people post-implantation. In doing so, the research aims to promote the psychosocial wellbeing of the expanding population of individuals using LVADs.

Qualitative methodology gathers a depth and richness of information that may not be captured using quantitative methodology. Interpretative Phenomenological Analysis (IPA) aims to "explore in detail participants' personal lived experience and how participants make sense of that personal experience" (Smith, 2004, pp.40) and as such is suitable to address the research question. IPA been shown to be successfully utilised to explore experiences of physical illness and was developed for use in health psychology research (Smith, 2011).

This is an educational project. With the support of experienced academic supervisors, the chief investigator will continue to develop research skills in qualitative methods.

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.*

The recruitment process will involve two stages, as follows:

1. Potential participants will be recruited by staff or by posters in the transplant unit which they attend for regular outpatient appointments with their LVAD care team (either [REDACTED] or [REDACTED]). Staff will have been briefed to identify people meeting the inclusion criteria of the research and to provide them with participant information packs during a routine outpatient appointment or by post. Potential participants will also be able to request information packs from their LVAD care team if they choose to do so after seeing the research poster in the transplant unit.

If staff provide potential participants with an information pack during a routine appointment they will ask them whether they wish to sign the expression of interest form enclosed in the pack, indicating they would like to know more about the research or register their interest in participation. By signing the expression of interest form, potential participants will have agreed to provide the chief investigator with a convenient method to contact them to further discuss the study.

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It is possible that potential participants will choose not to sign the form at this time, or they might collect a participant information pack from staff at the LVAD team without staff being able to go through the pack with them (e.g. after reading about it on a poster). In instances such as these, participants will be able to express an interest in taking part either by completing and returning the expression of interest form using the stamped addressed envelope provided in the pack, or by contacting the chief investigator directly by telephone (specific research telephone provided by Lancaster University) or by email. The prepaid envelopes will be posted to the chief investigator at their Lancaster University office address.

Potential participants who have received an information pack by post will also be able to return the expression of interest form using the stamped addressed envelope provided in the pack, or by contacting the chief investigator directly. The information pack explains that they may be contacted by their LVAD care team about the research; 'If you have received this information pack by post, it has been sent by a member of your transplant team. They will telephone you over the next couple of weeks to check you received this information and to talk a little bit more about the research if you wish.'

2. If the above strategy does not provide sufficient number of participants, the second stage of recruitment will involve the chief investigator contacting the administrators of an active, private Facebook group for UK LVAD users (LVAD life UK). The chief investigator will provide the administrators with a research poster which they can share with the group's members. The poster will inform potential participants that, if they meet the inclusion criteria and would like further information about the study, they can request an information pack directly from the chief investigator using the telephone number or email address provided. Information packs will be sent by email or by post. Any identifiable data received in order to distribute the packs will be stored electronically in a password protected word document or locked filing cabinet in the chief investigator's home. Once potential participants receive the information pack, they will be required to contact the chief investigator again to express an interest in taking part in the research by posting the expression of interest form or or by contacting the chief investigator directly either by telephone or by email (as above).

Once a potential participant has expressed an interest in participation in either of the above recruitment stages, they will be contacted by the chief investigator and given the opportunity to ask any questions they have about the research. The participant and chief investigator will then determine a convenient time and place to conduct the interview. Possible locations include the participant's home or a room in the transplant unit which they attend. If it is not possible to determine a convenient location the chief investigator will offer the participant the opportunity to conduct the interview by telephone or skype (research account).

Prior to the interview the chief investigator will go through the participant information sheet, offer the opportunity to ask questions, and ask the participant to sign a consent form. The semi-structured interview will last approximately one hour, breaks will be offered as required. The interview will be digitally audio-recorded.

Following the interview the participant will be given a debrief sheet with sources of support they may access if they feel distressed by anything discussed during the interview. Then, they will be asked whether they would like to choose a pseudonym to be used to refer to their data during write up, or whether they would like one to be chosen for them. Also, participants will be asked whether they would like to receive a summary of the findings on completion of the research.

It is hoped that recruitment will take place between January and March 2019. Interviews and analysis will take place between February and April 2019. The research will be written up between April and June 2019.

The nature of qualitative analysis means that the assumptions and perspectives held by the chief investigator will influence the interpretation of data. This influence is acknowledged in literature on Interpretative Phenomenological Analysis; 'the participant is trying to make sense of his/her world and the researcher is trying to make sense of how the participant is trying to make sense of his/her world' (Smith & Eatough, 2007, pp.36). To minimise the impact of this influence during the research, participants' words will be used as much as possible to ensure the interpretation is grounded in the data. The chief investigator will also keep a reflective journal so that they explicitly recognise their own assumptions, biases, values and judgements. Furthermore, the academic supervisors will provide feedback on the coding of the initial interview data and may undertake some comparative coding.

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?

- Design of the research
- Management of the research
- Undertaking the research
- Analysis of results
- Dissemination of findings

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 None of the above*Give details of involvement, or if none please justify the absence of involvement.*

LVAD-users under the care of Wythenshawe hospital (Manchester Foundation Trust) have had the opportunity to discuss the proposed research. Their input has been used to inform the interview schedule.

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
- 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: No upper age limit

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

- Adult (aged 18-years or above)
- Currently using a left ventricular assist device (LVAD)

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- Must have had their LVAD implanted for at least 6 months
- Must be an outpatient
- Participants will have capacity to give informed consent and will be assumed to have capacity unless there is reason to suggest otherwise (Mental Capacity Act, 2005).

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

- People who do not have capacity to give informed consent
- People who do not speak English (there are no financial resources to fund the use of interpreters).

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
Notification of research	1	0	5 minutes	Participants will be notified of the research by a clinical psychologist or nurse in their LVAD team during a routine outpatient appointment. They may have been identified as suitable by these professionals, or may self-select by asking for further information after reading a research poster in the outpatient waiting area. Potential participants may also be posted information about the research by staff in their LVAD team if they are identified as appropriate.
Reading information pack	1	0	10 minutes	Potential participants will read about the research in their own time, from the information pack given to them.
Sharing contact details with the chief investigator	1	0	Up to 5 minutes	People interested in participating or wanting further information will share their contact details and agree to be contacted by the chief investigator. They will do this either by completing the expression of interest form and returning it in the pre-paid envelope provided, or by making direct contact with the chief investigator themselves using the telephone number or email address provided in the information pack.
Optional - discussion about research/questions prior to agreeing to participate	1	0	Up to 20 minutes	Chief investigator via telephone.
Discussion to arrange time and location of the interview	1	0	5 minutes	Chief investigator via telephone or email.
Seeking consent immediately prior to interview	1	0	5-10 minutes	The chief investigator will go through participant information sheet and offer opportunity for the participant to ask questions. Following this, the participant will sign the consent form.
Semi-structured interview	1	0	Approx. 60 minutes	To take place at mutually agreed location with the chief investigator. This will include debrief procedures.

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

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Participants may be expected to spend up to 1 hour 55 minutes to undertake all aspects of the research procedure. The maximum length of time required will be used by those wishing to discuss the project further prior to deciding whether to take part, this is optional. It is likely to be 10 months between initial notification and contact about the research and being contacted with the findings.

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. However, talking about body image, appearance and the experience of living with an LVAD may be upsetting for adults participating. If a participant becomes upset, they will be asked whether they would like a break, and then offered the following options:

- a) to continue with the interview
- b) to end the interview and rearrange the rest of it for another time
- c) to end the interview and withdraw from taking part.

As part of the debrief procedure at the end of the interview participants may be signposted to talk to the clinical psychologist in their LVAD team, or access further support via their GP. Information regarding these sources of support, alongside contact details for The Samaritans (24 hour emotional support), and British Heart Foundation's 'Heart Helpline', will be provided within the debrief sheet.

Participants will be informed that they can withdraw their data at any time during the interview and up to two weeks after the interview date by contacting the chief investigator. Participants will not be able to withdraw their data more than two weeks after participating as it will have been anonymised.

Confidentiality will be maintained at all times. The participants will be informed of exceptions to this, via the participant information and by the chief investigator at the start of the interview. These exceptions include disclosure of risk to self or others which will trigger appropriate safeguarding procedures, and the academic supervisors listening to the audio recording and/or reading the transcript of at least one of the interviews.

Possible burdens for the participants include giving up their time for the interview and travel to the interview. Interviews will take place at a mutually agreed location, either at the hospital in which their LVAD care team is based, or their home. Telephone or skype interviews may be arranged if it is going to be too difficult to meet face-to-face with someone who wishes to participate (e.g. as there are only 6 UK hospitals who implant LVADs, some participants live significant distances from their LVAD care team, and it may not be feasible for the chief investigator to travel to their home address). Participants who travel to the interview will be reimbursed for their mileage or public transport costs, up to £10.

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 possible that participants might disclose risk to themselves or other people. If this occurs, participants will be reminded of the chief investigator's professional responsibility to report this to the appropriate individuals, perhaps including the person's GP, their LVAD care team, or the police.

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

There are no specific benefits for taking part in this research. But, some participants may value an opportunity to discuss their experiences and share knowledge to inform the evidence-base about the needs of LVAD-users.

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

The chief investigator will offer the opportunity for participants to be interviewed either at home or in a private room in the hospital in which their LVAD care team is based. The chief investigator will follow the lone worker policy for the trust by which they are employed (Lancaster Care Foundation Trust). The lone worker policies of the host trusts (in which recruitment takes place) will also be consulted and adhered to.

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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).

Potential participants will be identified as follows:

1. The chief investigator will provide clinical psychology and nursing staff in the LVAD teams with staff information sheets, explaining the research and ensuring facilitative recruitment of participants. They will also be provided with participant information packs which they will distribute to potential participants.
2. The clinical psychology and nursing professionals in the LVAD team will identify participants who meet the inclusion criteria during routine outpatient appointments, inform them of the research and provide them with a participant information pack.
3. There will also be research posters in outpatient waiting areas. This will inform potential participants who are interested in more information to request an information pack from their LVAD nurse or clinical psychology professional.
4. Staff in the LVAD teams may post information packs out to potential participants if they identify that they would be suitable but they do not have any upcoming outpatient appointments.

The participant information packs will include an expression of interest form. The chief investigator will not have access to any personal information or know the names of potential participants until they have signed and posted the expression of interest form, giving consent to be contacted. Alternatively, potential participants may contact the chief investigator directly on the contact details provided in the information pack.

If sufficient participant numbers have not been reached by recruiting within NHS LVAD services, the research will be advertised via a private Facebook group for UK LVAD-users. A poster will be shared by the group's administrator recommending that anyone who is interested in participating who would like further information (an information pack) should contact the chief investigator directly via email or their research telephone.

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:

Only those NHS staff (clinical psychologists and nursing professionals) in the LVAD team responsible for potential participants' care will access their data to identify whether they are suitable for the study. These staff will also tell potential participants about the research and hand information packs to those interested, the chief investigator will not be part of this process.

The chief investigator will not have access to the identifiable personal information of patients until they have consented for this and provided personal data via the expression of interest form.

If the potential participant has been recruited via Facebook they will have been responsible for providing their own personal data to the chief investigator in order to receive an information pack.

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).

Posters will be placed in outpatient waiting areas in the transplant units of the host trusts, where LVAD-users attend

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for their outpatient appointments. They will outline the research and inclusion criteria, and recommend that anyone interested in taking part should request an information pack from a nurse or clinical psychologist in the LVAD team. These staff will have been briefed on recruitment via a staff information sheet which will help them explain the research to potential participants and ensure recruitment is not coerced.

A version of the same poster has been adapted for use in the event that recruitment within NHS services does not provide enough participants and recruitment via Facebook is pursued. In this case, the poster will be shared with members of a private UK LVAD-user group by a group administrator. The poster will request that interested people should contact the chief investigator directly for more information.

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

Clinical psychologists and nursing professionals from the LVAD teams in the host trusts will talk directly to potential participants under their care about the research and give out participant information packs to those interested. The participant information packs will include a covering letter, a participant information sheet, an expression of interest form and a stamped addressed envelope.

Staff members will discuss the study and the contents of the participant information pack with potential participants and ask them whether they will sign the expression of interest form, providing their contact details to allow the chief investigator to contact them with further information. Alternatively, to maintain anonymity of participation, potential participants can return an expression of interest form via a stamped self-addressed envelope if they are interested in participating or would like further information. The decision to participate or not in the study will be entirely voluntary.

In the event that staff have posted participant information packs to potential participants who meet the inclusion criteria, they will telephone them within two weeks to confirm they have received the information and to discuss the study with them. Potential participants who receive the information packs by post will be required to show their interest in participating by completing the expression of interest form and returning it in the stamped self-addressed envelope provided, or by contacting the chief investigator directly.

Prior to this, the chief investigator will meet with (or have a telephone call with) a clinical psychologist in the LVAD team to thoroughly explain the study, the staff information sheet, and the participant information packs. Clinical psychologists will then share this information with nursing professionals in their team. All healthcare staff involved in recruitment will be told that they can share information about the study with potential participants but they should not coerce people into participating.

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.

Steps to obtaining informed consent:

1. The participants will receive an expression of interest form in the information pack, alongside a cover letter and participant information sheet for them to keep. If a signed expression of interest form is returned, or they make direct contact with the chief investigator by email or telephone, participants will be contacted by the chief investigator to provide more information and/or arrange an interview.
2. Immediately prior to each interview the chief investigator will gain fully informed consent from the participant. This will be done by ensuring that participants read the information sheet and that they understood it. Participants will be offered the opportunity to ask any questions they have about the research. Then the chief investigator will go through the consent form with the participant, checking that this has been fully understood, and that their decision to take part is voluntary. If the participant shows an awareness that they don't have to take part if they do not want to, demonstrates a good understanding of the project, and would still like to participate, then the consent form will be completed. Participants will be given a copy to keep.

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

n/a

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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?

Potential participants who show an interest in the study will have time to be able to decide whether to take part prior to completing an expression of interest form. They can continue to consider their decision between completing the expression of interest form and when they attend for interview (as this is when consent will be gained). This may be a few days or weeks after initial contact is made.

Participants may change their mind about taking part and withdraw their interest prior to or during the interview, or up to 2 weeks after the interview is completed. Recruitment will stop when enough people have been interviewed.

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)

The study has no financial resources to fund the use of interpreters. Therefore, people who do not speak English will not be invited to participate.

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 any participant who has given informed consent and completed an interview contacts the chief investigator within 2 weeks of their interview to withdraw consent their data will be withdrawn from the research. They do not need to give a reason for withdrawing. After two weeks the participant's data will no longer be identifiable as it will have been transcribed and anonymised.

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)

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- 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:

Participants will provide personal telephone numbers and/or email addresses and/or postal addresses in order to arrange interviews, request further information about the research (including requesting information packs), or for the chief investigator to conduct a telephone interview or contact the participant about findings. All personal data will be stored securely, if data is received electronically it will be stored as a password protected document, if any personal data is recorded on paper and/or received by post this will be stored securely in a locked filing cabinet in the chief investigator's home.

The use of anonymised, direct quotations from participants is central to qualitative methodology, ensuring the interpretation of findings remains grounded in the data. Audio recording is essential to accurately capture the words used by participants during the interview, as this is crucial for the analysis. Transcriptions and digital audio recordings will be stored as encrypted files.

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

Data on the portable digital audio-recorder cannot be encrypted. All identifiable data stored on the digital audio-recorder will be deleted as quickly as possible following transfer to a secure medium, namely encrypted files on a PC. In the meantime the recorder will be stored securely.

The paper copies of the expression of interest forms and consent forms completed by participants/potential participants will be stored in a locked filing cabinet in the chief investigator's home. Electronic documents containing personal data will be password protected and stored on a secure personal drive of the Lancaster University network.

All paper and electronic documents containing personal data and contact details, will be destroyed as soon as possible. This will take place following participation in the interview, or when a person decides they do not want to take part. The longest length of time personal data will be retained for, is if a participant says they would like to receive a summary of the research at the end of the study, in this case their contact details will be retained until this summary has been sent out.

At the end of the study, the paper consent forms will be electronically scanned and stored securely as encrypted files, the paper copies will then be securely destroyed.

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.

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The transcriptions and digital recordings will be stored as encrypted files. All identifying information will be removed from the data during the transcription process. The digital recordings will be destroyed as soon as they are transcribed (within 3 months).

Each participant will have the opportunity to choose a pseudonym, if they decline the offer to choose a pseudonym one will be assigned to them by the chief investigator.

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.

Only the chief investigator will have access to names and telephone numbers of participants who have registered their interest in the study using the expression of interest form completed by themselves. This is necessary for the chief investigator to be able to provide potential participants with more information, arrange interview times/locations, and feedback findings.

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?

The chief investigator will analyse the data, with support from the academic research supervisors (Dr Anna Daiches and Dr Clare Dixon). Analysis will take place in a private room either at the chief investigator's home or the Lancaster University premises.

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

	Title	Forename/Initials	Surname
	Professor	Bill	Sellwood
Post	Programme Research Director - Lancaster University Doctorate of Clinical Psychology		
Qualifications			
Work Address	Health Research, Lancaster University, Furness Building,		
Post Code	LA1 4YG		
Work Email	b.sellwood@lancaster.ac.uk		
Work Telephone	01524 593998		
Fax	n/a		

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

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

Years: 10
Months: 0

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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.

Following submission of the research project, the chief investigator will send the research coordinator at Lancaster University encrypted and password protected electronic copies of the consent forms, transcripts and coded data. Data will be transferred electronically using a secure method that is supported by the University (at present this is done using a secure, academic file on Box.com).

The research coordinator will save the files in password-protected file space on the university server. The chief investigator will send a separate email to the research coordinator including the passwords for the encrypted data and the year in which the files should be destroyed. This date will be 10 years after submission of the research, as per the procedures outlined by Lancaster University Doctorate in Clinical Psychology programme.

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 who incur travel costs to attend an interview will be reimbursed by Lancaster University, up to the value of £10. Participants will be required to provide tickets for travel on public transport, or mileage calculations for travel by car, to inform the amount they will be reimbursed. The procedure for reimbursing participants for travel is outlined on the participant information sheet.

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.

It is intended that the research will be published in a peer-reviewed journal and therefore have its abstract published

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on the journal's website.

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)

After completion of the research a summary of the findings will be shared with the participants if they said they would like to receive a copy. A summary of the findings will also be shared with staff in the LVAD teams who recruited to the study.

The findings will also be presented at Lancaster University to staff and students of the Doctorate of Clinical Psychology programme.

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

Any identifiable personal information will be removed from the data during transcription and pseudonyms will be used throughout, therefore ensuring anonymity at publication.

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.

After the interview, participants will be asked whether they would like to receive a summary of the findings upon completion of the research. This will be sent to them via email or post, according to their preference.

As described earlier, all of the participants' personal data will be stored securely either as password protected files or in a locked filing cabinet in the chief investigator's home and destroyed once participants are informed of the results of the research.

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

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- Review within a multi-centre research group
- 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:

A proposal of the research underwent a peer-review process by research staff on Lancaster University Doctorate of Clinical Psychology course. Please see the email correspondence enclosed confirming the peer-review.

The research has undergone further review during discussions between the chief investigator and both the academic and field supervisors.

During consideration for sponsorship, the study was reviewed by member(s) of Lancaster University Faculty of Health & Medicine Research Ethics Committee.

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): 12
Total in European Economic Area: 12

Further details:

Between 6 and 12 participants will be recruited for the research.

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.*

It is expected that between 6 and 12 participants will allow adequate data for interpretative phenomenological analysis (IPA) to be conducted, without becoming overwhelming or losing individual differences between the accounts. This number is considered appropriate for qualitative research, given the depth of analysis required.

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.

Data collected at interview will be analysed using Interpretative Phenomenological Analysis (IPA). This approach is commonly used in psychological research to explore how particular groups of people make sense of their individual personal and lived experiences (Smith, Flowers, & Larkin, 2009). The steps which will be taken are outlined below:

1. Interviews will be transcribed verbatim by the chief investigator
2. Transcripts will be analysed individually, one at a time.
3. For each case, the transcript will be read and re-read so that the chief investigator becomes familiar with the data.
4. The transcript will be examined line by line and initial notes/comments on the content and language will be made in the margins.
5. These comments will be chronologically examined to identify potential emergent themes (signifying a higher level of interpretation).
6. Patterns across these emergent themes will be identified, to understand how the data might fit together.
7. The above process will be repeated for the remaining transcripts.
8. Then, patterns will be identified across cases; the chief investigator will take note of similarities and differences.
9. The data will be organised into superordinate themes and subthemes.

Reference:

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Smith, J., Flowers, P., & Larkin, M. (2009). Interpretative Phenomenological Analysis: theory, method and research. London: Sage.

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
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: Non-Commercial
 Commercial

If Other, please specify:

Contact person

Name of organisation Lancaster University
 Given name Becky
 Family name Gordon
 Address Research Support and Systems Manager, Research Services, Faculty of Health and Medicine

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Town/city	Lancaster University, Lancaster
Post code	LA1 4YG
Country	UNITED KINGDOM
Telephone	+44 (0) 1524 592981
Fax	n/a
E-mail	ethics@lancaster.ac.uk

A65. Has external funding for the research been secured?*Please tick at least one check box.*

- 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:
n/a**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:**

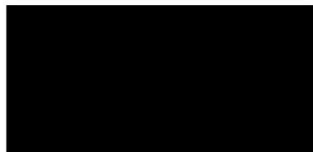
Title	Forename/Initials	Surname
Organisation		
Address		
Post Code		

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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: 01/01/2019

Planned end date: 01/08/2019

Total duration:

Years: 0 Months: 7 Days: 1

A71-1. Is this study?

- Single centre
 Multicentre

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

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

Total UK sites in study 2

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:

- NHS organisations in England 2
 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

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- Probation areas
- Independent (private or voluntary sector) organisations
- Educational establishments
- Independent research units
- Other (give details)

Total UK sites in study: 2

A73-1. Will potential participants be identified through any organisations other than the research sites listed above? Yes No**A73-2. If yes, will any of these organisations be NHS organisations?** Yes No*If yes, details should be given in Part C.***A74. What arrangements are in place for monitoring and auditing the conduct of the research?**

The chief investigator will provide regular email updates regarding the research to the research supervisor and field supervisors (minimum of once per month). The chief investigator and research supervisor will also speak about the research once a month, either in person or by telephone/skype, to monitor the conduct of the research.

A research contract has been agreed between the chief investigator, research supervisor and field supervisors. The contract includes the key responsibilities of each person during each stage of the research. A copy of this contract has been submitted to Lancaster University Doctorate of Clinical Psychology.

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*

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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)

Lancaster University legal liability cover will apply.

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 further information please refer to guidance.

Investigator identifier	Research site	Investigator Name
IN1	<input checked="" type="radio"/> NHS/HSC Site <input type="radio"/> Non-NHS/HSC Site Organisation name Address Post Code Country	Forename Middle name Family name Email Qualification (MD...) Country
IN2	<input checked="" type="radio"/> NHS/HSC Site <input type="radio"/> Non-NHS/HSC Site Organisation name Address Post Code Country	Forename Middle name Family name Email Qualification (MD...) Country

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 fulfil the responsibilities of the chief investigator for this study as set out in the UK Policy Framework for Health and Social Care Research.
3. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.
4. 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.
5. 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.
6. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.
7. 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.
8. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.
9. 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 2018.
10. 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.
11. 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 2018.
12. 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 Health Research Authority (HRA) together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after the issue of the ethics committee's final opinion or the withdrawal of the application.

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

HRA would like to include a contact point with the published summary of the study for those wishing to seek further

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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 Hannah Gordon on 01/02/2019 10:04.

Job Title/Post: Trainee Clinical Psychologist
Organisation: Lancaster University
Email: h.gordon@lancaster.ac.uk

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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 responsibilities of sponsors set out in the UK Policy Framework for Health and Social Care Research will be fulfilled 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 publicly 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 01/02/2019 14:52.

Job Title/Post: Deputy Head of Research Services
Organisation: Lancaster University
Email: b.gordon@lancaster.ac.uk

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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 UK Policy Framework for Health and Social Care Research.
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 Dr Clare Dixon on 01/02/2019 10:11.

Job Title/Post: Clinical Tutor
Organisation: Lancaster University
Email: c.dixon3@lancaster.ac.uk

Academic supervisor 2

This section was signed electronically by Dr Anna Daiches on 01/02/2019 10:33.

Job Title/Post: Consultant Clinical Psychologist
Organisation: Lancaster University
Email: a.daiches@lancaster.ac.uk

Research Protocol

(Version 2, 20/01/19)

Title

The Experience of Body-Image for People with a Left Ventricular Assist Device.

Introduction

It is estimated that 12-18 percent of NHS expenditure on long-term physical illness is related to difficulties with mental health (Naylor et al., 2012). Research by The King's Fund has shown that people with long-term physical health difficulties are two to three times more likely to experience mental health difficulties, such as anxiety and low mood; this can be particularly harmful and, if left untreated, may exacerbate physical illness (Naylor et al., 2012). For example, mortality rates after coronary bypass surgery are significantly increased for people experiencing depression (Blumenthal et al., 2003). In order to provide better, integrated psychological support for those with long-term physical illnesses, it is imperative to understand the types of difficulties that may be faced by those living with them (Naylor et al., 2016).

Changes to body image are one such challenge, which pose a risk to the psychological wellbeing of those with physical illnesses. Cash (2004) explains that "body image refers to the multifaceted psychological experience of embodiment, especially but not exclusively one's physical appearance...It encompasses one's body-related self-perceptions and self-attitudes, including thoughts, beliefs, feelings, and behaviors" (p.1-2). Physical health difficulties and their treatment may cause substantial changes to the appearance and functioning of an individual's body, positively or negatively altering their body image, psychological wellbeing and quality of life as a result (Cash, 2004).

Negative body image has been identified as a factor contributing to psychological distress for people experiencing a range of physical health difficulties (e.g. Friedman,

Reichmann, Costanzo & Musante, 2002; Khalid, Malik, Musharraf, 2018; Przewdziecki et al., 2013). Visible differences, such as scarring, can have a negative impact on body image, self-concept and adjustment, leading to social anxiety, isolation and low mood (Bessell & Moss, 2007). When bodily impairment negatively affects an individual's psychological experiences, feelings and attitudes towards their body, it can take some time for gradual adjustment and acceptance to their different body (Taleporos & McCabe, 2002). Therefore, it is important to understand the experiences of body image for those experiencing physical illnesses, so that the potentially harmful impact of changes to body image on psychological wellbeing may be recognised and addressed.

The number of patients waiting on the UK heart transplant list on 31st March 2018 showed a 205% increase since 2008, compared with only a 52% increase in the number of transplants conducted in the same period (NHS Blood and Transplant, 2018b, pp. 62). The development of Left Ventricular Assist Devices (LVADs), which are mechanical circulatory pumps, mean that some people with end-stage heart failure can be mechanically supported until a suitable donor heart is found. In these cases, the LVAD is life-sustaining and used a 'bridge to transplant' (BTT). The LVAD pump, which sits next to the heart, is connected to an external controller by a fine cable which exits through the skin. The controller connects to two external rechargeable battery packs which are carried on the person. The external LVAD components are bulky, heavy and usually carried in a bag or harness worn over the shoulders (British Heart Foundation, n.d).

Six sites in the UK offer adult LVAD implantation; 768 long-term VADs were implanted in the 10-year period 1 April 2007 to 31 March 2017 (NHS Blood and Transplant, 2018a, pp. 14). During 2016/2017, 106 VAD implantations took place nationally, 3.7 times higher than 2007/2008 (NHS Blood and Transplant, 2018a, pp. 14). For adults implanted between 1st April 2013 to 31st March 2016, the median time on long-term VAD was 675

days, ranging from 258-1708 days (NHS Blood and Transplant, 2018a, pp. 18). LVAD implantation can lead to improvements in an individual's functional capacity, daily physical activity levels, and perceived quality of life (QoL) (Grady et al., 2004; Jakovljevic et al., 2014; Kugler et al., 2011; Rogers et al., 2010).

As the number of people receiving LVADs in the UK increases, important research on the impact of LVAD-use on psychosocial wellbeing has emerged. Most of the current evidence base focuses broadly on quality of life and 'adjustment' or 'coping' post-implantation (e.g. Casida, Marcuccilli, Peters, & Wright, 2011; Chapman, Parameshwar, Jenkins, Large, & Tsui, 2007). One mixed-method study found that, despite perceived improvements in QoL early after implant, emotional distress remains high (Modica et al., 2014). A qualitative study of retrospective reflections on the use of an LVAD by those who went on to receive a heart transplant found that the LVAD dramatically changed an individual's body and sense of self (Chapman et al., 2007); for some the incorporation of the device into their body image occurred without much difficulty, for others restriction to their everyday functioning and perceived physical and psychological scars from the experience of LVAD implantation led to difficulties adapting.

Factors relating to the body and external components of the LVAD which may cause difficulties adjusting post-implantation e.g. difficulty showering, buying clothing, are briefly but frequently mentioned in the literature (e.g. Casida et al., 2011). For example, some people have reported changing the way they dress to hide the external components of the device, to appear 'normal' (Marcuccilli, Casida & Peters, 2013). Marcuccilli & Casida (2012) suggest that perception of body image is a key factor in the success of adapting to an LVAD. Furthermore, a recent metasynthesis concluded that interventions focused on body image recovery might be beneficial to support coping and reduce poor psychological outcomes for those living with an LVAD (Abshire, Prichard, Cajita, DiGiacomo & Himmelfarb, 2016).

However, experiences of body image in those currently using an LVAD are yet to be understood and explored in any detail. A single case study aimed to address the lack of knowledge around clothing issues relating to body image for people with LVADs. It found that appropriate choice of clothing was necessary to preserve function of the device and the individual's satisfaction with her body image (Marcuccilli & Casida, 2012).

Research of other illnesses, where external medical equipment/devices are a necessary part of treatment, may be considered to try and understand the possible impact of the LVAD on body image. Reporting on peoples' experiences of stoma surgery, Manderson (2005) found that the stoma bag undermined self-esteem and body image and suggested that there is a challenge during recovery to re-establish a sense of identity separate from the compromised body. At times, individuals are prevented from presenting a preferred 'normal' self and they may engage in strategies to try to conceal their medical device (Gately, Rogers, Kirk, & McNally, 2008). A qualitative metasynthesis of the use of medical devices in long-term condition management found that the use of a device made illness more tangible and visible to others; this, along with potential for stigma, shame and loss of dignity, impacted on body image and identity (Gately et al., 2008). As the LVAD equipment includes substantial external components, one might hypothesise a similarly significant, potentially negative, impact on an LVAD-user's body image.

Aims of this study

Although the research around adaptation following LVAD-implantation is growing, there remains a paucity of knowledge around the impact of LVAD use on body image. As research in the broader physical health setting indicates the potentially harmful impact of negative body image on psychological wellbeing, physical health and illness-management, it is important to gain a better understanding of the experience for those using an LVAD. This study aims to explore the experience of body image for adults implanted with an LVAD. It

will consider individuals' perceptions of their body and appearance and their perspectives on the changes to their body, in the form of weight/shape change and having to wear the external components of the device.

The International Society for Heart and Lung Transplantation guidelines (ISHLT; Feldman et al., 2013) recommend psychosocial support, including psychological assessment and intervention, as part of post-operative management for those receiving mechanical circulatory support. It is hoped that this research will contribute to the current evidence base and inform the practice of clinical psychologists in adult health settings. In addition, it is hoped that this study will inform the support offered by wider health professionals to promote the psychosocial wellbeing of the expanding population of individuals using LVADs.

Method

Design

A qualitative approach to the collection and analysis of data will be used for this study. Face-to-face interviews will be used where possible. However, due to the geographical spread of potential participants in the UK, interviews may take place via telephone or skype if a face-to-face interview is not achievable. A semi-structured interview schedule will be used to guide discussion around the aims of the research, whilst also allowing flexibility in the interview process to ensure participants are able to share their experiences and views. The schedule includes general topic areas and example questions (Appendix A). This was developed through a review of existing literature and consultation with service users.

Interpretative Phenomenological Analysis (IPA) will be used to analyse the data. The aim of this approach is to 'explore in detail individual personal and lived experience and to examine how participants are making sense of their personal and social world' (Smith & Eatough, 2007, p.51). The meanings that experiences hold for individuals are the focus of IPA; this approach has been shown to be well-suited within the fields of health, clinical and

social psychology research where there is interest in understanding how people make sense of significant life events (Smith, 2004; Smith, 2011; Smith & Eatough, 2007). Three theoretical positions underpin IPA; phenomenology, hermeneutics, and idiography. The phenomenological nature of IPA allows lived experience to be expressed through the analysis, rather than relying on categories which have been pre-defined. Hermeneutics allow for the interpretative role of the researcher to be recognised during the analysis process. The idiographic approach encourages the chief investigator to recognise and focus on the individual contexts and perspectives of each participant, as well as the generalised understanding of the sample (Smith, Flowers, & Larkin, 2009).

Materials

Transplant service staff members who are assisting with recruitment will be provided with a staff information sheet to support them with explaining the study and to ensure recruitment is conducted in a facilitative way (Appendix B). A poster advertising the study will be displayed in the patient waiting areas of the participating transplant services (Appendix C). Potential participants will be given an information pack (Appendix D). This will include a cover letter, a participation information sheet, an expression of interest form, and a stamped addressed envelope for participants to read about the study and to register their interest in finding out more information or taking part. Participants will be asked to complete a consent form before the interview commences (Appendix E). The interview will be guided by the semi-structured interview schedule (Appendix A), following which participants will be given a debrief sheet (Appendix F).

Lancaster University will provide secure space for data storage and the equipment used for the recording and transcription of the interviews e.g. digital recorder, foot pedal.

Participants

Participants will be primarily recruited from two of the six NHS transplant services offering LVAD implantation in the UK; [REDACTED], [REDACTED] and [REDACTED], [REDACTED]. From consultation with healthcare professionals [REDACTED], it is anticipated that the number of LVAD-users receiving care at these two sites will be sufficient to provide the sample required. A sample of 6-12 participants will be aimed for, selected on a first-come first-served basis. This will provide enough data for similarities to be drawn between accounts, without individual differences being lost (Smith et al., 2009). If further participants are required recruitment will be expanded and the study will be advertised on Facebook via a private support group for UK LVAD-users called 'LVAD life UK'.

Throughout the study a purposive sampling technique will be employed, potential participants will be deemed suitable for the study if they meet the following inclusion criteria:

- Aged 18 years or over.
- Capacity to consent.
- Currently using an LVAD, which was implanted at least 6 months ago. – Research suggests that some people experience weight gain after implantation (e.g. Thomas, Hanson, Woscyna, & Lowes, 2016); however, weight gain does not usually start to occur until after 3 months post-implantation. By interviewing people at least 6 months after implantation, weight changes may be captured. Furthermore, this means participants will have experienced adjusting to and living with their LVAD for some time.
- Must be an outpatient.
- Must speak English, as there are no financial resources to fund the use of interpreters.

Procedure

Participants will be recruited by staff members in their care team (LVAD nurses or clinical psychologists) or by posters in the transplant units where LVAD-users attend outpatient

appointments. Clinical psychologists for the LVAD services will facilitate the identification and recruitment of participants meeting the inclusion criteria by members of LVAD nursing staff. Potential participants identified by the team will either be given an information pack whilst attending for regular outpatient appointments, or it may be posted to them. Posters advertising the study will advise potential participants that they can request an information pack from clinical psychologists or LVAD co-ordinators within the team.

The research will be explained to members of staff in the LVAD team, they will be given staff information sheets (Appendix B) and the opportunity to ask questions. Staff will be provided with participant information packs (Appendix D) to be distributed to potential participants. Staff members will discuss the study with potential participants and ask them whether they will sign the expression of interest form, providing their contact details to allow the chief investigator to contact them with further information. Alternatively, to maintain anonymity of participation, each information pack will include a stamped addressed envelope in which potential participants can return the expression of interest form requesting further information or to register an interest in taking part. The participant information sheet will explain that involvement in the study is voluntary and confidentiality will be maintained, unless a risk to self or others is identified.

If further participants are required after the initial recruitment stage, the study will be advertised on a private Facebook page for LVAD-users in the UK ('LVAD life UK'). The chief investigator will ask the group administrators to share a research poster which will invite people who are interested to contact the chief investigator directly for further information (Appendix G). Information packs will be sent to these people by email or post, according to their preference.

All potential participants will be asked to express an interest in participating in the study by contacting the chief investigator directly by telephone, text or email, or by

completing the expression of interest form to share their contact details in order for the chief investigator to contact them. As only a small sample of participants is required for this study, it is possible that people will express an interest after the target sample is achieved. It will not be feasible to interview further participants after the target is achieved due to the limited time frame of this research. The participant information sheet will explain that in this instance, the chief investigator will contact the interested people to inform them that no further interviews are being conducted.

Interviews will be arranged at a mutually convenient time and place; this may be in a room at the hospital where participants attend for LVAD outpatient appointments, or at the participant's home. When conducting interviews, the chief investigator will continually monitor personal safety and follow lone worker policies, as provided by Lancaster University and Lancashire Care NHS Foundation Trust. The chief investigator will discuss the contents of the participant information sheet, confidentiality, and the consent form with the participant, giving the opportunity for any questions before the consent form is completed.

The semi-structured interview schedule will be used to guide questioning during the interviews, which are expected to last approximately 60 minutes. Should a participant become upset during the interview they will be offered the chance to take a break or to end the interview. At the end of the interview participants will be provided with a debrief sheet (Appendix F). The debrief sheet will outline sources of support for participants to contact if they feel distressed by anything that came up in the interview. Participants will be advised that they may speak to the clinical psychologist in their LVAD care team, or to their GP. Contact details for The Samaritans and British Heart Foundation's 'heart helpline' will also be provided. Following the interview participants will also be given the opportunity to choose a pseudonym for when their interview is anonymised during write-up. The recorded interviews will be transcribed verbatim and all identifying information will be removed e.g.

names, places. The digital recordings will be deleted following transcription, which may be up to 3 months after the interview.

Due to the large geographical area being recruited from, if face-to-face interviews are not possible telephone or skype interviews may be arranged. In this instance, a consent form will be posted to participants before the interview takes place and they will be asked to return it in a pre-paid envelope. Following the interview, the debrief sheet will be sent to the participant by email or post.

Proposed analysis

The data, namely subjective accounts, will be analysed using IPA in line with guidance from Smith et al. (2009). Given the idiographic nature of IPA, each case will be analysed in detail separately, before comparisons are drawn between the participants. The chief investigator will record a summary of their assumptions and impressions of each interview before analysing subsequent interviews, in an effort to isolate previous analyses. Personal reflections will also be recorded throughout the analysis process.

For each case, the transcript will be read and re-read to familiarise the chief investigator with the data and begin the process of entering the participant's world. The second stage of the analysis is initial noting; the transcript will be examined line by line so that semantic content and language use relevant to the research aims can be commented on. Next, the exploratory comments will be examined chronologically to look for potential emergent themes. Then, patterns and connections between these emergent themes will be identified, to get an understanding of how they might fit together. Following this, the chief investigator will move to the next case and repeat the above process. Once the initial analysis is completed for each case the next step will be to look for patterns across cases to identify similarities and differences, whilst referring to the original transcripts to check meaning and

ensure accuracy. Data will be organised into superordinate themes and subthemes, labelled according to their meaning.

Practical Issues

For this research there are several practical issues which will be addressed. It is important that participants can contact the chief investigator to ask questions about the study. The chief investigator will also require a means to contact participants who have expressed an interest in participating. Therefore, Lancaster University will provide the chief investigator with a mobile telephone to make and receive texts and calls from participants. Where travel costs have been incurred by participants, these will be reimbursed by up to £10 by the university. The chief investigator's travel expenses outside the north west region will be covered by Lancaster University. Further financial implications include printing, photocopying, postage, the provision of prepaid envelopes to participants, and telephone interview costs. These will be covered by the university.

Staff members at the LVAD services will offer support with booking rooms at the hospitals for interviews. All personal data received during the study will be stored securely. Electronic data, for example audio recordings and transcripts, will be stored as encrypted files on the secure university network which is accessible from the chief investigator's home by the virtual private network (VPN). Paper copies of any documents containing personal information e.g. consent forms and expression of interest forms, will be kept securely in a locked filing cabinet in at the chief investigator's home address. All paper and electronic documents containing personal information, including names and contact details, will be destroyed as soon as possible e.g. if someone chooses not to participate, if the target number of interviews has been achieved. The longest length of time personal data will be stored is if a participant has chosen to receive a summary of the findings at the end of the study. On such occasions, personal data will be destroyed as soon as this summary is sent to the participant.

Ethical Considerations

To achieve informed consent, clear information will be provided to potential participants in the information packs and during all discussions about the research prior to signing a consent form at the time of interview. The chief investigator will not have access to personal information until it is shared by participants themselves by expressing an interest in taking part in the study. As staff members who are known to potential participants will be supporting recruitment, their approach will be carefully considered. Prior to recruitment the research will be discussed with staff and they will receive staff information sheets. It is important that staff ensure that participants are fully informed that their participation is voluntary and their decision to participate or to not participate will not affect their care in any way. Furthermore, participants will be made aware that they have the right to withdraw from the research at any stage of the process, up until 2 weeks after the interview. Following this their data will have been transcribed and anonymised.

Confidentiality will be detailed in the participation information sheet and will be verbally discussed prior to the interview and consent process. Participants will be made aware that confidentiality will be maintained unless information arises which indicates a risk to themselves or other people. The chief investigator will familiarise themselves with the appropriate staff or services to inform should risk be indicated. The service or Facebook group from which participants are recruited will not be informed of who participates.

Confidentiality will be maintained during the write up and dissemination of the research by the removal of identifying information. The academic supervisors will review one of the digital recordings to offer guidance on any necessary adaptations to the interview schedule or style of questioning. Participants will be made aware that the academic supervisors may access the digital recordings and/or transcript, and that they will maintain the confidentiality of the interview. The digital recordings will be destroyed after transcription,

which is likely to be completed within 3 months. The transcripts will be stored securely by for up to ten years following submission of the research project, as per the procedures outlined by Lancaster University Doctorate in Clinical Psychology programme.

Participants will be informed via the participant information sheet that anonymised extracts from their interview will be used in the research report and any further dissemination strategies e.g. presentations and publications. Prior to the interview this will be discussed, and participants will be asked to provide their consent via the consent form. The findings of the study will be fed back to participants and UK LVAD centres, and written up for publication.

Distress. Prior to consenting to take part in the study participants will be aware that the interview will involve discussions about their body image and appearance. It is possible that the interview process may raise topics that make participants feel upset. At the beginning of the interview, participants will be reminded that they can choose not to answer any questions they do not feel comfortable with and they can withdraw their consent at any time, up until 2 weeks after the interview. If a participant becomes distressed during the interview it will be stopped immediately and they will be asked whether they would like to take a break or to not continue. In both cases, time will be given at the end of the interview to discuss their distress further with the chief investigator, to ensure they have appropriate support in place.

All participants will be given a debrief sheet at the end of the interview which will include guidance and contact details for sources of support, including their GP. If a participant has become distressed and they have been recruited via their LVAD service, they will be informed that a referral to the clinical psychologist in their LVAD team can be made by the chief investigator or requested by themselves at a later date. If a participant is recruited from the advertisement on Facebook they would be advised to visit their GP or contact their LVAD care team for support. If a participant were to become acutely distressed and in need of psychiatric support standard procedures would be followed. This would include ensuring

the participant attends the nearest accident and emergency department, where there is 24-hour psychiatric assessment support. The emergency services may be contacted by phoning 999.

Timescale

1. January 2019: submission of material for NHS research ethical committee approval.

The following timescales are subject to full ethical approval being obtained, any delays will lead to readjustment in the below schedule.

2. January 2019: local Research and Development teams at each of the planned sites will be contacted.
3. January/February 2019: approved research materials will be posted out to sites to be given out by known workers.
4. February - March 2019: recruitment of participants will take place.
5. February – April 2019: interviews, transcription and data analysis will be undertaken.
6. April – June 2019: research will be written-up, including draft reading process.
7. June 2019: research submission.
8. Following submission dissemination strategies will commence.

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Appendix 4-A

Interview Schedule

The Experience of Body Image for People with a Left Ventricular Assist Device



THE DIVISION OF HEALTH RESEARCH
Doctorate in Clinical Psychology

Interview schedule

Introduction

Thank you for agreeing to take part in my research. My name is Hannah and I am a Trainee Clinical Psychologist from Lancaster University. The aim of the interview is to hear about your experiences of body image and your appearance, relating to your LVAD. I will ask you some questions, but you can choose to not answer any of these questions. The interview should take about an hour. If you want to take a break or stop at any time please let me know.

As outlined in the information sheet, what we discuss will remain confidential. But, if you say anything that makes me believe that you or someone else is at risk of harm, or is being harmed, I will have to share this information with the appropriate people to keep that person safe.

I have a digital recorder to record our interview, this is to make sure I have captured exactly what you said. First, I will ask if you have any questions. Then, I will ask you to fill in a consent form which asks whether you agree to participate in the project. You will keep this consent form and I will take a copy for study records which will be stored securely.

- Do you have any questions you would like to ask me?
- Discuss and complete consent form.
- Collect basic demographic information e.g. type of LVAD device.

Each interview will be guided by general topic areas. However, specific questions will be influenced by, and attuned to, the responses given by individual participants.

****I WILL START RECORDING NOW****

General information regarding experiences of LVAD:

- Can you briefly explain what led you to be implanted with an LVAD? I'm particularly interested in whether this was after a long or short period of illness.
- What it is like for you to live with an LVAD?

Prompts:

How does the LVAD affect your everyday life?

How would you describe what the LVAD means to you?

Overall experiences of body image:

- How would you describe your physical appearance? This might include weight, shape, body and other aspects of appearance e.g. clothing.

- How do you think other people view your body/appearance?

Prompts:

Has your body/appearance changed since having an LVAD? If so, how?

How often do you think about the way you look? Is this different to before LVAD implantation?

How do you feel about your body/appearance?

Influence of LVAD on body image:

- How has having an LVAD influenced the way you view your body/appearance?
- Why do you think there's been a change in the way you view your body/appearance?
- How has having an LVAD made a difference to how others view your body/appearance?
- What has led to the change in the way others view your body/appearance?

Impact of body image on care/life:

- Do your beliefs (or what you think) about your appearance affect your day to day life? How?
- Do have any strategies or things you do differently to overcome this?
- Regarding how others view your body/appearance, do you do anything to manage this? e.g. wear different clothes

Prompts:

Day to day life - home, outside, activities, relationships, sex, health, wellbeing, LVAD care.

Do other people do anything to help you to manage your appearance?

Mood – anxiety about what others think? Shame/embarrassment? Avoidance of certain people, places or situations?

Is there anything else about the LVAD and your body image which it is important for me to know?

****STOP RECORDING****

Follow up:

- Give participants the debrief sheet – ensure they are not distressed about anything discussed in the interview, offer appropriate advice/signposting as needed in line with the protocol.
- As outlined in the participation information sheet ask:
 1. Would you like to choose a different name for yourself for me to use when I write up this research?
 2. Once the research is completed, would you like to receive a summary of the findings? By post or email? (Inform participants of the expected timescale for completion)
- Discuss/arrange reimbursement for travel expenses, up to £10 – as detailed in the participant information sheet.
- Ask participants if they have any further questions about the interview or the research overall. Thank participants for their time and involvement in the project.

Appendix 4-B

Staff Information Sheet

The Experience of Body Image for People with a Left Ventricular Assist Device

IRAS ID: 255988

Staff information sheet



THE DIVISION OF HEALTH RESEARCH
Doctorate in Clinical Psychology

Thank you for your time and support in helping with recruitment for this research, your efforts are much appreciated.

This sheet is intended to offer you some assistance when you are sharing information about this research with service users you are working with. If you have any questions about the research please contact me.

Who can I invite to take part in the research?

Anyone who is currently using a left ventricular assist device and has had their LVAD for at least 6 months. They must be outpatients and they also need to be able to speak English.

When should I share information about the research project with service users?

Your team should have received information packs about the research which are to be given to service users. When you have identified service users who could take part, information could be shared with them at their next outpatient appointment. If this is not possible, information packs could be sent to the identified service users by post.

How should I introduce the research?

I have been asked to tell you about some research that is taking place.

Hannah Gordon from Lancaster University is interested in talking to you about what it is like to have an LVAD and how this relates to your body image and appearance. It is hoped that the experiences people share with Hannah will be helpful in improving services and support for people living with an LVAD.

If this is something that you would like to know more about, or you think you might want to be involved in, Hannah has given me some information that I can give to you. The information pack tells you more about the research and how to contact Hannah if you want to take part or have any questions.

If you would like Hannah to contact you with more information or to talk about taking part there is a form (expression of interest form) you can complete.

Details for contacting Hannah:

Hannah Gordon Tel: [REDACTED] Email: h.gordon@lancaster.ac.uk
Address: Doctorate in Clinical Psychology, Furness College, Lancaster University, Lancaster,
United Kingdom, LA1 4YG.

Appendix 4-C**Research Poster**

IRAS ID: 255988

**THE DIVISION OF HEALTH RESEARCH**
Doctorate in Clinical Psychology

*The Experience of Body Image for People with a
Left Ventricular Assist Device*

Do you currently have an LVAD?

Have you had your LVAD for 6 months or more?

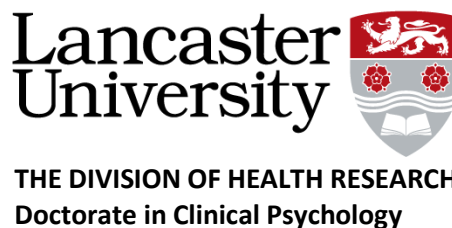
Are you an outpatient?

**Would you like to talk about your experiences of having
an LVAD and its impact on your physical appearance?**

If you answered yes to these questions and you are aged 18 or over, please speak to [insert name of team's clinical psychologist] (Clinical Psychologist) or an LVAD co-ordinator for an information pack. This will tell you more about the research that Hannah Gordon, from Lancaster University, is conducting and how you can take part.

Appendix 4-D

Participant Information Pack



Covering letter to participants

Hannah Gordon, a Trainee Clinical Psychologist studying at Lancaster University, is currently conducting a research project titled:

The Experience of Body Image for People with a Left Ventricular Assist Device.

I am writing to invite you to take part in this research. This information pack has been given or sent to you by your clinical team on Hannah's behalf; Hannah has not had access to your name or contact details. You have been asked because you have been living with an LVAD for 6 months or more. Hannah would like to talk to you about what it is like living with an LVAD and its impact on what you think about your physical appearance.

If you are interested in taking part, it is important for you to understand why the research is being done and what it will involve. Taking part would mean meeting with Hannah to discuss your experiences or speaking via telephone or skype. This would take approximately one hour. Please read the information sheet enclosed, it provides more details about this and it also tells you how to contact Hannah if you have any questions about the research or if you want to take part.

If you have received this information pack by post, it has been sent by a member of your transplant team; they may telephone you over the next couple of weeks to check you have received it. Please do not hesitate to get in touch with Hannah, or the transplant team, to talk a little more about the research using the details below:

*Hannah Gordon (Chief Investigator)
Doctorate in Clinical Psychology, Div. Of Health Research, Furness College
Lancaster University, Lancaster, LA1 4YG.
Tel: [REDACTED]
Email: h.gordon@lancaster.ac.uk*

Thank you for your time.

Kind regards,

[name of clinical psychologist], [exact professional title], [contact details]

[name and address of transplant unit]

The Experience of Body Image for People with a Left Ventricular Assist Device

IRAS ID: 255988



THE DIVISION OF HEALTH RESEARCH
Doctorate in Clinical Psychology

Information sheet

My name is Hannah Gordon and I am a Trainee Clinical Psychologist from Lancaster University. This information is about some research that I am currently conducting within UK heart and lung transplant centres, including [*insert name of recruiting hospital*]. The research is part of my doctorate training to become a clinical psychologist.

The research is supervised by Dr Anna Daiches, Deputy Programme Director and Clinical Director, Lancaster University (research supervisor), Dr Clare Dixon, Clinical Tutor, Lancaster University (research supervisor), and [REDACTED], [REDACTED] (field supervisor).

Why are we interested in talking to you?

You are someone who has had a left ventricular assist device (LVAD) for at least 6 months. Talking to you about your experiences will help us learn what it is like living with an LVAD. We are interested in hearing about your experiences of body-image, how you view your appearance, and your ideas of how this relates to having an LVAD. We are interested in learning from positive and negative experiences, as there is very little research about how LVADs influence the way people feel about their body. We hope that this information will help further inform services as to the needs of people living with an LVAD.

What would I have to do?

If you agree to take part, we will arrange to meet at a time and place that suits you. I will meet with you either in a room in your transplant service or at your home. Your travel expenses can be refunded up to £10. If you travel by public transport you will need to provide receipts. If you are travelling by car I will need to know the number of miles you will travel for the interview. If it is not possible for us to meet in person we might arrange a telephone or skype interview.

The interview will involve talking about your experience of having an LVAD and answering some questions. This will take about 1 hour. The interview will be audio-recorded so I have an accurate record of what you said. The recording will be deleted after it has been typed up.

After the interview I will ask whether you would like to choose a different name, which will be used to refer to your words and phrases when I write up the report, to make sure that your comments are anonymous. Then I will ask whether you would like to receive a summary of the findings of the research once it has been completed, either by telephone, post, or email.

Do I have to take part?

No, it is up to you. Taking part or not taking part will not change the care you receive from the transplant team. It is okay if you do not wish to participate. Also, it is okay if you choose to participate and then change your mind. You can stop, rewind or delete audio recordings

during the interview. You can withdraw any time during the interview and your data can be withdrawn afterwards, up to the point of transcription. After this time analysis will have started and I will not be able to remove individual comments. You do not have to give a reason for withdrawing.

Will my care team be told that I have taken part?

No, I am not part of the transplant team. If you agree to participate your involvement will remain confidential and the transplant team will not be told who has been interviewed. However, the transplant team may be aware that you have been given this information pack and you may disclose your participation if you wish - this will not affect your standard care.

What will happen with the information that I share?

When the interviews are typed up, any information that would identify you will be removed or changed e.g. names, places. Your typed interview will be kept as a password-protected, encrypted computer file. The audio recording or typed interview may be listened to or read by my research supervisors at the university. Every aspect of the study will be supervised by my research supervisors, who are bound by the same duties of confidentiality.

I will be writing a report about the findings of the research and this will include some anonymised quotes from the interviews, such as words or phrases. I will share the findings of the research with Lancaster University and UK transplant services. I also hope to publish the results in an academic journal to share with other people working in this field. Any information that could identify you will be removed and all real names and places will have been changed.

Your information will be kept confidential, I will not tell anyone who you are or what you have said to me. However, if you share any information which suggests a risk to the safety of you or someone else I have a duty to share this information with the relevant people so that additional support can be offered.

What happens if I get upset?

I will not ask any questions which are intended to upset you, but it is possible that talking about your experiences may be upsetting. In this situation, we can stop the interview, or you can take a break if you would like to. You can also choose not to answer particular questions. After your interview you will be given a debrief sheet which includes the contact details of people who are able to provide you with any further support you may need.

How do I get involved?

There are two ways you can ask for more information or let me know that you are interested in taking part:

1. You can contact me by telephone, text, or email:
Telephone: [REDACTED] Email: h.gordon@lancaster.ac.uk
2. You can fill in the expression of interest form enclosed in this information pack and post it to me in the stamped addressed envelope. This will give me your contact details and then I will contact you.

As this research requires only a small number of people to take part, it is possible that more people will be interested in participating than can be interviewed. In this case, I will contact you to tell you that the recruitment has ended.

Who has reviewed the project?

This study has been reviewed and approved by the NHS North West - Preston Research Ethics Committee.

What happens with my personal data?

Any personal data that you share (e.g. your name, telephone number) will be stored securely as a password protected file on Lancaster University's secure network. This information will be safely destroyed as soon as possible; the longest length of time personal information will be stored is if you take part in the study and have requested to see a copy of the findings at completion.

Personal data will only be accessed by Hannah Gordon (Chief Investigator). The one exception to this is that your audio-recorded interview may be listened to by my research supervisors at the university (Dr Anna Daiches and/or Dr Clare Dixon). In this event, they will hear personal data which you have shared during the interview. The research supervisors have a duty to maintain confidentiality and will not share this information. Audio-recordings will be destroyed as soon as possible, once they have been typed up, with all identifiable personal data removed.

Lancaster University will be the data controller for any personal information collected as part of this study.

Under the GDPR you have certain rights when personal data is collected about you. You have the right to access any personal data held about you, to object to the processing of your personal information, to rectify personal data if it is inaccurate, the right to have data about you erased and, depending on the circumstances, the right to data portability. Please be aware that many of these rights are not absolute and only apply in certain circumstances. If you would like to know more about your rights in relation to your personal data, please speak to the researcher on your particular study.

For further information about how Lancaster University processes personal data for research purposes and your data rights please visit our webpage:

www.lancaster.ac.uk/research/data-protection

Thank you for reading this.

Hannah Gordon (Chief Investigator & Trainee Clinical Psychologist)

If you would like to raise concerns or complain about any aspect of the research, please contact:

Dr Bill Sellwood, Programme Director, Doctorate of Clinical Psychology Course, Lancaster University, Lancaster, LA1 4YG. Tel: 0 1524 593998. Email: b.sellwood@lancaster.ac.uk

If you wish to speak to someone outside of the Clinical Psychology Doctorate Programme, you may also contact:

Professor Roger Pickup, Associate Dean for Research,
Faculty of Health and Medicine, Lancaster University, Lancaster, LA1 4YG.
Tel: 01524 593746. Email: r.pickup@lancaster.ac.uk

Version 6 (11/03/2019)

**The Experience of Body Image for People with a
Left Ventricular Assist Device**



**THE DIVISION OF HEALTH RESEARCH
Doctorate in Clinical Psychology**

Expression of Interest Form

I have read and understood the information sheet.

I agree that I would like more information / I am interested in taking part.

I am happy for Hannah Gordon to contact me on:

Telephone number	
Email address	

*(only complete if you **do** want to be contacted)*

A convenient time to call me is *(please tick)*:

	Monday	Tuesday	Wednesday	Thursday	Friday
Morning					
Afternoon					
Evening					

Name: _____

Although I am agreeing for you to contact me, I understand that I have not given my consent to participate in the research.

Signature: _____

Date: _____

THANK YOU FOR COMPLETING THIS FORM

Version 3 (11/03/2019)

Appendix 4-E**Consent Form****The Experience of Body Image for People with a
Left Ventricular Assist Device**

**THE DIVISION OF HEALTH RESEARCH
Doctorate in Clinical Psychology**

IRAS ID: 255988

Consent Form

Please write your initials in each box when you have read and understood the statements below.

- | | |
|---|---|
| 1. I have read and understood the information about participating in this research and I have been given the chance to ask questions. | <input style="width: 80px; height: 30px;" type="text"/> |
| 2. I understand what taking part will involve. | <input style="width: 80px; height: 30px;" type="text"/> |
| 3. I understand that my information will remain confidential, unless I disclose something that puts myself and/or someone else at risk of harm. | <input style="width: 80px; height: 30px;" type="text"/> |
| 4. I agree for my interview to be audio recorded. I understand that the recording will be listened to by the chief investigator and research supervisors, and that the audio recording will be destroyed once typed up (within 3 months). | <input style="width: 80px; height: 30px;" type="text"/> |
| 5. I understand that my interview will be typed up and that typed interviews will only be read by the chief investigator and research supervisors at Lancaster University. | <input style="width: 80px; height: 30px;" type="text"/> |
| 6. I understand that anonymised quotes from my interview may be used in written reports or publications and that all personal information will be removed or changed. | <input style="width: 80px; height: 30px;" type="text"/> |
| 7. I understand that participation is voluntary and I can withdraw at any time up until transcription without having to give a reason. Withdrawal will not affect my current care. | <input style="width: 80px; height: 30px;" type="text"/> |
| 8. I have read the above and agree to take part. | <input style="width: 80px; height: 30px;" type="text"/> |

Name_____
Date_____
Signature_____
Chief Investigator's Name_____
Date_____
Signature

Appendix 4-F**Debrief Sheet****The Experience of Body Image for People with a
Left Ventricular Assist Device**

**THE DIVISION OF HEALTH RESEARCH
Doctorate in Clinical Psychology**

Debrief Sheet

Thank you for taking part in this research.

What happens next?

A summary of findings from all of the interviews will be produced. If you have chosen to see this summary Hannah will email or post a copy to you at the end of the project.

What happens with travel expenses? (up to the value of £10)

Travel by car – Hannah will ask about your mileage either before or during the interview, this is all that is needed to claim back your travel expenses.

Travel by public transport – You will need to provide the receipts for your travel, the receipt for your return journey is needed. At the interview you will be given a travel expenses form to complete and a freepost envelope to return the form and your travel receipts in.

What should I do if I feel I need support after the interview?

If you are concerned about anything we discussed today or if you feel distressed, you should contact your LVAD care team and ask to speak to the clinical psychologist. You could also speak to your GP about how you are feeling.

Alternatively, you could contact the British Heart Foundation's Heart Helpline for information and support:

Heart Helpline – British Heart Foundation

Tel: 0300 330 3311 (Monday-Friday, 9am to 5pm)

Email: hearthelpline@bhf.org.uk

Web: <https://www.bhf.org.uk/information-support/support/health-and-emotional-support>

Or for 24-hour emotional support, you could contact the Samaritans by telephoning 116 123.

Appendix 4-G

Facebook Poster

IRAS ID: 255988



THE DIVISION OF HEALTH RESEARCH
Doctorate in Clinical Psychology

*The Experience of Body Image for People with a
Left Ventricular Assist Device*

Do you currently have an LVAD?

Have you had your LVAD for 6 months or more?

Are you an outpatient?

**Would you like to talk about your experiences of having
an LVAD and its impact on your physical appearance?**

If you answered yes to these questions, you are aged 18 or over and live in the UK, you can request an information pack by telephone, text or email:

Telephone: [REDACTED] Email: h.gordon@lancaster.ac.uk

This will tell you more about the research that Hannah Gordon, from Lancaster University, is conducting and how you can take part.

Appendix 4-H**Letter of REC Provisional Opinion****North West - Preston Research Ethics Committee**

Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0207 104 8196

05 March 2019

Miss Hannah Gordon
Trainee Clinical Psychologist
Lancashire Care NHS Foundation Trust
Clinical Psychology, Div. Of Health Research,
C-Floor, Furness College
Lancaster University, Lancaster
LA1 4YG

Dear Miss Gordon

Study Title: The Experience of Body Image for People with a Left Ventricular Assist Device
REC reference: 19/NW/0104
IRAS project ID: 255988

The Research Ethics Committee reviewed the above application at the meeting held on 22 February 2019. Thank you for attending to discuss the application. The REC meeting was reconvened on 01 March 2019 because the 22 February meeting was not quorate.

Provisional opinion

The Committee would be content to give a favourable ethical opinion of the research, subject to receiving a complete response to the request for further information set out below.

Authority to consider your response and to confirm the Committee's final opinion has been delegated to none.

Further information or clarification required

- Please change the expression of interest form to exclude the collection of demographic and medical data.

- Revise the covering letter to participant so that it is clear that the invitation has been sent from the clinicians and not from the researcher.
- Please make the following changes to the Participant Information Sheet and Consent Form;
 1. Make it clear that participants could withdraw their data from the study up to the point of transcription and remove the 2week timeline.
 2. Make it clear that every aspect of the study would be supervised by the academic supervisors.
 3. Replace “must” with “will” in the following statement; “The interview must be audio-recorded so I have an accurate record of what you said.”
 4. Replace “interview” with “recruitment” in the following statement; “I will contact you to tell you that the interviews have ended”.
 5. Include information that the participants can stop, rewind or delete audio recordings during the interview.
 6. Under the heading “Will my care team be told that I have taken part?” include the following statement; “they may be aware of your involvement in the study but this would not affect your standard care”.
 7. Under the heading “What will happen with the information that I share?”, move the first paragraph with information about reporting disclosure to the bottom of that section. Also make it clear in the Participant Information Sheet that other people within the research team may have access to the personal data shared in the audio recordings.
 8. Under the heading “What happens if I get upset?” include information to warn the participants that some people may find the experience upsetting.
 9. Include the name of the REC that has reviewed the study.
 10. Include independent contact details for complaints.
 11. Change the following statement in point 3 from “unless me or someone else is at risk of harm.” to “unless I disclose something that puts myself and or someone else at risk of harm”.
 12. Include “anonymised quotes” in point 6.
 13. Include information that withdrawal would not affect the participant’s current care in point 7 of the Consent Form.
- Please submit an interview topic guide to give a broad indication of what the interview questions would cover.

Recommendation:

- Consider removing the name of the researcher from points 4 and 5 of the Consent Form.

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 Miss Damilola Odunlami nrescommittee.northwest-preston@nhs.net 0207 104 8196.

When submitting a response to the Committee, the requested information should be electronically submitted from IRAS. Please refer to the guidance in IRAS for instructions on [how to submit a response to provisional opinion electronically](#).

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 04 April 2019.

Social or scientific value; scientific design and conduct of the study

The Committee considered this application and was of the opinion that it was an interesting study. The Committee however, noted that A78 of the IRAS form stated that this study could generate new intellectual property and was of this opinion that for this study to generate a new intellectual property, it would need to be bigger than it was in this current design.

Recruitment arrangements and access to health information, and fair participant selection

The Committee considered the recruitment process and thought it was unclear. The Committee sought clarification from the researcher.

The researcher stated that there were only 6 sites in the UK and they have chosen 2 out of the 6 sites for the research. She explained that they would meet with clinicians (research nurses, LVAD and clinical psychologists) at [REDACTED] to inform them of the study. The clinicians will in turn inform the participants of the study.

The Committee asked what their population size was for both chosen sites.

The researcher explained that there were around 100 people listed at any point in time and because they did not want the study to be northwest only, they made the decision to choose a London site because both sites had the number of patients that would be required for the study.

The Committee noted that A13 of the IRAS application form stated that "If staff provided potential participants with an information pack during a routine appointment they would ask them whether they wished to sign the expression of interest form enclosed in the pack, indicating they would like to know more about the research or register their interest in participation." The Committee sought

clarification on when exactly the participants would sign the expression of interest form and what would happen if they decided not to sign the form at the outpatient clinic.

The researcher clarified that the expression of interest form would be signed at the outpatient appointment. The researcher stated that it would be ok if they decided not to sign at the appointment. She then explained that the form would be placed in an envelope with a return label on it and they would be able to sign and return at a later date.

The Committee noted that the expression of interest form would collect demographic data including medical data and was of the opinion that they could not do this because the participants had not been consented into the study.

The researcher explained that this was included following discussions with her academic supervisors and it would be helpful to know which sites the participant were based.

The Committee stated that the participants' location could be identified at during the interview process after they had given consent.

The researcher agreed to change the expression of interest form.

The Committee noted that the covering letter to participants was from the researcher and sought clarification on who would send the letters to the participants.

The researcher clarified that the postal pack would be sent by the clinicians to patients who did not attend the outpatient clinic.

The Committee was satisfied with this response but requested that the content of the letter should be changed to reflect that the invitation was sent by the clinicians and not the researcher.

The researcher agreed to make this change.

The Committee observed that A13 of the IRAS application form stated the following "It is hoped that recruitment will take place between January and March 2019. Interviews and analysis will take place between February and April 2019. The research will be written up between April and June 2019." The Committee wondered if 6months was a sufficient amount of time for this research and sought assurance that data collection had not started.

The researcher confirmed that data collection had not started. She stated that although the 6months timeframe would be tight, it was feasible. She further explained that although she currently worked and studied fulltime, she would be dropping some hours to accommodate this research.

The Committee sought assurance that all gender identities would be included in the study.

The researcher confirmed that all gender identities would be included in the study.

Care and protection of research participants; respect for potential and enrolled participants' welfare and dignity

The Committee noted that A36 of the IRAS form stated that home computer would be used for the storage of study data and informed the researcher that they could not store study data on a home or personal computer.

The researcher confirmed that they would store the study data would be stored on the University network.

The Committee sought clarification if the audio recording would be encrypted from the point of recording to the point of transcription and was of the opinion that the Lancaster University should be able to provide this service.

The researcher confirmed that the University stated that the service was too expensive so the audio recording would not be encrypted until it is transcribed and would then be stored in an encrypted format.

The Committee wondered how distress would be managed and asked the researcher if there was a distress protocol in place.

The researcher stated that they would ask the participants if they would like to take a break or stop and resume at a later date should they become distressed during the interview.

The Committee accepted this response.

The researcher confirmed that they would provide a copy of this.

The Committee sought clarification if the mobile number listed in the study poster and Participant Information Sheet was a personal or work mobile.

The researcher confirmed that this was a work mobile provided by the University.

The Committee sought clarification on how long the interview would last and what the withdrawal process was for the participants.

The researcher confirmed that the interview would last for about an hour. They stated that data could be withdrawn up to 2 weeks after collection and once transcribed, the participants would not be able to withdraw any data.

The Committee accepted these responses but requested that they should be made clear in the Participant Information Sheet. The Committee suggested that the 2week timeline should be removed and it should state, "data could be withdrawn up to the point of transcription" in case they were able to transcribe the audio recordings earlier than the 2weeks stated.

The researcher agreed.

Informed consent process and the adequacy and completeness of participant information

The Committee considered the Participant Information Sheet and noted that it stated that the research supervisors may listen to the audio recordings and sought clarification if they would also

be involved in the analysis and interpretation of the data as this was not mentioned in the Participant Information Sheet.

The researcher stated that this was an error and confirmed that the study supervisors would be involved in every aspect of the study.

The Committee accepted this response and stated that it was very important to state very clearly that every part of the research would be supervised especially as this was a student study.

Upon further consideration of the Participant Information Sheet, the Committee requested that "must" should be replaced with "will" in the following statement; "The interview must be audio-recorded so I have an accurate record of what you said." The Committee also requested that information that the participants could stop, rewind or delete their recording at the interview should be included in the Participant Information Sheet. The Committee further requested that "interviews" should be replaced with "recruitment" in the following statement; "I will contact you to tell you that the interviews have ended".

The Committee noted that the Participant Information Sheet stated that the care team would not be aware that the participants would be part of the study as stated under the heading "Will my care team be told that I have taken part?". The Committee was of the opinion that the care team were actually involved in the recruitment of the participants by identification of potential participants or provision of clarification to enquiries via the study poster, and would know that they were involved in the study. The Committee requested that this should be corrected to state "they may be aware of their involvement in the study but this would not affect their standard care".

Under the heading "What will happen with the information that I share?", the Committee was of the opinion that the first paragraph with information about reporting disclosure should be moved to the bottom of that section and data security should be given priority. The Committee noted that the section stated that no one else would have access to what has been discussed in the interview and was in agreement that this was not correct because the supervisors may listen to the recording and audio is classed as identifiable information. The Committee requested that it should be made clear in the Participant Information Sheet that other people within the research team may have access to the personal data shared in the audio recordings.

Under the heading "What happens if I get upset?" the Committee noted that it was not possible to know that questions to be asked would upset the participants until they were asked and was of the opinion that the Participant Information Sheet should include information to warn the participants that some people may find the experience upsetting.

The Committee further requested that the name of the REC that has reviewed the study and an independent contact details for complaints should be included in the Participant Information Sheet.

The Committee considered the Consent Form and requested that the following statement in point 3 "unless me or someone else is at risk of harm." should be changed to "unless I disclose something that puts myself and or someone else at risk of harm".

The Committee was of the opinion that points 4 and 5 of the Consent Form did not need to state the name of the researcher. Although it was agreed that it was not an ethical issue, the Committee recommended that the name of the researcher could be removed from the Consent Form.

The Committee requested that point 6 of the Consent Form should state “anonymised quotes”.

The Committee also requested that withdrawal would not affect their current care should be included in point 7 of the Consent Form.

Suitability of supporting information

The Committee reviewed the interview questions and was of the opinion that they were very structured and asked the researcher if this was compatible with phenomenology.

The researcher stated that the questions were included as a worst case scenario if a participant did not engage as expected. She clarified that some of the questions may not be asked depending on how each participant engaged with the study.

The Committee accepted this response but requested that the interview questions should be re-submitted and should include all of the questions that the researchers would like to ask the participants.

Please contact the REC Manager if you feel that the above summary is not an accurate reflection of the discussion at the meeting.

Documents reviewed

The documents reviewed at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [Research poster for NHS services]	2	05 December 2018
Copies of advertisement materials for research participants [Poster for Facebook recruitment]	2	05 December 2018
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsor insurance]		
GP/consultant information sheets or letters [Staff Information Sheet (NHS LVAD teams)]	2	05 December 2018
Interview schedules or topic guides for participants [Interview Schedule]	2	05 November 2018
IRAS Application Form [IRAS_Form_01022019]		01 February 2019
Letter from sponsor [Sponsorship letter from FHMREC]	1	31 January 2019
Letters of invitation to participant [Cover letter to participants - participant info pack]	2	05 November 2018
Letters of invitation to participant [Expression of interest form - participant info pack]	2	05 November 2018
Participant consent form [Consent form]	2	05 December 2018
Participant information sheet (PIS) [Participant Information Sheet - participant info pack]	5	29 January 2019
Participant information sheet (PIS) [Participant debrief sheet]	2	05 November 2018
Referee's report or other scientific critique report [Peer-review feedback email]	1	12 February 2018
Research protocol or project proposal [Research Protocol]	2	20 January 2019
Summary CV for Chief Investigator (CI) [Chief Investigator CV -	1	29 January 2019

Hannah Gordon]		
Summary CV for student [Chief Investigator CV - Hannah Gordon]	1	29 January 2019
Summary CV for supervisor (student research) [Research supervisor CV - Anna Daiches]		
Summary CV for supervisor (student research) [Research supervisor CV - Clare Dixon]		

Membership of the Committee

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

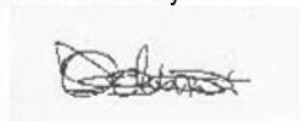
Statement of compliance

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.

19/NW/0104

Please quote this number on all correspondence

Yours sincerely



**Signed on behalf of;
Professor Karen Wright
Vice Chair**

Email: nrescommittee.northwest-preston@nhs.net

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

Copy to: Becky Gordon

[Redacted]

North West - Preston Research Ethics Committee
Attendance at Committee meeting on 01 March 2019

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Professor Carol Haigh	Professor of Nursing	Yes	
Ms Diane Halliwell	PhD Student Researcher	Yes	
Mrs Kate Kilshaw	Radiographer	Yes	
Mrs Susan Page	Senior Clinical Tutor	Yes	
Dr Karen Rouse	Principal Lecturer, Postgraduate Programmes	Yes	
Mr Colin Thain	Retired Lecturer	Yes	
Professor Karen Wright	Professor of Nursing	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Damilola Odunlami	REC Manager

Appendix 4-I**Cover Letter – Reply to REC Provisional Opinion**

Doctorate of Clinical Psychology
Division of Health Research,
C-Floor, Furness College
Lancaster University,
Lancaster
LA1 4YG

20th March 2019

North West - Preston Research Ethics Committee

Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Dear Professor Karen Wright,

Study Title: The Experience of Body Image for People with a
Left Ventricular Assist Device
REC reference: 19/NW/0104
IRAS project ID: 255988

Thank you for your letter, dated 5th March 2019, with regards to the Research Ethics Committee review of the above application. As you requested, I have addressed the below points:

- *Please change the expression of interest form to exclude the collection of demographic and medical data.*
- *Revise the covering letter to participant so that it is clear that the invitation has been sent from the clinicians and not from the researcher.*
- *Please make the following changes to the Participant Information Sheet and Consent Form;*
 1. *Make it clear that participants could withdraw their data from the study up to the point of transcription and remove the 2week timeline.*
 2. *Make it clear that every aspect of the study would be supervised by the academic supervisors.*
 3. *Replace “must” with “will” in the following statement; “The interview must be audio-recorded so I have an accurate record of what you said.”*
 4. *Replace “interview” with “recruitment” in the following statement; “I will contact you to tell you that the interviews have ended”.*

5. *Include information that the participants can stop, rewind or delete audio recordings during the interview.*
 6. *Under the heading “Will my care team be told that I have taken part?” include the following statement; “they may be aware of your involvement in the study but this would not affect your standard care”.*
 7. *Under the heading “What will happen with the information that I share?”, move the first paragraph with information about reporting disclosure to the bottom of that section. Also make it clear in the Participant Information Sheet that other people within the research team may have access to the personal data shared in the audio recordings.*
 8. *Under the heading “What happens if I get upset?” include information to warn the participants that some people may find the experience upsetting.*
 9. *Include the name of the REC that has reviewed the study.*
 10. *Include independent contact details for complaints.*
 11. *Change the following statement in point 3 from “unless me or someone else is at risk of harm.” to “unless I disclose something that puts myself and or someone else at risk of harm”.*
 12. *Include “anonymised quotes” in point 6.*
 13. *Include information that withdrawal would not affect the participant’s current care in point 7 of the Consent Form.*
- *Consider removing the name of the researcher from points 4 and 5 of the Consent Form.*

I have attached the amended documents to the email accompanying this letter and to the checklist of the IRAS form.

With regards to the interview schedule originally submitted to the committee, I have not completed the following request:

- *Please submit an interview topic guide to give a broad indication of what the interview questions would cover.*

Although it is not reflected in the meeting minutes, it is my memory that I explained to the committee that the four headings in bold on the interview schedule are the broad topic areas the interview questions will cover (general information regarding experiences of LVAD, overall experiences of body image, influence of LVAD on body image, impact of body image on care/life). Then, as the minutes suggest, any of the ‘prompts’ in each section will only be used if required (“worst case scenario if a participant did not engage as expected”).

At the meeting one committee member asked if it would be usual for an IPA study to have just a single open-ended interview question, I explained that this is not the case and that would be more in line with a qualitative study using a narrative analysis approach. The bullet point questions under each of the broad headings will be asked of each participant; 11 open questions total.

The existing schedule is in line with the design of an interview schedule for a study using interpretative phenomenological analysis (IPA) as suggested by Smith, Flowers, & Larkin (2009); including the total number of recommended questions, number of broad topics, and style of questions.

Apologies if I did not explain that clearly when addressing the committee's concerns about the structure of the schedule at the meeting. I am reluctant to submit an amendment of the interview schedule as it is in line with IPA interview schedule recommendations at present and I may move away from what is needed to answer the research question.

If you would like to discuss this further, please do not hesitate to get in contact with me.

Yours sincerely,

Hannah Gordon
Trainee Clinical Psychologist
Email: h.gordon@lancaster.ac.uk

Under research supervision of:
Dr Anna Daiches, Clinical Director, Lancaster University Doctorate of Clinical Psychology
Dr Clare Dixon, Clinical Tutor, Lancaster University Doctorate of Clinical Psychology

Reference: Smith, J. A., Flower, P., & Larkin, M. (2009). *Interpretative Phenomenological Analysis: Theory, Method and Research*. London: Sage

Appendix 4-J**Letter of REC Favourable Opinion****North West - Preston Research Ethics Committee**

Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ
Telephone: 0207 104 8196

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

05 April 2019

Miss Hannah Gordon
Trainee Clinical Psychologist
Lancashire Care NHS Foundation Trust
Clinical Psychology, Div. Of Health Research,
C-Floor, Furness College
Lancaster University, Lancaster
LA1 4YG

Dear Miss Gordon

Study title: The Experience of Body Image for People with a Left Ventricular Assist Device
REC reference: 19/NW/0104
IRAS project ID: 255988

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 Vice-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 hra.studyregistration@nhs.net outlining the reasons for your request.

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 HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System, at 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 publicly 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 times).

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 request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non- registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

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).

Non-NHS sites

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [Research poster for NHS services]	2	05 December 2018
Copies of advertisement materials for research participants [Poster for Facebook recruitment]	2	05 December 2018
Covering letter on headed paper [Covering letter to Preston REC]	1	20 March 2019
Evidence of Sponsor insurance or indemnity (non- NHS Sponsors only) [Sponsor insurance]		
GP/consultant information sheets or letters [Staff Information Sheet (NHS LVAD teams)]	2	05 December 2018
Interview schedules or topic guides for participants [Interview Schedule]	2	05 November 2018
IRAS Application Form [IRAS_Form_01022019]		01 February 2019
Letter from sponsor [Sponsorship letter from FHMREC]	1	31 January 2019
Letters of invitation to participant [Cover letter to participants - participant info pack]	2	05 November 2018
Letters of invitation to participant [Expression of interest form - participant info pack]	2	05 November 2018
Letters of invitation to participant [Cover letter to participants - participant info pack]	3	13 March 2019
Letters of invitation to participant [Expression of interest form - participant info pack]	3	11 March 2019
Letters of invitation to participant [Expression of interest form - participant info pack tracked]	3	11 March 2019
Letters of invitation to participant [Cover letter to participants - participant info pack tracked]	3	11 March 2019
Participant consent form [Consent form]	2	05 December 2018
Participant consent form [Consent form]	3	11 March 2019
Participant consent form [Consent form tracked]	3	11 March 2019

Participant information sheet (PIS) [Participant Information Sheet - participant info pack]	5	29 January 2019
Participant information sheet (PIS) [Participant debrief sheet]	2	05 November 2018
Participant information sheet (PIS) [Participant Information Sheet - participant info pack]	6	11 March 2019
Participant information sheet (PIS) [Participant Information Sheet - participant info pack tracked]	6	11 March 2019
Referee's report or other scientific critique report [Peer-review feedback email]	1	12 February 2018
Research protocol or project proposal [Research Protocol]	2	20 January 2019
Summary CV for Chief Investigator (CI) [Chief Investigator CV - Hannah Gordon]	1	29 January 2019
Summary CV for student [Chief Investigator CV - Hannah Gordon]	1	29 January 2019
Summary CV for supervisor (student research) [Research supervisor CV - Anna Daiches]		
Summary CV for supervisor (student research) [Research supervisor CV - Clare Dixon]		

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 Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities— see details at: <https://www.hra.nhs.uk/planning-and-improving-research/learning/>

19/NW/0104**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely



**Signed on behalf of;
Professor Karen Wright
Chair**

Email: nrescommittee.northwest-preston@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Appendix 4-K

Letter of HRA approval



Miss Hannah Gordon
Trainee Clinical Psychologist
Lancashire Care NHS Foundation Trust
Clinical Psychology, Div. Of Health Research,
C-Floor, Furness College
Lancaster University, Lancaster
LA1 4YG

Email: hra.approval@nhs.net

05 April 2019

Dear Miss Gordon

**HRA and Health and Care
Research Wales (HCRW)
Approval Letter**

Study title:	The Experience of Body Image for People with a Left Ventricular Assist Device
IRAS project ID:	255988
REC reference:	19/NW/0104
Sponsor	Lancaster University

I am pleased to confirm that [HRA and Health and Care Research Wales \(HCRW\) Approval](#) has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see [IRAS Help](#) for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?

HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to [obtain local agreement](#) in accordance with their procedures.

What are my notification responsibilities during the study?

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.

Who should I contact for further information?

Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **255988**. Please quote this on all correspondence.

Yours sincerely,



Approval Specialist

Email: hra.approval@nhs.net

Copy to: Sponsor Representative: Ms Becky Gordon, Lancaster University

List of Documents

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

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [Research poster for NHS services]	2	05 December 2018
Copies of advertisement materials for research participants [Poster for Facebook recruitment]	2	05 December 2018
Covering letter on headed paper [Covering letter to Preston REC]	1	20 March 2019
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsor insurance]		
GP/consultant information sheets or letters [Staff Information Sheet (NHS LVAD teams)]	2	05 December 2018
HRA Schedule of Events [HRA Schedule of Events Validated]	2.0	18 March 2019
HRA Statement of Activities [HRA Statement of Activities Validated]	1	29 January 2019
Interview schedules or topic guides for participants [Interview Schedule]	2	05 November 2018
IRAS Application Form [IRAS_Form_01022019]		01 February 2019
Letter from sponsor [Sponsorship letter from FHMREC]	1	31 January 2019
Letters of invitation to participant [Expression of interest form - participant info pack tracked]	3	11 March 2019
Letters of invitation to participant [Cover letter to participants - participant info pack tracked]	3	11 March 2019
Letters of invitation to participant [Cover letter to participants - participant info pack]	2	05 November 2018
Letters of invitation to participant [Expression of interest form - participant info pack]	2	05 November 2018
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Letters of invitation to participant [Expression of interest form - participant info pack]	3	11 March 2019
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Summary CV for supervisor (student research) [Research supervisor CV - Clare Dixon]		
255988 19NW0104 FIFO 05042019.pdf		05 April 2019

255988 19NW0104 Provisional Opinion 05032019.pdf		05 March 2019
255988 19NW0104 Validation Letter 07022019.pdf		07 February 2019

IRAS project ID	255988
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Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
<p>This is a multi-site study undertaking the same research-activities. There is therefore one site type.</p> <p>The study involves participants identified outside the NHS.</p>	<p>Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study.</p>	<p>A statement of activities has been submitted and the sponsor is not requesting and does not expect any other site agreement to be used.</p>	<p>No application for external funding will be made for this study.</p>	<p>As per the Statement of Activities provided a Local Collaborator Investigator will be in place at each participating NHS organisation.</p> <p>No assistance to identify potential Local Collaborators is required from the participating NHS organisations</p>	<p>It is unlikely that letters of access or honorary research contracts will be applicable, except where external staff employed by another Trust (or University) are involved (and then it is likely that arrangements are already in place). Where arrangements are not already in place, external staff would be expected to obtain a Letter of Access based on standard DBS checks and occupational health clearance would be appropriate.</p>

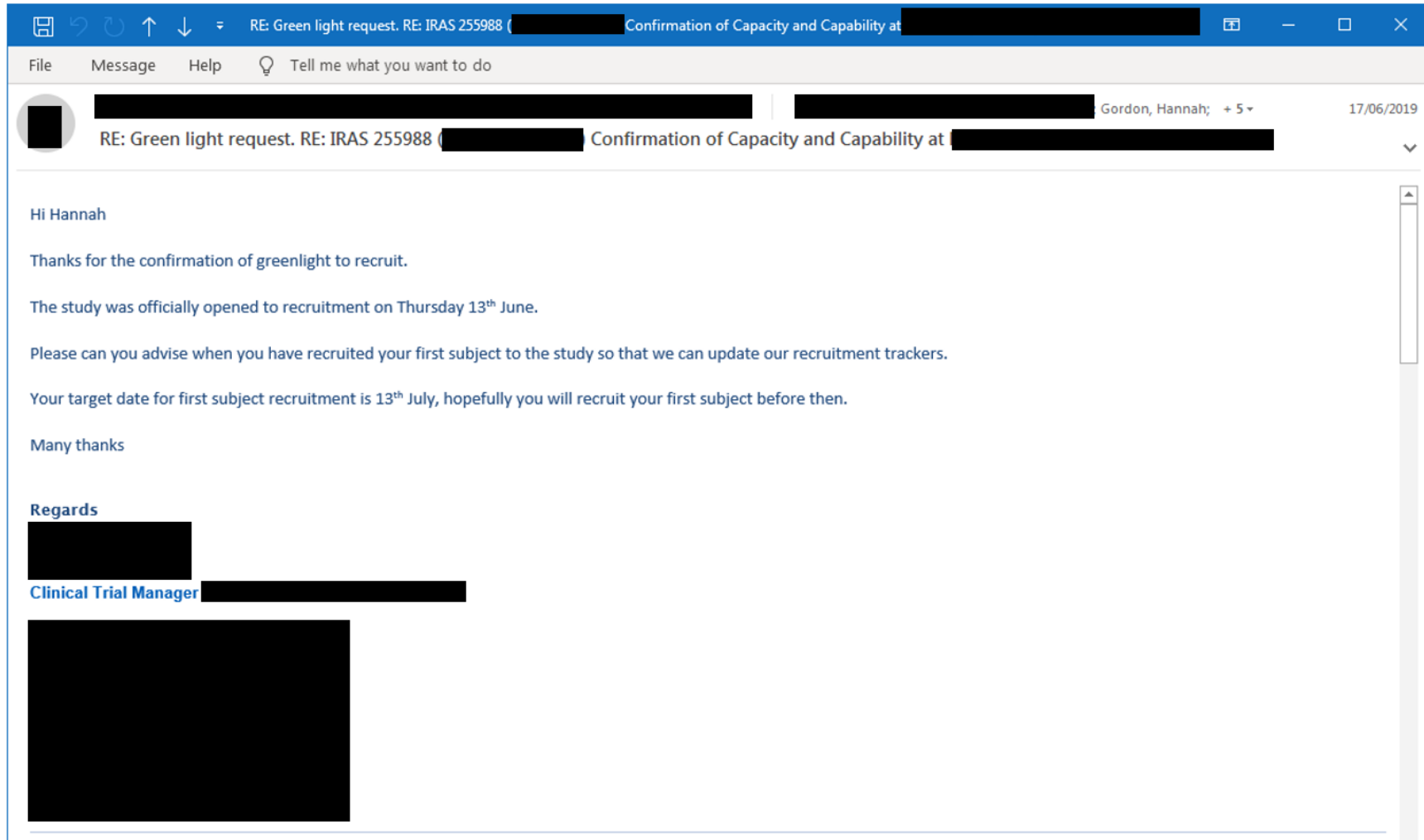
Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.

- The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.

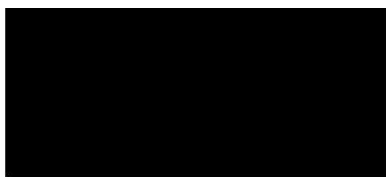
Appendix 4-L

Lead R&D approval - NHS site 1



Appendix 4-M

R&D approval - NHS site 2



Research Office




17 May 2019

Dear **Project Title:** The Experience of Body Image for People with a Left Ventricular Assist Device**REC Ref:** 19/NW/0104**IRAS Project ID:** 255988**EudraCT number:** N/A**Study Sponsor:** Lancaster University**Recruitment End Date:** 1 August 2019**Study End Date:** 31 August 2019**Recruitment target:** 3 - 6

Confirmation of Capacity and Capability

Thank you for registering the above research project with the Research Office.

I am pleased to provide confirmation that the Trust has 'capacity' to participate and 'capability' to deliver the above project in line with the requirements of the research protocol, as approved by the Health Research Authority (HRA).

This Confirmation of Capacity and Capability is granted on the basis that the study will be conducted as described in the study protocol and supporting documentation as approved by the HRA, and on the understanding that the study is conducted in accordance with the principles set out in the [UK Policy Framework for Health and Social Care Research](#) (V3.3, 07th November 2017 and its subsequent amendments), and 

It is the responsibility of the Principal Investigator (PI) to ensure that all members of the research team have appropriate training and experience to conduct the research project in accordance with the research protocol. The PI must ensure that appropriate employment contracts are in place prior to delegating any of the study related duties to a member of the research team.

Patient recruitment

The Trust is contractually obliged to measure and publish data on the days elapsing between the time we receive a valid research application and the time when the first participant is recruited to the trial. This applies to all clinical research where confirmation of capacity and capability has been issued.

The Trust is obliged to regularly report on various research metrics to the National Institute of Health and Research (NIHR) and Department of Health (DoH).

It is the responsibility of the local Principal Investigator (PI) to ensure that the following responsibilities are appropriately delegated within the project research team to ensure timely communication with the Research Office:



- The 1st project participant is recruited within 30 days of issue of this letter,

Study Amendments

HRA approval applies for the duration of the REC favourable opinion, unless otherwise notified in writing by the HRA. It is the responsibility of the Sponsor to ensure that all study amendments are submitted to the HRA and notified to the Research Office and study research team in a timely manner.

Changes to the status of the project, including study suspension or premature termination, should also be communicated to the Trust Research Office.

Safety Reporting

The research Sponsor, the Chief Investigator (CI) or the local Principal Investigator (PI) at a research site, may take appropriate Urgent Safety Measures in order to protect research participants against any immediate hazard to their health or safety. The Research Office should be notified of such measures immediately. The notification should include reasons why the measures were taken and the plan for further action.

All patient related incidents must be reported internally by the study team in line with the Trust [Adverse Incident Management and Reporting Policy](#) via the Quality and Safety Department database [Datix](#) and marked "research-related".

In addition, **all** Serious Adverse Events/Reactions (SAE/Rs) must be reported to the study Sponsor by a member of the study team immediately and as specified in the study protocol and sponsors' Pharmacovigilance SOP.

Copies of **all** SUSAR reports should be sent to the Research Office immediately and in parallel to informing the study Sponsor.

It is the responsibility of the study Sponsor to ensure that Development Safety Update Reports (DSURs) and quarterly safety reports are sent to the Research Office in a timely manner.

Audit

Please note the Trust is required to monitor research to ensure compliance with the Research Governance Framework and other legal and regulatory requirements. This responsibility is delegated to the Research Office and will be achieved by random audit of active research projects across the Trust in accordance with the [REDACTED]

Yours sincerely

[REDACTED]

[REDACTED]

Associate Director of Research

[REDACTED]

Cc: Hannah Gordon

[REDACTED]