A multi-modal intervention in management of left ventricular assist device outpatients: dietary counselling, controlled exercise and psychosocial support

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Received 6 December 2011; received in revised form 24 February 2012; accepted 13 March 2012

Abstract

OBJECTIVE: Newer generation left ventricular assist devices (LVADs) are established for long-term support. The aim of this multi-modal intervention was to improve the body weight, exercise tolerance and psychosocial status in outpatients on long-term LVAD support.

METHODS: Seventy patients participated in this non-randomized intervention study [intervention group (IGr) n = 34; control group (CGr) n = 36] over 18 months (T1–T4); the baseline sample characteristics showed no differences between groups. Dietary counselling and weight management intervention was performed by a dietician based on a specific algorithm. Physical reconditioning followed a home ergometry protocol and was supplemented by psychosocial counselling. The outcomes were measured based on the body mass index (BMI), cardiopulmonary exercise testing and self-report [hospital anxiety and depression scale (HADS), SF-36].

RESULTS: The intervention showed a strong positive effect on nutrition and weight management [95% confidence interval (CI): -0.71 to 0.69; effect size (ES): 0.907; P = 0.02], resulting in the normal BMI (kg/m²) values in the IGr (T1: 24.0 ± 0.6; T4: 24.5 ± 1.1; P = 0.35) compared with a significant BMI increase in the CGr (T1: 23.8 ± 0.6; T4: 29.7 ± 0.8; P = 0.05). Significant differences appeared regarding exercise tolerance (VO₂max/% predicted) in favour of IGr patients (IGr: 69 ± 2.9; CGr 62 ± 3.7; P = 0.04). This increase was reflected by patients’ self-reporting based on the SF-36 physical component score (IGr: P = 0.04; CGr: P = 0.54). SF-36 psychosocial component scores showed no changes for both groups. However, CGr showed a tendency for increased anxiety scores relative to their counterparts (IGr: 4.95 ± 0.4; CGr: 6.6 ± 0.9; P = 0.03).

CONCLUSIONS: IGr patients showed a strong benefit from a multi-modal intervention, including dietary counselling, controlled exercise and psychosocial support. Dietary counselling holds potential to prevent obesity in this patient population.

Keywords: Dietary counselling • Exercise • Quality-of-life • Left ventricular assist devices

INTRODUCTION

Newer generation left ventricular assist devices (LVADs) have been established for long-term outpatient support and continue to demonstrate an expansion of therapeutic indications for support and support time in selected patients with end-stage heart failure [1]. Besides survival, there is growing evidence indicating that LVAD therapy is beneficial for the individual in terms of health-related quality-of-life (HRQoL) outcomes [2–6]. Long-term improvements in HRQoL, however, can be diminished by a number of factors, including limitations in physical exercise tolerance [5–8] and prominent psychological symptoms [2, 7, 8]. In addition, malnutrition—in the form of both protein calorie-deficiency and obesity—warrants special attention, as it is associated with adverse events [9, 10].

Life on long-term LVAD support can be challenging in many ways and requires coping with the uncertainty of the illness trajectory, including support times, outcomes of support and the availability of donor organs, when device support is no longer an option. Not surprisingly, there is some evidence indicating a trend towards poorer physical and psychological functioning in patients with LVAD compared with patients who had undergone transplantation [2, 3, 6, 8]. However, the knowledge of management of LVAD outpatients is limited in this regard. A considerable knowledge base using preventative management programmes in other chronic populations including, but not limited to, heart failure and transplant recipients may provide some guidance [11, 12] to improve the patients’ self-management strategies addressing the educational/cognitive, counselling/behavioural and psychological/affective dimensions to initiate behavioural changes [13, 14].
Outcome parameters for this study did not differ taking attrition rates into account.

However, to our knowledge, no studies exist relating to the support of patients while being on LVAD support. As this was a behaviour-modifying study within the framework of the self-management theory [13], the following hypothesis was used as the guidance for this study: patients in the IGr will show better self-management accompanied by a lower likelihood of developing obesity, better exercise tolerance, higher reported perceived HRQoL and less anxiety and depression compared with the control group at the end of the study, respectively. Consequently, we decided to investigate the effects of a multi-modal intervention programme consisting of (1) nutrition management preventing cachexia or obesity, (2) controlled exercise training and (3) psychosocial counselling on respective outcome parameters in outpatients on long-term LVAD support.

METHODS

Design

The present work was a prospective, multi-modal intervention study and used as a preventative, motivational approach for patient management. Patients were consecutively referred to the intervention (n = 34) or control (n = 36) group and were tested at 6 weeks (baseline), and at 6, 12 and 18 months while being on LVAD support. The study protocol was approved by the Committee on Human Research at our institution. We report on this trial in concordance with the TREND Statement [15].

Sample and setting

All study participants provided written informed consent before inclusion in the study and subsequent allocation to the treatment group. The refusal rate was 8.8%, and one patient in the IGr withdrew consent after the initial baseline assessment. Subjects were eligible for this study if being followed-up at our centre while being on LVAD support, and were aged a minimum of 18 years. Patients were excluded if they had insufficient language skills to read and answer the battery of questionnaires, showed symptoms of tachycardia with anti-arrhythmic medical treatment, or had orthopaedic limitations that precluded exercise testing or training.

Patients were recruited at our LVAD outpatient clinic. As part of our routine, all LVAD patients are continuously followed-up for their entire support time. The study inclusion and baseline assessments (T1) were performed at the first or second LVAD outpatient clinical visit 6 weeks after implantation. After baseline testing, patients were reassessed at 6, 12 and 18 months (T2–T4) during their LVAD support time. Follow-up assessments were performed during regular clinical outpatient visits to avoid additional travel and expenses for study participants. Over the course of the study, the attrition rates were 29.4% for the intervention group (IGr) and 28.6% for the control group (CGr) patients, respectively. Reasons for an incomplete 18-month follow-up were heart transplantation (IGr n = 5; CGr n = 7), LVAD explantation due to recovery (IGr n = 1), the withdrawal of the study consent (IGr n = 1) or the death of the patient (IGr n = 3; CGr n = 3). Time-dependent outcome parameters for this study did not differ taking attrition rates into account.

Intervention

The intervention consisted of three modules. The behaviour-modifying strategies consisted of patient/family education, realistic goal setting, feedback and motivation for all three modules.

Nutrition management. Module 1 involved nutrition management based on a protocol for four basic 1:1 educational sessions on general nutritional guidelines and healthy food habits provided by a dietician. Session one offered information on ‘what is ‘healthy’ nutrition’; session two focused on ‘what is important to know about a healthy lifestyle’; in session three ‘energy—how does it work’ was the subject of discussion; the last formal session was on ‘nutrition and psyche—healthy eating is caring for our soul’. Sessions were offered during consecutive outpatient clinical visits, supplemented by the provision of written information materials, and were followed by an individualized nutrition intervention based on the patients’ body mass index (BMI) and the families’ lifestyle and nutritional habits. As part of the intervention, patients were followed-up by phone using an algorithm specifically developed for this study. Accordingly, for the first four telephone contacts, a call was scheduled every 14 days after study inclusion, for single patients, for those having a BMI outside normal ranges (<19 or >25) and/or for those cases with an increased weight gain (≥4 pound). Regular phone contacts were scheduled every 4 weeks after the first initial contact for those patients with a BMI within normal ranges or when the patient had gained <4 pounds within the last month. Patients were offered phone and email contacts in the time between sessions and scheduled phone calls.

Physical reconditioning programme. Module 2 focused on a home-based physical reconditioning based on an adapted protocol developed by Tegtbur et al. [12]. Briefly, patients were equipped with a bicycle ergometer and a tailored, home-based, smartcard-guided ergometry training programme, supplemented by regular phone calls for psychosocial support, training updates, to keep patients motivated for exercise training. Patients were recommended to exercise every other day. Reference values for the training programme were calculated based on cardiopulmonary exercise testing at the baseline and were readjusted based on repeated exercise testing. Both the individualized training programme and training data were stored on the smartcard. These data were transferred to the central database.

Psychosocial support and counselling. Module 3 was offered to both patients and their partners, with an emphasis on psychosocial support using stabilizing, and resource-activating strategies. In addition, problem-solving, coping with fear, anger and depression were part of discussions. Support was provided face-to-face and by phone and in a frequency as requested by the patient or his/her relative. The initial contacts were made either during the implant, in-hospital stay or in the outpatient clinic.

Controls. CGr patients received the standardized recommendations to stay on a healthy diet, to target the normal BMI ranges, to improve the physical fitness by exercising on a routine basis and to seek the psychosocial support, if necessary. Otherwise, no standardized interventions were given.

Intervention
Assessment instruments and outcome measures

Body mass index. The BMI (kg/m²) represents an indirect measure of the body weight, as this index cannot distinguish between heaviness due to adiposity, muscularity, bone density or oedema [16]. For the purposes of this study, the classification of weight in adults according to the BMI follows the recommendations given by the World Health Organization (WHO BMI classification). The global database on body mass index is available at: http://www.who.int/bmi/index.jsp (accessed 19 June 2011). Accordingly, the BMI values between 18.5 and 25.0 kg/m² were defined as the target range for this intervention. The BMI values were retrieved from the patient charts.

Cardiopulmonary exercise testing. The maximum exercise capacity was assessed by CPET diagnostics on a bicycle ergometer including an oxygen delta module (Jaeger, Wuerzburg, Germany) to allow for respiratory gas analysis on a breath-by-breath basis. For the purpose of this study, we present data on the maximum workload in watts (W) and on the maximum oxygen consumption (VO₂max), including the age- and gender-adjusted reference values [18]. The pump speed was adjusted individually in each patient, to allow maximum support while avoiding suction events. Adjustments were made based on the repeated echocardiography and the LVAD data download.

Medical outcomes survey SF-36. The SF-36 1.0 [24] in its German-validated version [18] was selected as being a reliable measure for the LVAD population [19]. The SF-36 consists of 36 items on eight subscales exploring subjectively perceived HRQoL by the individual. The physical component scale (PCS) capture scales on physical functioning, role physical, bodily pain and general health. The mental component scale (MCS) refers to patients’ perceptions on vitality, social functioning, role of emotional and mental health. Scores range between 0 and 100, with higher scores indicating the better HRQoL. Internal consistency, as measured by Cronbach’s α, was 0.801 for the PCS and 0.800 for the MCS in this study.

Hospital anxiety and depression scale. The HADS represents a widely used, validated screening tool for the symptoms of anxiety and depression, with an exclusion of the confounding effects of the somatic symptoms of a physical disorder [20]. The instrument consists of two scales of seven items capturing the symptoms of anxiety and seven items on depression. Scores ranging between 0 and 7 can be interpreted as normal, 8-10 mild, 11-14 moderate and 15–21 severe symptoms of anxiety or depression. Internal consistency, by Cronbach’s α, was 0.828 for the anxiety and 0.873 for the depression scale in this study.

Statistical analysis

Descriptive statistics were outlined as median and standard error for the time-dependent continuous variables, and frequencies were generated for other variables. Inferential statistics included cross-tabulations, χ² or non-parametric tests to investigate the baseline and follow-up characteristics. Analyses were performed using intention-to-treat principles. The repeated measures analysis of variance with one within-subjects factor being ‘time’ (6 weeks, and 6, 12 and 18 months after implant) and one between-subjects factor being ‘group’ (IGr, CGr) was used to determine the differences between the groups as a function of time. This approach allows assessing the main effects of the time and of the group as well as the interaction of the group by time. The group by the time interaction indicates whether the change with the time differs between the groups. Addressing the risk of Type I error inflation, individual P-values were Bonferroni–Holm adjusted for multiple testing. Effect size calculations based on the Cohen’s Kappa were performed to estimate whether the BMI groups differed by the chance as impacted by the sample size [21]. The level of significance was set at P < 0.05. Data analyses were performed using SPSS statistical software for windows (Version 18.0, SPSS Inc., Chicago, IL, USA).

RESULTS

Study subjects

The sample consisted of 70 patients: 34 were recruited for the intervention and 36 for the control group. The demographic characteristics and baseline data of variables of interest are outlined in Table 1. Patients were on long-term rotary blood pump support as a bridge to transplantation with 54.8% being bridged with a Heartmate II (Thoratec, Pleassenton, CA, USA) and 45.2% being on Heartware (HeartWare, Inc., Miramar, FL, USA) support. The baseline sample characteristics did not differ between the groups for relevant variables under investigation. Subgroup analysis controlling for whether device type influenced the outcome variables of interest showed no significant differences for the BMI, exercise tolerance and for HRQoL outcomes.

Nutrition management effect on body mass index changes over time

Nutritional status was assessed using the BMI changes over time. As outlined in Fig. 1, both groups showed comparable normal BMI ranges at the baseline. While being on the device, IGr patients remained within normal BMI ranges (P = 0.35), whereas CGr patients significantly gained weight during the same time period (P = 0.05). Assessing inter-group effects, the IGr and CGr patients’ BMI differed significantly at 18 months after implant (P = 0.05), favouring IGr patients.

Intensified nutrition management was provided for IGr patients with contact times ranging between 8 and 60 min per patient/session. Effect size calculations were performed, as appropriate for small sample sizes, and revealed a significant effect (EF = 0.907; P = 0.02) at T4 (Table 2).

Physical reconditioning and effect on exercise tolerance changes over time

The development of physical exercise tolerance, as determined by CPET diagnostics, revealed a significant increase in the workload for both groups during the course of the study (Fig. 2A). IGr patients showed a significant increase in their age- and gender-adjusted workload as predicted (P = 0.05); CGr patients’ workload also increased during this observation period (P = 0.21), but did not reach the statistical significance after Bonferroni–Holm adjustment. Group comparisons revealed a comparable
Table 1: Baseline characteristics of the study sample

<table>
<thead>
<tr>
<th>Variable</th>
<th>Intervention (n = 34)</th>
<th>Control (n = 36)</th>
<th>Coefficient</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographic variables</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years) (median ± SE)</td>
<td>52 ± 2</td>
<td>51 ± 2</td>
<td>z = -1.39</td>
<td>0.16</td>
</tr>
<tr>
<td>Gender (%) male</td>
<td>85.4</td>
<td>87.5</td>
<td>χ² = 2.33</td>
<td>0.13</td>
</tr>
<tr>
<td>Family (% married)</td>
<td>48.8</td>
<td>58.2</td>
<td>χ² = 5.37</td>
<td>0.25</td>
</tr>
<tr>
<td>Education (% higher)</td>
<td>37.9</td>
<td>44.5</td>
<td></td>
<td>0.09</td>
</tr>
<tr>
<td>Clinical variables</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Diagnosis leading to implant surgery</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DCM (%)</td>
<td>56.1</td>
<td>47.3</td>
<td>χ² = 1.98</td>
<td>0.58</td>
</tr>
<tr>
<td>CAD (%)</td>
<td>43.9</td>
<td>49.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myocarditis (%)</td>
<td>-</td>
<td>3.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital LOS post implant (days)</td>
<td>42 ± 16</td>
<td>46 ± 21</td>
<td>z = -0.81</td>
<td>0.42</td>
</tr>
<tr>
<td>Body weight and nutrition</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Body weight (kg/median ± SE)</td>
<td>74 ± 2.2</td>
<td>74 ± 2.4</td>
<td>z = -0.95</td>
<td>0.37</td>
</tr>
<tr>
<td>BMI (kg/m²/median ± SE)</td>
<td>24 ± 0.6</td>
<td>24 ± 0.6</td>
<td>z = -0.96</td>
<td>0.34</td>
</tr>
<tr>
<td>Physical exercise tolerance</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Workload (W)</td>
<td>80.0 ± 5.1</td>
<td>70.0 ± 3.7</td>
<td>z = -1.10</td>
<td>0.27</td>
</tr>
<tr>
<td>VO₂max (ml/min/kg)</td>
<td>18.5 ± 0.8</td>
<td>16.3 ± 0.6</td>
<td>z = -1.57</td>
<td>0.17</td>
</tr>
<tr>
<td>Health-related quality-of-life</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SF-36 PCS*</td>
<td>34.7 ± 1.5</td>
<td>30.4 ± 1.4</td>
<td>z = -1.38</td>
<td>0.66</td>
</tr>
<tr>
<td>SF-36 MCS*</td>
<td>50.7 ± 1.9</td>
<td>51.3 ± 2.3</td>
<td>z = 0.67</td>
<td>0.51</td>
</tr>
<tr>
<td>Anxiety and depression scores (HADS)</td>
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<td></td>
<td></td>
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<tr>
<td>HADS anxietyb</td>
<td>2.0 ± 0.6</td>
<td>5.0 ± 0.6</td>
<td>z = 1.76</td>
<td>0.08</td>
</tr>
<tr>
<td>HADS depressionb</td>
<td>4.5 ± 0.6</td>
<td>4.0 ± 0.5</td>
<td>z = 0.18</td>
<td>0.85</td>
</tr>
</tbody>
</table>

BMI: body mass index; CAD: coronary artery disease; CGr: control group; DCM: dilated cardiomyopathy; HADS: hospital anxiety and depression scale; IGr: intervention group; LOS: length of stay; LVAD: left ventricular assist device; SE: standard error; VO₂max: maximum oxygen consumption.

*SF-36 PCS: physical component score; MCS: mental component score, score range 0–100, higher scores indicate the better HRQoL perceptions.

bHADS score range (0–21): 0–7 normal, 8–10 mild, 11–14 moderate and 15–21 severe symptoms of anxiety or depression.

Figure 1: The BMI changes over time in the intervention and control group patients.

Table 2: Nutrition management effects on the BMI in the intervention and control group patients

<table>
<thead>
<tr>
<th>BMI</th>
<th>Intervention*</th>
<th>Control*</th>
<th>95% CI</th>
<th>*P-value</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI 6 weeks</td>
<td>24.0 (22.4–28.5)</td>
<td>23.8 (21.8–27.5)</td>
<td>-2.41 to 1.35</td>
<td>0.579</td>
<td>0.100</td>
</tr>
<tr>
<td>BMI 6 m</td>
<td>24.8 (22.8–28.1)</td>
<td>26.2 (22.4–28.4)</td>
<td>-1.65 to -0.71</td>
<td>0.078</td>
<td>0.145</td>
</tr>
<tr>
<td>BMI 12 m</td>
<td>25.3 (22.7–28.8)</td>
<td>27.4 (23.9–9.4)</td>
<td>-0.73 to -0.09</td>
<td>0.036</td>
<td>0.328</td>
</tr>
<tr>
<td>BMI 18 m</td>
<td>24.5 (22.5–28.7)</td>
<td>29.7 (24.4–30.9)</td>
<td>-0.71 to 0.69</td>
<td>0.020</td>
<td>0.907</td>
</tr>
</tbody>
</table>

BMI: body mass index (kg/m²); CI: confidence interval.

*Median (percentile 25–75).

*Bonferroni–Holm adjusted.
workload between groups at the baseline ($P = 0.27$), with IGr patients reaching higher workload levels compared with their counterparts ($P = 0.05$) at the end of the study.

Figure 2B depicts changes for age- and gender-adjusted VO$_2$max over time, which increased in both groups. However, this increase was significant only for IGr patients ($P = 0.01$). The group comparisons showed a significant group difference in favour of IGr patients after the course of the study ($P = 0.05$).

Psychosocial support and effect on psychosocial outcome changes over time

The evaluation of HRQoL using the SF-36 showed a significant increase in the physical score for IGr patients ($P = 0.04$), and a stable psychosocial score ($P = 0.79$) over the course of the study (Fig. 3) when assessing for intra-subject effects. CGr patients showed no HRQoL changes over time. However, inter subject effects revealed comparable baseline ratings in the physical ($P = 0.07$) and psychosocial ($P = 0.51$) SF-36 score. No significant differences in HRQoL perceptions (PCS $P = 0.54$; MCS $P = 0.37$) after the study were detected.

Assessing anxiety and depression levels changes over time (Fig. 4) revealed that IGr patients maintained symptoms within normal ranges (anxiety $P = 0.57$; depression $P = 0.32$) over the course of the study, whereas CGr patients reported anxiety levels approaching borderline for the abnormal scores ($P = 0.05$). The intergroup effect analysis also revealed significant differences favouring the IGr group ($P = 0.03$) at the end of the study.

DISCUSSION

This study was the first multi-modal intervention targeting LVAD outpatients’ self-management while being on long-term support. This intervention was effective in preventing significant weight gain as assessed by the BMI changes, and showed a benefit on physical exercise tolerance and on self-perceptions of psychosocial functioning as measured by HRQoL and anxiety and depression scores, relative to the usual care. LVAD patients and their relatives were enabled to better self-manage their nutritional habits and exercise training through a combined intervention consisting of educational, behavioural and motivational aspects. Adapted protocols for a controlled home-based exercise programme showed potential to improve the limitations in physical functioning by an increased exercise tolerance.

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**Figure 2:** Physical exercise tolerance changes over time in the intervention and control group patients.

**Figure 3:** Health-related quality-of-life changes over time in the intervention and control group patients.
However, these improvements remained below predicted norms. The psychosocial support appeared to be effective in avoiding the psychological symptoms of distress.

In our study, a dietician with expertise in LVAD therapy provided an intense nutrition management programme to patients assigned to the intervention. We followed the assumption that the BMI levels should remain within normal ranges or reach normal ranges in an attempt to prevent cachexia- or obesity-related perioperative complications [5, 9, 16, 23, 24]. First, this preventive approach proved to successfully change behaviours in the LVAD population. Secondly, this positive intervention effect became visible at the end of the study. This was consistent with our clinical observation and may be due to the fact that patients and their relatives needed time to develop a trusting relationship with the dietician to be able to modify their nutritional behaviours. Adjusted intergroup comparisons revealed a significant BMI increase in the control group. Most recent evidence on the effect of the BMI on outcomes, however, leads to controversial discussions and may indicate a paradigm shift with respect to target levels for nutrition and weight management within this population in the near future. Raymond et al. [10] investigated the association between obesity and driveline exit site infections. They found that LVAD patients who developed driveline exit site infections had a significantly higher BMI and continued to gain weight over the course of LVAD therapy, when compared with those without infection. In contrast, Martin et al. [23] retrospectively analysed a single-centre cohort of 145 LVAD patients and found, based on logistic regression analyses, that the BMI had no effect on the incidence of infectious outcomes. However, they may have missed an effect within this cohort by distributing the sample into six small sub-cohorts of BMI ranges, including underweight, normal weight, overweight, obese, severely obese and morbidly obese individuals on LVAD support. Further research warrants guidance on the BMI target levels for this population.

Patients in our study showed increases in their physical exercise tolerance due to a re-engagement with physical activities. However, levels achieved remained below the predicted norms in both groups. It might be concluded, albeit with caution, that LVAD outpatients are in need of more intensified physical rehabilitation programmes. Two other recent studies may further support this statement: comparisons of the maximum oxygen consumption (VO2max; % of predicted norms) in a recent Dutch [4] outpatient cohort showed 50 ± 12% and a German [6] outpatient cohort reached 56 ± 13% while being on LVAD support.

Although there is limited evidence on the implications of LVAD therapy on psychological symptoms including anxiety and depression, the preliminary data provide warning signs that the psychological distress levels may be under-recognized to some extent [2, 3, 6, 8]. Psychological distress may be due in part to the uncertainty of the lifetime of the assist device, the necessity of complying to a complex technical regimen—responding under pressure to warning signals by changing batteries or transition from battery to power base unit mode, coping with close medical follow-up, in addition to others. Recent data addressing the impact of listing for heart transplant on psychosocial adjustment before LVAD, implantation showed comparable outcomes on survival and disorders for the observation period after LVAD implantation [24]. Nevertheless, the utilization of psychotherapy before and/or after LVAD implantation seems to be important for the successful coping of LVAD patients and their families [24]. Particularly, in view of the increasing numbers of LVAD implantations along with the expansion of indications for LVAD implantation, further studies with an emphasis on psychological assessment and intervention strategies to better assist patients within this period are needed.

The main limitation of this study was the relatively small sample size. However, several approaches have been used to diminish this limitation. This included calculations of intrasubject...
effects by the time as an additional indicator for the efficacy of the intervention employed. In addition, effect size estimations were used for the major target level and the prevention of cachexia or obesity. Our findings suggest that patients benefit from the implementation of multi-dimensional interventions. As experimental designs can be expensive, and preventing those serving as controls from the benefit of the intervention, further research employing a pre- and post-test design may be warranted. Secondly, the healthcare provider–patient relationship, not controlled in this study, may limit the generalizability of our findings. Prior to initiating the recruitment period for this study, a dietician with expertise in working with LVAD patients, was added to the team running the LVAD outpatient clinic. However, the impact of subjective indicators, for example sympathy, was not controlled. Furthermore, if a patient perceived the professional relationship as not satisfying, no alternative professionals were there to step in, and this may have impacted our findings to some extent. On the other hand, the fact that all intervention- al elements were offered by one professional per module, we ensured that interventions were always provided in the same way. Finally, the study population was treated with two different pulsatile device types, which may have influenced our findings. However, taking the individuals’ perspective into account, Meyer et al. [25] found differences in satisfaction with external equipment, but no differences for these two device types with respect to patients’ HRQoL.

In conclusion, a multi-modal intervention consisting of nutrition management, controlled exercise training and psychosocial support showed a positive effect on patients’ self-management while on outpatient, long-term LVAD support. Our study demonstrated that preventive nutrition management, providing a combination of standardized educational and individualized sessions, was effective in preventing obesity. A home-based ergometry training programme resulted in improved exercise tolerance. Psychosocial counselling support prevented psychological distress. Nutrition and exercise management, as well as psychological assessment and intervention should become integral parts of the follow-up management for this population. Cost-effectiveness studies are needed to investigate the economic implications of such intervention programmes.

**Funding**

This study was supported in part by grants from the German Foundation of Heart Research (F/05/08) and the German Federal Ministry of Education and Research (01EO0802).

**Conflict of interest** The senior author, Martin Stueber, is an expert consultant for HeartWare and a member of the European Advisory Board Thoratec, Inc.

**REFERENCES**


