




Thoughts and Progress

Advancing the Science of Self-Management in Adults With Long-Term Left Ventricular Assist Devices

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Abstract: This study tested the applicability of the individual and family self-management theory (IFSMT) to self-management (SM) in patients with left ventricular assist devices (LVADs). From an existing data set, we extracted the following variables that correspond to IFSMT's conceptual dimensions: anxiety, depression, and cognition (context dimension); self-efficacy (SM process dimension); adherence and quality of life (QOL; outcome dimensions). Descriptive statistics and partial least squares path modeling procedures were used for data analyses. A total of 100 patients (mean age 52 ± 13.4 years) with continuous flow LVAD designs comprised the present study. Most patients were White (78%), married (69%), college-educated (72%), and on disability (53%). Their mean anxiety and depression scores were slightly above normal, while their cognitive function scores were slightly lower than normal. LVAD care self-efficacy, adherence, and QOL were within normal ranges. Factor loadings ranged from 0.50 to 1.0, and there were significant forward path relationships among the context, process, and outcome dimensions (β ranges from 0.02 to 0.60, all P values < 0.05). In conclusion, the IFSMT provides a good fit for SM in LVAD. Further research is needed to clarify how best to improve LVAD SM practice and treatment outcomes. **Key Words:** Left-ventricular assist devices—Circulatory support—Self-management—Self-management theory—Self-management of implantable artificial organs

Over the past two decades, the survival and quality of life (QOL) of patients suffering from advanced heart failure have been remarkably improved by implantable left ventricular assist devices (LVADs). This improvement in outcomes was attributed in part to the advancements in technology, surgical techniques, and postoperative management (1,2). However, despite the miniaturization and simplification of LVAD designs, the self-management (SM) of the LVAD care regimen post hospital discharge is still excessively complex for many patients (3). The LVAD care regimen consists of several tasks and procedures performed by patients on a daily basis to maintain the normal workings of the LVAD system, prevent complications, reduce heart failure symptom burden and re-hospitalization, and to ultimately optimize health and QOL (3–5).

During the first 6 months post discharge, most patients require assistance from family caregivers to manage the LVAD care regimen, as a result of their functional restriction, cognitive difficulty, and/or frailty (3,5). Enlistment of family caregivers in SM and available support from VAD nurses/coordinators (6) is a healthcare delivery model aligned with the contemporary conceptualization of SM in high acuity and chronically ill patients (7,8). Studies have shown that nurse-supported SM interventions, along with healthcare provider-supported SM programs in adults with multiple comorbidities, are associated with improved health and QOL, as well as reduced hospital readmission and mortality rates (8–10).

SM is a multidimensional construct, interchangeably referred to as “self-care” in the mechanical circulatory support literature (3). Self-care is conceptually related to SM, but there is a growing consensus in the health sciences literature clarifying the distinction between the two. Simply defined, self-care is used to describe health promotion and risk reduction behaviors (e.g., proper nutrition, exercise, and sleep) performed by individuals without assistance from family caregivers and/or guidance from licensed healthcare professionals, whereas SM is performed by individuals with assistance (11–13). Unfortunately, both SM and self-care remain understudied in LVAD, despite the customary practice of patients

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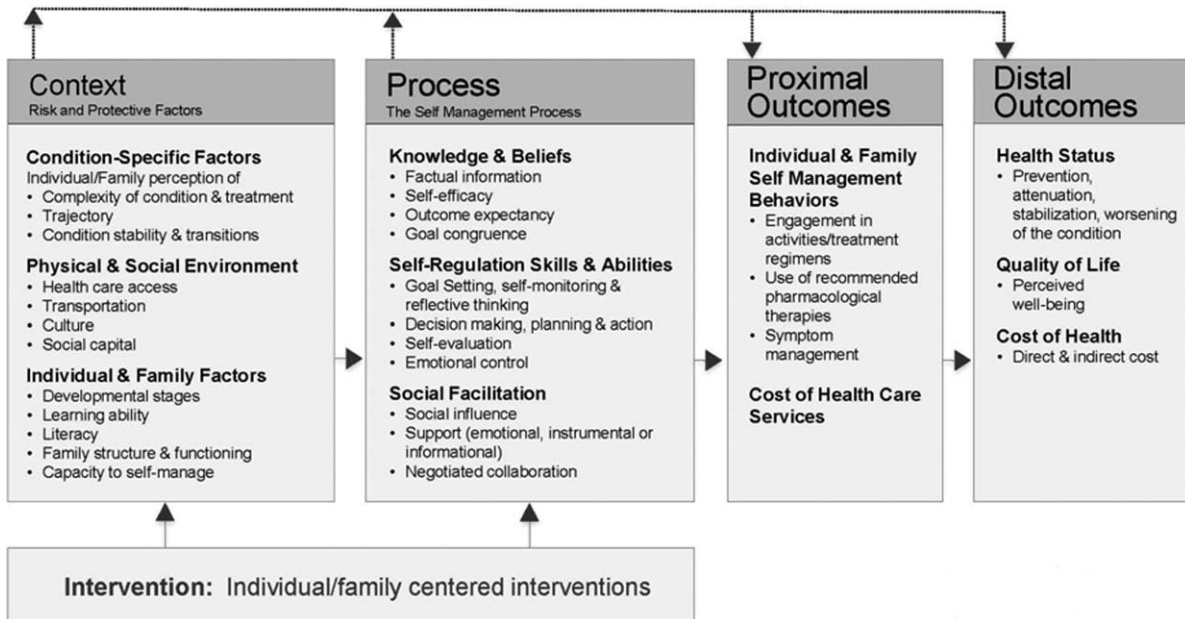


FIG. 1. Conceptual elements of the individual and family self-management theory (15). Adopted with authors' permission and the University of Wisconsin-Milwaukee College of Nursing.

and/or family caregivers being held responsible for LVAD care management post hospital discharge (5,14).

To address the dearth of scientific knowledge of LVAD SM, we identified a theory that can be used by scholars and clinicians alike as a guiding framework for LVAD SM research and practice. This article describes both a theory and a study aimed at explicating the conceptual elements or dimensions of the theory in adults with long-term LVADs. Future directions and applications of the theory in LVAD SM research and practice are discussed.

LVAD SM theoretical framework

The individual and family self-management theory (IFSMT; (8,15)) is a middle range descriptive theory that has been widely used in research involving adults with chronic and multiple conditions. The IFSMT describes SM as a complex phenomenon with three distinct but interconnected dimensions: context, process, and outcomes (Fig. 1; 15). The context dimension describes SM risks and protective factors at the individual or family level. For example, cognitive dysfunction, an absence of family caregivers, or lack of social support are all considered risk factors of an effective LVAD SM. On the contrary, sufficient LVAD care education and competent caregivers are protective factors of

LVAD SM. VAD nurses/coordinators (6) can be added as SM protective factors, as they provide continual SM support for LVAD care in the outpatient setting (6). The process dimension refers to elements of SM including self-regulation (e.g., health behavior change), self-efficacy, goal-setting, and others. Finally, the outcome dimension consists of proximal and distal outcomes. The proximal outcome is the actual engagement (e.g., treatment adherence) or direct result of the SM process, which in turn determines the distal outcomes (e.g., QOL; (8,15)).

The multidimensional constructs of the IFSMT are organized as a list of concepts clustered in each theoretical dimension, shown in Fig. 1 (15). The lines and arrows in this figure illustrate the underlying theoretical assumption that if context and/or SM process variable(s) is/are changed (e.g., interventions at individual and/or family level), then proximal and/or distal outcome dimension(s) is/are also expected to change. This assumption is supported by causal inference and association studies in adults with complex chronic diseases (8,10,15), but has yet to be tested in the LVAD population. Thus, we examined the relationships of variables operationalizing theoretical dimensions (context, process, and outcome) of the IFSMT in a sample of adults with long-term LVADs.

METHODS

Study design and sample

We analyzed existing data from a multistage instrumentation study (16) that received Institutional Review Board approval. A total of 189 LVAD patients from various regions of the United States participated in the study completed in 2015. The inclusion and exclusion criteria, as well as recruitment, consenting and screening process, and data collection procedures used in the parent study have been published elsewhere (16).

Data management and analyses

We inspected the data file of the parent study and extracted socio-demographics data, as well as seven variables that are conceptually related to the context, SM process, and outcome dimensions of IFSMT. Variables that comprised the context dimension included self-ratings of cognitive function (general and executive), anxiety, and depression. A single variable, self-efficacy, comprised the SM process dimension, whereas adherence and QOL comprised the proximal and distal outcomes dimension, respectively. The operational definition, measurement, validity, and reliability of measures used for the study variables are summarized in Table 1 (16–20).

Next, we examined the pattern of missing data from the extracted data set. Of the 189 participants, 100 LVAD patients had completed the socio-demographics and seven study variables data needed for analyses (i.e., theoretical testing). Subsequently, the final data set ($N = 100$) was analyzed with descriptive and inferential statistical procedures. Partial least squares path modeling (PLS-PM) (21) was used to infer the relationships among the IFSMT context, process, and outcome dimensions. Furthermore, we used the bootstrap resampling method to estimate the standard deviations of PLS-PM estimates and test the statistical significance of the estimated effect size of the relationship between theoretical dimensions, against a significance criterion of 0.05. As previously reported (16), we found no significant relationships among socio-demographics (e.g., age and gender), clinical (e.g., LVAD type and indications), and study variables (e.g., cognition and anxiety). Thus, socio-demographics and clinical variables were not included in the PLS-PM analyses. Data were analyzed using IBM SPSS 22.0 and R 3.4.1 Software (22,23).

RESULTS

Characteristics of the sample

The socio-demographic characteristics of the 100 patients in the present study are summarized in Table 2. Patient age ranged from 20 to 82 years (mean, 52 ± 13.4 years). Most patients were White (78%), male (69%), educated beyond high school (72%), and from the Midwestern (28%) region of the United States. Additionally, 69% of patients were married, on disability (53%), and living with a designated caregiver (88%). Before receiving their LVAD, patients lived with heart failure for an average of 8.1 ± 6.6 years. All patients had continuous flow LVAD designs, 86% with axial flow and 14% with centrifugal flow. The LVAD indications were bridge-to-transplant (70%), destination therapy (22%), and bridge-to-myocardial recovery (8%) with implant duration ranging from 2 to 74 months (mean 20.1 ± 15.6 months).

LVAD SM variables

Table 3 shows a descriptive statistics summary characterizing the seven study variables. As shown in this table, the LVAD patients' mean scores of general cognitive function and executive function were similar and slightly lower than normative samples (17). Their anxiety and depression respective mean scores were also similar, but were slightly higher than normative samples (18,19). LVAD care self-efficacy, LVAD care adherence, and QOL mean scores were within normal ranges (Table 3).

Theoretical fit of IFSMT in LVAD SM

The path diagram shown in Fig. 2 is a depiction of the quantified relationships among the LVAD SM variables fitted in each dimension of the IFSMT. Results of the PLS-PM showed the following forward path relationships among IFSMT dimensions: (i) context was associated with SM process; (ii) SM process was associated with proximal outcome; (iii) proximal outcome was associated with distal outcome; (iv) context was associated with proximal outcome; and (v) context was associated with distal outcome. All of these relationships were significant with effect sizes ranging from small ($\beta = 0.02$) to large ($\beta = 0.60$).

All relationships shown in the path diagram (Fig. 2) are supported by both P values less than 0.05 in PLS-PM and factor loadings of latent variables associated with IFSMT dimensions. The factor loadings of the latent variables associated with the context dimension were the following: 50%

TABLE 1. Study variables measurements and psychometric properties (16–20)

IFSMT Dimensions	Concept/Variable	Measures, Items and Response Scales	Uses and Scores	Reliability and Validity
Context (Risk and Protective Factors)	General cognitive function	PROMIS Applied Cognition Short Form – General (17)	Assesses patient’s perceptions of his/her general cognitive concerns such as memory and attention. Higher mean t-score signifies the concept (i.e., general cognitive function) being measured.	Cronbach $\alpha = 0.89$ PROMIS Standards of Psychometric Testing
		<ul style="list-style-type: none"> • 8 items • 5-point response scale: 1 = never to 5 = always 		
	Executive function	PROMIS Applied Cognition Short Form – Executive Function (17)	Assesses patient’s perceptions of his/her difficulties in applying cognitive abilities to daily tasks such as planning and learning. Higher mean t-score signifies the concept (i.e., executive function) being measured.	Chronbach $\alpha = 0.96$ PROMIS Standards of Psychometric Testing
		<ul style="list-style-type: none"> • 8 items • 5-point response scale: 1 = never to 5 = always 		
	Anxiety	PROMIS Short Form – Anxiety (18)	Assesses the universal symptoms of anxiety such as fear, nervousness, and dizziness. Higher mean t-score signifies more of the concept (i.e., anxiety) being measured.	Cronbach $\alpha = 0.94$ PROMIS Standards of Psychometric Testing
		<ul style="list-style-type: none"> • 8 items • 5-point response scale: 1 = never to 5 = always 		
	Depression	PROMIS Short Form – Depression (19)	Assesses the universal symptoms of depression such as feeling worthless and loss of interest. Higher mean t-score signifies more of the concept (i.e., anxiety) being measured.	Chronbach $\alpha = 0.96$ PROMIS Standards of Psychometric Testing
		<ul style="list-style-type: none"> • 8 items • 5-point response scale: 1 = never to 5 = always 		
Process (The SM Process)	Self-Efficacy	LVAD Patient Self-Efficacy Scale (16)	Assesses a patient’s knowledge and confidence about LVAD care management in home settings. Higher sum scores indicate greater knowledge and confidence in the ability to manage the LVAD home care regimen.	Chronbach $\alpha = 0.94$ Factor analytics
Outcome – Proximal	Adherence	LVAD Patient Home Management Adherence Scale (16)	Assesses the extent to which a patient follows the prescribed LVAD care regimen. Higher sum scores indicate greater adherence to LVAD home care regimen.	Chronbach $\alpha = .94$ Factor analytics
		<ul style="list-style-type: none"> • 20 items • 6-point response scale: 0 = not confident at all to 5 = extremely confident 		
Outcome – Distal	Quality of life	World Health Organization Quality of Life (QOL) –BREF 20	Generic QOL instrument, which assesses physical, psychological, social, and environmental domains of QOL. Sum scores of all domains of QOL indicate the person’s perception of his/her general or overall QOL. Higher sum scores indicate better QOL.	Chronbach $\alpha = 0.90$ Factor analytics and cross-cultural validity
		<ul style="list-style-type: none"> • 26 items • 5-point rating scale with various responses, e.g., 1 = very poor to 5 = very good or 1 = very dissatisfied to 5 = very satisfied 		

PROMIS, Patient-Reported Outcomes Measurement Information System.

TABLE 2. Socio-demographic characteristics of the sample

Characteristic	n (%)*	Characteristic	n (%)*
Gender:		Marital Status:	
Male	69 (69)	Married	69 (69)
Female	31 (31)	Single	31 (31)
Race:		Divorced	
White	78 (78)	Employment:	
Black	15 (15)	Full-time	15 (15)
Asian	2 (2)	Part-time	5 (5)
Mixed	3 (3)	Retired	21 (21)
Native American	1 (1)	Disability	53 (53)
Hispanic non-white	1 (1)	Unemployed	6 (6)
Region:		Designated Caregivers:	
Northeast	25 (25)	Yes	88 (88)
Midwest	28 (28)	No	12 (12)
Southeast	14 (14)	Education:	
Southwest	11 (11)	Less than high school	5 (5)
West	9 (9)	High school	23 (23)
Education:		Some college	43 (43)
Less than high school	5 (5)	College and higher	29 (29)
High school	23 (23)		
Some college	43 (43)		
College and higher	29 (29)		

Note: *Due to missing data not all percentages total 100.

(general cognition); 52.5% (executive function); 84.1% (anxiety); and 84.2% (depression). LVAD care self-efficacy, a latent variable associated with the SM process dimension, showed a factor loading of 99.9%. Respective factor loadings for LVAD care adherence and QOL, and latent variables associated with proximal and distal outcome dimensions, were 99.8% and 100%.

DISCUSSION

The results of the present study infer the theoretical fit of the IFSMT in LVAD SM, albeit with a small effect ($\beta = 0.02$), of the path relationship between proximal (adherence) and distal (QOL) outcome dimensions. We attributed the small effect to the relatively small sample size. However, previous research showed a moderately strong correlation between LVAD care adherence and QOL ($r = 0.50$), and LVAD care adherence was a predictor of QOL (3,24). Research in adults with chronic diseases also demonstrated the significant relationship between adherence (i.e., medication) and QOL (25). The moderate effects of the relationships we found between context and process ($\beta = 0.27$) and context and proximal outcome ($\beta = 0.15$) dimensions concur with much extant findings from other chronic disease populations (8–12,25). While there is evidence showing the relationships among cognition, anxiety, depression (context), self-efficacy (process), and adherence (proximal outcome) in chronic diseases and

LVADs (3,24–28), the relationships among anxiety, depression, and self-efficacy found in the present study are novel findings.

The large effects of the path relationships between context and distal outcome ($\beta = -0.54$) dimensions and SM process and proximal outcome ($\beta = 0.60$) dimensions are findings with notable significance. Perhaps more significant is the inverse relationship between context (e.g., anxiety) and distal outcome (QOL) dimensions. This finding can be explained by the fact that anxiety and depression are highly prevalent in the LVAD population (29,30). As shown in Table 3, our study patients’ anxiety and depression scores were slightly worse than the average score of U.S. adults living with the same condition (anxiety and depression; (18)). Remarkably, the coexistence of anxiety and depression, and associated negative influences on QOL, are commonly reported in heart failure studies and from data derived from the LVAD population (29–31).

The factor loadings for cognitive function (general and executive) further explain the inverse relationship between context and distal outcome dimensions. Cognitive dysfunction is common in heart failure, and its negative effect on the patient’s QOL is widely known. Thus, its presence is routinely assessed for pre LVAD implant (3). However, there is a paucity of data-based publications involving the cognitive function of adults who are supported by continuous flow LVADs. Two research teams reported the high prevalence of cognitive dysfunction (impairment) in patients implanted with continuous flow LVADs. They found that cognitive impairment is common up to 1-year post LVAD implant, and that such

TABLE 3. Summary statistics of study variables

Measures and Norms	Ranges	Mean and Standard Deviation
Cognitive Function – General	31–59.3	47.4 ± 8.0
Mean (t): 50 ± 10		
Cognitive Function – Executive	19.5–57.6	47.9 ± 8.7
Mean (t): 50 ± 10		
Anxiety	37.1–70	52.0 ± 9.0
Mean (t): 50 ± 10		
Depression	38.2–72	51 ± 9.3
Mean (t): 50 ± 10		
LVAD Patient Self-Efficacy	11–100	86.76 ± 14.5
Sum: 0 to 100		
LVAD Patient Home Management Adherence	7–45	39.0 ± 6.8
Sum: 0 to 45		
World Health Organization Quality of Life-BREF	26.5–98.5	69.4 ± 16.8
Sum: 0 to 100		

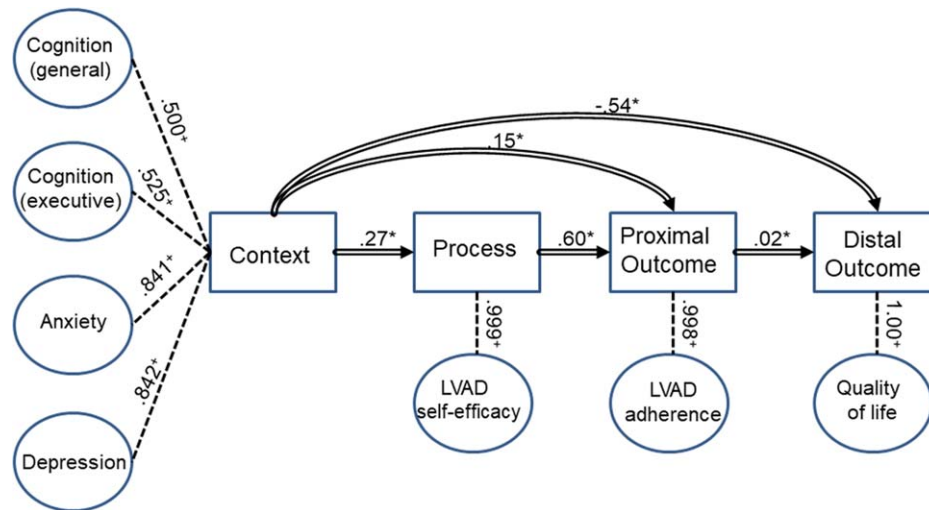


FIG. 2. Path diagram illustrating the associations among the context, process, and outcome dimensions of the Individual and Family Self-Management Theory (IFSMT). Circles with broken arrows are latent variables (concepts) for each dimension of the IFSMT; solid and broken arrows indicate forward associations between variables; *path coefficients significant at the 0.05 level (two-tailed); +factor loadings. [Color figure can be viewed at wileyonlinelibrary.com]

impairment is profound in older adults, aged 70 years and older (32,33). Comparatively, our sample is relatively younger (10% comprised of patients aged 70 to 82 years). Although we used a different measure than other studies (32,33), our measures of general cognition and executive function (Table 3) of our study patients were still slightly worse than the average score of adults in the United States with cognitive dysfunction (19).

Given the known adverse effects of anxiety, depression, and cognitive dysfunction on learning, as well as performing SM tasks accurately and regularly (3,34), further research is needed to fully examine these contextual variables. Research is also needed to examine the degree to which the family (e.g., caregiver) and healthcare providers' (e.g., VAD coordinators) support affect the individual SM outcomes. This triadic research design is crucial to identify the mechanisms or pathways by which the individual SM risk factors can be reduced and managed. According to the IFSMT (8), a supportive family or social structure is an essential "protective factor" of effective SM outcomes. Protective SM factors in LVAD can be achieved by the collaborative efforts of patients, family caregivers, and healthcare providers. Early assessment and intervention of the individual (e.g., anxiety, cognitive dysfunction) and family (e.g., caregiver competence and confidence) SM risk factors are examples of "protective" strategies that can be embedded in mechanical circulatory support programs to optimize LVAD SM outcomes. These

strategies can be implemented by VAD nurses/coordinators, who are responsible for providing long-term care and psycho-educational support for LVAD patients and caregivers (6).

It is worth noting that the relationship between process (self-efficacy) and proximal outcome (adherence) was the largest ($\beta = 0.60$) among the path coefficients we found in our study. This finding is expected due to the relatively high self-efficacy and adherence scores (Table 3), which are above the middle point of possible sum scores (16). We can infer from our data that a higher level of LVAD care adherence is directly influenced by higher LVAD care self-efficacy, parallel to the IFSMT's assumptions. According to the IFSMT, sufficient knowledge, beliefs, and confidence of disease management (self-efficacy) directly affect the results of SM behaviors, such as increased engagement (adherence) in following prescribed treatment regimens (8,15). Designing research to elucidate the causality between self-efficacy and adherence in adults with LVADs (bridge-to-heart transplant, destination therapy, or bridge-to-myocardial recovery) would be a logical next step to use the IFSMT framework to advance LVAD SM science (Table 4).

Limitations

The main limitations of our study included secondary data analyses, the concurrent observational research design, and the convenient sampling method used in the parent study. The use of self-administered questionnaires, which are a potential

TABLE 4. Recommendations for future research in LVAD SM guided by the individual and family self-management theory (IFSMT)

IFSMT Dimensions	Concept	Example of researchable topics and questions
Context (Risk and Protective Factors)	Individual factors	<ul style="list-style-type: none"> • Effect of functional capacity including frailty, co-morbidities, complications, and re-hospitalizations on SM • Mechanism of the influence or effect of sleep disruptions and excessive daytime sleepiness on SM • Effect of health literacy on SM process and outcomes • How do patient education, competency (LVAD care knowledge and skills), and competency reassessments affect SM? (Note: This topic should also address the need for using objective measures of cognitive function cited in the discussion section in the main text)
	Family factors	<ul style="list-style-type: none"> • What is the impact of family caregiver status (full-time, part-time, live-in, or nearby) on SM? • What are the caregiver characteristics (e.g., competency, health literacy, caregiving preparedness, and confidence) that are predictive of effective SM?
Process (The SM Process)	Knowledge and beliefs	<ul style="list-style-type: none"> • Intervention to optimize LVAD care self-efficacy • Explore interventions designed for individual goal setting and outcome expectations (e.g., goals for managing LVAD flows specific to the device and individual)
	Self-regulation skills and abilities	<ul style="list-style-type: none"> • Develop and test technology (e.g., mobile phone app) that are easy and efficient for self-monitoring of LVAD parameters (e.g., flow, power) and heart failure symptoms, etc., and features that provide feedback and coach how to manage abnormal parameters and symptoms • Intervention to address cognitive difficulties, anxiety, and/or depression and their impact on SM outcomes (can be classified as individual/context SM risk factor).
	Social facilitation	<ul style="list-style-type: none"> • Effect of the role of VAD nurses or coordinators (e.g., frequent follow up and psychoeducational support) on SM outcomes • What VAD care team (e.g., skill mix) characteristics are predictive of effective SM outcomes?
Outcome – Proximal	Individual and family self-management behaviors outcomes	<ul style="list-style-type: none"> • Intervention to improve adherence on LVAD-specific care, medications, diet, and physical activity • Apply health promotion, risk reduction, and symptom management interventions tested in heart failure patients with cardiac devices (e.g., pacemakers, defibrillators) or post cardiac surgery
	Healthcare utilizations	<ul style="list-style-type: none"> • Hospital re-admissions • Unscheduled emergency room and clinic visits
Outcome – Distal	Health status	<ul style="list-style-type: none"> • LVAD-specific and related complications, co-morbidity, functional status, frailty and mortality
	Quality of life Cost	<ul style="list-style-type: none"> • Use of generic and LVAD-specific QOL measures • Cost of technology used for LVAD SM and healthcare providers' cost supporting LVAD SM

source for response bias (16), further limits the interpretation of the study findings. This is a particular issue for self-ratings of cognition as depression and anxiety have been shown to influence self-ratings of cognitive impairment (35). Furthermore, self-ratings of cognition may not correlate with objective ratings of cognition (36,37). Moreover, 88% of the patients lived with their family caregivers (Table 2). Thus, the possibility of caregivers helping patients complete the questionnaires cannot be ruled out. Finally, the theoretical fit of the data was limited to select conceptual dimensions. Therefore, these limitations prevented us from making definitive conclusions and comprehensive empirical support for the IFSMT in LVAD SM.

Future directions

Despite the limitations, we hope that our efforts to initiate empirical support on the IFSMT will stimulate scholarly dialogue in the mechanical

circulatory support community, and heighten awareness regarding the current state of the science underpinning the customary practice of LVAD SM. To encourage other investigators and clinicians to move the LVAD SM science forward, Table 4 offers several examples of topics that are amenable for research and quality/performance improvement studies aimed at advancing LVAD SM science and practice. These topics are clustered around the IFSMT dimensions, which have been raised in the literature as pertinent variables or factors that may impact LVAD SM outcomes (3–6,14,16,24). Future studies should address our study’s limitations, as well as explore and expand on our recommendations in Table 4. Since LVAD SM is actualized by patients in collaboration with family caregivers and VAD nurses/coordinators (3–6,14,16), triadic longitudinal research designs will be imperative to explicate the caregiver and coordinators’ contributions in LVAD SM

outcomes. Equally important are large studies reflective of the LVAD population characteristics (e.g., race and education) in the United States covering concepts beyond the present study to establish a solid empirical base and generalizability of the application of IFSMT in LVAD SM.

CONCLUSION

Self-rated anxiety, depression, and cognitive dysfunction are individual contextual influences of the left ventricular assist device self-management process (self-efficacy) and outcomes (adherence and QOL). Our data provide initial evidence corroborating the multidimensionality of SM defined by IFSMT. The IFSMT is a comprehensive framework that can be used for conceptualizing research and clinical scholarly work aimed at advancing the science underpinning LVAD SM practice. Large mechanistic studies are still needed to move the current LVAD SM science from its formative stage to a well-circumscribed knowledge development. The latter is foundational to create and test interventions that will form evidence-based SM practice guidelines designed for preventing complications, reducing healthcare utilizations, and optimizing health and QOL outcomes among adults living with long-term LVADs.

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