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Left Ventricular Assist Device Adjustment Impacted by Patient Trajectory: A Qualitative Exploratory Study

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LEFT VENTRICULAR ASSIST DEVICE ADJUSTMENT IMPACTED BY PATIENT TRAJECTORY: A QUALITATIVE EXPLORATORY STUDY

A DISSERTATION

SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS

FOR THE DEGREE OF PHILOSOPHY OF NURSING

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

CIZIK SCHOOL OF NURSING

BY

BRITTANY D. RHOADES, MSN, APRN, CCNS, CCTN

MAY, 2020

UTHealth | Cizik
The University of Texas Health Science Center at Houston | School of Nursing

Approval Form D-3

3/10/2020
Date

To the Dean for the School of Nursing:

I am submitting a dissertation written by Brittany D. Rhoades and entitled "Left Ventricular Assist Device Adjustment Impacted by Assigned Patient Trajectory (LVAD-ADAPT): A Qualitative Exploratory Study." I have examined the final copy of this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy in Nursing.

Jennifer Beauchamp
[Insert Name], Committee Chair

We have read this dissertation
and recommend its acceptance:

NATHAN CARLIN

Joan Engebretson

Robert Casarez

Accepted

Dean for the School of Nursing

Acknowledgements

"Diseases desperate grown, By desperate appliance are relieved, Or not at all." Hamlet Act 4, Scene 3.

I am extremely grateful to my loving grandparents, Willie Gene and Faye Williams, who instilled in me the love and faith in Lord God. It is this faith that has provided the strength to withstand challenges and make it possible for me to complete this body of work. To my grandmother, although you may never know of my achievements to you much credit is due. I am forever grateful for the work ethic and perseverance that you modeled for me.

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Thank you to the LVAD participants that shared their stores of illness and adjustment with me. I am honored beyond words to share your story. You are so brave

and inspire me every single day. Your stories teach me, comfort me, and challenge me to pursue excellence and innovation in every aspect of clinical care.

This research was generously supported by Heart Exchange Support Group, Inc. Thank you for believing in research and sharing the passion for enhancing the patient experience. You are all heroes and hold a special place in my heart.

"I want to understand the world from your point of view. I want to know what you know in the way you know it. I want to understand the meaning of your experience, to walk in your shoes, to feel things as you feel them, to explain things as you explain them. Will you become my teacher and help me understand?"— James P. Spradley

Abstract

Brittany D. Rhoades, MSN, APRN, CCNS, CCTN

Left Ventricular Assist Device Adjustment Impacted by Assigned Patient Trajectory (LVAD-ADAPT): A Qualitative Exploratory Study

May, 2020

Background: Left Ventricular Assist Devices (LVADs) are used as an advanced therapy for advanced heart failure in order to sustain patients until a heart transplant is available (bridge to transplant, 'BTT') or until the end of life (destination therapy, 'DT'). Despite the differences in treatment trajectory, BTT and DT patients receive the same education. Currently, it is unknown how the two groups compare to living with the LVAD regarding the adjustment process.

Aims: This study aimed to explore LVAD patient experience, describe how patients construct the impact of the LVAD on daily life and self-care, and compare the findings between BTT and DT patients. It is imperative to understand how BTT and DT LVAD recipients construct the patient experience in order to provide patient-centric education for each group and promote optimal adjustment.

Methods: The study used a general qualitative methodology with a purposeful sampling of 20 LVAD recipients who self-reported as either BTT or DT. Atlas.ti V8 was used to manage transcribed interview data. Data content was analyzed, redundancy achieved, relevant themes identified through content analysis, and exemplars noted.

Findings: Participants reported the overarching theme, Living with an LVAD is inconvenient, but life-sustaining. BTT and DT LVAD participants contrasted the LVAD patient experience in three phases, (1) illness perception, (2) LVAD adjustment, and (3)

health aspirations. Six components emerged as necessary to LVAD adjustment among both groups: (1) physical ability, (2) caregiver dependence, (3) self-care, (4) roles, (5) LVAD public perception, and (6) connection. LVAD participants described differences in health aspirations based on the self-reported LVAD indication.

Conclusions: BTT and DT LVAD patients experienced a similar adjustment to the device. Despite the inconveniences of living with the LVAD, participants reported being grateful for the extended life. If faced with having to live with the LVAD for the remainder of life, most participants reported that it would not bother them, or they would be able to adjust. Increased knowledge regarding BTT and DT patient experience is required to develop patient-centric education and resources to ensure optimal LVAD adjustment.

Keywords: Left Ventricular Assist Device (LVAD), Adjustment, Heart Failure, Qualitative Research

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Summary of the Study

The purpose of the summary of the research study is to provide an overview of the study and to guide the readers through each section of the dissertation. The study proposal provides the specific aims, the background and the significance, the research design and methods, and information regarding the protection of research participants. The bibliography completes the dissertation proposal.

Two manuscripts, a review of the literature focusing on the current knowledge of influencing factors on LVAD adaptation (Manuscript A), and the primary findings of the current research study (Manuscript B) are included.

Manuscript A, Influencing Factors on Left Ventricular Assist Device Adaptation: A Systematic Review, identified a need to expand research among the LVAD population regarding all the influencing factors of adaptation. The review identified the patient centric influencing factors on LVAD adaptation and organized under the four categories (physiologic-physical, self-concept/group identity, interdependence, role function) identified by Roy's Adaptative Model (RAM). Emotional factors that did not clearly relate to any of the four RAM categories were associated with the patient as a bio-psycho-social being, an assumption of the RAM model. A comprehensive assessment and understanding of influencing factors from the patients' perspective are necessary to provide holistic LVAD care.

Manuscript B, Left Ventricular Assist Device Adjustment Impacted by Assigned Patient Trajectory: A Qualitative Exploratory Study, identified the overarching theme Living with an LVAD is inconvenient but life-sustaining. The model, Living with the LVAD: A Second Change at Life, depicts three separate phases representing the LVAD

patient experience, (1) illness perception, (2) LVAD adjustment, and (3) health aspirations. Within the model, six components were identified that impacted LVAD adjustment and the holistic self. The six components include (1) physical ability, (2) caregiver dependence, (3) self-care, (4) roles, (5) LVAD public perception, and (6) connection. The LVAD recipient's perceived LVAD trajectory (BTT or DT) influenced the LVAD adaption process. The holistic person, as well as health aspirations, were most heavily influenced by the perceived treatment trajectories and differed based on perceived BTT treatment trajectory or perceived DT treatment trajectory. The LVAD recipients that reported they were BTT expressed future motivations for heart transplantation. Those that reported DT described future aspirations of LVAD device longevity (e.g., support on LVAD therapy for more than ten years). Implications for future research and patient education are included.

The appendixes contain the internal review board approval letters, protocol document, and the curriculum vitae.

Specific Aims

Heart failure (HF) affects approximately 8 million people in the United States (US) and exceeds $53 billion in total annual medical costs (Heidenreich, et al., 2013). Individuals diagnosed with end stage HF have an estimated survival rate of 50% (Rogers, et al., 2014). Currently the superior treatment option for end-stage HF is heart transplantation (Yusen, et al., 2013); however, due to the limited number of available organs, left ventricular assist devices (LVADs) have become a life sustaining and effective treatment option. Prior to LVAD implant, HF patients are assigned an implant indication that communicates the device treatment trajectory. There are two primary indications for LVAD therapy: (1) increase survival until heart transplantation, "Bridge-to-Transplant" (BTT) or (2) manage HF symptoms until end of life, "Destination Therapy" (DT) (Rogers, et al, 2014). Most often DT patients do not meet heart transplant criteria due to age, increased body mass index (BMI), or compliance. Currently almost half of those in the US implanted with a device are listed as DT (Kirklin, et. al., 2014).

Living with an LVAD creates unique challenges and complexities due to the internal and external equipment required to operate the device (Abshire, et al, 2016). Some patients describe adjusting to the device as a "new reality" (Dwyer & Casida, 2016). However, it is unknown if the implant indication, BTT or DT, impacts the LVAD patient adjustment. BTT patients must adhere to LVAD pre-scribed medical therapy for a limited time until receiving a heart transplant. On the contrary, DT patients must adjust to LVAD prescribed medical therapy and the external device components until end-of-life.

LVAD patients are living greater than 10 years on a device and have an unknown potential life expectancy. BTT and DT patients receive the same LVAD education and follow the same self-care recommendations, despite the extreme differences in end of treatment trajectories and the length of time they must be supported on the LVAD. To understand the LVAD patient experience, researchers have utilized quality of life surveys; however, scarce information is available concerning the experience of living with an LVAD (Modica, et. al., 2014). **More specifically, it is unknown if the implant indication, BTT or DT, influences the patient experience and impact of the LVAD on adjustment and self-care.**

This study will use a focused, generic, qualitative design with group and individual interviews. Group interviews will be divided by self-reported implant indication, BTT or DT. This approach allows respondents to present personal perspectives as well as respond to the perspectives of others with the same treatment trajectory (Polit & Beck, 2012). **The overall objective of the study is to explore the patient BTT and DT LVAD experience.** The study will achieve the following aims:

Aim 1: Describe the BTT and DT LVAD patient experience.

Aim 2: Describe how BTT and DT LVAD patients construct the impact of the LVAD on daily life and self-care.

Aim 3: Compare the experience and impact of the LVAD on adjustment and self-care between BTT and DT patients.

The knowledge gained from this study is expected to have an impact on how we prepare and support LVAD patients from pre-implantation through the continuum of

care. The study will describe how LVAD patients construct living with a device and the adjustment process.

Research Strategy

Significance

LVADs are mechanical pumps that assist HF patients by unloading the left ventricle. Approximately 2,000 patients are implanted annually in the United States (US) (Kirklin, et al., 2014). Seventy-eight percent of LVAD recipients live for one year or greater and almost 50% survive four years or greater on LVAD support (Kirklin, et al., 2014). Due to the limited availability of hearts for transplant, BTT patients are waiting longer on LVAD support while on the transplant list. The redesigned HeartMate II was first implanted in 2003 (Frazier, et al., 2004) and the HeartWare in 2006 (Leibman, 2006). LVAD patients are living greater than 10 years on a device and have an unknown potential life expectancy. Both the BTT and DT population are increasing. Due to an increase in advanced HF patients that do not meet heart transplant criteria, it is estimated 2.5-4.2% of the 8 million patients suffering from HF in the United States could benefit from a LVAD (Kirklin, et al., 2014).

LVAD therapy is unique as compared to traditional HF management or other medical therapies. The LVAD internal and external components contribute to the complexities of adjusting to this treatment modality. The internal pump is implanted in the left ventricle and attaches to the aorta to increase the cardiac output. The internal pump is connected to external components through a set of wires that exits the abdomen known as the driveline. The driveline connects to an electronic microprocessor, the "controller", that operates the LVAD. The controller must be connected externally to an

AC power supply or a set of batteries always. The external LVAD components significantly impact the patients' activities of daily life (ADLs). Patients are not allowed to participate in water activities that might place the device at risk for getting wet or submerged (e.g., swimming, tub bathing, boating). LVAD implant centers and state laws very regarding VAD patient's ability to operate motor vehicles. Depending on the physical requirements of an occupation or the employer's comfort level with an LVAD, a patient's ability to return to work despite the physical recovery may vary. Patient's recount LVAD adjustment in distinct phases: "Pre-LVAD (the time from first discussions for the device to surgery", "Implant Hospitalization", "Early Home Adaptation" and "Late Home Adaptation" (Abshire, et al, 2016).

Review of the literature identifies some of the complexities of living with an LVAD. In the hospital, the LVAD patient learns to care for the LVAD and manage emergency alarms. Patients learn skills in the hospital related to the care of the LVAD. Upon hospital discharge they must learn to incorporate these skills into the home environment and daily activities (Casida, et al., 2011; Overgaard, et al., 2012; Sandau, et al., 2014; Ottenberg, et al., 2014; Chapman et. al., 2007). During the "Early Home Adaption" phase, patients work towards independence but are heavily dependent upon the assistance of a support person for LVAD dressing changes, transportation, bathing, among other self-care activities, which can be a source of frustration (Modica, et. al, 2014; Shapiro, Levin, & Oz, 1996). Often changes to the home environment, including electrical work, are required to optimally support the LVAD. Psychological stressors during this phase include alterations in body image due to surgical scars and LVAD

driveline. Additional stressors include weekly clinic visits, testing, and travel to and from appointments (Casida, et al., 2011; Ottenberg, et al., 2014).

During the "Late Home Adaptation" phase, patients report a change in their sense of normalcy including the ability to incorporate the LVAD into daily activities such as cooking, sleeping, and hygiene (Casida, et. al., 2011; Overgaard, et. al., 2012; Hallas, et. al, 2009; Chapman, et. al., 2007). In this phase patients describe mixed emotions ranging from fear of LVAD complications (Casida, et. al., 2011; Overgaard, et. al., 2012; and Chapman, et. at. 2007) to an increasing confidence in self-care. Some patients report a psychological transition from anxiety to gratitude towards the pump (Casida, et al., 2011; Ottenberg, et al., 2014). Many describe the importance of returning to normalcy (Overgaard, et al., 2012), but also describe the difficulty of returning to work and resuming previous roles (Casida, et. al., 2011; Overgaard, et. al., 2012; Sandau, et. al., 2014; Marcuccilli, et. al., 2011; Chapman, et. at. 2007). Personal and social aspects of life can be significantly impacted by the LVAD. Intimacy often requires modifications to accommodate the LVAD external equipment (Dwyer & Casida, 2016; Casida et. al., 2009; Casida et. al., 2011).

LVAD self-care requirements are the same for BTT and DT patients. The main differences in the two groups is the anticipated length of time on LVAD support and the hope for a heart transplant. The length of time BTT and DT patients live with an LVAD can vary dramatically. LVAD BTT patients generally live with the device for several months, greater than six months to a couple of years. In contrast, DT patients can live with a single device for greater than 10 years and longer if supported by consecutive devices. For many BTT patients transplant represents freedom from external equipment

and the ability to return to water activities. It is unknown if the length of time a patient must live with an LVAD impacts the adjustment process or if patients adjust to the device differently, adhere to medical therapy, or experience LVAD therapy differently based on implant indication. *Current qualitative literature fails to identify similarities and differences in the BTT and DT LVAD patient experience and the impact on daily life and self-care between the two groups.*

Significance of the Expected Research Contribution

The information gained through the exploratory study will increase the understanding of the complexities of living with a LVAD for BTT and DT patients. The study will also compare the similarities and differences in BTT and DT patient adjustment. This will provide a foundation that will be used to explore the influencing factors that lead BTT to adjust to meet transplant criteria (e.g., quit smoking, lose weight, increase medical therapy compliance). Future studies will also explore the patient experience of BTT patients transitioned to DT (e.g., increase in body mass index, noncompliance, increase in age). This study is the beginning of a research trajectory that will be used as a guide to evaluate and improve LVAD patient experience, education, improve LVAD nursing care and provide LVAD recommendations specific to implant indication.

Innovation

Limited information is known as to the differences and similarities between LVAD BTT and DT patient experiences and how each group adjusts. The status quo for clinical practice is to use the same education approach for BTT and DT patients despite the length of time the patient may be on LVAD support. Previous studies have explored

LVAD patient experience patient may be on LVAD support at a single LVAD center, utilized small sample sizes (n < 20), and have focused on one implant indication. No studies have compared or contrasted the BTT and DT LVAD patient experience. *The proposed research study is innovative because it will be a multisite qualitative study and will utilize group and individual interviews to compare patient experience among LVAD BTT and DT patients.*

Conceptual Framework

Callista Roy's Adaptation Theory (1970) is a grand theory that focuses on the individuals' ability to adapt with the internal and external environment and will be used to guide this research study. Roy's Adaptive Model (RAM) is comprised of four key components: person, health, environment, and nursing (Roy, 1970). A person is defined as a bio-psycho-social being that is constant interaction with a changing environment. Innate and acquired mechanisms are used to adapt. The model includes peoples as individuals or groups (i.e., families, organizations, and communities). How the patient interacts with the LVAD in the environment as well as influencing factors impact adjustment and mechanisms of adaptation will also be assessed. Adaptation is manifested in RAM by four interrelated modes of behavior: 1) physiological, 2) self-concept, 3) role function, and 4) interdependence (McEwen & Willis, 2014). Physiological includes the physical and chemical process involved in the function and activities of living organisms. Self-concept refers to the psychological and spiritual integrity, sense of unity, meaning, purposefulness of universe. Role function relates self to others, specifically the roles on people in society filling their needs for social integrity. Interdependence refers to the close relationships of people and their purpose, structure

and development. Currently no study has assessed how patients are impacted by an LVAD in the four modes of behavior. RAM aids in assessing the LVAD patient experience from a broad and comprehensive perspective.

Approach

A basic qualitative design, with an interpretative approach will be used to explore and describe LVAD patients' experience (Green & Thorogood, 2014). The aims for this research study are:

Aim 1: Explore the BTT and DT LVAD patient experience.

Aim 2: Describe how BTT and DT LVAD patient's construct the impact of the LVAD on daily life and self-care.

Aim 3: Compare the experience and impact of the LVAD on daily life and self-care between BTT and DT patients.

It is the *expectation* that knowledge gained from this study will provide insight into how clinical providers prepare and support LVAD patients from pre-implantation through the continuum of their care. The research will provide a better understanding of the patient experience and influence how LVAD patients can best be prepared for LVAD in a manner that supports the patient's specific implant indication and promotes adjustment. A better understanding of the differences in BTT and DT patient experience, including similarities and differences may allow for development of implant indication specific information and optimize LVAD adjustment.

Methods for Aims 1 - 3

Research Design. A basic qualitative design, with an interpretative approach will be used to explore, describe, and compare LVAD patients' experience (Green & Thorogood, 2014).

Sample and Setting. To accurately describe influencing factors of adjustment in both BTT and DT LVAD patients purposive sampling will be used. The PI will attempt to obtain variation in demographics, such as ethnicity, education level, age, gender, type of LVAD, and length of time supported by LVAD, in both groups. Extreme or deviant case sampling and typical case sampling will also be utilized (Green & Thorogood, 2004). The sampling methods will provide extreme and typical influencing factors affecting LVAD adaptation. The variety of demographics will provide perspectives among the LVAD patients across the adaptation experience, thereby increasing the credibility of the findings (Kuzel, 1999).

Participants will be interviewed until redundancy is reached in thematic content and saturation achieved in the depth and breadth of the topics discussed (Green & Thorogood, 2004). Therefore, based on other qualitative studies with in-depth interviews, it is estimated that redundancy and saturation will occur between 20-30 participants (Korstjens & Moser, 2018). The setting will be two LVAD programs located in a large metropolitan area in Southeast Texas. The programs collectively implant LVAD in approximately 200 LVADs annually and manage routine care for 300-400 collectively.

Group interviews will consist of patients from Baylor St. Luke's Medical Center (BSLMC) and Memorial Hermann (MH). Interviews will be conducted in quiet, comfortable locations within The University of Texas Health Science Center (UTH) at

Houston Cizik School of Nursing Center for Nursing Research to allow patients the opportunity to speak openly without a relationship to the institution. If interviews are unable to be conducted at UTH, alternative locations will be used (e.g. BSLMC and MH conference room). Patients from both BSLMC and MH will be clustered by device implant indication, BTT or DT, to allow patients, the opportunity to speak openly concerning their experience during group interviews. Interviews will be scheduled in a timely manner from the time of recruitment and convenient for interview participants.

Participant Recruitment. Study flyers will be placed in LVAD patient areas (e.g. LVAD outpatient clinics, LVAD inpatient units, patient support group meetings etc.). Clinical providers (e.g. Physicians, APRNs, LVAD Coordinators) will be asked to assist in identifying patients that meet study inclusion criteria and identify patient implant indication. Clinical providers will be asked to provide potential study participants flyers and ask them to contact the researchers if the PI is not available to consent in person. Prescreening and informed consent will occur in person in the LVAD clinics or via telephone. The information will be maintained in a screening log. To adequately represent both BTT and DT patients, the PI will attempt to recruit adequate numbers of both groups. Once redundancy and saturation is reached in either the BTT or DT group, recruitment will cease for the specific group and only patients with the non-saturated group will be recruited. Inclusion criteria includes adult (age > 18 years), English speaking, currently living with a HeartMate II, HeartMate 3, or HeartWare device, and greater than 1-month post LVAD implantation.

Potential research participants that meet inclusion criteria will be asked to provide informed consent, demographic information and interview dates will be provided.

Participants will be assigned a study number and information will be maintained in a linking log.

Instruments. The PI will serve as the research instrument in the proposed qualitative study (Lincoln and Guba, 1985) and use reflexivity to address bias. A reflective journal will be used for the PI to distinguish between the PI's subjectivity and the observable phenomenon. Research study field notes to capture other dynamics along with analytic and reflective notes will also be collected.

Data Collection. A basic qualitative design, with an interpretative approach is needed to identify the experiences of LVAD patients (Green & Thorogood, 2014). Participants will provide written consent prior to enrollment into the study and before group or individual interviews. After proving consent, patients will be asked to provide written contact information for follow up interviews. Self-report demographic data will be collected via survey (Appendix A). Data responses will be coded and blinded.

Participants will be asked to share their experiences in group or individual interviews. Semi-structured interviews will be used to address themes and topics of interest in an information or conversation-style dialogue with the LVAD patients. Semi-structured interviews allow the principle investigator (PI) to uncover and explore themes that might be unexpected but prove to be important in understanding the LVAD patient's experience and adjustment (Kvale & Brinkman, 2009). The interviewer will guide the participants to share perceptions of their adjustment to the LVAD through a series of open-ended questions (Appendix B). The semi-structured interview guide was developed based on prominent themes published and gaps identified in the current literature on living with an LVAD (Sandau et al., 2014; Ottenberg et al., 2014; Overgaard et al., 2012;

Marcuccilli et al., 2011; Casida et al, 2011; Hallas et al, 2008; Chapman et al, 2007). The interview guide will be further reviewed for relevance of questions and credibility will be established by the PI and 2-3 LVAD coordinators, who experts in care of the LVAD patient through the continuum of care (Polit & Beck, 2017). Triangulation will occur by interviewing different types of individuals in group and individual interviews to obtain multiple perspectives (Polit & Beck, 2017). The individual interviews will be conducted to further explore rich cases that align with the study aim or confounding cases (Brinkmann & Kvale, 2015). Individual interviews will be selected either from the group interviews or from interested research participants not able to attend the group interviews. Interviews will be emergent in design and allow the questions to adapt to further explore issues that arise from patient comments. (Brinkman & Kvale, 2015). Interviews will be conducted in English by the study PI using a semi-structured interview guide with grand tour and mini tour questions.

The group interviews will consist of approximately 5 to 10 patients and emergent in design and allow the questions to adapt to further explore issues that arise from patient comments. Patients will be clustered by device implant indication, BTT or DT, to allow patients, the opportunity to speak openly concerning their experience. The same semi-structured interview guide will be used for the BTT and DT interview groups to compare experiences of the two groups. The emergent design will allow the questions to adapt to further explore factors that are specific to each group. Field notes/observations will be taken by the PI during recruitment and interviews to document the inflections, tones, and nonverbal cues (Kvale & Brinkman, 2009). At the end of the interview dependability will be established by the interviewer by confirming that the participant's responses were

complete and accurate (Polit & Beck, 2017). Patients will be informed that all names mentioned in the interview will and protected health information will be removed in the transcription of the interview. Patients may be asked to participate in individual interviews following group interviews.

Data Management. Audio recordings will be downloaded onto a password-protected server at UTH. Every audio file will be identified with a study identification number and uploaded onto the server. Audio files will be downloaded and shared with the transcriptionist via a secured shared site. Once the transcription is complete it will be loaded onto the server, with study identification, and the PI will be notified by email. The transcript will then be verified for accuracy and authenticity by the PI by listening to the audio recording and comparing it to the transcript (Polit & Beck, 2017). All references to names or places will be removed from the transcription. Audio recordings will be kept on the secure server until all study interview and transcripts are finished. At completion all recordings will be deleted, and the transcripts will be stored by study number on the password-protected server.

Despite security measures and the use of study ID numbers, there could be a breakdown in protecting the identity of interview participants. If a breach in participant confidentiality were to occur, we will notify the participant and IRB as soon as the incident was discovered. We would create an action plan to prevent future breaches. Violations in the conduct of the study will also be reported to the IRB as soon as they are identified.

The PI will be appropriately trained for handling human subject-related data (including protected health information (PHI) that may be disclosed by a participant). All

protected health information (PHI) data collected by the PI or disclosed by a participant will be de-identified. Study participants will be assigned a study identification (ID) number in lieu of a participant name.

Data Analysis. Data analysis of interviews, field and analytical notes will begin as soon data is collected. This will allow for evaluation of the effectiveness of the group interview techniques and questions for collecting information, and any necessary adjustments will be made early in the interview process. Data collected will be de-identified. The PI will review and become familiar with the data collected from the first participants (group interviews, journals, field notes, and artifacts) (Miles, Huberman, & Saldana, 2014). Transcriptions will be imported into Atlas's version 8 for Windows (Scientific Software Development GmbH, 2017) for data coding, analysis, and management leading to preliminary themes. Codes will be identified and developed iteratively from the data and a codebook will be developed (Saldana, 2009). Codes will be established and categorized for themes, constructs, models, etc. (related to the research questions) by the PI. Supporting quotes will be used to support the data (Miles, et. al, 2014). Transcriptions will be analyzed recursively validating the emerging themes and patterns. Data will be compared and contrasted to ascertain similarities and differences between the BTT and DT participants. Lastly, peer debriefing will be done with dissertation committee members who are familiar with the research approach, to substantiate the themes, eliminate bias and make the finding resonate with the providers, thereby establishing trustworthiness (Saldana, 2009). In qualitative research, the PI will serve as the research instrument (Lincoln and Guba, 1985). Therefore, to further enhance the rigor of the data, reflexivity will occur by ongoing dialectical analysis, with the PI

keeping a journal with analytic notes, to avoid bias (Korstjens & Moser, 2018). Sampling will continue until good depth and repetition or "saturation" of themes is reached, and little new information emerges (Green & Thorogood, 2004). Analytical notes will be taken throughout data analysis.

Potential Problems and Alternative Strategies. Despite adequate population size, recruitment of patients can potentially be a challenge. Therefore, a contingency plan is in place. The Heart Exchange, a LVAD and heart transplant support group, is well established and eager for programs that may assist in increasing the understanding of LVAD patient illness perspective. Therefore, if recruitment lags, there are plans in place to work with Heart Exchange Support Group to supplement recruitment. Faculty advisors have experience recruiting from patient and family support groups for qualitative research interviews. They will provide guidance and recommendations for recruitment, as needed.

Because the PI works at BSLMC as an Advanced Practice Registered Nurse (APRN), she may have encountered some of the study participants in a clinician role. The PI will emphasize the research role and verbalize that no responses will impact clinical care provided. The PI will also attempt to minimize clinical contact with research participants. To maintain the PI role, group interviews will be conducted at UTH Center for Nursing Research if possible and patients from both MH and BSLMC will interviewed together. The PI will also attempt to recruit and include patients in whom there is limited or no previous clinical provider encounter. Additionally, the PI will consult faculty advisors if any conflicts arise.

Risks to Human Subjects and Ethics

Prior to study initiation, the study protocol will be reviewed and approved by the UTHealth Committee for the Protection of Human Subjects (CPHS) and Baylor St. Luke's Medical Center and Memorial Hermann Institutional Review Boards (IRB), and if deemed necessary, additional safeguards and monitoring will be added to the protocol. All research team members will receive and maintain the UTHealth Protection of Human Subjects training.

The potential risks involve discomforts related to discussing symptoms of end stage HF and either waiting for or ineligible for heart transplantation. Therefore, patients will be clustered by implant indication to create a more homologous group and increase the patients' ability to share openly. Additional potential risks associated with the study are loss of confidentiality. Mechanisms are in place to minimize these risks. All participating patients prior to the study onset will provide verbal informed consent approved by the UTHealth CPHS and IRB. All patients will be given the opportunity to refuse participation in the study and will be told that non-participation will not affect services (e.g., MH LVAD/HF Clinic service, BLSMC LVAD/HF Clinic, United Network for Organ Sharing (UNOS), etc.). To protect the confidentiality of the patients, all hard-copy records will be filed in locked cabinets and electronic records password protected computer systems within locked offices within the UTHealth School of Nursing for use by authorized personnel only. Hardcopy files (e.g., informed consents) will be saved securely during and after study completion until proper data destroying, if applicable following established UTHealth guidelines. All necessary firewall and password protections will be implemented to ensure confidentiality of data. No LVAD patient data

will be shared with their informal caregiver and vice versa. All patients' records will be given a unique study identification number. No PHI will be used in reports. No PHI will be kept on the secured computer where the study data is collected, managed or stored.

The PI will regularly consult with faculty advisors concerning confidentiality, data management and participant safety concerns. Although it is anticipated that any negative thoughts or feelings will be manageable, appropriate measures will be taken to ensure the safety of the patients. During the interviews if any of the patients become upset, they will be offered the option of withdrawing from the study without penalty or continuing at another time. Patients will also be informed that they may choose not to answer any item(s). In the event of any emotional distress, the PI and research staff will remain with the participant until the participant is no longer distressed or appropriate clinical care has been obtained.

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Influencing Factors on Left Ventricular Assist Device Adaptation: A Systematic Review

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Influencing factors on left ventricular assist device adaptation: A systematic review

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Introduction

The prevalence of heart failure (HF) continues to rise annually and is estimated to afflict 6.2 million Americans over the age of 20 years.[1] Patients who progress to advanced heart failure (AHF) have a mortality of greater than 50% within 5 years without advanced treatment modalities (e.g., heart transplantation or mechanical circulatory support).[2] The most widely used durable mechanical circulatory support, left ventricular assist devices (LVADs), have led to improved outcomes and quality of life in patients that are awaiting heart transplantation (Bridge-to-Transplant) or that do not meet transplant criteria (Destination Therapy) (e.g., advanced age or other transplant exclusion criteria).[3,4]

LVAD adaptation

Adapting to a LVAD presents unique challenges that can be attributed to the external device components (e.g., managing the batteries and external components, limitations in bathing and swimming, alterations in body image, effects on intimacy, and emotional distress). Patients have described the LVAD adaptation process as "adjusting to a new reality."[5] In order to optimize LVAD adaptation, it is critical to identify the patient centric factors that are self-reported or identified as having importance to the patient that influence LVAD adaptation and determine specific areas for clinical improvement and future research.

Theoretical framework

According to the Roy's Adaptation Model (RAM),[6] adaptation is defined as "the process and outcome whereby thinking and feeling people, as individuals or in groups, use conscious awareness and choice to create human and environmental integration."[6 p. 26]. The RAM framework was used organize and synthesis the factors identified within the articles included in this systematic review of the literature. The four modes of adaptation defined in RAM are (1) physiological-physical, (2) self-concept/group identity, (3) interdependence, and (4) role function.[6] The purpose of this systematic review was to answer the following question: What are the patient centric factors that influence LVAD adaptation?

Methods

With the assistance of an academic librarian, an electronic search of MEDLINE, EMBASE, CINAHL, and PubMed databases was conducted to identify articles published between January 2004 and June 2018. Clinical use of the HeartMate II LVAD[7] began in 2004 in the United States, and this system continues to be the most widely used LVAD design. Medical Subject Heading (MeSH) terms were used to identify the following search terms: "acclimatization," "adaptation," "adaptation, psychological," "adherence," "artificial heart ventricle," "coping," "coping behavior," "health-related quality of life," "heart-assist device," "heart assist pump," "left ventricular assist device," "self concept," "self efficacy," "self esteem," "self perception," "quality of life," and "ventricular assist device." Additional searches of bibliographies were conducted manually.

Study selection

Studies were included if (a) the sample comprised adults (≥18 years of age) living with a continuous flow LVAD (e.g., HeartMate II, HeartWare, or HeartMate 3) at the time of data collection; (b) the articles investigated patient centric factors influencing LVAD adaptation; and (c) the articles were available as full text after an exhaustive search and published in English. Articles were excluded if the sample consisted of LVAD patients who received heart transplant and data was collected retrospectively. Literature or systematic reviews, conference abstracts, or editorials were also excluded.

Data abstraction and quality assessment

A PRISMA[8] flow diagram depicts the selection of the articles considered for inclusion and details regarding exclusion (Fig. 1). The initial search yielded 1073 articles, including 329 from PubMed, 719 from Embase, 20 from CINAHL, and 5 from the manual search. These were screened for duplicates ($N = 264$), and the remaining articles

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($N = 809$) were screened by title by the first author (BR) and eliminated based on the set inclusion and exclusion criteria. The abstracts of the remaining articles ($N = 209$) were evaluated by first and last authors (BR & DW), who determined which full-text articles to review ($N = 35$). Of the full-text articles reviewed, the first author (BR) identified 24 studies that met the inclusion criteria for the synthesis of the findings. Notably, three of the identified 24 articles were authored by Casida and Co-authors[9–11] The data reported in all three Casida studies were collected from the same cohort of research participants. Additionally, one of the articles authored by Casida and Parker[12] was a preliminary report of the study by Casida et al.[13] Therefore, only the two primary studies published by Casida et al. in 2011[9] and 2012[13] were included in our systematic review count ($N = 21$). However, any additional LVAD adaptation-influencing factors reported in the other two articles by Casida and Co-authors[10,11] were identified and included in our results.

The final 21 studies were further assessed to ensure rigor by the first author (BR) using the Consolidated criteria for Reporting Qualitative research (COREQ)[14] checklist, the Strengthening the Reporting of OBservational studies in Epidemiology (STROBE)[15] checklist for cross sectional and cohort studies, and Critical Appraisal of a Survey.[16] None of the 21 studies were excluded based on methodological quality, but threats to validity and potential sources of bias were noted along with their strengths.

Results

Information on study purpose, research design, data collection, analysis methods, sample size, sample characteristics, and factors observed was extracted and included in Table 1 (qualitative studies; $n = 5$) and Table 2 (quantitative studies; $n = 15$). The qualitative and quantitative components of the mixed-methods study were included in Table 1 and Table 2, respectively. Studies were performed in the United States ($n = 10$), Germany ($n = 6$), the United Kingdom ($n = 2$), Italy ($n = 1$), Denmark ($n = 1$), and Israel ($n = 1$). The qualitative studies explored the LVAD patient experience using general qualitative, phenomenology, grounded theory, or qualitative explorative design and collected data through individual in-depth and semi-structured interviews. Of the qualitative studies, sample sizes ranged from 9 to 31 participants with continuous flow LVADs, and the mean age ranged from 38 to 69 years. The qualitative studies included 60%–96% men, and mean duration of LVAD support ranged from 0.36 to 1.5 years. The quantitative studies used a variety of study designs (e.g., cross-sectional, prospective case review) and instruments (e.g., Perceived Stress Scale or Pittsburgh Sleep Quality Index) to identify factors influencing LVAD adaptation. In the quantitative studies, the sample sizes ranged from 12 to 87 LVAD participants and the mean age ranged from 49 to 66 years. The quantitative studies included 67–100% male participants, and the mean duration of continuous flow LVAD support ranged from immediately after device implantation to over 2 years post implantation.

The included studies were reviewed to identify the patient centric influencing factors on LVAD adaptation and organized under the four categories (physiologic-physical, self-concept/group identity, interdependence, role function) identified by RAM. Emotional factors that did not clearly relate to any of the four RAM categories were associated with the patient as a bio-psycho-social being, an assumption of the RAM model.[6] Table 3 depicts the number of times an influencing factor related to LVAD adaptation was examined and categorizes each factor under a mode of adaptation identified in the RAM.

Physiologic-physical

According to RAM, the physiologic-physical mode is associated with the physical response of the person to the environment.[6] The most prevalent physiologic-physical factors identified in the literature and seen as critical factors in influencing LVAD adaptation were related to sexual activity.[17] Limited research discussed patients' comfort discussing sexual intercourse with clinical providers or when sexual activity is resumed.[18] Disturbances in sexual activity and lack of sexual intercourse were independently associated with higher rates of depression in LVAD patients.[17] Sexual dysfunction was reported in as high as 71% of men and 79% of women.[19] LVAD patients identified the following factors that may have contributed to decreased sexual function and performance: increased age (>60 years); history of ischemic heart disease; erectile dysfunction or vaginal dryness; failure or problems with the external LVAD equipment (e.g., controller, driveline/cable, or batteries); problems with orgasm; fear of injury or sudden cardiac arrest; feeling depressed; partner issues or avoidance of partner disappointment; issues with self-image; and pain.[17–20]

Despite reported decreased sexual function, sexual arousal, and orgasm in both male and female LVAD patients, males reported sexual desire comparable to that of participants in the control groups.[17,19,20] Qualitative research exploring sex and intimacy identified three main themes: (1) improved sexual relations with LVAD, (2) sexual adjustment, and (3) nonsexual intimacy, and LVAD patients reported an increase in overall health, improvement in sexual functioning, and satisfaction with sexual relations.[11] LVAD patients reported being insecure about starting a sexual relationship with a new partner and feeling empathy toward their spouse/partner's concerns of harm or injury, including death during sexual intercourse.[11] Patients described self-care behaviors to promote a sexually satisfying experience (e.g., preference for batteries or AC power, frequent sexual position changes, protective barriers for external components, such as abdominal binders). Some older LVAD patients placed emphasis on non-sexual physical gestures and intimacy.[11]

Additional physiologic-physical factors reported in the literature that influenced LVAD adaptation included sleep, pain, body mass index (BMI), physical activity/function (e.g., cardiopulmonary exercise), and cognition. During the first six months after LVAD implant, patients reported poor sleep quality and excessive levels of daytime sleepiness,[13,21] despite significant improvements in pain levels, functional status, and quality of life during the same time period.[22] One patient described trying to sleep with the new device stating, "Well, I can hear it 'sing' once in a while, and it can be irritating when I want to sleep…"[23]

Instrumental activities of daily living improved significantly from 1 to 6 months post-LVAD, and self-care capability ranged from "good" to "excellent" before and after LVAD.[13,21] Initially following LVAD implantation (baseline to 3 months), daily energy expenditure and the number of steps significantly increased, however patients reached a plateau (3 to 12 months).[24] LVAD patients expended significantly less energy per day as compared to heart transplant patients and participated in significantly less physical activity/exercise capacity.[24] Studies also evaluated BMI and cardiopulmonary exercise, and cognition.[25,26] Improvements in LVAD patients' BMI and cardiopulmonary exercise were seen after dietary counseling, weight management interventions, home ergometry protocols, and psychosocial counseling. Lastly among reported physiologic-physical factors, LVAD patients reported difficulty focusing and concentrating (e.g., computer use and newspaper reading) after LVAD implantation,[5,26] in addition to poor memory.[5]

Self-concept/group identity

The self-concept RAM mode is defined as the individual's mixture of beliefs and feelings about himself or others at a specific time and consists of the physical self and personal identity.[6] Self-concept/group identity LVAD adaptation influencing factors reported in the literature included self-care, device external equipment management and visibility, device management during travel, body image, clothing selection, self-confidence, desire for normalcy, and spirituality. LVAD patients reported a disconnect between the anticipated and realistic challenges to daily

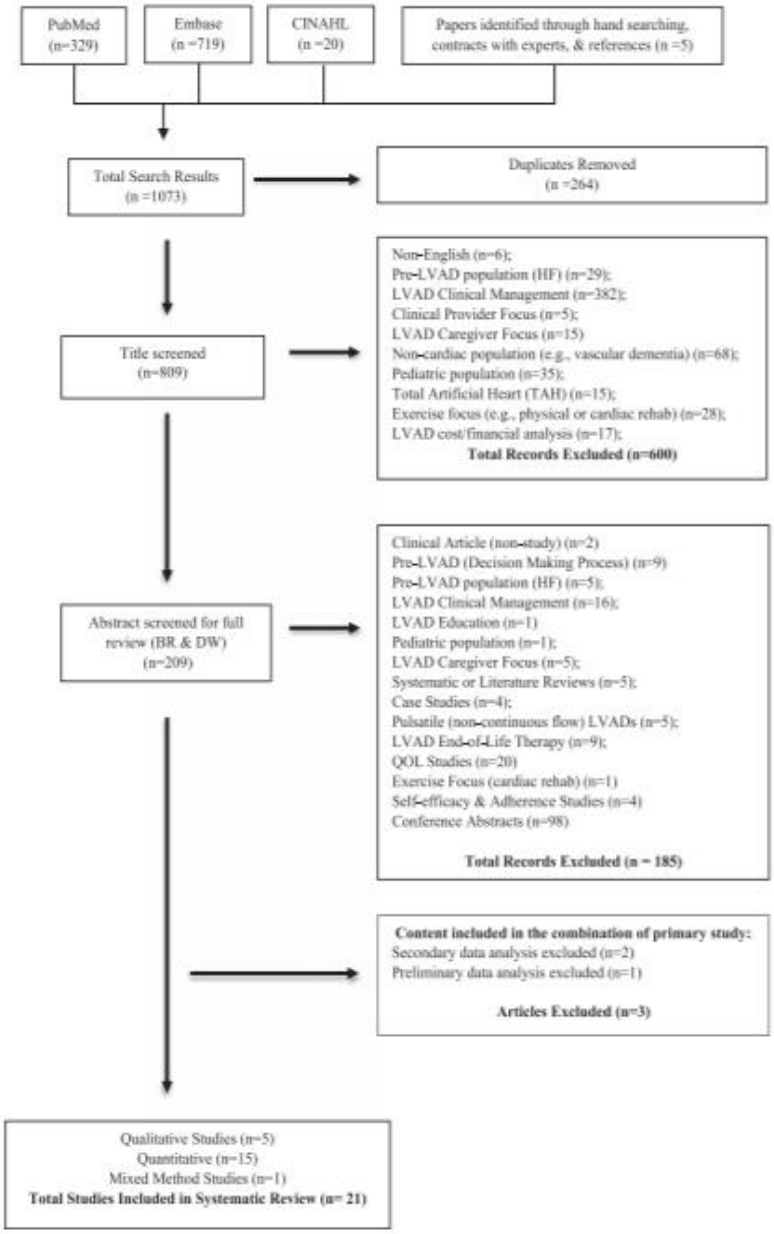

Fig. 1. PRISMA flowchart. Abbreviations: CINAHL, Cumulative Index to Nursing and Allied Health Literature; MeSH, Medical Subject Headings; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

self-care and life after surgery (e.g., managing the external equipment, daily dressing changes, showering, and anticoagulation monitoring).[27]

LVAD self-care is imperative for patients to maintain healthy relationships with oneself (e.g., self-concept) and others. Self-care factors during the early adjustment period, generally focused on physical (e.g., showering), psychological (e.g., confidence to care for the LVAD), and routine self-care of the device (e.g., monitoring the LVAD batteries and troubleshooting alarms).[9] For example, most LVAD patients reported feeling safe when caring for their LVAD; however, confidence in their ability to manage the device appeared to differ according to age, from 80% of LVAD patients feeling confident at age 20–30 years to only 33% of LVAD patients at 70–80 years.[28] When assessing LVAD equipment and usability, patients reported influencing factors such as dropping their controller bag, disconnecting the driveline unintentionally, the volume of the device alarms and powerbase unit (HeartMate II), the length of the driveline (HeartWare), and a large majority of patients used the LVAD emergency phone number for clinical assistance.[28,29] Patients' also experienced difficulty adjusting to interpretations of others' perceptions of the

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Table 1
Description of included qualitative studies associated with influencing factors on left ventricular assist device adaptation.

Study							Participants				Factors observed		
Study Author/ Year/Country	Focus	Design	Data collection	Data analysis	N	Mean Age, y	% Male	Mean LVAD support, y	Physiologic-physical	Interdependence	Self-concept - group identity	Role function	Bio-psycho-social being
[a]Casida et al.; 2011; USA[9]	Lifestyle adjustments Modified self-concept Sex & intimacy	Phenomenology	Semi-structured interviews	Thematic Analysis	9	56	78	1.5	✓	✓	✓	✓	✓
[b]Modica; 2015; Italy[27]	Device acceptance & acceptability	General qualitative	Individual in-depth psychological interviews	Thematic Analysis	28	54	96	1.3	✓	✓	—	—	✓
Ottenberg et al.; 2014; USA[32]	Outcomes & attitudes of DT LVAD	General qualitative	Individual Interviews	Thematic Analysis	12	69	92	1.85	✓	✓	—	✓	✓
Overgaard et al.; 2012; Denmark[23]	Lived experience	Qualitative explorative	In-depth individual semi-structured interviews	Thematic Analysis	10	40	60	0.83	✓	✓	✓	✓	✓
Sandau et al.; 2014; USA[5]	Conceptual definition of quality of life with a LVAD	Grounded theory	Semi-structured interviews	Thematic Analysis	11	60	72.7	0.36 initial interview 0.48-second interview	✓	✓	✓	✓	✓
[c]Standing et al.; 2017; UK[24]	'Being' a VAD recipient.	Phenomenology	Semi-structured interviews	Thematic Analysis	31	NR	85	NR	✓	—	✓	✓	✓

LVAD: Left ventricular assist device.
[a] The same study participants were used for each of these studies.
[b] Qualitative findings from the mixed methods study have been included.
[c] Participants included 20 VAD recipients (living with or previously implanted with a LVAD & 11 partners. Demographics ranges did not delineate between LVAD recipients and partners.

Table 2
Description of included quantitative studies associated with influencing factors on left ventricular assist device adaptation.

Study						Participants					Factors Observed		
Study Author/ Year/Country	Focus	Design	Data analysis	Variable: Instruments	*N*	Mean Age, y	% Male	Mean LVAD support, y	Physiologic-physical	Inter-dependence	Self-concept - group identity	Role function	Bio-psycho-social being
Abshire et al., 2018, USA[35]	Psychosocial indicators of stress	Cross-sectional survey	Descriptive statistics, correlation, and multiple linear regression analysis	Stressful life events: Homes and Rahe Stressful Life Events Scale Perceived stress: Perceived Stress Scale Depressive symptoms: Perceived Health Questionnaire Fatigue: Multidimensional Assessment of Fatigue Coping: Brief COPE Social support: ENRICHD HRQOL: KCCQ	62	56.5	77	2.1	✓	✓	—	—	✓
Casida; 2012; USA[13]	Sleep quality & HF symptoms following LVAD	Exploratory research design Descriptive longitudinal design	Descriptive and inferential statistics Paired t-tests Pearson's moment correlation	**Self-Report Instruments**[12]: Fatigue Severity Scale Global Anxiety Visual Analogue Scale Beck Depression Inventory-II **Additional Instruments:** PSQI ESS MLHFQ	12	54.3	67	0.02 Preimplant (baseline) 0.02 0.04 0.08 0.25 0.5	✓	—	—	—	—
Casida et al.; 2017; USA[10]	LVAD self-management	Observational study design	Person's product-moment correlation ANOVA Multiple linear regression	Cognitive Function: Applied Cognition Short Form (ACSF) general & executive. Self-efficacy: LVAD Patient Self-Efficacy Scale (LPSES) v2. LVAD care dependency: LVAD Care Dependency Scale (LCDS). Overall QOL: World Health Organization QOL-BREF	87	51.4	70	1.5	✓	—	—	—	—
Casida et al.; 2018; USA[21]	Sleep	Observational, repeated measure design	Descriptive statistics, Linear mixed models, Partial least	Sleep quality (SQ): PSQI Daytime sleepiness (DS): ESS Instrumental activities of daily living (IADL):	38	56.3	68.4	NR	✓	—	—	—	—

(continued on next page)

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Table 2 (*Continued*)

Study						Participants					Factors Observed		
Study Author/ Year/Country	Focus	Design	Data analysis	Variable: Instruments	*N*	Mean Age, y	% Male	Mean LVAD support, y	Physiologic-physical	Inter-dependence	Self-concept - group identity	Role function	Bio-psycho-social being
			square models.	IADLQ Self-care capability (SCC): ASAS									
Coyle et al.; 2008; USA[30]	National & international travel	Prospective case review	Descriptive Statics	NA	15	66	93.3	1.1	✓	–	✓	–	✓
Eckman et al.; 2013; USA[19]	Sexual functioning	Survey	Descriptive Statistics	CSFQ-14 Self-recall questions: desire, arousal, orgasm, and pain	59	>60 (39%)	76	> 1 (49%)	✓	–	–	–	–
Hasin; 2014: Israel[20]	Sexual functioning	Cross-sectional study with consecutive sampling (Hebrew)	Descriptive statistics Two-sided Wilcoxon signed rank test Fisher's exact test	*Validated sexual function questionnaire (Translated to Hebrew and back-translated to English) *A visual analog scale from 0 to 10 (0 for low, 10 for full satisfaction) was used to rate satisfaction with sexual life.	14	64	86%	NR	✓	–	✓	–	✓
Heim et al.; 2017; Germany[31]	Travel/Holidays	Cross-sectional survey	Descriptive statistics	Travel: Holiday questionnaire (e.g., destination, duration, a reason for denial)	29	NR	NR	NR	✓	–	–	–	✓
Jakovljevic et al.; 2014; UK[24]	Impact of LVAD on physical activity	Prospective, observational, repeated-measures	z-distribution cut-offs Mahalanobis distance tests Kolmogorov-Smirnov test ANOVA	Activity was evaluated using a portable multisensory array (Sensewear Por3, Body-Media Inc., Pennsylvania)	14	49	100	NR	✓	–	–	–	–
Kugler; 2012; Germany[25]	Body weight & exercise tolerance after LVAD	Non-randomized intervention study	Inferential statistics Repeated measures analysis of variance Cohen's Kappa	NA	Control (36) Intervention (34)	52 (median)	85.4	T1: 0.12 T2: 0.5 T3: 1 T4: 1.5	✓	–	–	–	✓
Kugler et al.; 2017; Germany[17]	Sexuality in LVAD patients	Cross-sectional, observational study	Descriptive statistics Binary logistic regression analyses	Sexual Adjustment Scale 6-item subscale of the Psychosocial Adjustment to Illness Scale (PAIS); Sexual Activity in Left Ventricular Assist Device Patients or	72	60 (median)	84.7	1.78 (median)	✓	–	✓	–	–

(*continued on next page*)

Table 2 (*Continued*)

Study						Participants					Factors Observed		
Study Author/ Year/Country	Focus	Design	Data analysis	Variable: Instruments	*N*	Mean Age, y	% Male	Mean LVAD support, y	Physiologic-physical	Inter-dependence	Self-concept - group identity	Role function	Bio-psycho-social being
				PaRtners (SALVADOR) Scale SF-36 Hospital Anxiety and Depression Scale (HADS) Work Performance Index (WPI)									
Merle et al., 2015; Germany[18]	Sexual concerns in LVAD patients	Survey questionnaire	Descriptive statistics	Sexual and psychosocial survey (17 questions)	26	54	88	0.6 years (median)	✓	–	–	–	–
Meyer et al.; 2010; Germany[29]	LVAD extracorporeal components	Survey questionnaire	ANOVA Non-parametric Mann Whitney test	LVAD differential assessment questionnaire SF-36	HMII: 17 HW: 10	HM II: 50 HW: 58	HM II: 82 HW: 100	HM II: 1.8 HW: 1.5	✓	–	–	–	–
[a]Modica et al.; 2015; Italy[27]	QOL, Psychological emotional, & cognitive reactions post LVAD	Mixed methods	Descriptive statistics Pearson's correlation coefficient Paired Student's *t*-test	SF-36 MLHFQ [a]Hospital Anxiety and Depression Scale (HADS) [a]Coping Orientation for Problem Experiences (COPE) Inventory	28	54	96	1.5	✓	✓	–	–	✓
Schima et al.; 2014; Germany[28]	LVAD usability	Survey questionnaire	Descriptive statistics	LVAD usability and safety questionnaire HRQOL: KCCQ	T_1 = 273 T_2 = 73	53	T_1 = 85 T_2 = 88	T_1 = 1.2 T_2 = 1.7	✓	–	–	–	–
Weerahandi et al.; 2016; USA[22]	Pain, functional status & HRQOL	Prospective cohort study	Descriptive statistics Linear mixed model regression	Pain: Brief Pain Inventory (BPI) Functional Status: Katz Independent Activities of Daily Living (IADL) Questionnaire HRQOL: KCCQ	87	58	77	Pre-implant 0.0 (after implant) 0.4 (2 wks.) 0.8 (4 wks.) 0.23 (12 wks.) 0.46 (24 wks.) 0.69 (36 wks.) 0.92 (48 wks.)	✓	–	–	–	–

HRQOL: Health-Related Quality of Life; KCCQ: Kansas City Cardiomyopathy Questionnaire; MLHFQ: Minnesota Living with Heart Failure Questionnaire; PSQI: Pittsburgh Sleep Quality Index.
ESS: Epworth Sleepiness Scale; IADLQ: Instrumental Activities of Daily Living Questionnaire; ASAS: Appraisal of Self-Care Agency Scale; SF-36: Short Form-36; ANOVA: One-way analysis of variance; CSFQ-14: Changes in Sexual Function Questionnaire.

[a] Quantitative findings from the mixed methods study have been included.

Table 3
The number of times an influencing factor related to LVAD adaptation was examined in the literature.

Categories of factors identified by Roy's adaptive model	Number of times an influencing factor was examined
Physiologic-physical	Sex and intimacy ($n = 5$), Sleep ($n = 2$), Pain ($n = 1$), Physical activity/exercise ($n = 4$), Functional status ($n = 1$), Nutrition ($n = 1$), Cognitive function ($n = 2$)
Self-concept - group identity	Body image ($n = 4$), Outward equipment visibility ($n = 2$), Clothing selection ($n = 2$), Self-confidence ($n = 1$), Desire for normalcy ($n = 2$), Self-care ($n = 4$), Environment modifications ($n = 1$), Equipment ($n = 2$), Travel preparation ($n = 1$), National and international travel ($n = 3$), Perception of time ($n = 1$), Treatment/device duration ($n = 2$), Liminality ($n = 2$) Spirituality ($n = 1$)
Interdependence	Dedicated caregiver (e.g., spouse, parent, adult children, etc.) ($n = 5$) LVAD coordinator ($n = 1$), Physician/clinical provider ($n = 2$), Multidisciplinary team (e.g., nurses, chaplains, nurse educators, palliative medicine clinicians) ($n = 1$) Community members and others who contribute to the patient's wellbeing ($n = 1$), Other LVAD patients ($n = 2$), Family and friends ($n = 1$)
Role function	Student ($n = 1$) Parent ($n = 2$), Spouse/provider ($n = 1$) Employee ($n = 3$), Business owner ($n = 1$), Loss of employment ($n = 2$), Retirement ($n = 1$) Community servant, "giving back" ($n = 2$) Disability/sick role ($n = 2$) Educator (instructing non-LVAD clinical providers in device therapy and clinical care) ($n = 1$)
Bio-psycho-social being	Gratitude "second chance on life" ($n = 1$), Enjoyment ($n = 1$), Humor ($n = 1$), Pragmatism ($n = 1$), Perceived stress ($n = 2$), Anxiety ($n = 4$); Depression ($n = 4$), Loss of control ($n = 1$), Anger ($n = 1$)

LVAD and alterations in their body image (e.g., self-concept).[11,20] Patients reported that the highly visible external components made concealing the device and selecting clothing difficult,[9] which was confirmed with the reported statement, "You can't dress the way you used to."[5]

Travel with a LVAD varies greatly from due to necessary LVAD self-care and device related travel preparations. LVAD self-care regarding air and ground travel included increased communication and coordination with the LVAD center to ensure adequate LVAD equipment maintenance and flight arrangements (e.g., meeting Federal Aviation Administration safety requirements),[30] notification and sharing of pertinent medical data with LVAD centers near travel destinations, pre-filled prescriptions for medications, and scheduling with local laboratories for electrolyte or warfarin monitoring.[30,31] When using transportation for routine travel, LVAD self-care focused on device securement and protection. For example, "I didn't like to take public transportation as I usually did during rush hour. I was simply afraid that someone would yank the wires and unplug the device…"[23]

Notably, within the self-concept/group identity mode of adaptation, Roy addresses ones' spiritual self.[6] The idea of having "faith in a Higher Power," as compared to those who identified as non-religious, reporting "meaning or purpose" in life or having "peace" surfaced as factors influencing personal adaptation to LVAD implantation.[5] Facing death with AHF also resonated in the spiritual domain with LVAD patients.[5]

For LVAD patients, time was reported as taking on a new meaning.[32] Patients described the LVAD as having a "cord come out of my belly" and being "literally tethered" to the device 24 h a day.[5] Anticipating the duration of device support appeared to be a profound influencing factor on one's self-concept (e.g., self-ideal or self-expectancy) in one study. In countries where LVAD therapy is approved for Bridge to transplant (BTT) only (e.g., UK, Netherlands),[33] patients perceived LVAD therapy as a temporary treatment to AHF rather than a long term treatment therapy.[34] Patients also reported a lack of knowledge related to the longevity of the device, expressing fear or anxiety about device failure after a couple of years.[34] While the hope of transplantation often appeared as a motivating factor to endure the burdens of an LVAD, it also represented a constant state of limbo as the patient waited for the telephone to ring to present to the hospital for transplantation.[32–34] One study's exemplar clarified this point stating, "My life was on standby until the heart surgery. After living with a HM, you long for a normal life…I thought it [heart transplant] would probably be within the first 6 months, but it took almost 2 years."[23] Destination Therapy (DT) patients noted the amount of time from LVAD consent to implant, the time required to sustain LVAD therapy (e.g., frequent follow-up appointments, weekly lab monitoring, LVAD self-care) and feelings of beating the odds of their AHF prognosis.[32]

Interdependence

The RAM interdependence mode includes relationships with others that are meaningful to the person, and support system.[6] The sense of confidence and integrity of these relationships is important to the adaptation process.[6] In the initial post-operative phase immediately after surgery and in the hospital, inpatient LVAD support groups were found to provide a great source of support.[32] Three additional studies identified that the LVAD clinical team (e.g., nurses, chaplains, LVAD coordinators, and palliative medicine clinicians), particularly the LVAD coordinator, were found to be valuable members of the LVAD patients' social network, as studies reported that these sources of support further alleviated LVAD patients' fears of uncertainty.[26,27,32] Six studies identified influencing factors associated with the LVAD patients' interdependence on relationships, social support, and interactions with others, such as relying on support of family in the hospital setting and insecurity about being alone immediately after LVAD implant.[9,23,27,32,34,35] For example, the following study exemplar illustrated this point, "I didn't want to be alone just after I got the HeartMate, so I moved in with my aunt, who was home all day."[23] LVAD self-care needs (i.e., self-care maintenance, self-care monitoring, and self-care management) were also attributed to interdependence.[35,36] LVAD driveline site care was found to be frequently performed by a dedicated care provider.[27,32] Patients ages 25 to 45 years appeared to place a greater emphasis on social contacts and often relied on their parents or spouses for care and social support, whereas older LVAD patients generally relied on their spouses, adult children, and close friends for their social and psychological needs.[23] Additionally, adult children of the middle (45–64 years) and late adult (≥65 years) LVAD patients were often integral for providing psychosocial support for both parents (the LVAD patient and the spousal care provider).[23] Furthermore, many LVAD centers required patients to have a dedicated care provider throughout the continuum of care and around the clock immediately after discharge.[5,23]

While most LVAD patients require assistance from a care provider initially after LVAD, two studies emphasized the importance of regaining independence in LVAD self-care activities, leaving the patients with a greater sense of control and independence.[9,23] For example, the following study exemplar illustrated this point, "I prefer to [change my own bandages]. If I don't, I feel sick, like I can't do anything, then I feel disabled."[23]

Role function

The role function RAM mode addresses the individual's role, designated and informal, in society and is divided into three areas: (1) primary roles; the role of gender (female, male), (2) secondary roles; different roles (family and occupational), and (3) tertiary roles (president of an organization, etc.).[6] LVAD adaptation was found to be influenced by the familiar and professional roles the patient assumed and stage in life at the time of LVAD implantation. One study found adolescent (14–24 years) LVAD patients were often attempting to navigate academia, occupational choices, or early careers, and traditional milestones (e.g., moving away from home, marriage, education) and advancement in these areas was found to be delayed due to the LVAD device (e.g., parental caregiver dependence, professional physical limitations).[23] Patients who had already married and started their families described the adjustment of incorporating the LVAD into the parenting role as frustrating, often due to physical limitations or the precautions required to care for the external equipment when playing with children or trying to contribute to the family's well-being.[5,34] The following study exemplar illustrated this point, "I can't play with the bairn [child] properly…it's the small things that you wouldn't have thought would get to you that do."[34]

An LVAD patient who received his LVAD at the onset of establishing his own business and was able to resume work shortly after recovering,[23] while others described disappointment due to the loss of employment due to LVAD complications and illness severity,[9] and others were faced with changing employment. One LVAD patient stated, "I would like to [go back to work], but I won't be able to do what I want…"[23] The ability to return to work influenced LVAD patient adjustment differently across studies. One study emphasized the importance of work identity to Danish men and women and how the LVAD impacted employment and establishing normalacy.[23] Two studies found older LVAD patients more often found themselves secure in employment or approaching retirement, during which they indicated they would find purpose in domestic activities.[5,23] Furthermore, regardless of formal employment, LVAD patients emphasized the need to be productive, which manifested through volunteering or "giving back" by encouraging other LVAD patients.[5,32] Being able to share one's personal LVAD experience, as well as hearing the experience of others, minimized social isolation.[5,27] One study identified the lack of adjustment to incorporating the LVAD into daily roles was related to LVAD patients' inability to transition out of the "sick" role.[23] Additionally, LVAD patients identify as being in an educator role, having to explain the LVAD or explain to local medical service providers or hospital clinical providers how to use a Doppler to monitor blood pressure.[32]

Bio-psycho-social being

One of the metaparadigm concepts embedded within the RAM includes "person" and is defined as "a whole with parts that function as a unity…" resulting in the bio-psycho-social being.[6] LVAD adaptation was found to be heavily influenced by the emotions that LVAD patients reported, including gratitude[5] and moderate to severe depression and anxiety.[27] For example, the following study exemplar illustrated this point, "[The initial 3 days home] I was depressed; like I just didn't want to talk to anybody… this just was a lot to process…"[5] Additionally, six studies reported stress and inhibition in various modes of adaptation (e.g., physiological-physical, self-concept-group identity, and bio-psycho-social being) due to potential complications (e.g., LVAD malfunction, driveline disconnection, damaging LVAD equipment, taking the wrong medications, breaking sterile technique with dressing change).[5,17–20,31]

Discussion

In this review, the authors have highlighted the utility of using the RAM as a foundation for organizing and synthesizing the patient centric factors identified within the included articles. In order to provide holistic care to LVAD patients using the RAM, nurses must first understand how the LVAD impacts each of the specific modes of adaptation from a patient's perspective. Typically, previous research using RAM assessed behavior in response to a stimuli (e.g., chronic illness) in which behaviors are either identified as positive or negative responses regarding adaptation.[37] In this review, patient centric influencing factors organized under the RAM were self-reported as having importance in qualitative studies (e.g., body image, interdependence on dedicated caregiver, employee role, etc.) or were found within quantitative studies (e.g., sleep, travel, sexual intimacy, etc.). All identified factors were reported in at least one or more included qualitative or quantitative studies.

The findings from this systematic review identified areas needed for future research regarding LVAD adaptation that will likely provide clinical providers with a greater understanding of how to support LVAD patients. Overall, this review sheds light on the paucity of literature related to how LVAD implantation impacts primary, secondary, and tertiary roles in the process of adapting to a LVAD.[38] Specifically, clinical providers should provide patient centric care depending on the role or roles the patient is currently experiencing (e.g., college student, parent with young children, worker, or retiree). Additionally, the review identified that exercise activity is a potential influencing factor of LVAD adaptation.[24] However, there is a knowledge gap regarding the patient perspective on how the LVAD influences physical activity. Lastly, the findings provide knowledge regarding areas that should be discussed with patients in the pre-LVAD phase. This will allow for patients to be more knowledgeable going into the adjustment process. These identified gaps in the literature should be addressed through further research in order to provide a strong foundation for future clinical interventions.

Currently, many of the guidelines and recommendations regarding patient centric LVAD care is center specific and there is lack of standardized best practices. Additional research and a greater understanding of the factors that influence LVAD adaptation will allow clinic providers to establish best practice guidelines regarding areas that are of greater importance to LVAD patients (e.g., physical activity, LVAD self-care, travel, or employment).

Strengths and limitations

The strengths of this review include a comprehensive assessment of influencing factors using the RAM which included review of qualitative and quantitative research. Aspects of the RAM are exemplified in researching the LVAD population and the model, with the inclusion of bio-psycho-social factors, and serves as an appropriate fit to comprehensively explore adaptation for the LVAD population. Certain limitations of the review should be noted. Since the articles included in the review were not designed using the RAM, the authors may have demonstrated a tendency to 'overfit' the model to the results. The exclusion of gray literature (e.g., conference abstracts) may have limited the identification of other relevant influencing factors. Additionally, studies were not excluded based on quality and instead were included to maintain the depth and breadth of the review while noting each studies' potential limits.

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The limited number of research studies for each influencing factor identified contributed to a limited synthesis. This clearly identifies the need for further research in the area of LVAD adaptation. Influencing factors that have only been identified in a single or limited number of studies have been identified as of value to patients; however, these factors should be further explored in order to provide a greater breath of knowledge and ensure applicability across the LVAD population. For example, one study identified that LVAD patients expend significantly less energy per day and participated in less physical activity/exercise capacity than heart transplant patients,[24] however there is no research to identifying possible patient centric factor for decreased energy expenditure (e.g., external LVAD equipment, limited beliefs concerning activity, lack of resources).

Lastly, this review was limited to continuous flow LVADs most commonly implanted currently (i.e., HeartMate II, HeartWare, HeartMate 3). Several studies contributed to the body of knowledge related to the LVAD patient experience, however were excluded from the review due to sample size (e.g., case studies) or older LVAD technology.[39–42] Excluded studies identified influencing factors for further analysis, such as body image (e.g., body and self, trust, physical scarring, clothing selection)[39,43] and should be further explored in the current device technology.

Conclusions

This systematic review identified a need to expand research among the LVAD population regarding all the influencing factors of adaptation. Specifically, limited research has been conducted on how the LVAD impacts patients' roles and body image. Additionally, even though research has been conducted in the physical adaption areas of exercise and activity it has not adequately sought the patient's perspective. Also, there is a paucity of literature that explores patient adaption from the perspective of LVAD indication (e.g., BTT and DT). In order to provide holistic LVAD care, research should not only measure influencing factors of adaptation but also seek to gain the patient perspective.

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Dear Dr. Redeker,

I am pleased to submit an original research article entitled "Left Ventricular Assist Device Adjustment Impacted by Assigned Patient Trajectory (LVAD-ADAPT): A Qualitative Exploratory Study" by Brittany Rhoades, Jennifer E. Sanner Beauchamp, Rebecca Casarez, Nathan Carlin & Joan C. Engebretson for consideration for publication in Heart and Lung: The Journal of Acute and Critical Care. This manuscript uses presents original research on LVAD adjustment with the comparison of patient perception among treatment trajectories, Bridge-to-transplant and Destination therapy.

In this manuscript, we show the six influencing factors of LVAD adjustment: physical ability, caregiver dependence, self-care, roles, LVAD public perception, and connection. We highlight new findings regarding LVAD adjustment in the areas of roles, LVAD public perception, and connection.

We believe that this manuscript is appropriate for publication by Heart & Lung because it is an original research and on the cutting edge of LVAD patient centered care.

This manuscript has not been published and is not under consideration for publication elsewhere. We have no conflicts of interest to disclose.

Thank you for your consideration!

Sincerely,

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Left Ventricular Assist Device Adjustment Impacted by Assigned Patient Trajectory: A Qualitative Exploratory Study

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Left Ventricular Assist Devices (LVADs) are mechanical pumps that assist advanced heart failure (AHF) patients by unloading the left ventricle and increasing cardiovascular circulation throughout the body. LVADs are the most widely used heart pump. There are two primary indications for LVAD therapy (e.g., bridge to transplant [BTT] and destination therapy [DT]). Both groups experience similar self-care requirements with the LVAD; however, the length of time supported on therapy for the two groups can vary greatly. At present, LVAD training and patient education are the same for both groups. To date, no studies have explored if patients adjust differently to the devices based on the implant indication. This information is essential to optimize patient experience and facilitate the LVAD patient's adjustment to living with the therapy. Furthermore, LVAD adjustment has the potential to impact patient morbidity and mortality directly.

LVADs are increasing as a therapy option for patients experiencing AHF. Over 30,000 AHF patients were implanted globally in the past decade, and approximately 2,000 patients are implanted with LVADs annually in the United States (U.S.) (K.L et al., 2014). LVADs have demonstrated the ability to improve the quality of life and improve the mortality of AHF patients (Grady et al., 2014). The internal pump is implanted in the left ventricle and attaches to the aorta to increase the cardiac output. It connects to external components through a set of wires that exit the abdomen known as the driveline, which connects to an electronic microprocessor, the "controller," that operates the device. LVAD patients must always rely on external batteries or an AC power source to support the device.

Unlike other medical therapies with only internal components, LVAD patients have external equipment that the LVAD recipient and caregiver must learn to manage. LVAD patients cannot participate in activities that place the patient, driveline, and equipment at risk of getting wet or submerged in water. Due to these factors, the external LVAD components significantly impact the patients' activities of daily living (e.g., driving, swimming, tub bathing, or boating) and create a complex adjustment process. In addition to modifications necessary for ADLs, LVAD recipients must learn to change power sources, ensure access to an adequate power supply, perform regular sterile dressing changes to the driveline exit site, and respond to hazardous and critical LVAD alarms.

Review of Qualitative Literature

To date, a limited number of qualitative studies have explored LVAD adaptation in patients living with a second or third generation continuous-flow LVAD. One study described the importance of LVAD patients being able to be independent in most ADLs living or activities that the LVAD recipient valued as important (Sandau et al., 2014). Multiple studies have reported participants' gratitude for the LVAD. The gratitude was reported and expressed as the opportunity to 'feel alive again' or gaining a 'new lease on life', previously thought as impossible while living with AHF (Casida et al., 2011; Ottenberg et al., 2014; Overgaard et al., 2012). In contrast, some participants verbalized ambivalence towards the LVAD (Overgaard et al., 2012).

Multiple studies reported the importance of LVAD recipients to regain a sense of normalcy (Casida et al., 2011; Sandau et al., 2014), which included being able to participate in activities that LVAD recipients valued as essential. Communication was

valued as extremely important in the adjustment process and minimized the sense of isolation and loneliness of living with the device (Modica et al., 2015; Ottenberg et al., 2014). Vocational adjustments were important component of regaining normalcy. A Danish study identified younger LVAD recipients struggled more returning to employment than older recipients that may be more established in careers before the LVAD or retired (Overgaard et al., 2012). This study emphasized the importance of evaluating physical, psychological, social, and vocational adjustments of LVAD recipients based on developmental age (Overgaard et al., 2012).

A study focused on DT LVAD recipients, emphasized preparedness planning before receiving the LVAD, optimizing support networks, systemic limitations of living with an emerging therapy (Ottenberg et al., 2014). In another study exploring BT LVAD recipients' experience, the emphasis was placed on a sense of freedom from AHF only to be dependent on the LVAD. Waiting on a heart transplant only magnified the desire for freedom (Modica et al., 2015). During the waiting period for a heart transplant, the concept of time also took on a new meaning (Ottenberg et al., 2014). LVAD recipients viewed the LVAD as a prosthetic organ or 'experimental,' and the reliability of the device questioned over time (Modica et al., 2015). A study conducted in the United Kingdom, reported the LVAD created a liminal identity, served as a temporal disruption to one’s life while waiting on a transplant, and the devices itself served as a liminal object supporting the recipient only until a new heart was available (Standing et al., 2017).

Complexities of Living with an LVAD

The external equipment presents unique challenges and complexities of living with an LVAD. Before hospital discharge, LVAD recipients must learn essential skills

regarding LVAD maintenance (e.g., e.g., system maintenance, securing adequate power, driveline immobilization, and driveline dressing changes) (Kato et al., 2014) and managing emergency alarms. Once patients return home, they must learn to incorporate these skills into their home environment and activities of daily living (e.g., hygiene, medication adherence, physical activity, nutrition, sleep, and rest) (Kato et al., 2014).

One study identified that adjustment and incorporating LVAD self-care to the LVAD is a process that occurs in two phases: (1) early home adaptation and (2) late home adaptation (Casida et al., 2011). During the early home adaptation phase, patients often notice an increase in energy and physical ability. Despite this increase, LVAD patients remain heavily dependent upon a caregiver for assistance performing activities related to hygiene, medication adherence, and transportation, among other self-care activities, which can be a source of frustration (Casida et al., 2011). Often changes to the home environment (e.g., electrical work to support the device, home generators) are required to support the LVAD optimally.

Additional studies identified the following inconveniences during LVAD adjustment: frequent travel for clinical appointments and laboratory services, psychological stressors (e.g., alterations in body image and surgical scares) (Chapman et al., 2007; Linda Marcuccilli et al., 2013), and modifying equipment during physical activity (e.g., exercise and sexual intimacy) (Alonso et al., 2018; Hallas et al., 2009; Marcuccilli et al., 2011).

In other studies, patients discussed a change in their sense of normalcy including the ability to improve in the management of the LVAD and incorporate daily activities such as cooking, sleeping, and hygiene (Casida et al., 2011; Chapman et al., 2007; Hallas

et al., 2009; Overgaard et al., 2012). In the early home adaptation phase, the LVAD patient often describes mixed emotions ranging from fear of LVAD complications to increasing confidence in self-care (Casida et al., 2011; Chapman et al., 2007; Overgaard et al., 2012). During late adaptation, LVAD patients also described difficulties returning to work and resuming previous roles. Patients discussed the difficulty of returning to work and resuming previous roles (Casida et al., 2011; Chapman et al., 2007; L. Marcuccilli & Casida, 2011; Overgaard et al., 2012; Sandau et al., 2014). Most importantly, LVAD patients described the importance of returning to normalcy, including the desire to appear normal in public (Casida et al., 2011; Ottenberg et al., 2014; Sandau et al., 2014)

LVAD Implant Indication

The two most commonly used device implant strategies include bridge to transplant (BTT) and destination therapy (DT). BTT is an implant indication used for patients actively listed for heart transplantation, utilizing an LVAD to prevent death or progressive end-organ dysfunction while awaiting transplant (Shudo et al., 2017). DT is an implant indication for patients who are not eligible for heart transplantation due to relative or absolute contraindication (e.g., body mass index, age, substance abuse, or malignancies) that will be supported by the LVAD for the remainder of life (Shudo et al., 2017). Despite the clinical implant indication at the time of LVAD surgery based on the recipients' ability to meet heart transplant criteria, implant indication can also evolve as the patient's conditions regarding transplant eligibility change over time (e.g., abstinence from illicit drugs, cessation of tobacco use, or weight loss) (Shudo et al., 2017).

The self-care requirements are the same for BTT and DT patients. The main differences in the two groups are the anticipated length of time on LVAD support and the anticipation of a heart transplant. The length of time BTT and DT patients live with an LVAD can vary dramatically. LVAD BTT patients may receive a heart transplant as early as six months after LVAD implant or may wait a couple of years supported on the device. Twenty to thirty percent of BTT patients receive a heart transplant by one year after device implantation (Kirklin et al., 2015). LVAD therapy is often most beneficial to patients that have extended time on the transplant waiting list (e.g., ABT blood type, large body habitus, or the presence of anti-HLA antibodies) (Shudo et al., 2017).

Due to the advancements in technology and improvements in patient care, the use of LVADs for patients has increased dramatically for patients not meeting transplant eligibility. In the 2006-2007 INTERMACS registry, 14.7% of patients received an LVAD as DT, which quickly increased to 46% by 2011-2014, making DT the prevailing strategy among all LVAD implantations (Kirklin et al., 2014, 2015). Patients can live as DT with a single device for greater than ten years and longer if supported by consecutive devices. DT LVADs have the potential to not only reduce the burden of limited organ supply but eventually may challenge heart transplantation as the standard of care for AHF patients (Kirklin et al., 2012).

Purpose

There is limited literature exploring the LVAD patient experience and adjustment to the device. Additionally, no known studies have explored if there is variation in how patients construct the impact on daily life and self-care or the LVAD patient experience based on implant indication. Therefore, the specific aims of this study were to explore

LVAD patient experience, describe how patients construct the impact of the LVAD on daily life and self-care, and compare the findings between BTT and DT patients. The following research questions were posed: (1) How do patients living with an LVAD perceive the comprehensive experience? (2) What are the perceived issues and challenges regarding LVAD adjustment? and (3) Do LVAD patients adjust differently according to the self-reported treatment trajectory (BTT or DT)? It is imperative to understand how BTT and DT LVAD recipients construct the patient experience in order to provide patient-centric education for each group and promote optimal adjustment.

Methods

The study used a general qualitative methodology with an interpretative approach to explore the perspectives of LVAD patients and achieve the aims of this research (Crabtree & Miller, 2009).

Setting

The setting for this study was the Texas Medical Center (TMC) located in southeastern Texas. The TMC is the largest life sciences location in the world. It is home to 54 institutions, five of which implant LVADs. Pioneering heart surgeons from the TMC have profoundly contributed to the development and advancement of the LVADs. Participant recruitment and sampling occurred in the outpatient clinic of two LVAD programs within the TMC, Baylor St. Luke's Medical Center (BSLMC), and Memorial Herman-Texas Medical Center (MH-TMC). The two programs collectively implant approximately 150 LVADs annually and manage routine care for over 300 patients.

The University of Texas Health Science Center at Houston, Cizik School of Nursing (UTHSC-CSON) served as the preferred location for both group and individual

interviews due to clinical neutrality. If participants were unable to access the CSON or had scheduling conflicts, interviews occurred at the LVAD clinics coinciding with a routine clinic visit.

Participants and Sampling

Participants were men and women currently implanted with an LVAD. The inclusion criteria for participants with LVADs were (a) adult participants (age > 18 years), (b) able to speak English, (c) currently living with a HeartMate II, HeartMate 3, or HeartWare device, and (d) greater than one-month post LVAD implantation. Sampling began with a purposeful sampling of LVAD outpatients from the two LVAD centers (Polit & Beck, 2017). As recruitment began to become saturated among a specific typology (i.e., BTT), the researcher used theoretical sampling to explore further the differences and similarities between the two typologies in question (BTT and DT) (Polit & Beck, 2017). To achieve variation within the sample, extreme or deviant case sampling and typical case sampling were also utilized (e.g., participants with challenging postoperative courses, device malfunctions, and replacements) (Green & Thorogood, 2004; Polit & Beck, 2017). Participant sampling and recruitment ceased once data saturation was reached.

Data Collection

Data was collected using open-ended group, and one-on-one interviews using a semi-structured interview guide (Table 1). The guide was developed based on the conceptual framework, Callista Roy's Adaptation Theory (Roy, 2009), a grand theory that focuses on the individuals' ability to adapt with the internal and external environment. Faculty with expertise in qualitative research also provided input on the interview guide.

Key questions included (a) How did you first learn about an LVAD? (b) How the LVAD impacted you physically. Psychologically? (c) Tell me about how the LVAD has impacted your ADLs. (d) How has the LVAD impacted your self-concept? (e) How has the LVAD has impacted your personal and professional roles (e.g., parent, spouse, employee, student)? As data analysis and collection continued, interview questions evolved in order to explore further emerging themes or concepts related to the adaptation process. Interviews were audio-recorded with participant written consent, and field notes were collected. The recordings were transcribed verbatim by a professional transcriptionist and verified for accuracy. All data were de-identified in order to protect confidentiality.

All LVAD participants completed a demographic survey. Demographic characteristics collected included self-reported age, race, gender, marital status, educational level, employment status, household income, LVAD device type, the reason for LVAD (e.g., BTT or DT), and length of time with LVAD.

Procedures

The UTHSC Institutional Review Board approved the study before data collection initiated. Study flyers were placed in outpatient clinic rooms or distributed by LVAD clinical providers at both AHF clinics. Onsite recruiting and screening for eligibility criteria also occurred at both clinics. If individuals met inclusion criteria and expressed interest in participating in the study, written informed consent was obtained and self-reported demographic data were collected. Participants then scheduled an appointment for an interview. Other participants who learned of the study from a study flyer contacted the researcher by phone or email and scheduled an appointment for an interview at the

CSON or one of the AHF clinics. These participants provided written informed consent and completed the demographic survey before the interview initiated.

Interviews were conducted in a quiet, comfortable location within the UTHSC-CSON or LVAD clinics. Participants from both LVAD centers were scheduled for group interviews according to self-reported LVAD indication (e.g., BTT or DT) in order to attain homogeneity and allow participants to speak openly concerning their experiences. Faculty from the UTHSC-CSON with expertise in qualitative research observed three of the interviews and provided feedback to ensure consistent data collection techniques. After the interviews, participants received a small honorarium ($10 gift card) and a parking voucher.

Data Analysis

Data analysis began shortly after data collection was initiated and continued throughout the data collection process. All audio recorded interviews were transcribed verbatim by a professional transcriptionist. Transcripts were proofread in order to develop a comprehensive understanding of the data and validate the transcription. The research team used peer debriefing and discussion to ensure credibility and dependability. Field notes, reflexive journaling, and an audit trail were collected to ensure transferability and confirmability (Lincoln & Guba, 1985).

Participants were assigned a study identifier and de-identified data (e.g., transcripts, field notes) were obtained. Hard-copy data was secured and stored behind a double lock at the UTHSC-CSON. Electronic data was stored within a secure online database (REDCap) behind UTHSC-CSON encrypted drive and firewalls. Transcripts were imported into ATLAS.ti version 8, a data management software program for

qualitative research (Scientific Software Development GmbH, 2017) to iteratively identify codes and a codebook developed. Themes, constructs, and a model were developed with recursive analysis and peer debriefing. Sampling continued until a good depth and repetition of themes were reached and little new information emerged.

Findings

Sample Characteristics

The sample consisted of 13 men and seven women (Tables 2 and 3). Eight identified as black, ten white, and two as more than one race (black/white and white/another race not indicated). The participants had been supported by LVAD therapy for a mean of 35.6 months and ranged from three months to 146 months. Three of the participants had experienced LVAD complications requiring device replacement. Two participants had two consecutive pumps, and one of the participants required two pump exchanges resulting in a total of three LVAD devices over an 11-year time frame (two HeartMate II devices and one HeartWare device).

At the time of data collection, HeartMate II devices supported five of the participants, HeartWare devices supported 12 participants, and HeartMate 3 devices supported three participants. Fourteen participants self-identified as bridge to transplant (BTT) (70%) LVAD recipients and six identified as destination therapy (30%) LVAD recipients. Of the participants that reported BTT, eight of the participants self-reported being listed for a heart transplant and six of the participants self-reported not listed for a heart transplant (Table 3). Most of the participants were married (55%), had some college, but no degree (40%), were retired (45%), and reported an income of less than $20,000 annually (50%).

Living with the LVAD: A Second Chance at Life

In order to describe how LVAD patients construct the impact of the LVAD on daily life and the holistic self, a linear and sequential model was developed (Figure 1). The model depicts the three separate phases representing the LVAD patient experience, (1) illness perception, (2) LVAD adjustment, and (3) health aspirations. Each phase directly influences the phase(s) that follow. Before receiving the LVAD, participants recalled aspects of living with AHF and what it was like to first learn about LVAD therapy. The perception participants of the illness process before LVAD directly impacts how one perceives LVAD adjustment.

Following the LVAD implant, participants described six components that impacted LVAD adjustment and the holistic self. The six components include (1) physical ability, (2) caregiver dependence, (3) self-care, (4) roles, (5) LVAD public perception, and (6) connection. The factors that participants discussed as the most relevant following LVAD implantation included one's physical ability and caregiver dependence. As time progressed and recipients progressed through the LVAD adjustment process, self-care and roles became important, followed by LVAD public perception and connection.

The LVAD recipient's perceived LVAD trajectory (BTT or DT) influenced the LVAD adaption process. It is this perception that influences all aspects of LVAD adjustment but does not differ based on implant indication. The holistic person, as well as health aspirations, were most heavily influenced by the perceived treatment trajectories and differed based on perceived BTT treatment trajectory or perceived DT treatment trajectory. The LVAD recipients that reported they were BTT expressed future

motivations for heart transplantation. Those that reported DT described future aspirations of LVAD device longevity (e.g., support on LVAD therapy for more than ten years). Overall, both BTT and DT participants reported various inconveniences associated with living with an LVAD; however, they also expressed the LVAD was life-sustaining. Most participants expressed heartfelt gratitude for a second chance or "New Lease on Life."

Illness Perception

Illness perception includes descriptions of the AHF disease process and symptoms before receiving the LVAD. Additional key findings worth noting included: experiences regarding AHF care from community providers (e.g., local primary care providers or cardiologists not specializing in AHF treatment options [LVAD or heart transplant]), initial introduction to an LVAD, having a limited choice regarding the acceptance of the LVAD, and the surgical recovery following the LVAD implant. Table 4 provides participant exemplars.

Advanced Heart Failure (AHF).

Almost all participants described significant AHF symptoms (e.g., shortness of breath, edema, orthopnea, dyspnea on exertion, and limited mobility). Participants emphasized being able to walk only a short distance without having to stop and sit down. The symptoms also limited the participants' ability to perform ADLs. Participants' symptom burden with AHF was directly influential on the participant's expectations post-surgical implant of the LVAD.

Community Care.

Many participants noted positive experiences regarding initial AHF care by community providers and expressed gratitude for being referred to an LVAD center.

Others noted frustration in delayed referrals for AHF treatment or "not being heard" by providers in the community, requiring the participant to seek advanced therapies independently. One female participant reported instructions from her health care provider to lose weight and that would resolve all her AHF symptoms would resolve. Her concerns were ignored despite her persistence that something was wrong aside from her increased weight. Participants also reported participants also discussed a lack of community awareness of LVADs. Many of the participants had very limited or no prior knowledge of LVAD therapy. Participants that were less familiar with the LVAD before receiving the device experienced increased challenges in the LVAD adjustment phase. In contrast, one participant that received the LVAD after her bother received a device. She described a seamless transition through the phases of LVAD adjustment after witnessing her brother's experience.

Introduction to an LVAD.

All participants discussed thorough education about the LVAD by clinical providers (e.g., physicians, LVAD coordinators); however, the time from initial introduction to device implant varied significantly among participants. A couple of the participants noted being supported by medical therapy for approximately one to three years before receiving the LVAD. Other participants described being admitted to the hospital for the LVAD either immediately or within days after the initial AHF clinic visit. The participants with extended time between first introduction and LVAD implant reported researching LVADs through social media (e.g., Facebook groups, online chats, YouTube), appeared to more readily adjust than those that had a short period between introduction to the LVAD and device implant.

Limited Choice.

During AHF symptoms, participants expressed having a limited choice when having to decide on an LVAD; however, participants recognized that death was a choice. Several participants verbalized being comfortable with the thought of death, however opting to give the LVAD a try. A female respondent discussed being very reluctant to receiving the LVAD; however, after discussing in-depth with her cardiologist and thinking on aspects of her life that she valued (e.g., family, grandchildren), she opted to proceed with an LVAD. Male and female participants alike reported being in the hospital and acknowledging they would die or discharge on hospice if they chose not to receive the LVAD. Patients that self-reported DT often felt they had a limited choice regarding treatment options (e.g., LVAD vs. heart transplant). Some participants adjusted well, regardless of having a limited choice in treatment options. Others, most commonly DT participants, did not adjust optimally due to limited choice.

Cardiac Surgery and Recovery.

Several participants described anxiety related to anticipation of a sternotomy, cardiothoracic surgery, waking up with an endotracheal tube inserted, and being mechanically ventilated. Multiple participants described anxiety and stress when recounting aspects of the cardiac surgical recovery (e.g., intubation and ICU delirium). Some respondents described a lack of pre-surgical knowledge of intubation. Additional respondents expressed fear and great distress recalling waking up with the breathing tube inserted and not being able to communicate effectively. Multiple participants vividly recalled the trauma of intubation and surgical recovery despite how long the recipient had been living with an LVAD.

LVAD Adjustment

LVAD adjustment refers to an individual's ability to adapt or incorporate the LVAD into daily life. Both BTT and DT participants described a similar LVAD adjustment process. When describing adjustment, participants described six components of LVAD adjustment that progress from left to right in order of importance (e.g., moving from LVAD implant towards the Future): (1) physical ability, (2) caregiver dependence, (3) self-care, (4) roles, (5) LVAD public perception, and (6) connection.

Overall, participants all discussed successfully achieving LVAD adjustment. Participants noted challenges related to adjustment, and the time required for getting back to normal varied among participants from a couple of weeks to approximately two years.

Components of LVAD Adjustment.

This study identified six specific components of LVAD adjustment, as previously described. Each component is independent of the other components, yet directly influences the holistic self. Components can influence one another through the transformation of the holistic self. Table five presents participant exemplars regarding the specific components of LVAD adjustment.

Physical Ability.

Physical ability refers to one's ability to perform a physical act. Many participants described a noticeable difference in their physical ability very quickly after the LVAD, while others noted a gradual improvement over many months. Because of the dramatic physical impairments before the LVAD, often, physical improvements were one of the first items that participants expressed, as demonstrated in the model (Figure 1). Multiple

respondents described having increased energy. A few participants noted having this increase in energy as early as a couple of days to weeks post-operatively.

In contrast, others reported it taking one to two years to return to what the recipient considered 100%. Others discussed being able to do significantly more activities (e.g., cooking, washing the dog, mowing the grass, planting a garden) than before receiving the LVAD. One participant reported a very lengthy post-operative recovery lasting over ten months. This decrease in acute physical ability post-LVAD negatively impacted adjustment. The participant noted that while he was still improving in his strength, he still noted remarkable differences from the participants in the group interview.

Caregiver Dependence.

Despite improvements in physical ability, participants initially required assistance from caregivers. Caregivers varied, one participant described his wife, a nurse, being his primary care provider due to her healthcare background. Others noted parents, spouses, or multiple family members collectively taking on the caregiver role. As time progressed with the LVAD, many participants described gaining more independence and requiring little help from a caregiver, and some eventually achieved independence. One participant reported living completely alone and successfully managing her LVAD for over three years with a limited support system.

Self-Care.

Self-care refers to the behaviors performed in order to improve well-being, preserve health, maintain physical ability, and emotional stability (Riegel et al., 2012). One of the largest aspects of LVAD self-care is self-care maintenance (Kato et al., 2014).

Multiple participants reported an acute awareness of the driveline and battery cables. This acute awareness of the external equipment often became a social barrier as participants described a fear of having the battery cables or driveline disconnected in large crowds. Participants also described difficulty managing the equipment in stadium seating for professional sporting events (e.g., baseball) or entertainment venues (e.g., symphony, concerts).

Aside from the external LVAD equipment, the device weight was the next most impactful aspect of device management. One participant who received his device soon after being introduced to the device described being very surprised about the weight of the external equipment. Many participants noted the device weight limited exercise tolerance and limited ADLs.

Due to the inability to get the LVAD wet, LVAD recipients had to take precautions to ensure the driveline exit site and external equipment stayed dry when performing hygiene. Securing the driveline exit site and equipment could take up to 30 minutes to an hour and required assistance from a caregiver. Due to the complex process of taking a shower, many participants described taking "hospital type" sponge baths.

Universally, the women reported significant inconveniences with clothing selection. Women were also overall more concerned with the bag and accessories used to manage the external LVAD equipment. One male participant, currently employed as a law enforcement detective, expressed concerns regarding clothing and device wearables. He reported that despite modifications, most clothing made it extremely complicated for him to manage the LVAD and law enforcement equipment. He noted that when trying a

tactical shirt used by many LVAD recipients, the controller overheated while performing routine job duties due to prolonged exposure to the heat.

Participants described inconveniences related to sleep and the management of the external LVAD equipment. The most common inconvenience reported was positioning the LVAD in order to be comfortable for sleep. One participant expressed anxiety and fear of the device controller falling off the bed in the middle of the night and pulling the driveline out of his chest. Another participant reported sleeping on batteries, despite medical recommendations to sleep on AC power, due to the necessity to get up and urinate throughout the night.

Participants described various practices and clinical recommendations regarding driving. Many participants described the return to driving and even completing some long-distance trips by care, while others noted returning to driving but only in a limited area. Others reported not returning to driving at all due to medical recommendations. One participant highlighted that with the LVAD, the lap belt now sits appropriately across his upper thighs rather than incorrectly across the abdomen.

Participants noted complications regarding recreational and leisure activities. Due to the inability to get the LVAD equipment wet, almost all participants reported inconveniences and frustrations with not being able to participate in water activities. Other participants reported inconveniences and frustrations regarding travel. One female reported feeling uncomfortable and embarrassed about going through airport security. Other participants report abstaining from or limiting travel due to being temporarily inactivated from the transplant waiting list while greater than four hours away from the transplant center.

Roles.

Roles include the duties that someone has or is expected to have ("Role definition in the Cambridge English Dictionary," n.d.). Participants report changing roles that often started due to AHF. Participants reported decreased ability to participate in family activities or perform ADLs around the house. Often these roles and ability to contributed to one's family improved after the LVAD. A woman described the inconveniences regarding the LVAD equipment and her interactions as a grandmother. At the same time, two gentlemen discuss the frustration of not being able to care for grandchildren as previously before the LVAD.

Several participants reported the loss of employment and having to go on disability or retire early, while others discussed how the LVAD was preventing a return to employment. In contrast, participants that reported higher education were often able to return to employment. These participants often had jobs that did not require heavy lifting, pose infection risks, and flexible hours to accommodate clinic appointments.

LVAD Public Perception.

LVAD public perception refers to how one perceives people in general, or people in a country or community, think about the LVAD or the impression they have of the device. The LVAD bag and accessories were also significant for how women were publicly perceived and how the weight was physically supported. One woman selected to carry her LVAD with the controller and batteries strapped around her chest across her sternum. The unique positioning of her LVAD equipment served as a function to help support the weight of the device despite outward appearance. Due to the positioning of her equipment, the participants described situations in which security perceived the

LVAD as a threat (e.g., bomb). While some participants described a disregard to the visibility of the external LVAD equipment and public perception, others reported concern for others perceiving the LVAD was of value and the possibility of attempted theft. Public misperception was especially true for participants that carried the LVAD, where it was outwardly visible and used public transit.

Connection.

Connection is defined as "The energy that exists between people when they feel seen, heard, and valued; where they can give and receive without judgment; and when they derive sustenance and strength from the relationship" (Brown, 2012). Participants expressed a connection with clinical providers when they felt seen, heard, and valued. When waiting for an LVAD, participants often reported connecting to LVAD patients and gaining insight and strength to pursue and adapt to the LVAD. Once implanted with the LVAD, participants often derived sustenance from friendships and activities with other LVAD recipients. It was in these relationships that participants expressed the ability to share without being judged. Lastly, participants valued connecting with AHF patients awaiting an LVAD or people in the community that expressed interest in learning more about the LVAD.

Holistic Person.

The LVAD participant as a holistic person involves being aware of the entire being and understanding all the components that contribute. All the identified and described areas of LVAD adjustment identified in Figure 1 contribute to the holistic person. One of the predominant topics of describing oneself was the desire for normalcy after receiving an LVAD. Respondents described “normal” as being able to achieve

specific tasks (e.g., return to golf, grocery shopping, returning to work). Participants also described how the LVAD prevented specific normal activities (e.g., driving, water activities).

Participant Perceived LVAD Trajectory.

Within the theme LVAD Adjustment, two trajectories emerged: Perceived BTT LVAD Trajectory and Perceived DT LVAD Trajectory. The concepts were overarching influences on the holistic person and the six components of adaptation depicted in Figure 1. However, the trajectory was perceived, either BTT or DT demonstrated the most significant influence on the holistic person and health aspirations.

Participants that self-reported BTT grappled their holistic self. Internal issues such as the statistical odds of receiving a heart transplant, perceived disabilities, the realization that someone must die in order for the LVAD recipient to receive a heart transplant, equity regarding organs, beliefs regarding artificial life support, and spirituality regarding life and death.

The holistic self of participants that did not meet transplant criteria, destination therapy, struggled with inadequacies regarding ineligibility for a heart transplant (e.g., age, illicit substance or tobacco use, or BMI). One DT participant reported confidence in her decision, "it was my choice," to proceed with the LVAD for the duration of her life.

Participants that perceived they were BTT, whether currently on the transplant list or not, discussed factors that motivated them to the goal of a heart transplant, while those that perceived themselves as DT discussed the desire for device longevity and outliving current technological trends.

Health Aspirations

Health Aspirations referred to hopes or ambitions of achieving something specific to their health. Overall, participants' initial health aspirations focused on the tasks necessary for survival. Many described acute awareness that without the LVAD, death was imminent.

Motivation for Heart Transplant.

BTT and DT participants' responses differed regarding health aspirations of living with AHF treatment (i.e., LVAD). BTT participants listed for heart transplant reported specific reasons for the pursuit of a heart transplant. One individual expressed that he was a public speaker and felt that his story would be complete with the transplant. Another reported that he could live for the remainder of his life with the LVAD; however, he was on dialysis, which significantly decreased the quality of his life. In order to receive a kidney transplant, he would also need a heart transplant.

LVAD participants that were not on the transplant list expressed aspirations of achieving heart transplant criteria (i.e., weight loss, achieving a period tobacco-free) and the intent to continue to the transplant list. One participant reported her struggles to lose weight, ultimately delaying her from transplant listing, and attributed such difficulties to the possibility that she was not entirely comfortable with someone dying for her to receive a heart transplant

Device Longevity.

Due to the relatively new advancements in LVAD technology, the comprehensive longevity of the LVAD is unknown. Currently, some patients have been supported by a single LVAD for over a decade. Additionally, if LVAD recipients experience

complications with one pump, the pump can be exchanged for a new device. LVAD replacement is often a relatively uncomplicated surgery that generally yields favorable results. DT participants expressed health aspirations of extended life on the LVAD (i.e., greater than ten years) or technologic advancements that could replace the current LVAD (i.e., future generation LVAD pumps). One participant discussed how his heart was overall in great condition; therefore, the pump should last a very long time (e.g., greater than ten years).

Living with an LVAD is Inconvenient but Life-Sustaining

The single overarching theme of the study reported by participants; living with an LVAD is inconvenient, but life-sustaining. Participants constructed the LVAD patient experience in three phases: (1) illness perception, (2) LVAD adjustment, and (3) and health aspirations. Participants described the LVAD adaptation process in greater detail with emphasis on six components: (1) physical ability, (2) caregiver dependence, (3) self-care, (4) roles, (5) LVAD public perception, and (6) connection. Each of these independent components of LVAD adaptation impacts the holistic person and vice versa. The independent components do have the potential to influence other components as it influences and changes the holistic person.

Both groups of participants (BTT and DT) constructed similar phases of how the LVAD impacted daily life and self-care (e.g., illness perception, LVAD adjustment, health aspirations). Perceived LVAD trajectory begins at the time of LVAD implant and influences LVAD adaptation and the respondents' health aspirations. Participants who identified as BTT expressed individual and specific motivations for pursuing a heart transplant, where participants who reported they would have the LVAD for the rest of

their life (DT) reported hope and desire to live greater than ten years with the LVAD technology. The overarching theme acknowledged that living with an LVAD certainly has its challenges; however, it allows for the patients to experience a second chance at life.

Discussion

Living with the LVAD: A Second Chance at Life

Understanding the process in which LVAD recipients construct the overall patient experience is essential to optimizing LVAD adjustment resulting in improved patient outcomes. The model (Figure 1) depicts the three phases described by participants in this study.

Previous studies have identified components of LVAD self-care (Casida et al., 2011; Chapman et al., 2007; Kato et al., 2014; Overgaard et al., 2012); however, this study notes the emphasis on individuals striving to achieve independence in caring for the LVAD. For example, one participant reported living alone with the LVAD for over three years. The study also identified inconsistencies in patient-perceived LVAD self-care instructions or requirements (e.g., dressing change frequency and supply process, driving allowances, and dietary recommendations). The researcher observed these inconsistencies among participants within the same LVAD center in addition to the two separate LVAD centers.

Previous research highlighted the phases in which LVAD self-care occurred: (1) early home adaptation and (2) late home adaptation (Casida et al., 2011) and noted the adjustment to self-care activities could be a source of frustration (Casida et al., 2011).

This study expanded on the components of LVAD adjustment and highlighted the importance of roles, LVAD public perception, and connection in the adaptation process.

Previous studies highlighted the desire for normalcy. In these studies, participants described normalcy as incorporating the LVAD into ADLs the recipient valued or looking normal in public. (Alonso et al., 2018; Casida et al., 2011; Chapman et al., 2007; Hallas et al., 2009; Marcuccilli et al., 2013; Ottenberg et al., 2014; Overgaard et al., 2012; Sandau et al., 2014). In this study, participants emphasized specific activities by which participants measured normalcy (e.g., golf, grocery shopping) rather than public appearance.

Clinical Impact Trajectory vs. Patient Perceived Trajectory

All LVAD recipients are assigned a clinical implant indication based upon the recipient's ability to meet transplant criteria. Recipients must often wait a minimum period of six months post LVAD implant in order to allow for surgical recovery before heart transplant listing. Additional factors (e.g., BMI, substance abuse, health care compliance, limited social support) may delay an LVAD recipient's activation on the heart transplant list. The study identified a possible disconnect regarding clinical the clinical implant trajectory and the self-reported LVAD trajectory and self-reported heart transplant listing status. Fourteen participants self-identified as BTT candidates; however, only nine self-reported actively on the list for a heart transplant. This discrepancy presents the need for further research as to why participants would perceive they are BTT candidates despite not being active on the heart transplant list.

Future Implications

Clinical Practice

The model developed in this study identifies six modes related to the LVAD adaptation process. In order to promote adaptation, clinical providers should be knowledgeable regarding the various modes of each LVAD patient's adjustment processes. Clinical providers can assist patients through the various modes of adaptation identified (e.g., physical, caregiver dependence, device management, roles, LVAD public perception, and connection). For example, an understanding of a patient's caregiver dependence allows the LVAD team to provide patient-centric education regarding the care of the device. Patient-centric education is critical if the patient has limited social support or will be living alone. Additionally, providers can expedite teaching the patient to perform LVAD dressing changes independently and monitor for clinical signs of infection if the provider knows there is a strong desire to be independent and has a fear of being a burden to caregivers. Also, younger LVAD patients that are planning to assume the roles of college students may need special considerations regarding clinic appointment scheduling in order to accommodate classes.

In this study, participants discussed a strong desire to connect with clinical providers and other LVAD patients. Several of the participants described strong existing connections with LVAD patients, reporting frequent contact and encouragement along with participating in social activities together (e.g., golf, travel, and social activities). The connection among LVAD patients provides the opportunity to express challenges and frustrations as well as receive advice and recommendations in a safe, nonjudgement environment. LVAD centers should provide opportunities for LVAD recipients to

connect in order to establish friendships, exchange information, provide peer support, and connect with others experiencing LVAD adjustment.

Patient Education

Overall, participants noted satisfaction concerning LVAD education and preparation for the patient or caregiver to care for the device upon hospital discharge. However, several participants mentioned a lack of preparation and even traumatic experiences regarding aspects of cardiac surgery (e.g., intubation, intensive care unit psychosis, post-surgical pain). Providers have the opportunity to optimize LVAD patient education and include information regarding the cardiothoracic surgery, intubation, and post-operative recovery.

Additional areas for patient education include how to modify clothing and LVAD accessories (e.g., belts, vests, pants) to accommodate a patient's various activities. Male and female participants also noted frustration regarding wearing the LVAD and external equipment. It often takes a lengthy period and much trial and error for patients to achieve personal ways to wear or carry LVAD equipment. This process has the potential to delay or frustrate participants as they move through the LVAD adaptation process. Often patients do not have access to try various ways to wear or carry LVAD equipment before purchasing products. LVAD centers should consider investing in a variety of LVAD equipment and accessories for education, and so patients may try on at clinic visits. Optimizing the LVAD adaptation process has the potential to improve LVAD patient satisfaction with the device and increase stabilization of the LVAD, thus preventing mishaps (e.g., device drops, driveline exit site injuries, device malfunctions).

Future Research

The findings of this study present several opportunities for further research. This study identified the potential disconnect between the clinical LVAD implant indication and the patient perception of the LVAD treatment trajectory. Of the participants, six (30%) self-reported BTT, however, indicated they denied current heart transplant listing. Research is needed to determine if participant perception aligns with the LVAD clinical team perception of the participants' perception and what factors are hindering participants from being listed for transplant. This study also identified inconsistencies regarding clinical care requirements (e.g., medication adherence, risks for infection) regarding heart transplantation. For example, some participants discussed returning to activities after heart transplantation that clinical providers might feel pose an increased risk of infection (e.g., parks, activities with large crowds). Participants expressed the desire for a heart transplant due to the ability to have increased energy, improved tolerance to the heat, and extended life greater than ten years. Despite perception, there are no guarantees that clinical outcomes after transplant will achieve the above. There is a need to fully understand the LVAD patient's perspective regarding motivation for heart transplantation in order to establish realistic expectations.

Employment often fulfills one's ability to contribute financially to one's household as well as provides a purpose for individuals. Limited research is available regarding employment with an LVAD device. One study describes the challenges with assisting younger LVAD patients to find occupations conducive to the LVAD as well as helping other transition from the sick role into meaningful employment (Overgaard et al., 2012). This study identified the loss of employment before receiving the LVAD due to

AHF symptoms. Participants also varied in responses regarding an ability to return to employment. Participants noted being employed previously in positions that presented challenges to returning due to physical requirements (e.g., lifting heavy objects, driving heavy machinery) and risks for driveline infection (e.g., exposure to weather, heat). Participants who expressed the ability to return to work possessed similar occupational characteristics: work that could be completed remotely from home. These flexible schedules can accommodate frequent healthcare clinic visits and requiring little to no physical requirements. However, occasionally participants who identified prior occupations that met the above criteria did not return to work. It is essential to further explore motivating factors regarding obstacles and barriers related to employment after the LVAD. LVAD clinical providers should have an understanding of this vital component of LVAD adjustment.

The study also depicts discrepancies among patient perceptions regarding activities such as support system, driving, dressing change frequency, anticoagulation management. Often these activities or inconveniences create frustration and more significant challenges regarding LVAD adaptation. Incongruences regarding modes of LVAD adjustment included the following: (a) living independently vs. being required to have continual care provide (e.g., having to relocate to live with family), (b) center recommendations regarding driving (e.g., physician approval to return to driving vs. inability to drive at all), (c) frequency of driveline dressing changes (e.g., daily vs. biweekly or weekly), (d) dietary recommendations (e.g., ability to eat vitamin K rich foods vs. having to refrain from such foods), and (e) frequency, and convenience of lab

monitoring (e.g., home INR monitoring). Further research and standardization of best practices between LVAD centers could profoundly impact the LVAD adaptation process.

Strengths and Limitations

This study provided, to our knowledge, the first qualitative study to explore LVAD adaptation and the patient perceived LVAD implant indication among participants from two LVAD centers. Using study participants from two centers allowed researchers the ability to confirm responses among participants and increase generalizability. The semi-structured interview guide used Roy's Adaptative Model (RAM) (Roy, 2009) as a theoretical structure served as a strength of the study allowing the researchers to explore the holistic approach to LVAD adjustment. The concepts derived from the study (e.g., caregiver dependence, device management, roles, LVAD public perception, connection, and holistic person) varied from that traditionally described in RAM, the researchers were able to develop a model more specific to the experiences of LVAD participants regarding the adjustment experience.

The sample attempted to capture a similar demographic representation of the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS), national LVAD data registry, in order to increase study applicability (e.g., 46% DT and 54% BTT in 2011-2014)(Kirklin et al., 2015). However, more participants identified as BTT than one would anticipate based on the INTERMACS registry. Despite these participants identifying as BTT, they self-reported they were not active on the transplant waiting list, leaving room to question if these participants may have received an LVAD as a DT implant indication at the time of device implant.

A limitation of the study included a lack of confirmation regarding LVAD implant indication, current transplant listing status, and specific factors contributing to heart transplant ineligibility. Additionally, participants self-selected to be interviewed, thus their overall health may be more optimal than other LVAD patients. Finally, the sample consisted of BTT and DT participants; although we noted overall consistency in responses regarding LVAD adjustment among the groups, other studies may discover different findings.

Conclusion

Roles, public perception, and connection were significant to LVAD patients but are often not addressed in this population. Results provided a basis for topics for further exploration and study, such as how patients adapt to the LVAD without caregiver support. This study identified the need for opportunities for LVAD patients to connect with clinical providers and participate in activities with other LVAD patients. Topics identified for further education among LVAD patients included the following: post-surgical care, showering/bathing, clothing, equipment options, travel, navigating security, and an annual refresher for managing clinical complications. Finally, results provided a basis for further qualitative exploration regarding the patient perspective of challenges in transplant listing in BTT patients that have a delay in transplant listing.

Table 1

Semi-structured guide for group and individual interviews.

Opening:
1. Please share your first name and how long you have had your LVAD, and if you have ever had your LVAD replaced.
Transition:
2. How did you first come to learn about an LVAD?
Key Questions:
3. Can you share how the LVAD has impacted you physically? Psychologically?
4. Tell me how the LVAD has impacted your self-concept both positively and negatively?
5. How did your family and friends initially respond to the LVAD?
6. What are some of the "roles" that you have among your family and professionally (e.g., spouse, family member, parent, financial provider, caretaker)? Can you share how the LVAD has impacted these roles?
7. Tell me about how the activities that require assistance from someone because of the LVAD?
8. How has the LVAD impacted your activities of daily living?
9. How would it impact your life if you knew you were going to live with the LVAD for the rest of your life?
Ending:
10. After having the LVAD for a period now, what information do you wish you would have known before receiving the LVAD?
11. What information would you share with someone thinking about getting an LVAD to best prepare them?

Note. Based on the interview structure outlined by (Crabtree & Miller, 2009) and questions guided by the RAM (Roy, 2009)

Table 2

Sociodemographic Characteristics of Participants

Characteristic	Value (%)
Age, mean	57 years
Black or African American	8 (40%)
White	12 (60%)
More Than One Race	2 (10%)
Gender	
Female	7 (35%)
Male	13 (65%)
Length of Time with LVAD	
< 1 year	3 (15%)
1 – 2 years	9 (45%)
3 – 4 years	5 (25%)
5 – 6 years	2 (10%)
7 – 8 years	0 (0%)
9 – 10 years	0 (0%)
> 10 years	1 (5%)
Device Type:	
HeartMate II[a]	5 (25%)
HeartWare[b]	12 (60%)
HeartMate 3[c]	3 (15%)
Reason for LVAD:	
BTT	14 (70%)
DT	6 (30%)
Marital status:	
Single (never married)	3 (15%)
Married	11 (55%)
Widowed	1 (5%)
Divorced	4 (20%)
Separated	1 (5%)
Education level	
High school degree or equivalent[d]	5 (25%)
Some college, no degree[e]	8 (40%)
Bachelor's degree[f]	4 (20%)
Master's degree[g]	1 (5%)
Professional degree[h]	2 (10%)
Employment Status:	
Employed full time[i]	1 (5%)
Employed part-time[j]	2 (10%)
Unemployed and not currently looking for work	1 (5%)
Student	1 (5%)
Retired	9 (45%)
Self-employed	1 (5%)

Unable to work	5	(25%)
Household Income		
Less than $20,000	10	(50%)
$20,000 to $34,999	1	(5%)
$35,000 to $49,999	2	(10%)
$50,000 to $74,999	2	(10%)
$75,000 to $99,999	1	(5%)
>$100,000	2	(10%)
Did not disclose	1	(5%)

Note. *N* = 20. LVAD, left ventricular assist device; BTT, Bridge-to-transplant; DT, Destination therapy; [a] HeartMate II®; [b] HeartWare® (HeartWare, Inc., Framingham, MA); [c]HeartMate3®
[d]High school degree or equivalent (e.g., GED), [e]Some college, no degree, [f] Bachelor's degree (e.g., BA, BS), [g] Master's degree (e.g., MA, MS, Med), [h] Professional Degree (e.g., MD, DDS, DV, Ph.D., EdD), [i](40 or more hours per week); [j](up to 39 hours per week)

Table 3

Sociodemographic Characteristics and Recruitment Site of Participants

Screening Site	Age	Gender	Race	LVAD Device	Length of Time on Device(s)	Marital Status	Education Level	Current Employment Status	Income	S-R Indication & Listing
MH-TMC	64	Male	Black	HeartMate II®, [a]	5-6 yrs.	Divorced	Some college[e]	Retired	$35,000 to $49,999	BTT – (L)
MH-TMC	55	Female	White	HeartWare®, [b]	1-2 yrs.	Divorced	High school[f]	Unable to work	< $20,000	BTT – (L)
MH-TMC	70	Male	White[d]	HeartWare®, [b]	1-2 yrs.	Married	Some college[e]	Retired	< $20,000	BTT – (L)
BSLMC	64	Male	White	HeartWare®, [b]	3-4 yrs.	Married	Professional[g]	Retired	> $100,000	BTT – (L)
BSLMC	57	Male	Black	HeartMate 3®, [c]	1-2 yrs.	Married	Some college[e]	Self-employed	$20,000 to $34,999	BTT – (L)
MH-TMC	62	Female	Black	HeartWare®, [b]	5-6 yrs.	Divorced	Bachelor's[h]	Unable to work	< $20,000	BTT – (L)
BSLMC	54	Male	Black	HeartWare®, [b]	> 10 yrs.	Single	High school[f]	Unable to work	< $20,000	BTT – (L)
MH-TMC	23	Female	Black	HeartWare®, [b]	1-2 yrs.	Single	Some college[e]	Student	< $20,000	BTT – (L)
MH-TMC	39	Female	White	HeartWare®, [b]	1-2 yrs.	Married	Some college[e]	Employed PT	$75,000 to $99,999	BTT – (L)
MH-TMC	62	Male	White	HeartMate II®, [a]	3-4 yrs.	Married	Some college[e]	Retired	Did not disclose	BTT – (NL)
BSLMC	61	Male	Black	HeartMate 3®, [c]	< 1 yr.	Divorced	High school[f]	Retired	< $20,000	BTT – (NL)
BSLMC	68	Male	Black[d]	HeartWare®, [b]	< 1 yr.	Married	Bachelor's[h]	Employed FT	> $100,000	BTT – (NL)
BSLMC	47	Female	White	HeartWare®, [b]	1-2 yr.	Separated	Some college[e]	Unable to work	< $20,000	BTT – (NL)
BSLMC	46	Female	White	HeartMate II®, [a]	3-4 yrs.	Single	Bachelor's[h]	Retired	< $20,000	BTT – (NL)
MH-TMC	49	Male	Black	HeartMate II®, [a]	3-4 yrs.	Married	High school[f]	Unable to work	< $20,000	DT
BSLMC	66	Male	White	HeartWare®, [b]	1-2 yrs.	Married	Master's [i]	Retired	$35,000 to $49,999	DT
BSLMC	74	Male	White	HeartWare®, [b]	1-2 yrs.	Married	Professional[g]	Employed PT	> $100,000	DT
BSLMC	73	Male	White	HeartWare®, [b]	1-2 yrs.	Married	Bachelor's[h]	Retired	$50,000 to $74,999	DT
MH-TMC	66	Female	White	HeartMate II®, [a]	3-4 yrs.	Widowed	High school[f]	Retired	< $20,000	DT
MH-TMC	34	Male	White	HeartMate 3®, [c]	< 1 yr.	Married	Some college[e]	Unemployed[j]	$50,000 to $74,999	DT

Note. N=20. LVAD, left ventricular assist device; S-R Implant & Listing, Self-Reported Implant Indication & Listing Status; MH-TMC, Memorial Herman – Texas Medical Center, Houston, TX; BSLMC, Baylor St. Luke's Medical Center, Houston, TX; PT, Part-Time; FT, Full-Time; BTT, Bridge-to-transplant; (L), Listed for heart transplant; (NL), Not listed for heart transplant; DT, Destination therapy
[a] HeartMate II®; [b] HeartWare® (HeartWare, Inc., Framingham, MA); [c] HeartMate 3®
[d] Identified as More than one race, [e] Some college, no degree, [f] High school degree or equivalent (e.g., GED), [g] Professional Degree (e.g., MD, DDS, DV, Ph.D., EdD), [h] Bachelor's degree (e.g., BA, BS), [i] Master's degree (e.g., MA, MS, Med), [j] Unemployed and not currently looking for work.

Table 4

Living with the LVAD: A Second Chance at Life participant exemplars.

Illness Perception	AHF	"I went from gasping from breath and not being able to do a lot of things. Like, I could get out to the driveway and get my newspaper and come back in; that was it. That was my eight-hour job for the day." [Participant 26] "I developed breast cancer, and then the second year, I developed breast cancer again. And after that, the doctor did tell me that I will---with all the chemo, it weakened my heart and that eventually, I would be needing some kind of heart treatment or et cetera." [Participant 3]
	Community Care	"They wouldn't listen to me. It was, you just need to lose the weight, and it'll fix itself. You need to lose the weight; it'll fix itself. No, you're not hearing me, there's something wrong with me…This [LVAD] is unknown…Y'all deal with it every day. This [the LVAD] is a common occurrence for you all. For us, it's not…It's not out there at all [community LVAD knowledge]." [Participant 46]
	Introduction to an LVAD	"Well, first of all, they wanted me to decide. I had to go home for a couple of weeks and sit on the front porch and pray and figure it out with God, and I decided that it was the route to go because they [family] all wanted me to stay around a while." [Participant 20] "And I thought I was just going in to ask questions you know, to—you know, just the routine…checkup thing—just routine questions and stuff. And it didn't happen like that. The same day that I had the appointment with him, he put me in [hospitalized]. I mean, you know, he told me about the LVAD, but that very day he put me in. And total, after the operation and everything else, I was in there for a little over three months. That's how I found out about it [an LVAD]." [Participant 42]
	Limited Choice	"I was told I need an LVAD; I was reluctant against it. And, [cardiologist], she had to talk me into getting one. So, after she made me realize things [my grandkids and my three boys], then I went on and agreed with it" [Participant 45]. "And then, of course, after I'm in the hospital and I'm going downhill pretty fast, you know, where they can't get me out of AFib. And basically, I'm just really feeling bad. And then they tell me, well, we can do-, we can do this. And frankly, that's your only choice. You know? So, it was an easy decision for me to make. I had no qualms

		about going through with it because if it was my only chance, you know, I feel like I've got a lot of things that I want to see and do" [Participant 37].
	Cardiac Surgery Recovery	"When they told me that they were going to have to put a tube down—a breathing tube down me, and I kind of freaked out, and she said, 'Oh, no, it will be removed before you wake up.' I was not prepared for what happened because all I knew—I didn't think about the tube—all I knew is that I couldn't breathe, nobody was in there, I couldn't remember where I was. There were no nurses, no family, no nothing. And, like I said, it was only a couple minutes at a time, maybe a couple of seconds at a time, that I would come to. But each time that it happened, it was the same thing. And honestly, I thought—that I was in some madman's house chained up because I couldn't move my hands. They were tied down. And they didn't tell me that I was going to happen either" [Participant 42].
LVAD Adjustment		"So, you know, I've gotten used to it now, and I've come to realize that, you know, I think, if I hadn't had got it, I don't think I'd been here now. I don't know. It's been an experience. So, I'm good to go for right now." [Participant 2]
Health Aspirations		"That was the whole point of getting the surgery. That was the reason behind letting them put a steel titanium pump in my heart, getting on the golf course. "And what about your family?" I said, 'Well, here it is, golf course, dog, wife, and kids. Sorry. That's priority.'" [Participant 26] "The destination was not leaving the hospital alive without it. So I said, hook me up." [Participant 47]

Table 5

LVAD adjustment components and participant exemplars

Physical Activity	"As far as the LVAD, I would say, within a week or two, I was doing pretty much anything I wanted to, even taking, you know, doing showers and stuff by myself, which I couldn't before" [Participant 2]. "It made things easier for me to do around the house. So, it took a while for me to get back to my normal routines…maybe two years to get back at 100. Maybe two years…but I'm okay now" [Participant 45].
Caregiver Dependence	"My wife has, kind of, taken the brunt of that just since being a nurse and doing most of every-, pretty much doing all of the actual care for the driveline, things like that." [Participant 44] "That [LVAD] has changed my independence because they're—my family, we're a very close family, so, you know, they want to make sure that, you know, I'm in good hands at all times" [Participant 3].
Self-care	"I don't like to be in a lot of crowds because of the wire hanging out [driveline], you know, because somebody could bump it, especially kids or stuff." [Participant 3] "I have two adapters at the house. I could sit and watch TV, or I can lay in bed and hook the adapter to it" [Participant 20]. "It's like 8 pounds or maybe 10, and it's a little difficult sometimes because you get tired easier. You're already running on a certain level, and then with this, it tacks onto it"[Participant 32]. "My shower went from 30 minutes too, now, an hour, and hour and 20 minutes by the time you wrap and make sure everything is just right and secure stuff" [Participant 37]. "Yeah, I—you know, that's a process that's just too time-intensive. It's easier for me to take a hospital-type bath, you know. I'll get in front of the sink and strip completely naked and do that all right there and shampoo my hair—the whole thing, and I've found that to be more efficient than encapsulating myself to take a traditional shower, you know. Yeah, it's a pain" [Participant 39]. "I can't wear a dress unless I get it special made. I can't wear heels…I've adjusted. You know, I just have to wear pants. I can wear a skirt and a top, anything two-piece. I can't wear like I said, a dress" [Participant 45]. "I've only driven once since having LVAD…Safety just because of having, then having to re-fix the sternum wiring once, going to have to go through that surgery again [transplant]. And also, just-, I'm a shorter statured guy. How close to the steering wheel I am, even to have a pillow there, it was very discomforting" [Participant 44].
Roles	"Participant in family matters, get-togethers, doing stuff around the house, shredding, working, it just started to decrease and decrease and decrease, and then, once I got the LVAD, this all started coming back in place…So, it's, kind of, just rebuilding my life back slowly. And, I can't get out there and work all day long, but if the weather's right, if it's cool,

	I can get out there and work for several hours, where I couldn't do anything hardly, not even walking to the car. I just had to stop, sit down, walking to the car" [Participant 20]. "My grandkids, you know, they don't know. One of them, she was still hopping in my lap and stuff, you know. I just had to put her on this Participant e and let her know she can't sit on my left Participant e" [Participant 45]. "I didn't realize what I had when I was so sick, but I had to retire several years before this came up" [Participant 2]. "I can't go back to the career I was just because it's lifting heavy bags of coffee" [Participant 44].
LVAD Public Perception	"I don't care what people say or look or how—about me, so I'm not that type of a person" [Participant 3]. "As far as like going places, with all the crime and stuff, I'm so worried about [someone] thinking it's a purse, you know, and yank it off my body." [Participant 3]. "I've often wondered, I've often thought… Am I going to walk in a place, and they're going to be freaking out thinking I've got bombs on me because I've got a strap and these [batteries]." [Participant 42]
Connection	"When I go get my blood taken, in the store, anybody I talk to when the subject [LVAD] comes up, I tell them, 'Do not hesitate to get it, whether it's permanent or it's getting in line for a transplant.' I just, I would recommend to any and everybody for the LVAD now that I've been in it this long."
Holistic Self	"The true reason [to receive the LVAD] was to get on the golf course. That's my normal" [Participant 26]. "Before I had the surgery, I could go to the grocery store, and I could, one, pick out the groceries, or I could put the groceries on the conveyor belt. Or, if someone else did the first and second thing, I could put them in the car. If someone else did the first three things, then I could take them from the car to the house. I could not do all four things…And, once I had the LVAD, I could do all four things, and the first time I could do all four things, I cried. I was just like, "I'm normal" [Participant 50]. "Not being able to, kind of, be myself, drive, things like that has felt like a little setback sometimes. And so…" [Participant 44].

Table 6

Implant indication exemplar comparison of Holistic Person and Health Aspirations

Self-Reported Implant Indication	Holistic Person	Health Aspirations
BTT	"I told XXX [Cardiologist] two years ago, "I won't be getting an organ… I said, "Dr. XXX, I did a lot of gambling. I've gambled all my life, for 17 years—sports gambling, I know the odds." [Participant 26] "It's like getting out of your car, and you park in the handicap, and somebody starts yelling at you. I used to carry the letter that says I'm on the transplant list. But I can't quell their anger." [Participant 26] "For me, when I first, you know—I won't say when I first got it—after I got, after I was put on the transplant list, I just always come in here and cried to XXX [Cardiologist], because, somebody had to die in order for me to get a transplant, somebody has to lose their life. I wish they could find another way that you could get a transplant, but I know they can't." [Participant 45] "A lot of people don't understand when you say that you question whether you want a transplant because—I'm a single woman. I don't have any children. I don't have any family. There are people, and lots of them, that have situations where they have people that are dependent on them, and they're trying to get a heart, and that heart would benefit not just them, but the other people in their family, and impact other families.	"I'm a public speaker. My story's not complete. I want to have a full story." [Participant 26] "I'm looking forward to it [heart transplant]…Maybe go back to work because I don't like being at home. I've very active" [Participant 3] "Well, just to go fishing more, not necessarily swimming, but at least going fishing and just living in general…Just family altogether…If I get the transplant and if it agrees with me, I can see me, see us, you know, barbequing and having holidays meals and stuff, get-togethers, going fishing, maybe getting on the tractor and going, you know, a little bit in the pasture, different things like that…Enjoy animals. I mean, I do that, but right now, my wife is helping to do more part of my share." [Participant 20] "My grandkids. My grandkids. I'll be able to go places with them, like go to the zoo, go to the park, you know, I'd just be able to enjoy them. Yeah. It'd be a big weight off of me…Because, I get tired, you know, from walking with it [LVAD] so long. Yeah. Like, I want to go to Disney World with them, but I can't take the heat. So, you know, all this medicine I'm on, I can't take the heat. And then, like, when you take different trips and stuff, you have to pack all this equipment and stuff. You know, it's not just like packing a suitcase and, okay, you go. You've got

	And so, if you look at the big picture, if I got a heart, it just impacts me. If they got a heart, it impacts them and their children and their children, and it goes on and on and on. So, it's kind of, like who am I to take that away from them. So, now, if I say that out loud, some people get upset. "Well, no. You deserve that too." [Participant 50] "I thought I compromised my beliefs a little bit just because it was-, it's still a struggle thing and a machine, a mechanical thing is pumping my heart for me, basically. And then, you know, after getting transplanted in a few years, even if it has you back on breathing machines and stuff like that..." [Participant 44] “I put, as far as living or dying, I put that in God's hands, and I put all the decision-making, medical, and educational part in the doctor's hands.” [Participant 20]	to pack all your equipment, all your medicine, and stuff" [Participant 45].
DT	"Well, in my case, they wouldn't give me a heart, and the distilled version was, 'well, you've got uncontrolled diabetes,' which is actually not true. I can routinely keep it under 200, routinely. And, sometimes, if I'm really diligent, at 100. But what they can't tell you or won't tell you is, you're too old. Because they'd have the old people union on them, right? There'd be pitchforks out front—they'd be wanting to burn the building down, so they cannot say you're too old. But, in my case, that's exactly what it was." [Participant 39] “During the time I was going through the process of getting on a heart transplant, they told me about the possibility of a bridge, you	"But many people on LVADs when their opportunity comes up to get a replacement heart, or a transplant, I said, well, they turned it down because truthfully this thing's really not that big of a pain in the butt and I was somewhat shocked to find out that the average life span with a transplanted heart is ten years, ten years. So, if you think about it, I would expect to live longer with this thing than ten years. I mean, I think so." [Participant 39] “And, you know, I had hopes that this thing is not going to be just a 10-year deal for me. Because, you know, because of the fact that they have told me that my heart is otherwise good. I mean, basically, my electro cardiologist said, you know, he was in there. And he said, your heart looked

know, to transplant type situation. But then once I ended up going through the cancer situation, they told me I was going to be too old. And that it would end up being a destination deal for me. I mean, they never say never. But, you know, they said, you know, likely you're going to be too old when-, you know, because you're going to have to be free of cancer for three years basically. And then you're going to be too old. You know? I'll be 75 at that time." [Participant 37]

"I think they're full of crap. As far as the hearts go, because they're like, 'oh, you've got to have this under control, and this needs to be did.' Why am I sitting here jumping through all these damn hoops, you know? I quit smoking, started losing weight, started taking my calcium pills because of the osteoporosis, which was caused by the medicine they gave me, to begin with, so. . . I'm not trying to do it for battle. A year and a half trying to get on the transplant list, I'm like . . . it don't make sense to try to go through all this." [Participant 1]

"So, right now, I'm currently labeled as destination. But, kind of, just my BMI is too much for, to be listed right away. So, we did a gastric sleeve at the same time. So, right now, I started at a weight of 340. Now I'm down to right around 275. So, once I hit, I did 220, 200-pound mark, we will start actively looking at more being on the list at that point." [Participant 44]

"It was my choice because, like I said, I'm not strong enough to be pristine. And as a matter of fact, they had checked. And they said the one area of the heart that had had the issues with the electrical impulses, he said, it's still active. And he thought there was a chance that my heart-, you know, I'd be among the few, relatively few that my heart would heal. But, of course, I talked to Doctor XXX [Cardiologist], and he says, well, because of your age, we're not going to turn it off [LVAD explant] or mess with it or whatever, you know, because it's working." [Participant 37]

able to push everything away. And if you're not strong enough, you know, like I said, if you can't do it, then you're wasting someone else's heart. And I just don't want to do that. And I feel comfortable with my decision and—because, I mean, if I took that heart knowing that I wasn't strong enough to finish it, so..." [Participant 42]

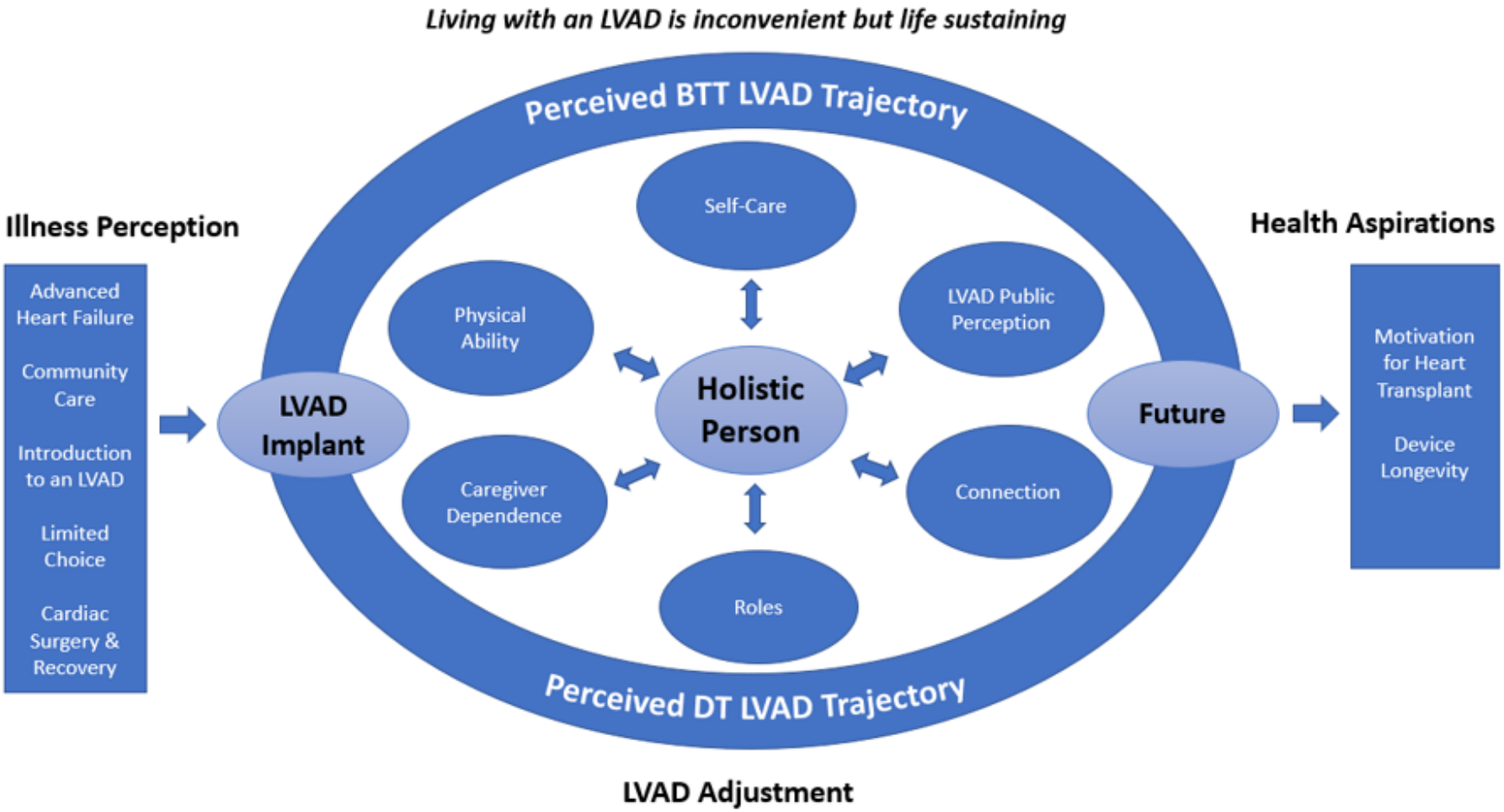

Figure 1. Living with the LVAD: A Second Chance at Life.

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Appendix A

University of Texas Health Science Center at Houston

Committee for the Protection of Human Subjects Approval

UTHealth
The University of Texas
Health Science Center at Houston

Committee for the Protection of Human Subjects
6410 Fannin Street, Suite 1100
Houston, Texas 77030

Brittany Rhoades
School of Nursing

July 10, 2019

HSC-SN-19-0583 - *Left Ventricular Assist Device Adjustment ImpacteD by Assigned Patient Trajectory (LVAD-ADAPT): A Qualitative Exploratory Study*

The above named project is determined to qualify for exempt status according to 45 CFR 46.101(b)

***CATEGORY #2** : Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:*

a. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; AND ,

b. any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(NOTE: The exemption under Category 2 DOES NOT APPLY to research involving survey or interview procedures or observation of public behavior when individuals under the age of 18 are subjects of the activity except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.)

CHANGES: Should you choose to make any changes to the protocol that would involve the inclusion of human subjects or identified data from humans, please submit the change via iRIS to the Committee for the Protection of Human Subjects for review.

INFORMED CONSENT DETERMINATION:
Signed Informed Consent Required

INFORMED CONSENT: When Informed consent is required, it must be obtained by the PI or designee(s), using the format and procedures approved by the CPHS. The PI is responsible to instruct the designee in the methods approved by the CPHS for the consent process. The individual obtaining informed consent must also sign the consent document. Please note that only copies of the stamped approved informed consent form can be used when obtaining consent.

HEALTH INSURANCE PORTABILITY and ACCOUNTABILITY ACT (HIPAA):
Exempt from HIPAA

STUDY CLOSURES: Upon completion of your project, submission of a study closure report is required. The study closure report should be submitted once all data has been collected and analyzed.

Should you have any questions, please contact the Office of Research Support Committees at 713-500-7943.

Appendix B

Memorial Hermann Health System Approval

MEMORIAL HERMANN
Clinical Innovation & Research Institute

August 12, 2019

MEMORIAL HERMANN HEALTHCARE SYSTEM APPROVAL FOR MEMORIAL HERMANN – TEXAS MEDICAL CENTER

Thank you for choosing Memorial Hermann as your service provider for this research study.

IRB ID: HSC-SN-19-0583 PRINCIPAL INVESTIGATOR: Brittany Rhoades

STUDY TITLE: Left Ventricular Assist Device Adjustment ImpacteD by Assigned Patient Trajectory (LVAD-ADAPT): A Qualitative Exploratory Study

NUMBER OF SUBJECTS: 40 MH RESEARCH BILLING ACCOUNT NUMBER: N/A

Approval is hereby granted by Memorial Hermann Healthcare System to initiate this research study at the Memorial Hermann – Texas Medical Center location. This approval is subject to the Principal Investigator's acceptance of the following stipulations:

STUDY-SPECIFIC STIPULATIONS:

Researcher MH Facility Credentialing:

1. The Principal Investigator will ensure that study team members complete research credentialing for Memorial Hermann – Texas Medical Center. If needed, please contact Joann Ivey, CIRI Executive Secretary at joann.ivey@memorialhermann.org to begin the research credentialing process.

Data Security and HIPAA:

2. All data security computer devices and Protected Health Information used in this study must be password protected and/or data encrypted.

3. The Principal Investigator will please note to use a separate linking log to connect study data to the identifiable patient information. The linking log should be stored and secured in a separate location form the data collection tool.
   - The PATIENT NAME may not be used on the linking log.
   - The MRN may not be used on the data collection tool.

Other Stipulations:

4. Please remember to acknowledge the Memorial Hermann Healthcare System in any publications resulting from this study, and provide a copy of the publication to the Director of Clinical Research Operations for Memorial Hermann Clinical Innovation & Research Institute (Sheila.Ryan@memorialhermann.org). The methods of acknowledgement may include:
   a. Memorial Hermann Healthcare System as an author's affiliation;
   b. mention in an "acknowledgement" section; or
   c. as a footnote.

5. To request data extracts via Information Systems Department (ISD), please submit an online form available at: http://datarequest.memorialhermann.org. You will need to be connected to the Memorial Hermann Network to access the form. You may also contact a member of the Clinical Innovation and Research Institute to submit this form on your behalf. In the online request, this letter authorizing release of the data as well as the approved UT IRB document will be required as an attachment. You will be contacted within 5 business days of submitting the form to begin the process of determining the scope of work and deliverable timeframe

Please sign and return a copy of this letter to the Memorial Hermann Clinical Innovation & Research Institute to the attention of Eleanora.Balibalita@memorialhermann.org to indicate your acceptance of our terms and policies (guidelines attached).

MEMORIAL HERMANN

This study may not be initiated until the letter is signed and returned to the Memorial Hermann Clinical Innovation & Research Institute.

If you have questions or need additional information, please contact the Memorial Hermann Clinical Innovation & Research Institute at (713) 704-3430.

APPROVED:

Sheila L. Ryan 08/13/2019

Sheila L. Ryan JD, MPH, CCRP Date
Director, Clinical Research Operations
Clinical Innovation & Research Institute
Memorial Hermann Health System

ACCEPTANCE:

Brittany Rhoades 8-15-2019

Brittany Rhoades Date
Principal Investigator

cc:
Jennifer Beauchamp, MD – Co-Investigator
Marie Clark – AVP, Heart Failure Clinic TMC
Paul Lampi – Director, Technical Services
CPHS

Attachments:
Memorial Hermann Clinical Innovation and Research Institute Guidelines
Research e-PHI Security Attestation

MEMORIAL HERMANN

MEMORIAL HERMANN CLINICAL INNOVATION & RESEARCH INSTITUTE GUIDELINES

INSERVICE EDUCATION
The Investigator will provide in-service education regarding study procedures and requirements to all unit, clinic and/or department staff participating in the study including unit directors and managers.

DATA SECURITY
All data security computer devices used in this study must be password protected and/or data encrypted.

CONTINUING IRB REVIEW
Memorial Hermann requires continuous approval by the IRB for all research studies. The Principal Investigator is responsible for maintaining continuing review approval during the conduct of the study.

FEDERAL REGULATORY AGENCY
The MH Clinical Innovation & Research Institute must be notified, in advance, of any regulatory agency visit or review. Contact Sheila Ryan, MHHS Director of Clinical Research Operations.

Appendix C

CHI Institute for Research and Innovation System Approval

CHI Institute for Research and Innovation

FWA Number: FWA 00019514
OHRP IRB Number: IRB00009715

DATE:	September 20, 2019
TO:	Brittany Rhoades, PhD(c), MSN,BSN,BS
PROJECT TITLE:	[1466034-1] Left Ventricular Assist Device Adjustment ImpacteD by Assigned Patient Trajectory (LVAD-ADAPT): A Qualitative Exploratory Study
SUBMISSION TYPE:	New Project - Ceding Request
ACTION:	Request to Cede IRB Review APPROVED
EFFECTIVE DATE:	September 20, 2019
REVIEW TYPE:	Administrative Review

Thank you for your submission to the Catholic Health Initiatives Institute for Research and Innovation Institutional Review Board (CHIRB). The CHIRB has APPROVED your request to rely upon the University of Texas Health Sciences Center at Houston IRB.

Please note the following:

1. **It is your responsibility to obtain any additional local institutional or departmental required approvals prior to initiating your study**
2. **You must submit a modification request to CHIRB when there is a change in personnel working on this study.**
3. **You must notify the CHIRB when the study is closed at the University of Texas Health Sciences Center at Houston IRB**
4. **You must notify the CHIRB when the University of Texas Health Sciences Center at Houston IRB makes a determination of an Unanticipated Problem involving risks to subjects or others, serious or continuing noncompliance, or suspension or termination of IRB approval**

CHIRB has administratively revised the Stand-Alone HIPAA Authorization form. You are required to use this authorization form to enroll new participants. This Stand-Alone HIPAA Authorization form can be found under the "Reviews" tab in IRBNet. If you would like to make further changes to the Stand-Alone HIPAA Authorization form, please submit an Amendment/Modification through IRBNet.

The following documents have been reviewed and revised as part of this approval and are required to be used for the conduct of this research going forward.

- Other [Stand-Alone HIPAA Authorization_TRACK CHANGE]
- Stamped Document [Stand-Alone HIPAA Authorization - APPROVED FOR USE]

This Stand-Alone HIPAA Authorization consent form can be found under the "Reviews" tab in IRBNet. If you would like to make further changes to the consent form, please submit an Amendment/Modification through IRBNet.

If you have any questions at any time, please feel free to contact the CHIRB at 1-844-626-2299 or CHIRB@CatholicHealth.net. Please include your project title and reference number in all correspondence with the CHIRB so that we can best assist you

Thank you.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within Catholic Health Initiatives Institute for Research and Innovation Institutional Review Board (CHIRB)'s records.

Appendix D

CHI Institute for Research and Innovation Waiver of HIPPA Authorization Approval

CHI Institute for Research and Innovation

FWA Number: FWA 00019514
OHRP IRB Number: IRB00009715

DATE:	September 20, 2019
TO:	Brittany Rhoades, PhD(c), MSN,BSN,BS
PROJECT TITLE:	[1466034-1] Left Ventricular Assist Device Adjustment ImpacteD by Assigned Patient Trajectory (LVAD-ADAPT): A Qualitative Exploratory Study
SUBMISSION TYPE:	New Project - Cede Request - HIPAA Waiver
ACTION:	APPROVED
APPROVAL DATE:	September 20, 2019
REVIEW TYPE:	Administrative Review

Your request for a waiver of HIPAA authorization has been APPROVED for the use or access to the limited amount of protected health information described in the submission noted above for identification and recruitment.

The following document(s) have been approved with this HIPAA Waiver of Authorization:

- HIPAA Waiver LVAD_ADAPT_CIRI Authorization2017-07-18_FINAL.docx

The CHIRB determined that the waiver of HIPAA authorization satisfies the following criteria:

A. The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals based on (1) an adequate plan to protect the identifiers from improper use and disclosure, (2) an adequate plan to destroy the identifiers at the earliest opportunity or a justification to maintain the identifiers, and (3) adequate written assurances that the PHI will not be reused or disclosed to any other person or entity;

B. The research cannot practicably be conducted without the waiver; and

C. The research cannot practicably be conducted without access and use of PHI.

If you have any questions at any time, please feel free to contact the CHIRB at 1-844-626-2299 or CHIRB@CatholicHealth.net. Please include your project title and reference number in all correspondence with the CHIRB so that we can best assist you.

Thank you.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within Catholic Health Initiatives Institute for Research and Innovation Institutional Review Board (CHIRB)'s records.

Appendix E

University of Texas Health Science Center at Houston

Informed Consent

UTHealth
The University of Texas

INFORMED CONSENT TO TAKE PART IN RESEARCH

Study Title: Left Ventricular Assist Device Adjustment ImpacteD by Assigned Patient Trajectory (LVAD-ADAPT): A Qualitative Exploratory Study

Principal Investigator/ Brittany Rhoades, APRN, PhD Candidate,
The University of Texas Health Science Center at Houston Cizik School of Nursing

Study Contact Brittany.D.Rhoades@uth.tmc.edu
832-355-9691

We are inviting you to be in a research study conducted by investigators at the University of Texas Health Science Center at Houston. We are studying the LVAD patient experience.

If you agree to be in our study, we will ask you to participate in a group interview and respond to questions related to the LVAD patient experience. You will be given a $10 gift card and paid parking for participation. If you are unable to attend the group interview or have more to share than time allows during the group interview, you may be invited to return for an individual interview. You do not have to be in the study if you do not want to; it is your choice. You can change your mind at any time and there will be no penalty. Your total time commitment is expected to be approximately 60 minutes for group or individual interviews.

You do not have to share any information that you are not comfortable sharing. You can stop participating in the interview at any time. Some people may be upset or angry if they hear others in the group interviews expressing views different from their own. During the interviews, if you express information that is a concern for harming yourself or others you consent for that information to be reported to your LVAD clinical team (i.e., cardiologist, LVAD coordinator, Psychologist).

We will be careful to keep your information confidential by not including any identifiable information with the data we collect. We will ask you and all group interview participants to keep the discussion confidential as well. There is always a sma[illegible] invited of

UTHealth IRB NUMBER: HSC-SN-19-0583
IRB APPROVAL DATE: 07/10/2019

UTHealth
The University of Texas

accidental disclosure of information shared during the interviews. We plan to audio record and take written field notes (e.g., observations, tones, emotions) during the interviews with your permission. The audio recordings will be converted to written text. Any notes, recordings, or interview text will be kept secure by the PI. When the results of the research are published, presented in reports, or discussed in conferences, no information will be included that would reveal your identity. All study related files will be secured according to the UTHealth data security policy.

If you have any questions about this study, please contact the PI at 832-355-9691 or Brittany.D.Rhoades@uth.tmc.edu. If you have any complaints, suggestions, or questions about your rights as a research volunteer, please contact the UTHealth Committee for the Protections of Human Subjects (CPHS) at 713-500-7943.

Printed Name of Subject	Signature of Subject	Date

Printed Name of Person Obtaining Informed Consent	Signature of Person Obtaining Informed Consent	Date

Appendix F

CHI Informed Consent

Authorization to Use or Disclose (Release) Health Information for Research

Study Title: Left Ventricular Assist Device Adjustment Determined by Assigned Patient Trajectory (LVAD-ADAPT): A Qualitative Exploratory Study

Principal Investigator: Brittany Rhoades, PhD(c), APRN, CCNS, CCTN

Baylor St. Luke's Medical Center, Principal Investigator, and the study team follow federal and state laws to protect your privacy, including the Health Insurance Portability and Accountability Act (HIPAA). Your permission for the Use and Disclosure of your information is called "Authorization." If you choose not to sign this Authorization, you cannot take part in the research study. Refusing to sign this form will not affect your present or future health care, payment for your health care, or any other benefits to which you are otherwise entitled. Your Authorization will allow the use or disclose (release) your health information for this study.

The health information that we may use or disclose (release) for this research includes: name, address, telephone number, email address, LVAD device, LVAD implant indication, LVAD implant date, and age.

The health information listed above may be used by and/or disclosed (released) to the following as applicable:

- Researchers and research staff,
- Applicable Institutional Review Board,
- Representatives of Catholic Health Initiatives, including the CHI Institute for Research and Innovation or others responsible for research oversight and operations,
- Representatives of The University of Texas Health Science Center,
- Domestic and foreign agencies that regulate research such as the US Food and Drug Administration, Office of Civil Rights, and Office for Human Research Protections, and
- Others as required by law.

The purposes of these uses and disclosures are to (1) conduct the study and (2) make sure the study is being done correctly. Once your health information has been disclosed under this authorization, it may no longer be protected by federal privacy laws (such as HIPAA). The individuals who receive your health information may share your information with others without your additional permission.

This Authorization will expire when the research activities are complete including data monitoring and data analysis. You may change your mind and revoke (take back) this Authorization at any time, except to the extent that Baylor St. Luke's Medical Center, Principal Investigator, and the research team have already used or disclosed your health information based on this Authorization. To revoke this Authorization, you must write to Brittany Rhoades, 6720 Bertner Avenue, MC 2-114A, Houston, TX 77030. If you revoke this Authorization, you may no longer be allowed to participate in this research study.

FOR PARTICIPANT/LEGALLY AUTHORIZED REPRESENTATIVE

I have read this authorization form or it has been read to me. My questions about the research study and my participation in it have been answered. I voluntarily give my consent to participate in the research study and I authorize my health information to be used and disclosed as described earlier in this consent form.

_____
Printed Name of Subject

_____ _____
Signature of Subject Date

_____
Printed Name of Witness

_____ _____
Signature of Witness Date

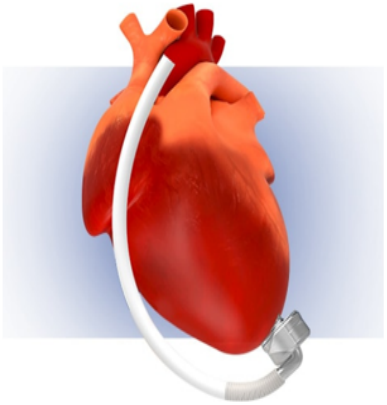
Appendix G

Recruitment Flyer

Are you living with a *Left Ventricular Assist Device (LVAD)*?

Would you like to share your experience?

We are interested in hearing your experiences to improve how LVAD care is provided.



We want to speak to LVAD patients who are:

- 18 years of age or older
- English speaking
- Living with a HeartMate II, HeartMate 3, or HeartWare LVAD
- At least 1-month after LVAD surgery

As a study participant you would:

- Complete a brief questionnaire
- Participate in a group and/or individual discussion
- Receive a gift card for participating and parking reimbursement

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The University of Texas Health Science Center at Houston

For more information contact:
Brittany Rhoades
832-355-9691
Brittany.D.Rhoades@uth.tmc.edu

Appendix H

LVAD-ADAPT Protocol

Protocol Title:	**Left Ventricular Assist Device Adjustment ImpacteD by Assigned Patient Trajectory (LVAD-ADAPT): A Qualitative Exploratory Study**
Principal Investigator:	Brittany D. Rhoades, PhD(c), APRN, CCNS, CCTN
Co-Investigators:	Dr. Jennifer E. Sanner Beauchamp, PhD, RN, FAAN Dr. Joan Engebretson, DrPH, AHN-BC, RN, FSfAA, FAAN Dr. Rebecca Casarez, PhD, RN, PMHCNS-BC Dr. Nathan Carlin, PhD
Population:	20-40 adult (> 18 years of age) left ventricular assist device (LVAD) patients recruited from Baylor St. Luke's Medical Center (BSLMC) and Memorial Hermann – Texas Medical Center (MH-TMC) greater than 1-month post LVAD implantation.
Number of Sites:	Three sites: UTHealth School of Nursing – Interview Site Baylor St. Luke's Medical Center (BSLMC) – Recruitment and Interview Site Memorial Hermann – Texas Medical Center (MH-TMC) – Recruitment and Interview Site
Study Duration:	1 year
Subject Duration:	Participants will be assessed in 1 or 2 interviews lasting approximately 60 minutes each: group interview (60 minutes), individual interviews (60 minutes); if participants are unable to attend group interviews or attend a group interview, but have additional information to share, these participants may be asked to participate in an additional one-on-one, individual interview.

General Information

- A basic qualitative design, with an interpretative approach will be used to explore, describe, and compare LVAD patients' experiences. Potential participants meeting established inclusion criteria will be approached for recruitment during LVAD clinic visits. We will enroll up to 30 LVAD patients for group and/or individual interviews.

Background Information

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- **Background**: LVADs are mechanical pumps that assist heart failure (HF) patients by unloading the left ventricle. Approximately 2,000 patients are implanted annually in the United States (US)[1]. Seventy-eight percent of LVAD recipients live for one year or greater and almost 50% survive four years or greater on LVAD support[1]. Due to the limited availability of hearts for transplant, Bridge-to-transplant (BTT) patients are waiting longer on LVAD support while on the transplant list. The redesigned HeartMate II was first implanted in 2003 and the HeartWare in 2006[2]. LVAD patients are living greater than 10 years on a device and have an unknown potential life expectancy. Both the BTT and Destination therapy (DT) population are increasing. Due to an increase in advanced HF patients that do not meet heart transplant criteria, it is estimated 2.5-4.2% of the 8 million patients suffering from HF in the United States could benefit from a LVAD[1].
- LVAD therapy is unique as compared to traditional HF management or other medical therapies. The LVAD internal and external components contribute to the complexities of adjusting to this treatment modality. The internal pump is implanted in the left ventricle and attaches to the aorta to increase the cardiac output. The internal pump is connected to external components through a set of wires that exits the abdomen known as the driveline. The driveline connects to an electronic microprocessor, the "controller", that operates the LVAD. The controller must be connected externally to an AC power supply or a set of batteries always. The external LVAD components significantly impact the patients' activities of daily life (ADLs). Patients are not allowed to participate in water activities that might place the device at risk for getting wet or submerged (e.g., swimming, tub bathing, boating). LVAD implant centers and state laws very regarding VAD patient's ability to operate motor vehicles. Depending on the physical requirements of an occupation or the employer's comfort level with an LVAD, a patient's ability to return to work despite the physical recovery may vary. Patient's recount LVAD adjustment in distinct phases: "Pre-LVAD (the time from first discussions for the device to surgery", "Implant Hospitalization", "Early Home Adaptation" and "Late Home Adaptation"[3].

- **Literature Review**: Review of the literature identifies some of the complexities of living with an LVAD. In the hospital, the LVAD patient learns to care for the LVAD and manage emergency alarms. Patients learn skills in the hospital related to the care of the LVAD. Upon hospital discharge they must learn to incorporate these skills into the home

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environment and daily activities[4–8]. During the "Early Home Adaption" phase, patients work towards independence but are heavily dependent upon the assistance of a support person for LVAD dressing changes, transportation, bathing, among other self-care activities, which can be a source of frustration[9,10]. Often changes to the home environment, including electrical work, are required to optimally support the LVAD. Psychological stressors during this phase include alterations in body image due to surgical scars and LVAD driveline. Additional stressors include weekly clinic visits, testing, and travel to and from appointments[4,7].

- During the "Late Home Adaptation" phase, patients report a change in their sense of normalcy including the ability to incorporate the LVAD into daily activities such as cooking, sleeping, and hygiene[4,5,8,11]. In this phase patients describe mixed emotions ranging from fear of LVAD complications[4,5,8] to an increasing confidence in self-care. Some patients report a psychological transition from anxiety to gratitude towards the pump[4,7]. Many describe the importance of returning to normalcy[5], but also describe the difficulty of returning to work and resuming previous roles[4,4–6,8,12]. Personal and social aspects of life can be significantly impacted by the LVAD. Intimacy often requires modifications to accommodate the LVAD external equipment[13–20].
- LVAD self-care requirements are the same for BTT and DT patients. The main differences in the two groups is the anticipated length of time on LVAD support and the hope for a heart transplant. The length of time BTT and DT patients live with an LVAD can vary dramatically. LVAD BTT patients generally live with the device for several months, greater than six months to a couple of years. In contrast, DT patients can live with a single device for greater than 10 years and longer if supported by consecutive devices. For many BTT patients transplant represents freedom from external equipment and the ability to return to water activities. It is unknown if the length of time a patient must live with an LVAD impacts the adjustment process or if patients adjust to the device differently, adhere to medical therapy, or experience LVAD therapy differently based on implant indication. *Current qualitative literature fails to identify similarities and differences in the BTT and DT LVAD patient experience and the impact on daily life and self-care between the two groups.*

Significance.

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- The information gained through the exploratory study will increase the understanding of the complexities of living with a LVAD for BTT and DT patients. The study will also compare the similarities and differences in BTT and DT patient adjustment. This will provide a foundation that will be used to explore the influencing factors that lead BTT to adjust to meet transplant criteria (e.g., quit smoking, lose weight, increase medical therapy compliance). Future studies will also explore the patient experience of BTT patients transitioned to DT (e.g., increase in body mass index, noncompliance, increase in age). This study is the beginning of a research trajectory that will be used as a guide to evaluate and improve LVAD patient experience, education, improve LVAD nursing care and provide LVAD recommendations specific to implant indication.

Innovation.

- Limited information is known as to the differences and similarities between LVAD BTT and DT patient experiences and how each group adjusts. The status quo for clinical practice is to use the same education approach for BTT and DT patients despite the length of time the patient may be on LVAD support. Previous studies have explored LVAD patient experience patient may be on LVAD support at a single LVAD center, utilized small sample sizes ($n < 20$), and have focused on one implant indication. No studies have compared or contrasted the BTT and DT LVAD patient experience. *The proposed research study is innovative because it will be a multisite qualitative study and will utilize group and individual interviews to compare patient experience among LVAD BTT and DT patients.*

Conceptual Framework.

- Callista Roy's Adaptation Theory[21] is a grand theory that focuses on the individuals' ability to adapt with the internal and external environment and will be used to guide this research study. Roy's Adaptive Model (RAM) is comprised of four key components: person, health, environment, and nursing[21]. A person is defined as a bio-psycho-social being that is constant interaction with a changing environment. Innate and acquired mechanisms are used to adapt. The model includes peoples as individuals or groups (i.e., families, organizations, and communities). How the patient interacts with the LVAD in the environment as well as

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influencing factors impact adjustment and mechanisms of adaptation will also be assessed. Adaptation is manifested in RAM by four interrelated modes of behavior: 1) physiological, 2) self-concept, 3) role function, and 4) interdependence[21]. Physiological includes the physical and chemical process involved in the function and activities of living organisms. Self-concept refers to the psychological and spiritual integrity, sense of unity, meaning, purposefulness of universe. Role function relates self to others, specifically the roles on people in society filling their needs for social integrity. Interdependence refers to the close relationships of people and their purpose, structure and development. Currently no study has assessed how patients are impacted by an LVAD in the four modes of behavior. RAM aids in assessing the LVAD patient experience from a broad and comprehensive perspective.

Approach.

- A basic qualitative design, with an interpretative approach will be used to explore and describe LVAD patients' experience[22].

Aims

The aims for this research study are:

Aim 1: Explore the BTT and DT LVAD patient experience.

Aim 2: Describe how BTT and DT LVAD patient's construct the impact of the LVAD on daily life and self-care.

Aim 3: Compare the experience and impact of the LVAD on daily life and self-care between BTT and DT patients.

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Study Design

- The research study will utilize a basic qualitative design, with an interpretative approach using group and one-on-one interviews. The interviews will be emergent, using a semi-structured interview guide. The proposed research study is innovative because it will be a multisite qualitative study comparing responses among LVAD BTT and DT patients.

Study Population

- To accurately describe influencing factors of adjustment in both BTT and DT LVAD patients' purposive sampling will be used. The PI will attempt to obtain variation in demographics, such as ethnicity, education level, age, gender, type of LVAD, and length of time supported by LVAD, in both groups. Extreme or deviant case sampling and typical case sampling will also be utilized[22]. The sampling methods will strive to provide extreme and typical influencing factors affecting LVAD adaptation. The variety of demographics will provide perspectives among the LVAD patients across the adaptation experience, thereby increasing the credibility of the findings[23].
- Participants will be interviewed until redundancy is reached in thematic content and saturation achieved in the depth and breadth of the topics discussed[22]. Therefore, based on other qualitative studies with in-depth interviews, it is estimated that redundancy and saturation will occur between 20-40 participants. The setting for this study will be two LVAD programs, Baylor St. Luke's Medical Center (BSLMC) and Memorial Hermann – Texas Medical Center (MH-TMC) located in a large metropolitan area in the Texas Medical Center (TMC), Houston, Texas. The programs collectively implant LVAD in approximately 200 LVADs annually and manage routine care for 300-400 collectively.
- Group interviews will consist of patients from BSLMC and MH-TMC. Interviews will be conducted in quiet, comfortable locations within The University of Texas Health Science Center (UTH) at Houston Cizik School of Nursing Center for Nursing Research to allow patients the opportunity to speak openly without a relationship to the institution. If interviews are unable to be conducted at UTH, alternative locations will be used (e.g. BSLMC and MH conference rooms, phone interviews). Patients from both BSLMC and MH will be clustered by device implant indication, BTT or DT, to allow patients, the opportunity to speak openly concerning their experience during group interviews. Interviews

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will be scheduled in a timely manner from the time of recruitment and convenient for interview participants.

Study Participant Screening and Recruitment

- Study flyers will be placed in LVAD patient areas (e.g. LVAD outpatient clinics, LVAD inpatient units, patient support group meetings etc.) at BSLMC and MH-TMC. Clinical providers (e.g. Physicians, APRNs, LVAD Coordinators) will be asked to assist in identifying patients that meet study inclusion criteria and identify patient implant indication. Specifically, clinical providers will be asked to provide potential study participants the study flyer and ask them to contact the PI, if willing. Prescreening and explanation of the study and informed consent will occur in person in the LVAD clinics or via telephone. However, each participant will sign the informed consent in-person prior to study onset (e.g., prior to in-person interview). Participants name, telephone number, email address, preferred method of contact, type of LVAD device, LVAD implant indication, and current heart transplant waiting list status will be collected in a screening log. To adequately represent both BTT and DT patients, the PI will attempt to recruit both types of patient groups. Once data redundancy and saturation are reached in either the BTT or DT group, recruitment will cease for the specific group and only patients with the non-saturated group will be recruited.
- Inclusion criteria includes adult (age > 18 years), English speaking, currently living with a HeartMate II, HeartMate 3, or HeartWare device, and greater than 1-month post LVAD implantation.
- Potential research participants that meet inclusion criteria will be asked to provide written informed consent. Participants will provide demographic information and interview dates will be scheduled. Participants will be assigned a study ID generated by the UTHealth Biomedical Informatics Group's REDCap instance and the study ID, participant name, participant initials, and patient reported LVAD indication obtained from the demographic survey will be maintained in a linking log.

Data and Sample Collection Protocol

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- **Instruments:** The PI will serve as the research instrument in the proposed qualitative study[24] and use reflexivity to address bias. A reflective journal will be used for the PI to distinguish between the PI's subjectivity and the observable phenomenon. Research study field notes to capture other dynamics along with analytic and reflective notes will also be collected.
- **Participant Incentives:** Study participants will receive paid parking and a $10 gift card for participation for each group and/or individual interview.
- **Data Collection:** After proving consent, participants will be asked to provide written contact information for interview(s). Self-report demographic data will be collected via survey. Survey data will be de-identified labeled with only the study ID.
- Participants will be asked to share their experiences in group or individual interviews that will be audio-recorded. Semi-structured interviews will be used to address themes and topics of interest in an information or conversation-style dialogue with the LVAD patients. Semi-structured interviews allow the principle investigator (PI) to uncover and explore themes that might be unexpected but prove to be important in understanding the LVAD patient's experience and adjustment[25]. The interviewer will guide the participants to share perceptions of their adjustment to the LVAD through a series of open-ended questions. The semi-structured interview guide was developed based on prominent themes published and gaps identified in the current literature on living with an LVAD[4-8,11,16]. The interview guide will be further reviewed for relevance of questions and credibility will be established by the PI and 2-3 LVAD coordinators, who experts in care of the LVAD patient through the continuum of care[26]. Triangulation will occur by interviewing different types of individuals in group and individual interviews to obtain multiple perspectives[26]. The individual interviews will be conducted to further explore rich cases that align with the study aim or confounding cases[25]. Individual interviews will be selected either from the group interviews or from interested research participants not able to attend the group interviews. Interviews will be emergent in design and allow the questions to adapt to further explore issues that arise from patient comments[25]. Interviews will be conducted in English by the study PI using a semi-structured interview guide with grand tour and mini tour questions.
- The group interviews will consist of approximately 5 to 10 patients and emergent in design and allow the questions to adapt to further explore issues that arise from patient comments.

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Patients will be clustered by device implant indication, BTT or DT, to allow patients, the opportunity to speak openly concerning their experience. The same semi-structured interview guide will be used for the BTT and DT interview groups to compare experiences of the two groups. The emergent design will allow the questions to adapt to further explore factors that are specific to each group. Interviews will be audio recorded. Field notes/observations will be taken by the PI during recruitment and interviews to document the inflections, tones, and nonverbal cues[25]. At the end of the interview dependability will be established by the interviewer by confirming that the participant's responses were complete and accurate[26]. Patients will be informed that all names mentioned in the interview will and protected health information will be removed in the transcription of the interview. Patients may be asked to participate in individual interviews following group interviews.

- **Data Management:** Audio recordings will be downloaded onto a password-protected server at UTH. Every audio file will be identified with a study identification number and uploaded onto the server. Audio files will be downloaded and shared with the transcriptionist via a secured shared site. Once the transcription is complete it will be loaded onto the server, with study identification, and the PI will be notified by email. The transcript will then be verified for accuracy and authenticity by the PI by listening to the audio recording and comparing it to the transcript[26]. All references to names or places will be removed from the transcription. Audio recordings will be kept on the secure server until all study interview and transcripts are finished. At completion all recordings will be deleted, and the transcripts will be stored by study number on the password-protected server.
- Participant name, telephone number, email address, preferred method of contact, type of LVAD device, LVAD implant indication (self-reported), and heart transplant wait list status for BTT patients will be collected on the LVAD-ADAPT screening log and securely maintained in Research electronic data capture (REDCap) hosted at The University of Texas School of Biomedical Informatics (SBMI).
- Study ID, enrollment status, consent status and document (if enrolled), the reason for study participant declined will be entered and securely maintained into an enrollment document in REDCap.

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- Demographic information will be obtained from the demographic survey and maintained in REDCap. Demographic information includes: patient name (last, first), address, telephone number, email address, preferred method of contact, request for permission to contact participant in the future, age (years), ethnicity, gender, marital status, highest degree, LVAD device type, LVAD implant date, LVAD implant indication (self-reported), length of time with LVAD device, current employment status, and household income.
- Despite security measures and the use of study ID numbers, there could be a breakdown in protecting the identity of interview participants. If a breach in participant confidentiality were to occur, we will notify the participant and IRB as soon as the incident was discovered. We would create an action plan to prevent future breaches. Violations in the conduct of the study will also be reported to the IRB as soon as they are identified.
- The PI will be appropriately trained for handling human subject-related data (including protected health information (PHI) that may be disclosed by a participant, e.g., contact sheet, linking log).
- Study participants will be assigned study identification (ID) and all data will be de-identified and labeled with only the study ID.
- **Data Analysis:** Data analysis of interviews, field and analytical notes will begin as soon as data is collected. This will allow for evaluation of the effectiveness of the group interview techniques and questions for collecting information, and any necessary adjustments will be made early in the interview process. Data collected will be de-identified. The PI will review and become familiar with the data collected from the first participants (group interviews, journals, field notes, and artifacts)[27]. De-identified transcriptions will be imported into Atlas.ti[28] version 8 for data coding leading to preliminary themes. Codes will be identified and developed iteratively from the data and a codebook will be developed[29]. Codes will be established and categorized for themes, constructs, models, etc. (related to the research questions) by the PI. Supporting quotes will be used to support the data[27]. Transcriptions will be analyzed recursively validating the emerging themes and patterns. Data will be compared to ascertain similarities and differences between the BTT and DT participants. Lastly, peer debriefing will be done with dissertation committee members who are familiar with the research approach, to substantiate the themes, eliminate bias and make the finding

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resonate with the providers, thereby establishing trustworthiness[29]. In qualitative research, the PI will serve as the research instrument[24]. Therefore, to further enhance the rigor of the data, reflexivity will occur by ongoing dialectical analysis, with the PI keeping a journal with analytic notes, to avoid bias. Sampling will continue until good depth and repetition or "saturation" of themes is reached, and little new information emerges[22]. Analytical notes will be taken throughout data analysis.

Data and Safety Monitoring

- **Data storage:** All data will be stored and maintained in a secure manner according to UTHealth policies, in accordance with human subject protection regulations, and Research electronic data capture (REDCap) hosted at The University of Texas School of Biomedical Informatics (SBMI). (see confidentiality section below).
- **Alternative Recruitment:** Despite adequate population size, recruitment of patients can potentially be a challenge. Therefore, a contingency plan is in place. The Heart Exchange, a LVAD and heart transplant support group, is well established and eager for programs that may assist in increasing the understanding of LVAD patient illness perspective. Therefore, if recruitment lags, there are plans in place to work with Heart Exchange Support Group to supplement recruitment. However, additional IRB approval will be sought first. Faculty advisors have experience recruiting from patient and family support groups for qualitative research interviews. They will provide guidance and recommendations for recruitment, as needed.
- Because the PI works at BSLMC as an Advanced Practice Registered Nurse (APRN), she may have encountered some of the study participants in a clinician role. The PI will emphasize the research role and verbalize that no responses will impact clinical care provided. The PI will also attempt to minimize clinical contact with research participants. To maintain the PI role, group interviews will be conducted at UTH Center for Nursing Research if possible and patients from both MH and BSLMC will interviewed together. The PI will also attempt to recruit and include patients in whom there is limited or no previous clinical provider encounter. Additionally, the PI will consult faculty advisors if any conflicts arise.

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Confidentiality

- All data will de-identified and any PHI (linking log) will be maintained in a secure database system, on a secure UTHealth server (accessible by only authorized UTHealth personnel) and REDCap. Source documents will be accessible by only authorized study personnel (e.g., the PI with authorized username and password). Hard copies of informed consents will be stored in locked file cabinets behind locked doors (i.e., double lock system) and accessed by authorized study personnel only (e.g., the PI, Co-I).
- All records will be retained from this study for a period that complies with UTHealth policies (15 years), and the data on secure UTHealth servers will be backed up according to UTHealth Data Center Operations policies.
- Any research report resulting from findings of this study will present only de-identified study participant information.

Ethics

- IRB approval is being sought from UTHealth CPHS and Catholic Health Initiatives (CHI).
- UTHealth CPHS will serve as the primary institutional review board.
- Our informed consent process will include the following steps:
    - The PI will discuss and obtain written informed consent from potential study participants. The discussion will occur in a private room in either the BSLMC or MH-TMC LVAD clinic or over the telephone if it is not possible to hold the discussion in person during a scheduled LVAD clinic visit or if the potential participant requests additional time to consider whether to participant after the initial consent discussion during a LVAD clinic visit was conducted. However, obtaining written informed consent will take place in-person.
    - Potential participants will be allowed to take the consent document home to consider participation and/or allowed a waiting period during the LVAD clinic visit to consider their decision.
    - Participants will be allowed to exit the group or individual interviews at any time.
    - We will not seek a waiver of consent or waiver of documentation.

Publication Plan

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- Our de-identified research findings will be disseminated through conference poster and podium presentations and articles will be submitted to peer-reviewed journals for publication.
- Results will not be returned to research study participants directly, but a compilation of the results will be available in peer-reviewed publications.

ATTACHMENTS

1. LVAD-ADAPT Study Recruitment Flyer
2. LVAD-ADAPT Recruitment Script
3. LVAD-ADAPT Consent Document
4. LVAD-ADAPT Screening Log (REDCap)
5. LVAD-ADAPT Enrollment Document (REDCap)
6. LVAD-ADAPT Linking Log
7. LVAD-ADAPT Demographic Survey Form (REDCap)
8. LVAD-ADAPT Interview Guide
9. LVAD-ADAPT Semi Structured Interview Guide
10. LVAD-ADAPT Interview Probing Questions
11. Approval Letter for Use of UTHealth School of Nursing Center for Nursing Research for Group and Individual Interviews
12. BSLMC Approval Letter
13. Heart Exchange Approval Letter
14. LVAD-ADAPT Study Schedule
15. Human Research Group 1 Biomedical Researcher and Key Personnel – Basic Course
16. Human Research Group 2 Social and Behavioral Researchers and Key Personnel – Basic Course
17. Brittany Rhoades UTH Investigator Briefing Informed Consent in Human Subjects Research Certificate

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IRB APPROVAL DATE: 07/10/2019

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Appendix I

Screening Log

LVAD-ADAPT Screening Log

Study ID _____

Left Ventricular Assist Device Adjustment ImpacteD by Assigned Patient Trajectory (LVAD-ADAPT): A Qualitative Exploratory Study

Tool: LVAD-ADAPT Screening Log

Purpose: To record the screening information on those potential LVAD-ADAPT study participants who are screened for study eligibility.

Audience/User: Study coordinators, principal investigators, other site or research staff.

Details: This log should provide a comprehensive list of all subjects who are screened for study eligibility.

Best Practice Recommendations:

- **Record subjects as they are screened, to ensure completeness and accuracy of the data.**
- **Include all subjects who were screened, including screens that do not result in enrollment.**
- **The screening log will contain identifying information, as well, as a screening number; however, for subjects who are determined ineligible or who are eligible but do not agree to participate, all identifying information will be destroyed and not retained.**
- **Number each page and maintain this log along with the other IRB approved LVAD-ADAPT study documents.**
- **Store pages in reverse chronological order, with the newest pages of the log placed at the front of the section.**
- **At the conclusion of the study, identify the final page of the log by documenting as such as the end of the final page.**

Tool Revision History:

Version Number: 2.0
Date: 9-9-2019
Summary of Revisions Made:
1.0 Initial IRB Approved Version
2.0 Revisions:
Study ID Removed
Question Readability Edited
Do we have your permission to contact you in the future regarding your interview responses or to extend an invitation to participate in a single interview from the demographic survey)

UTHealth IRB APPROVAL DATE: 09/17/2019

Screening Site	○ Baylor St. Luke's Medical Center ○ Memorial Hermann Hospital - Texas Medical Center
What is your full name (last, first)?	_____
What is the best address to contact you?	_____
What is the best telephone number to reach you?	_____
What is the best email address to reach you?	_____
What is your preferred method of contact?	○ Phone ○ Email
Type of LVAD Device	○ HeartMate II ○ HeartWare ○ HeartMate 3
LVAD Implant Indication	○ Bridge-to-Transplant (BTT) ○ Destination Therapy (DT)
If BTT, are you currently on the heart transplant waiting list?	○ Yes ○ No ○ Unsure
Do we have your permission to contact you in the future regarding your interview responses or to extend an invitation to participate in a single interview?	○ Yes ○ No
Participant eligible for enrollment?	○ Yes ○ No
Ineligibility reason (if applicable)	_____

UTHealth
IRB NUMBER: HSC-SN-19-0583
IRB APPROVAL DATE: 09/17/2019

Appendix J

Demographic Survey

LVAD-ADAPT Demographic Survey

Study ID	_____

Left Ventricular Assist Device Adjustment ImpacteD by Assigned Patient Trajectory (LVAD-ADAPT): A Qualitative Exploratory Study

Demographic Survey Questions

Version Number: 2.0
Date: 9-9-2019
Summary of Revisions Made:
1.0 Initial IRB Approved Version
2.0 Revisions
PHI Removed From Survey
Answer Selections Clarified
LVAD Replacement Date (2nd LVAD Implant Date if Applicable) Included

What is your age (years)?	_____
Are you of Hispanic, Latino, or of Spanish origin?	○ Yes ○ No
How would you describe yourself?	○ American Indian or Alaska Native ○ Asian ○ Black or African American ○ Native Hawaiian or Other Pacific Islander ○ White ○ More Than One Race
What is your marital status?	○ Single (never married) ○ Married ○ In a domestic partnership ○ Widowed ○ Divorced ○ Separated
What is your gender?	○ Female ○ Male
What is the highest degree or level of school that you have completed?	○ Less than a high school diploma ○ High school degree or equivalent (e.g. GED) ○ Some college, no degree ○ Associate degree (e.g. AA, AS) ○ Bachelor's degree (e.g. BA, BS) ○ Master's degree (e.g. MA, MS, MEd) ○ Professional degree (e.g. MD, DDS, DV, PhD, EdD)

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IRB APPROVAL DATE: 09/17/2019

What type of LVAD do you currently have?	○ HeartMate II ○ HeartWare ○ HeartMate III
LVAD Implant Date	_____
LVAD Replacement Date (2nd LVAD Implant Date if Applicable)	_____
LVAD Implant Indication	○ Bridge-to-Transplant (BTT) ○ Destination Therapy (DT) ○ Unknown
How long have you had your LVAD?	○ < 1 year ○ 1 - 2 years ○ 3 - 4 years ○ 5 - 6 years ○ 7 - 8 years ○ 9 -10 years ○ > 10 years
What is your current employment status?	○ Employed full time (40 or more hours per week) ○ Employed part time (up to 39 hours per week) ○ Unemployed and currently looking for work ○ Unemployed and not currently looking for work. ○ Student ○ Retired ○ Homemaker ○ Self-employed ○ Unable to work
What is your household income?	○ Less than $20,000 ○ $20,000 to $34,999 ○ $35,000 to $49,999 ○ $50,000 to $74,999 ○ $75,000 to $99,999 ○ > $100,000

Appendix K

Interview Guides

Left Ventricular Assist Device Adjustment ImpacteD by Assigned Patient Trajectory (LVAD-ADAPT): A Qualitative Exploratory Study

Interview Guide

Introduction

- Welcome by the PI and co-investigator
- Present purpose of the study
- Review reason for audio recording and note-taking
- Discuss informed consent
- Discuss confidentiality by researchers and participants
- Discuss group interview and discussion etiquette (respect and consideration of others, one speaker at a time)
- Request completion of the "Demographic Survey Form"

Semi-Structured Interview Guide for **L**eft **V**entricular **A**ssist **D**evice **A**djustment Impacte**D** by **A**ssigned **P**atient **T**rajectory (LVAD-ADAPT): A Qualitative Exploratory Study

Principal Investigator Brittany Rhoades, APRN, PhD Candidate,
The University of Texas Health Science Center at Houston Cizik School of Nursing

Semi-Structured Guide Questions (Q)

Q1 How did you first come to learn about a Left Ventricular Assist Device (LVAD)?

Q2 Can you tell me how the LVAD impacted you physically? Psychologically?

Q3 Can you tell me about how the LVAD impacted your self-concept (positively and negatively)?

Q4 Can you tell me about some of the roles that you have among your family and professionally? How did the LVAD impact these roles? (e.g., spouse, family member, parent, financial provider, care taker, etc.)

Q5 How did your family and friends respond to the LVAD?

Q6 Can you tell me a little about the activities that require assistance from someone because of the LVAD?

Q7 Can you tell me how the LVAD impacted your activities of daily life?

Q8 What information would you give to best prepare someone for an LVAD?

Q9 How does the LVAD impact your plans?

Interview Probing Questions Guide for **L**eft **V**entricular **A**ssist **D**evice **A**djustment Impacte**D** by **A**ssigned **P**atient **T**rajectory (LVAD-ADAPT): A Qualitative Exploratory Study

Principal Investigator Brittany Rhoades, APRN, PhD Candidate,
The University of Texas Health Science Center at Houston Cizik School of Nursing

Semi-Structured Guide Probes (P)

P1 Recall the first time that you were informed you were going to need an LVAD? Describe how learning that you need an LVAD made you feel.

P2 What were you able to do that you could not do prior to the LVAD? Were there activities that the LVAD hindered you from participating?

P3 What helped you adjust to living with the LVAD?

P4 Please describe your "role" within your family or your family dynamics. How did the LVAD impact your role within your family? Can you describe your occupation or professional role? How did the LVAD impact this role?

P5 Tell me about the how your family responded when they first encountered your LVAD? What was it like to participate in social activities with the LVAD?

P6 Overall, as time increases what activities have you become more independent because of the LVAD?

P7 What activities do you find most challenging since LVAD implantation? What activities were better with the LVAD?

P8 What information do you wish you would have known before implant regarding living with the LVAD? How would knowing this information have impacted your adjustment to your LVAD?

P9 What do you look forward to being able to do now that you have an LVAD? What activities are you disappointed that you cannot participate or achieve due to your LVAD?

CURRICULUM VITAE
Brittany D. Rhoades, PhD, APRN, CCNS, CCTN

EDUCATION:

University of Texas Health Science Center Houston, TX	2020	PhD	Nursing
University of Alabama at Birmingham Birmingham, AL	2012	MSN	Nursing
Union University Jackson, TN	2006	BSN	Nursing
Ouachita Baptist University Arkadelphia, AR	2005	BS	Biology

PROFESSIONAL POSITIONS:

Clinical Nurse Specialist Cardiothoracic Transplant Program Baylor St. Luke's Medical Center Houston, TX	2014 – Current
Clinical Nurse Educator Solid Organ Transplant & VADs Baylor St. Luke's Medical Center Houston, TX	2013 – 2014
Staff Nurse Heart & Lung Transplant Intensive Care Unit University of Alabama at Birmingham Birmingham, Alabama	2007 – 2012
Staff Nurse Trauma & Burn Nursing Unit University of Alabama at Birmingham Birmingham, Alabama	2006 – 2007

PROFESSIONAL MEMBERSHIPS & COMMITTEES

American Society for Artificial Internal Organs (ASAIO)	2019 – present
The International Society for Heart & Lung Transplantation (ISHLT)	2016 – present
The Transplantation Society (TTS)	2016 – 2019
International Transplant Nurses Society (ITNS)	2013 – present
Board of Directors - Director-At-Large	2015 - 2019
Annual Symposium - Local Planning Chair	2014
Texas Medical Center ITNS	2013 – present
President	2017 - 2020
Vice – President	2015 - 2016
National Association of Clinical Nurse Specialist (NACNS)	2018 – present
Texas Clinical Nurse Specialist	2013 – present
Communications Chair	2015 – 2016
Education Committee	2015 – 2016
Sigma Theta Tau International	2017 – present
Zeta Pi Chapter – Sigma Theta Tau International	2017 – present
American Association of Critical Care Nurses (AACN)	2011 – present
Gulf Coast Association of Critical Care Nurses	2013 – present

CERTIFICATIONS:

American Association for Critical-Care Nurses	2013 - present
Critical-Care Clinical Nurse Specialist (CCNS)	
American Board for Transplant Certification	2014 – Current
Certified Clinical Transplant Nurse (CCTN)	
State of Texas Advanced Practice Nurse (#AP124065)	2013 - Current
State of Texas Registered Nurse (#829219)	2013 - Current
State of Alabama Registered Nurse (#1-111786)	2007 - 2016

GRANTS:

Heart Exchange Support Group, “LVAD Patient Experience Grant”, $2,520

PUBLICATIONS:

Rhoades, B. D., Sanner Beachamp, J. E., Engebretson, J. C., & Wardell, D. W. (2020). Influencing Factors on Left Ventricular Assist Device Adaptation: A Systematic Review. Heart & Lung. (Accepted for publication).

LECTURE PRESENTATIONS:

November 2016 — Solid Organ Transplantation
Texas Women's University (N4045 Adult Health Comp. II
Houston, TX

PRESENTATIONS:

International

Rhoades, B., Whitehead, M., Evans, K., Woodard, M. (2019, June). Left Ventricular Assist Device (LVAD) Metropolitan Emergency Medical Service (EMS) Provider Education Pilot. Presented at the 65th ASAIO Annual Conference: Dare to Innovate – Shape the Future, San Francisco, CA. (poster presentation).

Rhoades, B. (2017, June). Novice to expert: reflections on successful abstract development. Accepted for the 26th Annual ITNS Symposium. Reflections of Transplant Nursing Excellence, Lake Buena Vista, Florida (poster presentation).

Rhoades, B. (2016, October). Bridge to recovery: the holy grail of mechanical circulatory support. Presented at the 25th Annual ITNS Symposium. Transplant Nursing: Bridging Passion, Practice, and Patient Care, Pittsburgh, Pennsylvania (podium presentation)

Williams, B. (2015, June). Implementation of a multidisciplinary ventricular assist device validation process. Presented at the ITNS Summer Symposium. Transplant Nursing: A Journey to the Top, Chicago, Illinois. (podium presentation)

Williams, B. and Johnson, K (2014, September) Implementation of a 12-week transplant certification pathway on an acute care solid organ transplant unit. Presented at the 23rd Annual ITNS Symposium: One World of Caring, Houston, Texas. (podium presentation)

Regional/State

Rhoades, B. and Johnson, K. (2016, June). Adapting to challenges related to staff nurse specialty certification. Presented at the 2016 Texas Clinical Nurse Specialists Conference, Round Rock, Texas. (podium presentation)

Malveaux, S. and **Williams, B.** (2015, May). Transformation of the multidisciplinary ventricular assist device validation process. Presented at the 2015 Texas Clinical Nurse Specialists Conference, Round Rock, Texas. (podium presentation)

Williams, B. and Malveaux, S. (2014, January). Clinical nurse specialist collaboration to enhance education and mobilization through the continuum of care for a high-volume ventricular assist device (VAD) program. Presented at the 2014 Texas Clinical Nurse Specialist Conference, Austin, Texas. (poster presentation). 2nd Place Poster Award

Local

Rhoades, B., Drake, J., and Carter, R. (2016, April). Characteristics of the U.S. mental health facilities that utilize telemedicine. Presented at The University of Texas Health Science Center at Houston – School of Nursing Research Day: Advancing Nursing Science and Research to Improve Health Outcomes, Houston, TX (poster presentation).

Williams, B., Malveaux, S., Johnson, K., Smith, C., and Clark, M. (2011, October) Enhancing education and mobilization for ventricular assist device patients through the continuum of care. Presented at the St. Luke's Episcopal Hospital Nursing Research Annual Conference. World Class Nursing with a Personal Touch: A Research Perspective 2013, Houston, Texas. (poster presentation).

AWARDS AND RECOGNITION:

Sigma Theta Tau Induction	2018
Transplant Service Award	2017