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Living with a left ventricular assist device: psychological burden and coping: protocol for a cross-sectional and longitudinal qualitative study

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ABSTRACT

Introduction Due to technological progress and persistent shortage of donor hearts, left ventricular assist devices (LVADs) have become established in the treatment of advanced heart failure. Accordingly, more patients live with LVADs for prolonged periods. Related research focused primarily on clinical issues and little is known about psychosocial aspects of living with an LVAD. This study aims to explore psychological burden and coping following LVAD implantation.

Methods and analysis An exploratory qualitative study with cross-sectional and longitudinal elements will be carried out. At least 18 patients with LVAD who have the device implanted from a few weeks to more than 3 years will be interviewed in the cross-sectional component using an interview guide. A subsample of patients who live with the LVAD for up to 3 months when recruited will be interviewed two additional times in the following year. The cross-sectional interviews will be analysed using an inductive qualitative content analysis to describe psychological burden, coping resources and behaviour from the patient's perspective. Based on the findings, the longitudinal interviews will be analysed with a deductive content analysis to explore psychological adjustment during the first year after implantation. The findings will provide a deeper understanding of the complex and specific situation of patients with LVAD and of psychological adjustment to living with a life-sustaining implant. This can help clinicians in considering individual aspects to promote patient outcomes and is the basis for further research on healthcare interventions or technical solutions to reduce burden and for developing rehabilitation measures to promote psychosocial outcomes.

Ethics and dissemination Ethical approval was obtained from the ethics committee of the School of Medicine and Health Sciences at the University of Oldenburg (2019-023). Study findings will be disseminated at national and international conferences and through peer-reviewed journals.

Trial registration number German Clinical Trials Register (DRKS00016883).

Strengths and limitations of this study

- The qualitative design allows developing an in-depth understanding of how the patients coping and psychological adjustment to living with a left ventricular assist device.
- Patients with diverse nature and extent of experiences will be recruited in a purposeful sampling.
- This is the first longitudinal study investigating psychological adjustment to a dependable medical implant.
- Involving patients and practitioners in preparation and analysis ensures the adequacy of the study design and interpretations.
- Time restriction can limit the possibility of recruiting the targeted sample size in the longitudinal study.

INTRODUCTION

Due to changes in the global population's age structure, the prevalence of heart failure (HF) is rapidly increasing.[1] It is estimated that 37.7 million people worldwide are affected by this health condition.[2] It is associated with an increased mortality risk, substantial healthcare costs and major limitations in the patient's quality of life.[3] Therapy of HF usually begins with modification of the patients' lifestyle and pharmacotherapy in order to prevent a progression of the disease and to maintain the heart's functioning. If these approaches do not succeed and drug treatment options have been exhausted, heart transplantation is considered to be the therapeutic gold standard for advanced HF. However, this is not always possible, since the demand for donor hearts exceeds the availability and some patients are not eligible for heart transplantation.[4 5] Meanwhile, there are alternatives due to the rapid development of medical technologies in recent decades.[6] As such, left ventricular assist devices (LVADs) have become established in the treatment of advanced HF. In 2016, the annual amount of 965 LVAD implantations tripled 291 heart transplantations in Germany. LVADs are

artificial blood pumps that can be implanted into the patient's chest to normalise the circulation while it stays interconnected with extracorporeal controls and batteries by drivelines exiting at the abdomen.[5] Initially, these devices were developed for short-term support in order to bridge critically ill patients to transplantation. By now, LVADs are predominantly used for destination therapy (DT) over extended periods of time.[7 8] This technology has evolved significantly over the past two decades, with the most important milestone being the transition from pulsatile to continuous flow pumps. The latter are more durable and have significantly fewer complications. Thus, they are able to provide support over extended periods of up to 14 years.[5] In the course of this development, psychosocial outcomes of LVAD therapy receive increasing attention in the scientific literature.[3 4 7] Available studies highlight the potential of LVAD therapy for improving the patients' quality of life and reducing severity of HF symptoms.[9 10] Nevertheless, an LVAD also entails functional limitations as well as psychological burden for the patients and their social environment. Fear of complications such as strokes and the dependence of one's life are permanently present because of the extracorporeal components.[9–11] Those affected have to adjust to the situation of living with an LVAD.

Psychological adjustment to a chronic disease is commonly defined by presence or absence of psychological disorders, symptoms or distress, but it can also result in personal growth. Patients adjust to a health condition by dealing with disease-related challenges in various life domains under the influence of the disease progression and contextual factors. The extent to which patients master these challenges varies interindividually.[12] This variation can be explained with the transactional model of stress and coping (TMSC) of Lazarus and Folkman.[13 14] This is an established model in coping research and the conceptual basis of assessment instruments such as the Ways of Coping Questionnaire,[15] Ways of Coping Checklist[16] and the Perceived Stress Scale.[17] Studies that used these instruments underline the model's validity.[18 19] The TMSC distinguishes between two processes, cognitive appraisal and coping (see figure 1). Cognitive appraisal consists of two phases. First, there is the primary appraisal in which a person evaluates if a stress encounter may be positive, harmful or irrelevant to one's well-being. In case of a potentially harmful stress encounter, the secondary appraisal follows. The person evaluates which coping options are available, applicable and effective to overcome or prevent the potential harm. The primary and the secondary appraisal converge in an evaluation whether the situation is challenging, harmful or threatening. This is followed by the process of coping, in which the protagonist applies cognitive and behavioural efforts to cope with the stressful event using available resources. The changed relationship with the stressor is then reappraised and can lead to further coping efforts.[15 20]

In order to investigate the psychological adaption and coping of patients with LVAD, Abshire *et al* conducted a meta-synthesis of seven qualitative studies published between 2007 and May 2015, that is also based on the TMSC. They identified four stages in the adaption process, of which each faces the patients with physical, psychological and social challenges: pre-LVAD, implant hospitalisation, early home adaptation and late home adaptation. The review also highlights a lack of research. The seven papers included are based on six relatively small samples of 5 to 12 patients, most of whom have had the LVAD for less than a year.[21–23] Certain studies also included explanted patients[24 25] or patients with pulsatile devices.[26] However, recent studies highlight an improvement in the patients' well-being despite substantial emotional distress and that a new normality establishes as a result of favourable coping processes requiring changes in one's lifestyle and look on life.[21 23–25 27 28] An influence of patient-related factors on psychological adjustment is also indicated, for example, social support is advocated as a facilitator.[23 25 27 29] Clinical factors such as therapy strategy are relevant as well. For example, patients with LVAD expecting a heart transplant tend to experience living with an LVAD as living on standby.[25]

Rationale

LVAD therapy affects an increasing number of patients for prolonged periods and therefore psychosocial aspects of living with the device are gaining in relevance. This is particularly applicable for DT patients, who probably live with the LVAD for the rest of their lives. Present research shows that these patients live in a very complex and specific situation that entails psychological burden and challenges. Patients cope with these challenges in a process of psychological adjustment with varying outcomes using individually available strategies as well as personal and situational resources. Pertinent qualitative research is needed to gain a deeper understanding of psychological adjustment to living with an LVAD so that the situation of patients with LVAD can be adequately addressed in healthcare.

Objectives

This study aims to explore psychological burden and coping of patients under DT following LVAD implantation. Specifically, the cross-sectional investigation aims to describe coping strategies, related resources and barriers from the perspective of patients under DT living with the LVAD from a few weeks to more than 3 years. The longitudinal component aims to explore the course of psychological adjustment to living with an LVAD during the first year after implantation.

METHODS AND ANALYSIS

A qualitative approach will be adopted due to the explorative research focus. The study design comprises a cross-sectional and a longitudinal investigation. Cross-sectional in-depth interviews will be conducted with at least 18 DT patients. A subsample will be interviewed longitudinally

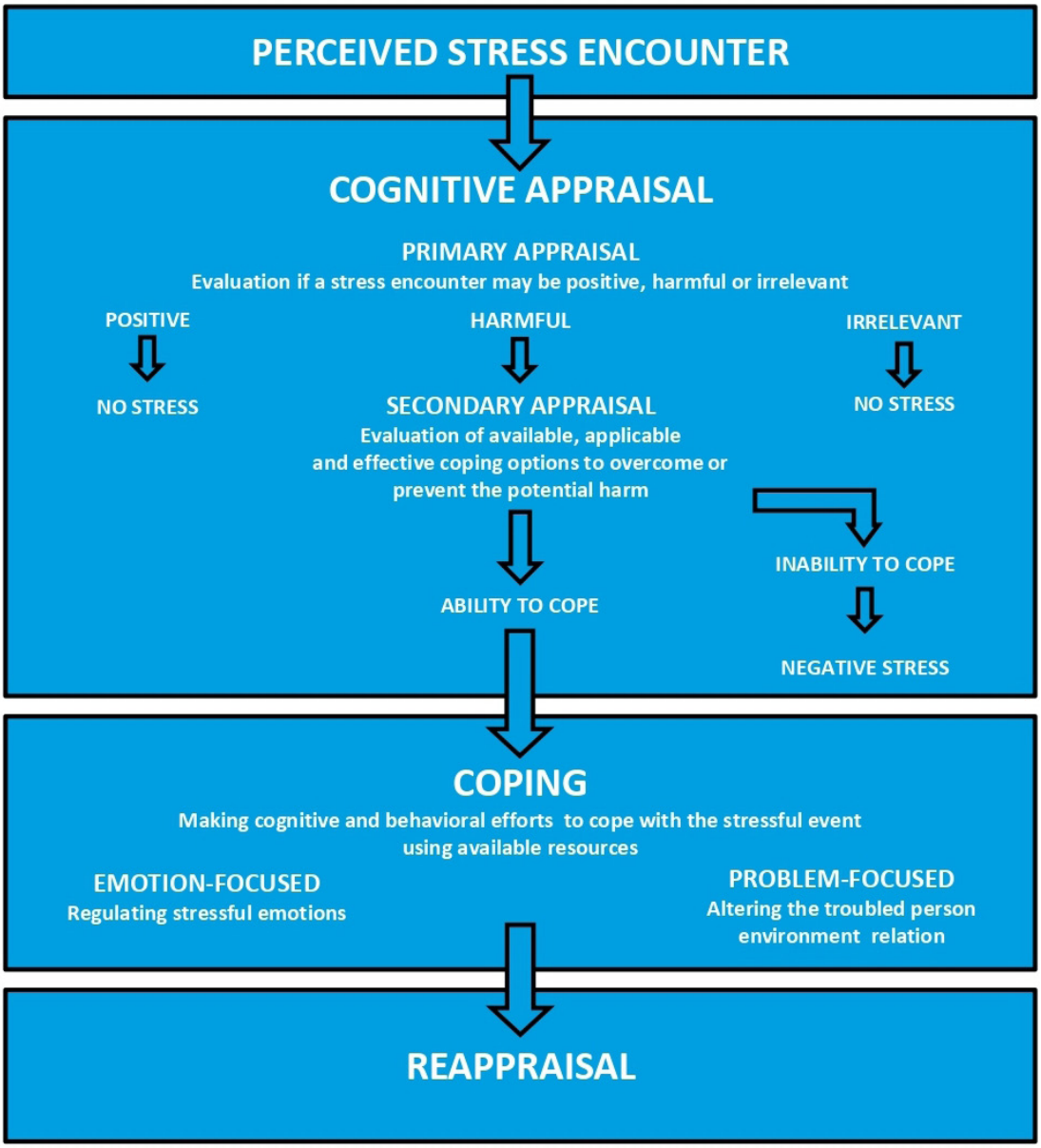

Figure 1 Transactional model of stress and coping (own illustration based on Folkman *et al*,[15] Lazarus and Folkman[14]).

for two additional times within the following year. The study is conceptually aligned with the TMSC,[15] since it has shown to be adequate for examining coping processes of patients with various life-threatening diseases[12] and of patients with LVAD[30] in particular. Since there is no reporting guideline for qualitative study protocols, the present protocol is guided by the Consolidated criteria for Reporting Qualitative research (COREQ) checklist (see online supplemental appendix).[31]

Sample and recruitment

All patients to be included in this study will be implanted with an LVAD, undergoing DT, at least 18 years old and fluent in German. Beyond this, no explicit exclusion criteria will be applied. For the cross-sectional study, we will purposefully sample for the elapsed time since implantation, because psychological adjustment and coping change over time.[21] At least 18 patients will be included who spent varying time on LVAD support. We aim to include at least six patients, who live with the LVAD for a maximum of 3 months, 9–15 months and 3 years or longer (see figure 2). In order to recruit the subsample of patients who have the LVAD implanted for a maximum of 3 months, all patients who are implanted with an LVAD at the collaborating clinic from July 2019 to April 2020 will be asked for participation. Based on estimates provided by the clinicians, we expect to recruit nine recently implanted patients this way. These patients will also be asked to participate in two additional interviews for the longitudinal investigation. We aim to recruit about nine patients for the longitudinal component, because we expect a drop out of 25%. For this estimate, methodological literature,[32–36] suggestions of affiliated

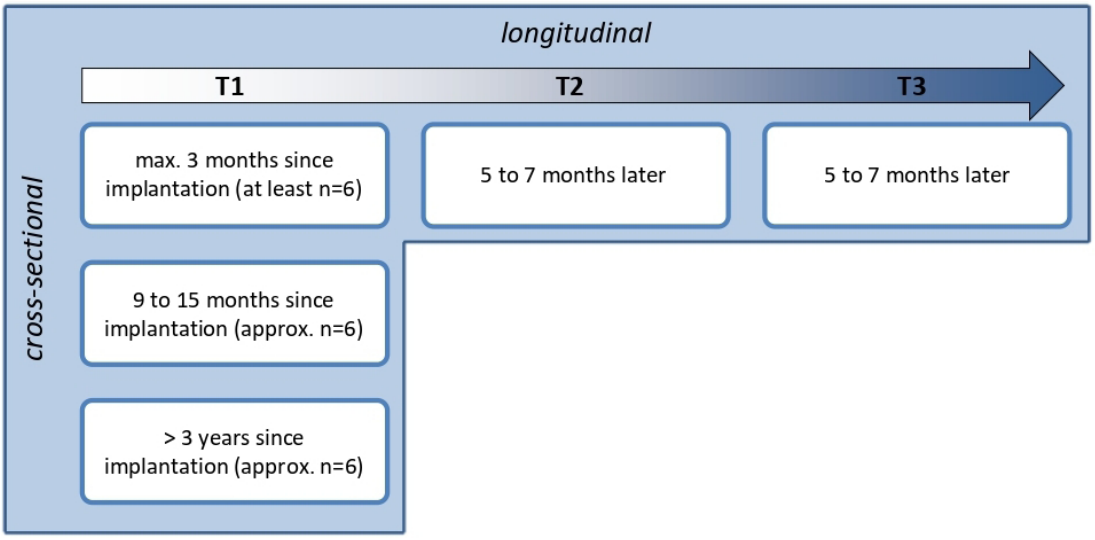

Figure 2 Survey and case number planning.

physicians treating patients with LVAD and mortality of patients under DT based on a recent large scale study[37] were taken into consideration.

Further criteria for purposeful sampling are age, gender, cohabitation and whether the patients were able to decide on LVAD implantation themselves, since these factors are expected to be relevant for the coping process. Choices in participant selection are expected to be limited due to the small population size and the serious health condition of which the patients are affected. Therefore, we aim to include at least one patient per characteristic, so that varying perspectives are taken into account.[34]

Timing of the longitudinal studies will be based on key transitions in the course of disease and treatment in accordance with methodological literature for qualitative longitudinal studies on coping.[35] Therefore, the phases identified by Abshire *et al* will be used and adapted to the German healthcare system.[30]

The sample will include at least 18 patients living with the LVAD for different lengths of time. This is to ensure a certain degree of variability and validity and to make the project manageable.[33 34] However, the final sample size will depend on the amount of LVADs to be implanted during the time frame.

Participants will be recruited at a ventricular assist device (VAD) outpatient department by the treating physicians and VAD coordinators. They will inform eligible patients during their follow-up visits about the opportunity to participate in the study. Patients who are interested will be handed out preliminary study information and asked for written consent to arrange an appointment with the interviewer at the next outpatient visit. At this appointment the patient will be approached by the interviewer who comprehensively explains the study information and provides a copy. If the patients then consent, the interview will be conducted.

Various measures will be taken to promote the recruitment efforts and to prevent substantial dropout from the longitudinal study that goes beyond the natural attrition. The study will be conducted in close collaboration with the VAD outpatient clinic that is closely related to its patients. The patients come there for follow-up visits every 4–8 weeks. The interviews will be conducted as part of these obligatory visits during idle times. Thus, study participation will not require additional time or travel. When convenient, patients will also be interviewed during inpatient hospital stays.

Data collection

Data will be collected via semistructured face-to-face interviews. Some patients come to the outpatient visits by themselves and others are accompanied by caregivers. These patients can decide, whether the caregiver takes part in the interview. All patients will be interviewed by the same male researcher (ML), who is qualified in qualitative research and interview techniques. Each interview is expected to last 30–60 min. The interviewer will write a postscript immediately after conducting the interviews. In the postscripts first ideas for interpretation and situational, non-verbal or other outstanding features, will be retained.[38] All interviews will be recorded digitally with a dictation device and transcribed afterwards. The interviewees will be offered the opportunity to check their respective transcripts.

The interviews will be based on an interview guide that was developed to address patients' experiences on burdens, resources and coping behaviour as outlined in the TMSC. The according questions for the cross-sectional interviews are based on previous literature research and discussions with patients and practitioners (see box 1 and the Public and patient involvement section). All main questions will be addressed in each interview to ensure comparability. These ask for the perceptions of LVAD healthcare, for barriers and facilitators in everyday life with an LVAD, for key transition phases as identified by Abshire *et al* and for different aspects of the coping process as pointed out by

Box 1 Interview guide (translated from German into English)

Living with a left ventricular assist device (LVAD)

1. I have a theoretical and technical understanding of how an LVAD works, but would like to know more about how it feels to live with it. **Can you tell me what it is like to live with an LVAD?**

Participation and healthcare

2. **What areas of your everyday life does the LVAD affect?** (If recreational activities are not discussed: How does the LVAD affect your recreational activities?)
3. **What makes it easier or harder for you to deal with everyday challenges due to the LVAD?**
4. **Think about your hospital stay after implantation and the related healthcare, was there anything that made your situation easier or harder?**
5. **Was there anything in inpatient rehabilitation that made life with an LVAD easier or harder for you?**
6. **What has helped or made it more difficult for you to live with the LVAD since returning home?**
7. **Would you change anything in healthcare for patients with LVAD? If so, what would that be?**

Burden, resources and coping

(Referring to the visual analogue scale on the questionnaire.): On this questionnaire you see a scale on the perceived stress level. Can you indicate your level of perceived stress on this scale with a cross?

8. **What causes this burden?**
   You indicated a low/medium/high perceived stress level due to the LVAD.
   (If no stress is indicated: You indicated that you feel no stress due to the LVAD. Is that correct?)
9. **What has burdened you most in the course of LVAD therapy?**
   (If no burden is mentioned, the following questions refer to psychological burdens after LVAD implantation in general.)
10. **How do you cope with psychological burden due to the LVAD?**
    To what extent has it changed how they felt 'burden'? (Probing for emotion-oriented coping strategies.)
    To what extent have you done something to change the burdening situation? (Probing for problem-oriented coping strategies.)
11. **What has helped you in dealing with psychological burden due to the LVAD?**
    Which of your personality traits have helped you in dealing with psychological burden? (Probing for personal resources.)
    What factors in your personal environment have helped you in dealing with the psychological burden? (Probing for situational resources.)
12. **If you look back on the entire time span since the implantation of the LVAD, how has the way in which you experience psychological burden through the LVAD changed?**

Ending

13. **Is there anything you have not said yet that would be of interest to the study?**

Main questions=bold.

the TMSC.[14] The interview guide was pilot tested with one patient. The included questions serve as guidance, but also allow the interviewees to contribute their own topics and suggestions (eg, on ways to improve healthcare). Interview guides for the second and third longitudinal interview will be developed from preceding analysis of the first survey cycle. The structure of the main topics (participation, healthcare and coping) from the first interview guide will be retained, but the questions will more specifically address burdens, coping resources and behaviour identified to be relevant in the previous interviews.

Interviewees will also be asked to complete the German version of the TMSC-based Perceived Stress Scale (PSS).[17 39] In addition, they will receive a short questionnaire that asks for age, gender, marital status, cohabitation, education, occupational status, device type, perceived stress level (on a visual analogue scale), ability to decide on implantation, date of implantation and HF onset. This quantitative data will be used to describe sample characteristics with relevance for psychological burden and coping. The PSS will also be used in the longitudinal interviews to monitor the perceived stress level over time on a descriptive level.

Data analysis

The data collected with the questionnaires will be analysed descriptively using the statistics software SPSS V.24.[40] The audio recordings of the interviews will be transcribed using the software f4transkript,[41] following transcription rules that have been adapted from McLellan *et al* and Kuckartz.[42 43] Since the analyses focus on manifest contents, dialects and fillers are not transcribed. The transcripts will then be anonymised and imported into the qualitative data analysis software MAXQDA.[44] For quality assurance, all recordings and transcripts are cross-checked by at least two persons. As a form of triangulation and to ensure intersubjective validity, at least two researchers are involved in each step of analysis.[45] Key decisions in the analyses will be discussed and consented with three or more researchers.

Cross-sectional interviews

An inductive qualitative content analysis as outlined by Elo and Kyngas will be carried out[46 47] to explore coping strategies, related resources and barriers from the perspective of DT patients living with the LVAD. Manifest contents in interview texts about coping with psychological burden after LVAD implantation and related resources or barriers will be the unit of analysis. The analysis will follow six steps, which are adapted from pertinent methodological literature[45 46 48]:

1. *Familiarising with the data*: two coders familiarise themselves with the data by reading the transcripts. Six interviews that differ in content as far as possible will be selected for the first three steps of analysis. Both coders read the six interviews and extract single meaning units (sequence of content or context-related words) about coping with psychological burden after LVAD implantation from the interview texts.
2. *Open coding*: the extracts will be subjected to an inductive open coding which is conducted independently by the two coders. Every meaning unit will be labelled with a code. This process is oriented to explore burdens, resources and coping behaviour ac-

cording to the TMSC. The developed codes are then checked for consistency and refined. As many codes as necessary to label all relevant meaning units will be developed.
3. *Grouping*: the codes of both coders will be compared and similar codes will be merged. The codes are then grouped under higher order headings and linked to each other in a hierarchical coding system. Adequacy of the coding system will then be tested against three further interviews by both coders.
4. *Coding all data*: the coding system will be applied to all further interviews by one coder. If there are further relevant meaning units that cannot be classified in the existing system, new codes will be developed and added.
5. *Categorisation*: a category system comprising generic categories with subcategories (in terms of Elo and Kyngas[46] will be developed from the coding system. Each generic category will be described in a memo with its subcategories. The generic categories are then contrasted against each other and refined. The category system is considered to be finalised when no extracted meaning units fall between two categories or fit in more than one.[45] This state will be ascertained by three researchers.
6. *Abstraction*: main categories on the highest level of abstraction are developed from the category system. The findings will then be translated into the TMSC as the theoretical framework. Thus, a TMSC-based model will be developed from the data that describes coping of patients with LVAD with related strains, resources and barriers. The final interpretation will be consented with all researchers involved.

Longitudinal interviews

The analysis of the longitudinal interviews aims to explore psychological adjustment to living with an LVAD during the first year after implantation using a deductive content analysis as outlined by Elo and Kyngas.[46] The structure for this analysis will be operationalised based on the findings of the previously analysed cross-sectional interviews. The following steps for a deductive content analysis will be applied to the interviews of T2 and T3 separately.[46] The cross-sectional and longitudinal interviews will be analysed by the same researchers, who are already familiar with the data.

1. *Extraction*: two researchers read the interviews of the interview cycle and extract relevant meaning units from the patient's statements in the transcripts. All meaning units considered to be relevant by one researcher will be included in the analysis.
2. *Developing a categorisation matrix*: based on the model that was developed in the preceding inductive content analysis, a categorisation matrix comprising its main themes will be developed by one researcher and then discussed with the three researchers.
3. *Categorisation*: the extracted meaning units will be assigned to the categorisation matrix by both researchers. The codings will then be discussed and consented by both researchers. If the two researchers disagree, a third researcher will be consulted.
4. *Extending the categorisation matrix:* unassigned meaning units will be aggregated and checked for relevant contents that are not represented in the matrix. If both coders agree, new categories will be developed based on the principles of inductive content analysis. The final categorisation matrix maps the process of psychological adjustment over the first year after an LVAD implantation.

The results of the analyses can help to critically evaluate current healthcare practice and to support patients more adequately in coping with the emerging challenges. While the study focus is on patients under DT in Germany, insights can partly be applicable to patients with LVAD in other countries or and with other dependable medical devices.

Patient and public involvement

Patients and healthcare practitioners are involved at different stages of the research process. Reporting is based on the Guidance for Reporting Involvement of Patients and the Public (GRIPP2) short form (online supplemental appendix).[49]

Patient and practitioner involvement during study preparation aimed to ensure adequacy of methodology and study information, reasonableness of the interviews and consideration of all relevant aspects in the interview guide. During initial study planning, the research question was developed in collaboration with a physician experienced in LVAD healthcare. Two further physicians, two VAD coordinators and two patients were consulted in individual meetings for developing the study design. This has been beneficial to develop a comprehensive understanding of the actual healthcare situation and to get a clear impression of the patient group. Based on their feedback, various specific changes were made: a more structured interview technique was chosen, which was considered to be more appropriate for the patient group; the criterion whether a patient was able to decide on the LVAD implantation was adopted for purposeful sampling; the question about recreational activities was added to the interview guide.

Patients and practitioners will be involved in the analysis to ensure validity of interpretations and to explore ways for disseminating the results to patients. Therefore, a preliminary category system will be discussed with a practitioner and a patient as part of the inductive content analysis after grouping the codes (third step of analysis). The results of the inductive content analysis and preliminary results of the deductive content analysis will also be discussed with patients at a self-help group meeting.

ETHICS AND DISSEMINATION

The study obtained ethical approval from the ethics committee of the School of Medicine and Health Sciences at the University of Oldenburg (2019-023).

Although the study is non-interventional, talking about consequences of the LVAD implantation could affect the patients' psychological well-being. The participants will be fully informed about this and further potential risks as

part of the study information. In order to prevent harmful consequences, various measures are taken. The interviews are conducted in the clinic, which is familiar to the patients. Accordingly, psychological support by the clinic staff is available when needed and the interviewer himself is experienced in dealing with vulnerable groups. In addition, interview contents and setting were discussed with patients and practitioners to ensure reasonableness. The patients' voluntary participation can be revoked at any time without stating any reason.

The data will be deposited at the University of Oldenburg and processed according to data management and security requirements of the applicable data protection regulations, particularly the General Data Protection Regulation (EU) 2016/679. The anonymised results of this study will be published in scientific journals and presented at national and international conferences.

Study status

Recruitment for the study started in October 2019 and will continue until April 2020. For the cross-sectional investigation data, collection will presumably continue until April 2020. For the longitudinal study, data collection is expected to take until April 2021.

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Supplementary material

Appendix I – COREQ Checklist

Appendix II – GRIPP2 short form

Levelink M, *et al. BMJ Open* 2020; 10:e037017. doi: 10.1136/bmjopen-2020-037017

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Appendix I – COREQ Checklist

Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist [1]

Domain 1: Research team and reflexivity	Page
1. Interviewer/facilitator - Which author/s conducted the interview or focus group?	7
2. Credentials - What were the researcher's credentials? E.g. PhD, MD	t.p.
3. Occupation - What was their occupation at the time of the study?	t.p.
4. Gender - Was the researcher male or female?	7
5. Experience and training - What experience or training did the researcher have?	7-6
6. Relationship established - Was a relationship established prior to study commencement?	6
7. Participant knowledge of the interviewer - What did the participants know about the researcher? e.g. personal goals, reasons for doing the research?	6
8. Interviewer characteristics - What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic?	6-7
Domain 2: study design	
9. Methodological orientation and Theory - What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	7
10. Sampling - How were participants selected? e.g. purposive, convenience, consecutive, snowball	5
11. Method of approach - How were participants approached? e.g. face-to-face, telephone, mail, email	6-7
12. Sample size - How many participants were in the study?	6
13. Non-participation - How many people refused to participate or dropped out? Reasons?	n.a.
14. Setting of data collection - Where was the data collected? e.g. home, clinic, workplace	6-7
15. Presence of non-participants - Was anyone else present besides the participants and researchers?	7
16. Description of sample - What are the important characteristics of the sample? e.g. demographic data, date	6
17. Interview guide - Were questions, prompts, guides provided by the authors? Was it pilot tested?	7-8
18. Repeat interviews - Were repeat interviews carried out? If yes, how many?	6
19. Audio/visual recording - Did the research use audio or visual recording to collect the data?	7
20. Field notes - Were field notes made during and/or after the interview or focus group?	7
21. Duration - What was the duration of the interviews or focus group?	7
22. Data saturation - Was data saturation discussed?	n.a.
23. Transcripts returned - Were transcripts returned to participants for comment and/or correction?	7
24. Number of data coders - How many data coders coded the data?	8-10
Domain 3: analysis and findings	
25. Description of the coding tree - Did authors provide a description of the coding tree?	n.a.
26. Derivation of themes - Were themes identified in advance or derived from the data?	8-10
27. Software - What software, if applicable, was used to manage the data?	8
28. Participant checking - Did participants provide feedback on the findings?	10
29. Quotations presented - Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. participant number	n.a.
30. Data and findings consistent - Was there consistency between the data presented and the findings?	n.a.
31. Clarity of major themes - Were major themes clearly presented in the findings?	n.a.
32. Clarity of minor themes - Is there a description of diverse cases or discussion of minor themes?	n.a.

n.a. = not applicable to this protocol

t.p. = title page

Appendix II – GRIPP2 short form

GRIPP2 short form[2]

Section and topic	Item	Page
1: Aim	Report the aim of PPI in the study	10
2: Methods	Provide a clear description of the methods used for PPI in the study	10
3: Study results	Outcomes—Report the results of PPI in the study, including both positive and negative outcomes	10
4: Discussion and conclusions	Outcomes—Comment on the extent to which PPI influenced the study overall. Describe positive and negative effects	10
5: Reflections/critical perspective	Comment critically on the study, reflecting on the things that went well and those that did not, so others can learn from this experience	10

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