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Self-management for patients on ventricular assist device support: a national, multicentre study: protocol for a 3-phase study

Christiane Kugler ,[1] Hannah Spielmann,[1] Maiken Seemann,[1] Volker Lauenroth,[2] Renata Wacker,[3] Wolfgang Albert,[3] Christine Spitz-Koeberich,[4] Sandra Semmig-Koenze,[5] Maja von Cube,[6] Katharina Tigges-Limmer[2]

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For numbered affiliations see end of article.

Correspondence to
Dr Christiane Kugler;
christiane.kugler@uniklinik-freiburg.de

ABSTRACT

Introduction Self-management (SM) may facilitate patient participation and involvement to become active and knowledgeable partners in the care of complex chronic conditions such as ventricular assist device (VAD) therapy. The 'SM model for patients on VAD support' will serve to distinguish between SM components, and will guide the development, implementation and evaluation of an evidence-based curriculum.

Methods and analysis This is a 3-phase, multicentre study. In phase 1, a prevalence study will be performed. Phase 2 aims to develop an evidence-based, interprofessional curriculum for SM support for VAD patients. In phase 3, a non-blinded block-randomised controlled trial (RCT), allocation ratio 1:1, intervention group superiority, with an unblinded multifacetted intervention with assessments before (T1) and after (T2) the intervention, and two follow-up assessments at three (T3), and 12 (T4) months after VAD implantation, will be performed. The curriculum guides the intervention in the RCT. Patient recruitment will consider centre-related volume: power analyses require 384 patients for phase 1, and 142 patients for phase 3.

Ethics and dissemination Ethical considerations will be continuously taken into account and approved by the institutional review boards. Central ethical review board approval has been obtained by the Albert-Ludwigs University Freiburg. This study will be performed in concordance with the Declaration of Helsinki and the European data protection law. Publications will exclusively report aggregated data and will be distributed in the scientific community, and patient support groups. Report languages will be German and English.

Trial registration numbers NCT04234230 and NCT04526964; Pre-results.

Strengths and limitations of this study

- This study will develop, implement and evaluate an evidence-based curriculum for self-management support for patients on durable ventricular assist device support.
- All three phases for this study will be executed by a multiprofessional group of experts.
- The study design is a tailored, non-blinded, block-randomised controlled trial.
- Gender will be taken into consideration for randomisation and data analysis.
- The curriculum, manual, smartphone application and patient materials may adjust the standard of care for the patient cohort under investigation nationwide.

INTRODUCTION

Ventricular assist device (VAD) implantations have become a common therapeutic strategy for patients suffering from end-stage heart disease.[1–3] The second European Registry for Patients with Mechanical Circulatory Support report (EUROMACS) presents data on 2947 registered implantations in 2016, numbers are expected to increase further.[4 5] VAD implantations are performed both as a bridge to transplant in 64%, and as a destination therapy in 16%.[4 6] In Germany, a 36.6% increase in VAD implantations has been reported between 2011 and 2015.[7] The German Heart Surgery Report 2019 indicates VAD implantation activities remaining on a high plateau.[8] Psychosocial evaluation and standardised self-management (SM) support for patients before, and in the long-term postimplant is strongly recommended according to two recent consensus statements.[9 10] However, German implant centres follow differing procedures in this regard. Namely, current discharge management and educational efforts may vary between heart centres with respect to the psychological and psychosocial support services available for VAD patients.

Despite improvements in quality of life (QoL) following VAD implantation, life with a VAD is far from normal and requires psychological and psychosocial adjustment

for the individual. However, QoL on VAD support can be significantly diminished due to potentially lethal complications which still persist, including thromboembolic neurological events (stroke 13%), wound infections on the driveline exit site (20%) and major bleeding events (5%).[4] In addition, QoL can be impaired by the number of strokes, infections, device malfunction and pain at the exit site.[10 11] With an increasing time on device, increased risk ratios associated with physical inactivity, overweight and psychic disorders have been reported in up to 64% of patients on VAD support.[10–18] Symptoms of anxiety, depression and post-traumatic stress can occur as a result of the VAD implant procedure or the related in-hospital care, or from adverse events and its related treatment procedures.[14 15 17–19] Brouwers *et al*[15] detected VAD treatment-related post-traumatic stress symptoms in 21% of their VAD population. Alarms and malfunctioning of technical equipment may count for psychological distress and sleep disorders in 52%.[17 19 20] For long-term assist device therapy, reduced social reintegration, financial and social constraints have been reported.[17 19 20] Limited data suggest that body image can be impacted by the external part of the VAD.[21–23]

Theoretical framework

Evidence suggests that SM may facilitate patient participation and involvement to become active and knowledgeable partners in the care of complex chronic conditions such as VAD therapy.[9 17 24] SM, as the individual's ability to manage the symptoms, treatment, physical and psychological consequences and lifestyle changes inherent in living with a chronic condition requires a process of organised learning experiences in partnership with patients, caregivers and healthcare providers.[25] The SM model has been developed by Lorig *et al*[25] and provides important guidance suggesting that theory-based interventions are more effective towards behavioural changes, in comparison to interventions that do not use a theoretical approach.[25–27] This is particularly important since adoption to a life on VAD support requires uniform operationalisation of behavioural and cognitive determinants.[26 27] Disease-specific SM programmes for patient cohorts with chronic conditions have been developed and provide increasingly needed support to improve outcomes by providing strategies and content for organised and structured learning experiences designed to facilitate the adoption of health-related behaviours.[28] However, no SM programme for VAD patients was identified.

Thus, for the purposes of this study, the authors developed an 'SM model for patients on VAD support' (see figure 1) based on the work by Schäfer-Keller *et al*.[29] This model may serve to distinguish between three SM task components: component one outlining the content and strategies of managing the therapeutic regimen necessary to enable patients to adopt their health-related behaviours following the implant procedure.[20 27] Component two targets managing emotions and psychological adjustment given the evidence for increased prevalence rates of depression, impaired body image, post-traumatic stress, anxiety/fear of device malfunction and complications due to the device.[14 15 17 19 21 27] SM in component two, targets psychological stability and QoL for the VAD patients with a palpable and visible escort for the heart. Component three focuses on managing new life roles, for example, professional activities with a VAD, and may relate to familial dynamics.[14 15 19 20 27]

Need for SM support

Following VAD implantation, learning and adjusting to very specific SM capabilities is crucial for the individual

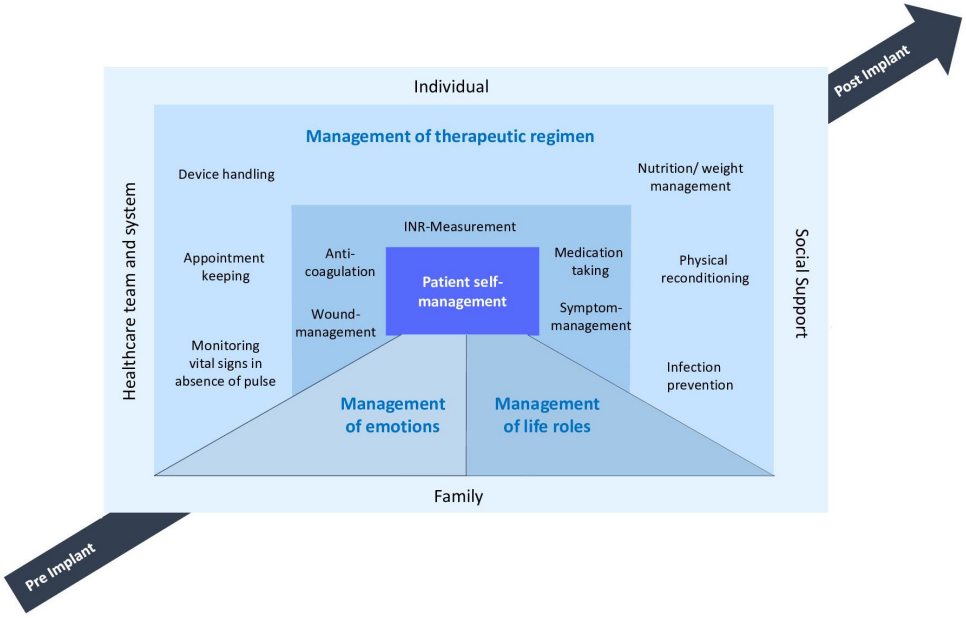

Figure 1 Self-management model for patients on VAD support (modified after Schäfer-Keller *et al*[29]). INR, international normalised ratio; VAD, ventricular assist device.

and their caregivers. However, for the individual to become capable to self-manage life on VAD support, evidence-based and well-designed SM programmes are a prerequisite. Such programmes should target all three SM components and thus require multi-professional VAD teams. Figure 1 outlines teaching and learning elements within all three components of the 'SM model for patients on VAD support' to enable them to self-manage their daily life within their home environment successfully and safely. For the management of component one, managing the therapeutic regimen, device handling, battery exchange, monitoring of the controller and technical equipment, wound management and wound dressing change, anticoagulation and internationalised normalised ratio measurement, medication management and monitoring of vital signs are essential.[20 25 27 30 31] Thus, lifestyle changes represent a necessary element of SM on VAD support, which leads to component two, managing emotions and psychological adjustment. Within this component, psychosocial adjustment is necessary to support patients to cope with symptoms of anxiety, depression, post-traumatic stress, body image changes and emotional acceptance.[14 17 19 21 23] Component three, managing new life roles, aims to support social reintegration including professional adjustment while being on VAD support.[14 15 19 20 30] Thus, SM support for VAD patients based on an evidence-based modular curriculum, delivered by interprofessional trained VAD teams, is required.

This paper presents the study protocol for the self-management project (SELMA) (self-management for patients on VAD support) with the overarching aim to improve SM and QoL for patients on VAD support. We hypothesise that improved SM capabilities will result in decreased complication rates specific for this population including thromboembolic neurological events, driveline exit site infections and bleeding events. We further hypothesise that improved SM capabilities may reduce rehospitalisation and mortality rates in VAD patients.

Within our SELMA study, we aim our focus on the initial patient SM education in the immediate inpatient postimplantation period and thus aim to answer the most urgent patient concerns. Results from this 3-phase study will provide guidance and direction on the benefits of standardised, immediately postimplant initiated, modular, App-supported SM on reduced adverse events, pre-defined as a combined endpoint for the study purposes. Rehabilitation programmes represent an essential prerequisite for VAD patients' recovery and their aftercare and SM efforts, they hold potential for collaboration to sustain the results from this study.

Objectives

This 3-phase study encompasses the following steps: In phase 1, a multicentre analysis on SM in patients on VAD support and moderating determinants will be performed. Phase2 aims to develop the content and requirements for an evidence-based, interprofessional curriculum for VAD-specific SM support delivered face-to-face, supplemented by a smartphone-based application (App). In phase 3, the curriculum content will be implemented and evaluated at all four participating centres simultaneously. This multifacetted complex intervention aims to (1) reduce VAD-specific complication rates (thromboembolic neurological events, driveline exit site infections and bleeding events (primary combined outcome) and related rehospitalisations during the first year following VAD implantation, and to (2) improve patient reported SM, QoL and psychosocial adjustment (patient-reported outcomes (PROs); secondary outcomes).

METHODS

The conduct and reporting of phase 1 will follow the Strengthening the Reporting of Observational Studies in Epidemiology[32] guidelines, whereas for phase 3, the Standard Protocol Items: Recommendations for Interventional Trials[33] and Consolidated Standards of Reporting Trials[34] guidelines will guide conduct and reporting in unison. Phase 2 will be a theoretical phase aiming to develop a 'to be tested' evidence-based, interprofessional curriculum for SM support for VAD patients. Central ethical approval for trial phases 1 and 3 has been obtained by the ethics committee of the Albert-Ludwigs University Freiburg and by joined approval by the review boards of the participating sites (phase 1 304/19, 1.1; phase 1 41/20, 1.1).

Study design

This is a 3-phase, multicentre study. In phase 1, a prevalence study will be performed. Phase 2 aims to develop an evidence-based, interprofessional curriculum for SM support for VAD patients. In phase 3, the trial design is a non-blinded block-randomised controlled trial (RCT), allocation ratio 1:1, intervention group superiority, with an unblinded multifacetted intervention with assessments before and after the intervention, and two follow-up assessments at 3 months after the intervention, and 12 months after VAD implantation. Patient recruitment will consider centre-related volumes and will recruit study participants simultaneously. Patients with implantable VADs on long-term outpatient support will be considered. Data collection methods will be carefully designed in order to reduce non-response, and missing values for this study.[35–39] Figure 2 depicts the study design for this 3-phase study including the time of enrolment, intervention and follow-up per participant timeline.

Study setting

This study will be conducted at four established university-based heart centres throughout Germany. Two of the participating sites are high volume centres; one centre is a medium, and one a medium-low volume site.

In phase 1, data collection will take place at all four sites simultaneously for patients in the outpatient setting. In phase 3, the intervention will start during the postimplant

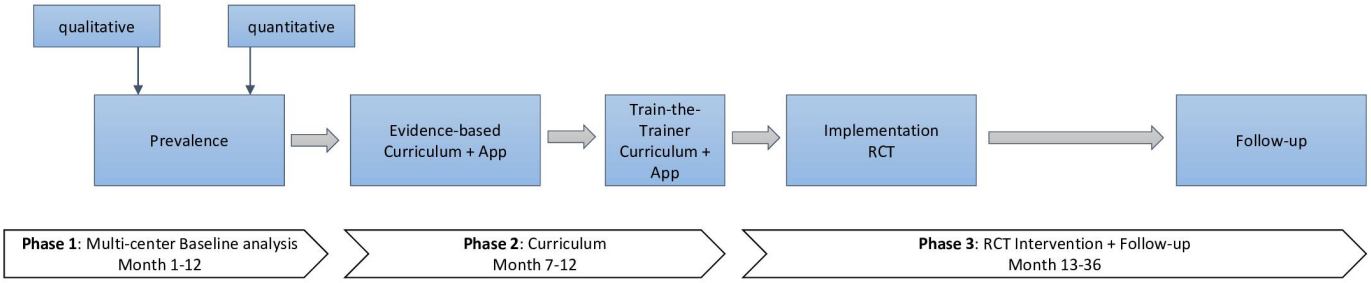

Figure 2 Study design for the 3-phase study. App, Smartphone-based application; RCT, randomised controlled trial.

hospitalisation for participants being assigned to the intervention or control group. Initiation of the intervention will be performed at the step down units immediately postimplant in clinically stable patients and will be continued in the outpatient setting for the entire intervention period of time.

Study participants

Eligibility criteria

Stable patients with ongoing VAD support will be considered for phases 1 and 3 for this study. Table 1 outlines eligibility criteria for participants.

Expected sample size

For phase 1, the power analysis revealed that 384 participants need to be included according to the formula recommended by Naing *et al*.[40]

For phase 3, power calculations considered gender, and centre-related implant activities. Based on an 80% power, and a two-sided significance level of ≤0.05, 71 participants in both the intervention and control groups are needed to detect statistically significant differences. Based on reports from comparable, previous studies,[18 19] a 10% refusal rate and a 20% drop-out rate have been contemplated.

Recruitment

Recruitment will be performed by authorised staff from the participating centres. As a prerequisite to participate into the patient recruitment procedure, staff needs to agree to regulations, and to learn relevant study information materials, for example, the study protocol.

In phase 1, patients will be recruited during regular outpatient clinical visits at the respective heart centres. Patients, not having regular appointments scheduled during that period of time, will be contacted via telephone by the authorised staff. Those which agree orally will then receive all study materials containing two informed consent forms (one to remain with the patient, one to be send back to the treating heart centre), a battery of questionnaires, contact data for requests or concerns regarding study content and a prestamped preaddressed envelope to send their questionnaires back to the study centre. Patients, who agree orally and do not send back the study materials within a 2-week period of time, will receive another letter as a gentle reminder. Patients, who do not respond, will be considered as non-responders.

In phase 3, the design requires recruitment at the step-down units immediately following VAD implantation.

Table 1 Eligibility criteria for participants

	Criterion	Phase 1	Phase 3
Inclusion criteria	Age 18+	x	x
	Ongoing VAD support	x	x
	Cognitive ability to participate	x	x
	Sufficient language skills	x	x
	Follow-up at the participating site	x	x
	Time post-VAD implantation	3–36 months	3–5 days
	Stable health condition	At home	At step-down unit
	Written informed consent	x	x
Exclusion criteria	Patient does not live at home (eg, nursing home)	x	x
	Patient was not at home yet/cannot judge—management in home environment	x	-//-

VAD, ventricular assist device.

Recruitment will again be performed by authorised staff and following standardised procedures.

Randomisation

Patient recruitment for phase 3 requires randomisation, which will be based on gender (80% male), and centre according to implant activities (35% high, 20% medium, 10% low volume centres) for a stratified block randomisation procedure. This anticipated procedure intends to balance stability for intervention and control group participants in all strata.[39] Anticipating drop-outs (15.5%), 142 patients need to be randomised in a ratio 1:1 per group, in order to ensure complete data for 120 patients for the final analyses. Randomisation for each stratum will be performed with R (blockrand or randomiseR). Random allocation sequence is seven per block provided by sequentially numbered lists. In order to avoid a selection bias, allocation concealment to hide the sequence until interventions have been assigned, will be performed: block randomised sequentially numbered lists will be provided by the trial statistician and delivered to the study coordinating team. Two team members will store the list, and the recruiting staff from the study centres will be given the consecutive randomisation code number to be able to assign the potential study participant to either intervention or control. Participant code numbers will be documented and monitored for quality assurance purposes.

Intervention

Phase 3 of this study will deliver the SM intervention based on the evidence-based SELMA curriculum and SELMA App developed in phase 2 of this study (see figure 3).

Train-the-trainer workshop

A 1-day train-the-trainer workshop will conclude phase 2, and will prepare the interprofessional study group for a standardised delivery of the simultaneous intervention at all four sites. This workshop aims to prepare intervention delivering professionals to receive a standardised training focusing on content and didactic elements, in order to have the intervention delivered at a comparable standard. This training intentionally prepares for the 'what' (goals and content), and 'how' (methods and didactics), and by 'whom' (roles and professions) to deliver. Hence, the training will contain theoretical aspects, and for the majority of the time hands-on, technical skills and simulation training based on the modules of the SELMA curriculum.

In addition, peer group advice for the participating interprofessional team from all four sites will be scheduled for the overall intervention period of time to enable experience exchange between the heart centres, and to minimise potential centre-related biases in the delivery of the intervention. Two certified trainers will moderate the train-the-trainer workshop and the peer group exchange between the participating heart centres.

SELMA curriculum

The SELMA curriculum will be based on a synthesis of the current evidence. A curriculum draft will be developed, reviewed and approved by the core study team. The curriculum will contain 11 modules aiming to deliver knowledge, skills and competencies to VAD patients and preferably their partners. The curriculums' content and didactics will enable newly implanted patients and their partners to better self-manage their day-to-day life on

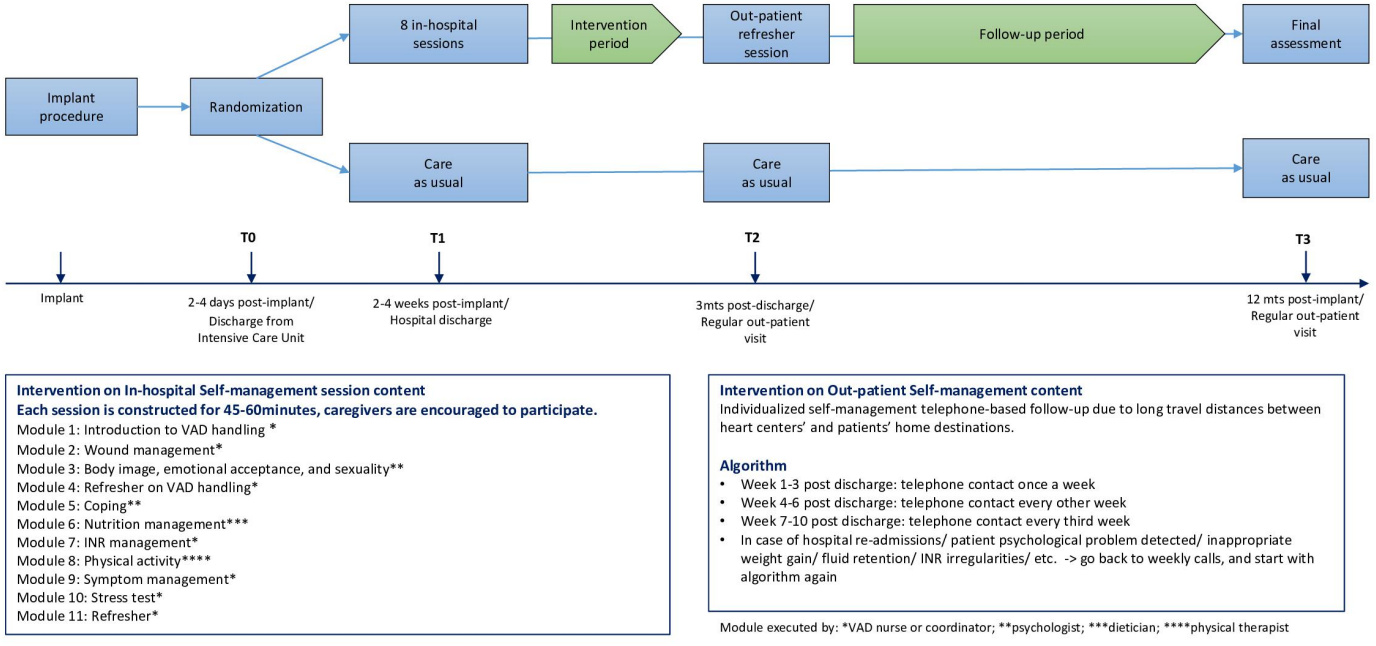

Figure 3 Study design for the randomised clinical trial in phase 3 of this study. INR, international normalised ratio; VAD, ventricular assist device.

Table 2 Overview of intervention content based on the SELMA curriculum

No	Module	Session content	Setting	Media/training equipment	Lead profession
1	Introduction to VAD handling	Explanation, handling of VAD equipment	Inpatient	Hands-on training with VAD equipment	VAD coordinator
2	Wound management	Instruction, handling of aseptic wound dressing change, fixation of the driveline	Inpatient and outpatient	Hands-on training with wound dressing materials	VAD coordinator
3	Body image, emotional acceptance and sexuality	Integration of VAD into body image, emotional acceptance and sexuality	Inpatient and outpatient	none	Psychologist
4	Refresher on VAD handling	Teachback sessions on VAD equipment handling	Inpatient and outpatient	Hands-on training with VAD equipment	VAD coordinator
5	Coping	Resource activation and coping facilitation	Inpatient and outpatient	Multiple training styles, for example, worksheets	Psychologist
6	Nutrition management	Strategies for adjusting to healthy eating behaviours	Inpatient and outpatient	Multiple training styles, for example, worksheets	Nutritionist
7	INR management	Preparation and execution of INR measurement; adequate INR interpretation and behaviour response (preventive and therapeutic)	Inpatient and outpatient	INR measurement equipment; INR reference tables	VAD coordinator
8	Physical activity	Physical activity and physical reconditioning with a VAD	Inpatient and outpatient	For example, video clips, worksheets	Physiotherapist
9	Symptom management	Interpreting and handling of potentially distressing heart failure symptoms, and symptoms of medication-related side effects	Inpatient and outpatient	None	Nurse
10	Stress test	Training of handling emergency conditions	Inpatient	Hands-on exercise with VAD equipment	VAD coordinator
11	Refresher	All self-management aspects	Outpatient	Hands-on exercise with VAD equipment; INR measurement, wound dressing materials, worksheets, etc.	VAD coordinator

App, application; INR, international normalised ratio; SELMA, self-management project; VAD, ventricular assist device.

VAD support and to prepare them with the best skills and knowledge to prevent and/or to respond adequately to early signs and symptoms of potential adverse events: bleeding, driveline exit-site infections, and neurological events. The curriculum content will be delivered by the trained multiprofessional VAD teams and will be initiated immediately post-implant as part of the educational sessions before hospital discharge and will continue in the outpatient settings (table 2). Each module will use different didactic feedback and evaluation elements. Modules 4 and 11 are conceptualised as a refresher. The curriculum will be supplemented by the SELMA App containing information related to the modules delivered.

SELMA APP

All curriculum content will be offered to intervention group patients as a supplement to the SM intervention. The SELMA App will be downloadable to the patients' smartphones (computed for different mobile platforms) and can be used optionally as a reading mode only, or by the login mode. The reading mode will provide content related to the SELMA modules and aims to re-enforce content delivered in the face-to-face training sessions provided in table 2 using pictorial, textual and animated education. The login mode will be computed to offer a self-monitoring platform of relevant health parameters to the intervention group patients, for example, weight, body mass index, temperature, sleep patterns and mood. All parameters can be displayable as graphical lines over time. In addition, the App will be programmed to store the individual patients' medication schedule with memory functions, in order to support medication adherence. All data entered via the login mode will be exclusively displayed to the individual patient; no information will be transferred to the participating heart centres or to the central database of the study centre. Data will be stored at an external server monitored by the subcontracted IT specialist.

Usual care

Usual care for both groups will include the standardised VAD-specific education as the current standard of care

delivered by trained professionals at each participating site.

Intervention procedure

The intervention (figures 2 and 3) will provide individualised VAD-specific SM training based on the modular curriculum for intervention group patients consecutively following randomisation starting during the postimplant hospital stay. Module 10 is designed as a 'stress test' to be delivered immediately before hospital discharge and to ensure successful SM skills as a prerequisite for hospital discharge postimplant. Intervention training will continue in the outpatient setting in order to refresh and sustain SM skills on agreed topics between the VAD training staff and the patient/ caregiver. This will be done with a bidirectionally adjustable algorithm allowing a tailored intervention based on the individualised needs expressed by the individual and/or offered by the executing training staff members. Different didactic feedback and evaluation elements will help navigate and prioritise the SM content for the outpatient intervention along with the algorithm. During the outpatient intervention period of time, the intervention content can be provided by communication channels preferred by the individual (eg, phone, email, video conferencing) and appropriate with respect to the topic, for example, wound management might be best delivered via video conference line (eg, FaceTime). The refresher session concludes the intervention period for each patient.

Instruments and outcome measures

Comparable instruments and measurement methods will be used for empirical phases 1 and 3. An overview is given in table 3.

PRO measures

Following the US Department of Health and Human Services Food and Drug Administration updated report (2009),[41] PRO outcome measures will be captured using psychometrically valid instruments.[38] Instruments identified for this study are depicted in table 3. Taking into account the patient population under investigation, a paper-and-pencil format has been chosen.[35] All patient materials will be designed with the SELMA, and the heart centres' corporate designs for recognition purposes.

Demographic measures

Demographic measures will be collected by patient self-reports and are depicted in table 3.

Morbidity and clinical measures, constitution-related measures and laboratory values

Disease-specific measures and comorbidities may act as mediator variables for the outcomes of interest for phases 1 and 3. Thus, potentially relevant variables have been identified through a combined approach of synthesising the evidence and clinical expertise for this study.[39] Data will be collected from the patient chart (table 3).

Adverse events

Adverse events are critical to estimate the outcomes of this costly procedure.[4] Relevant thromboembolic events (pump, vascular), neurological events (stroke), bleeding (location, internal, external), driveline infections and death are monitored. For definitions of adverse events, we used the EUROMACS[4] recommendations, and the corresponding INTERMACS[42] definitions for adverse events. Data will be collected from the patient chart (table 3).

Adverse events, not predefined within the study protocol, and other unintended effects of the intervention or conduct will be monitored and reported.

Data collection and management

In phases 1 and 3, all PRO measures will be gathered by patients after written informed consent has been received. In addition, clinical data will be drawn from the patient records and entered into electronic case report forms by trained staff at the participating centres. Data collection will preferably be performed during regular outpatient clinical visits. For phase 1, one data collection per participant will be performed. In phase 3, intervention and control group patients will be followed up at the respective measurement points outlined in figure 3. All data will be merged by the study centre into one centralised database using a combined pseudonymised code containing centre-related letters, and participant-related numbers resulting in a centralised data management. For phases 1 and 3, two separate databases will be created and managed. Data storage of all paper-based materials will be kept in locked cabinets, and electronic data will be stored on institution-based servers with limited access to the password-protected files at any time. Data will be archived in concordance with the German law for storage of medical patient-related data.[43]

Statistical analysis

Statistical analyses will be performed by the trial statistician using R or SAS (Version 9.4). Power calculations for phases 1 and 3 have taken recent implant activities of the participating heart centres into account. An initial data analysis will be carried out to check for data quality including allowable ranges, missings, data structure and errors. Descriptive and univariate between-group analyses will be performed for relevant demographic and clinical variables in order to describe sample characteristics in both substudies in phases 1 and 3.

In phase 1, the prevalence rates of relevant psychosocial variables such as anxiety, depression and post-traumatic stress symptoms will be calculated and outlined along with the 95% CIs. PRO measures for social support, QoL and the level of integration of the VAD into body image will be presented in concordance with the user manuals for those PRO instruments being used. Demographic and medical measures will be analysed for their potential to serve as prediction models for adverse psychopathological outcomes by performing mixed linear regression

Table 3 Instruments and outcome measures

Outcome domain/concept	Instrument/measure	No of scales/ items	Recall period	Phase 1	Phase 3			
					T0	T1	T2	T3
Patient-reported outcome measures								
Self-management	QoL VAD[44]	1 scale/8 items	Not reported	x	x	x	x	x
	SELMA VAD	1 scale/14 items	2 weeks	--	--	x	x	x
Quality of Life	QoL VAD[44]	4 scales/35 items	Not reported	x	x	x	x	x
	KCCQ[45]	6 scales/23 items	2 weeks	x	--	--	--	--
Social support	FSoZu-K14[46]	f4 scales/14 items	Not reported	x	--	x	x	x
Anxiety & Depression	HADS[47]	2 scales/14 items	2 weeks	x	x	x	x	X
Depression	PHQ-9[48]	1 scale/9 items	2 weeks	x	x	x	x	x
Body Image	FKB-20,[49] subscale vital body dynamics	2 scales/10 items	Not reported	x	x	x	x	x
Body Image Integration[50]	BII	1 scale/7 items	2 weeks	x	x	x	x	x
Decision for Implant	Patient reported items	2 items	None	--	x	--	--	x
Demographic Measures								
Age	Patient reported item	1 item	n.a.	x	x	--	--	--
Gender	Patient reported item	1 item	n.a.	x	x	--	--	--
Family Condition	Patient reported item	1 item	n.a.	x	x	--	--	x
Living Situation	Patient reported item	1 item	n.a.	x	x	--	--	x
Education and Schooling	Patient reported item	1 item	n.a.	x	x	--	--	--
Professional Employment	Work Performance Index[51]	1 scale/6 items	n.a.	x	x	--	--	x
Morbidity and Clinical Measures								
Diagnosis and Relevant Morbidity								
NYHA class	Patient chart	1 item	n.a.	x	x	--	--	--
INTERMACS level	Patient chart	1 item	n.a.	x	x	--	--	--
Implant-related Diagnosis	Patient chart	1 item	n.a.	x	x	--	--	--
Diabetes	Patient chart	1 item	n.a.	x	x	x	x	x
Hypertension	Patient chart	1 item	n.a.	x	x	x	x	x
Renal Insufficiency	Patient chart	1 item	n.a.	x	x	x	x	x
Dialysis	Patient chart	1 item	n.a.	x	x	x	x	x
Peripheral arterial vascular disease	Patient chart	1 item	n.a.	--	x	x	x	x
Relevant VAD-specific Measures								
VAD-Type	Patient chart	1 item	n.a.	x	x	--	--	--

Continued

Table 3 Continued

Outcome domain/concept	Instrument/measure	No of scales/ items	Recall period	Phase 1	Phase 3			
					T0	T1	T2	T3
Time since Implant at Study Inclusion	Patient chart	1 item	n.a.	x	x	--	--	--
Type of Implant Procedure (emergency, elective)	Patient chart	1 item	n.a.	x	x	--	--	--
Type of Implant Reason (bridge-to-transplant, bridge-to-recovery, destination)	Patient chart	1 item	n.a.	x	x	--	--	--
Device failure	Patient chart	1 item	n.a.	x	x	x	x	x
Implantable cardioverter-defibrillator	Patient chart	1 item	n.a.	x	x	x	x	x
Inpatient rehabilitation post-implant hospital discharge	Patient chart	1 item	n.a.	--	--	x	--	--
Relevant Constitution-related Measures and Laboratory Values								
Body Mass Index (BMI, kg/ m^2)	Patient chart	1 item	n.a.	x	x	x	x	x
International Normalised Ratio (INR)	Patient chart	1 item	n.a.	x	x	x	x	x
Relevant Adverse Events								
Thromboembolic event	Patient chart	1 item	n.a.	x	x	x	x	x
Neurologic event	Patient chart	1 item	n.a.	x	x	x	x	x
Bleeding	Patient chart	1 item	n.a.	x	x	x	x	x
Driveline Infection	Patient chart	1 item	n.a.	x	x	x	x	x
Death	Patient chart	1 item	n.a.	x	x	x	x	x

BII items specifically developed for this trial based on work by Hartmann *et al*.[50]
BII, body image integration; BMI, body mass index; CHF, chronic heart failure; FKB, Questionnaire Body Image (Fragebogen Körperbild); F-SozU, Questionnaire Social Support (Fragebogen Soziale Unterstützung); HADS, Hospital Anxiety and Depression Scale; INR, international normalised ratio; KCCQ, Kansas City Cardiomyopathy Questionnaire; NYHA, New York Heart Association classes; PHQ-9, Patient Health Questionnaire 9-Item Version; QoL VAD, Quality of Life Ventricular Assist Device; SELMA VAD, Self-management Ventricular Assist Device, instrument specifically developed for this trial; VAD, Ventricular Assist Device.

analyses. In the same way, we expect to identify protective factors for psychosocial outcome variables under investigation.

In phase 3, a primary combined endpoint capturing adverse event rates (number of thromboembolic events, wound infections, bleeding) according to the INTERMACS[7 42] definition will be calculated for the intervention and control group separately. Secondary endpoint analyses will calculate rehospitalisation rates during the 3-month intervention, plus 9-month follow-up per consecutive participant, occurring after hospital discharge following the implantation procedure. Analyses will be conducted based on an intention-to-treat principle and all participants, subsequently, will be analysed as randomised. Generalised linear mixed models will be used for between-group analyses, and will be calculated using the primary combined outcome at 3 and 12 months following VAD implantation. The model will include fixed effects for time, group, and their interactions. A random intercept will be used to account for repeated measures on individuals. The final regression model will be calculated exclusively on complete data sets. Bivariate subgroup analyses will be performed taking potentially relevant parameters (eg, gender, depression) into account. For the primary combined endpoint, Kaplan-Meier analyses will depict the event-free progress of participants in the intervention and control group separately. Secondary outcome measures (SM, QoL, anxiety, depression and body image) will be analysed descriptively, and by linear regression models for their association with SM. All tests performed will be two sided, and the level of significance set at ≤0.05.

Monitoring

In line with ethical considerations, monitoring will be an integral component of this study, specifically for the RCT in phase 3. Monitoring will be incorporated by an independent, neutral professional from the clinical research centre, not being a member of the study group. Each heart centre will have at least one monitoring visit. In case of any non-conformity with the rules laid out by the study protocol, a report will be given to the principal investigator, and a second visit scheduled. For monitoring purposes, a specific monitoring protocol will be conducted per centre.

Patient and public involvement

Members of a VAD patient support group and their caregivers have been involved in the preparations for this study. They will provide advice on the content and usability of the SELMA App. Findings of the study will be disseminated through a lay language summary posted to participants, as well as publications distributed by a national patient support group for VAD and transplant patients and their caregivers.

Ethical considerations and dissemination

Ethical considerations will be continuously taken into account throughout the research process. For phases 1 and 3, study protocols have received central ethical approval by the ethics committee of the Albert-Ludwigs University Freiburg (phase 1, 304/19, 1.1; phase 3, 41/20, 1.1), and joint approval by the participating heart centres' review boards, namely, the institutional review board (IRB) of the Ruhr University Bochum, site Bad Oeynhausen, the IRB of the Leipzig University, and the IRB of the Charité University medicine for Berlin.

This study will be performed in concordance with the concerns raised by the Declaration of Helsinki in relation to dignity and integrity of participants in a research project, and the European data protection law.[43] Participants will receive comprehensive information in oral and written formats regarding the study purposes, management of the data in pseudonymised format, and their rights to withdraw from the study as long as data have not been analysed without any prejudice to future therapeutic treatment. They will receive contact data for study related content, and for representatives for data protection under research conditions.[43]

The SELMA-App, provided to intervention group patients in phase 3, will be exclusively designed for SM information and optional as a platform for self-monitoring purposes for clinical data by the patient (eg, body weight). No transmission function is programmed as part of this application. Storage of all data will be handled by an IT specialist and by using protected server capacities in line with the European data protection law.[43]

Results from the outcome measures will not be presented in a way that may adversely affect confidentiality of participants. Reports and publications will exclusively report aggregated data and will be distributed in the scientific community at conference meetings, and by submission in peer-reviewed journals. Report languages will be German and English.

Trial status

Phases 1 and 2 for this study will advise the preparation of the intervention in phase 3, and the intervention is envisioned to start by the end of September 2020. We expect patient recruitment to be complete in May 2021. The expected completion of the overall project, including all follow-up assessments, is June 2022. Dissemination of the findings from the intervention will be initiated thereafter.

Author affiliations
[1]Institute of Nursing Science, University of Freiburg, Faculty of Medicine, Freiburg, Germany
[2]Medical Psychology, Heart and Diabetes Center North Rhine-Westphalia, Bad Oeynhausen, Nordrhein-Westfalen, Germany
[3]Psychosomatics, German Heart Center Berlin, Berlin, Germany
[4]University Heart Center Freiburg - Bad Krozingen, Bad Krozingen, Germany
[5]University Clinic for Heart Surgery, Heart Center Leipzig, Leipzig, Germany
[6]Institute of Medical Biometry and Statistics, University of Freiburg, Freiburg, Germany

Contributors Study design: CK, HS, MvC, KT-L. Writing of draft manuscript: CK. Revision of draft/finalising manuscript: HS, MS, VL, RW, WA, CS-K, SS-K, MvC and KT-L.

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ORCID iD

Christiane Kugler http://orcid.org/0000-0002-1422-2718

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