

The Efficacy of an Empowerment Program for End-Stage Renal Disease Patients Treated with Hemodialysis

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Abstract

Background: End-stage renal disease (ESRD) is a serious illness with substantial health consequences. Patients undergoing dialysis are frequently affected by a multitude of clinical problems, with a tremendous symptom burden and substantially impaired quality of life (QOL). Developing empowerment-based interventions that can help patients to rebalance their lives warrant further research.

Aim: To investigate the efficacy of an empowerment program in promoting compliance among patients with ESRD undergoing hemodialysis and thus reducing symptom burden and improving QOL.

Design: An experimental study design was used to assess the effectiveness of the empowerment program among study participants.

Methods: An intervention study was conducted at Dialysis Unit of King Abdulaziz Medical City, Jeddah. Sixty ESRD patients participated in the study. Thirty patients were randomly assigned to empowerment program group and thirty others to a control group. Data were collected during 2013-2014 using dialysis symptom index, dietary and fluid compliance indices, kidney disease health related quality of life and Beck depression inventory.

Results: Majority of compliance parameters were not significantly different between groups neither before nor at 6 weeks follow up; except for Urea Reduction Ratio (URR), Dialysis Adequacy (Kt/V) and albumin. The empowerment group had achieved significant reduction in systolic blood pressure and interdialytic weight gain at follow-up. They had also significantly lower DSI symptom prevalence and severity at 6 weeks post-program ($p < 0.001$) compared to the control group. Lastly, patients in empowerment group achieved a higher QOL score at six weeks.

Conclusion: The study should provide guidance to healthcare professionals in their efforts to adapt and transform their practices so they can lead their patients toward greater autonomy, better compliance and improved QOL.

Keywords : Empowerment; Nursing; End-stage renal disease; Hemodialysis; Compliance; Symptom burden, Quality of life

Introduction

End-stage renal disease (ESRD) is a progressive, debilitating condition characterized by irreversible kidney dysfunction and severe health consequences Zelmer, 2007 [1]. ESRD can adversely affect quality of life (QOL), and influence patients' physical and psychological health, general well-being, and social interactions Kazemi et al. 2011 [2]. Hemodialysis, despite being one of the most important and effective treatment modalities for ESRD, poses major challenges to patients' QOL. As described by Cukor and Kimmel, 2010 [3], a life dependent on a hemodialysis machine, nurses, technicians, and continuous treatment for up to 15 hours per week presents is overwhelming. It implies having to

cope with major stressors including the symptoms of ESRD and their associated social and societal consequences [4].

It is well established that patients with ESRD experience substantially in addition to impaired health-related QOL (HRQOL), a tremendous symptom burden [5-8]. In a systematic review of 61 studies on ESRD, fatigue was found in 12-97% of patients, pruritus in 10-77%, difficulty sleeping in 20-83%, nausea in 15-48% and restless leg syndrome in 8-52% [8]. A high prevalence of psychological and social disturbances in patients receiving HDT [9,10], could negatively influence all aspects of hemodialysis patients' HRQOL [11,12]. Understanding symptom

burden in patients with ESRD is, therefore, crucial if efforts to improve HRQOL are to be successful. Moreover, a comprehensive assessment of the relationship between symptom burden and HRQOL is an important step in highlighting the need for routine implementation of symptom assessment and management in dialysis units.

Physical symptoms of ESRD are usually accompanied by psychological stressors such as a loss of self-concept and self-esteem, feelings of uncertainty about the future, and depression [4,12,13]. High rates of depression in patients with ESRD have been associated with diminished QOL and increased mortality [14]. Moreover, complications related to the end stage renal disease state and dialysis therapy negatively affect patients' physical conditions and behavior and result in more problems that need to be solved [13]. Thus, the development of interventions to ameliorate these effects and enhance QOL among patients with ESRD is essential, and should be directed toward empowering affected individuals. The shift within health services worldwide to a patient-centered approach has underlined the necessity of engaging people in their own health to improve clinical outcomes [15]. Patient empowerment is a dynamic process that allows individuals to both solve their own problems and work with others to improve their QOL through self-directed behavioral changes [16].

Empowerment-based interventions are usually designed for increasing patient's capacity to think critically; thereby enhancing their ability to make autonomous, informed decisions [16]. Lewin & Piper [17], Aujoulat et al. [18], Heikkinen et al. [19], Henry [20] suggest that empowerment should be seen as a process of enablement-that places a focus on how to help patients gain knowledge about the condition that oppresses them, and get control over their bodies, disease, and treatment. Piper [21] further explained that with empowerment comes the ability to exercise choice, accept responsibility for health, and resist external pressure to pursue a particular course of action to prevent future psychological and physical health problems.

The purpose of applying the empowerment concept is to change the relationship from one of professional leadership to a partnership between healthcare professionals and patients. In the empowerment process, there is a need to use both the individuals' and the health professionals' knowledge to identify individual strategies for continuing the empowerment process [22]. Gaps in individuals' perception of empowerment need to be identified, along with barriers to self-management such as frustration, fatigue, financial concerns, transportation, and scheduling difficulties [23].

Among healthcare providers, nurses have an essential role in assisting individuals with ESRD to engage in their own health care, fostering an environment of shared collaboration to empower patients and thus ultimately improving health outcomes [24]. Kring & Crane [25] emphasized that nurses' interventions,

helping patients to rebalance their lives through innovative therapies using holistic approaches to healing, may promote healthier adaptation to ESRD. Therefore, nurses have a unique and independent opportunity to educate and empower patients to adapt positively to illness, increase their sense of control and in turn their compliance [26].

Compliance among patients receiving hemodialysis therapy (HDT) reflects the extent to which an individual's behavior corresponds to the healthcare team's treatment advice [27]. Compliance with fluid restrictions and with other therapeutic regimens for HDT is a major problem among patients with ESRD [4]. Failure to follow a prescribed diet and fluid regimen is associated with an increased risk of poor clinical outcomes and mortality [15,28]. Compliance with treatment regimens may be influenced by knowledge and perceptions of consequences [29,30]. Therefore, there is a need for an adequate teaching program on therapeutic regimens that allows patients to make informed decisions about whether to adhere to recommendations or not [28]. Cognitive and behavioral interventions that promote illness perception may also improve compliance among patients receiving HDT [31].

On the other hand, patients with ESRD often experience high levels of stress, negative moods, and a poor QOL. Treatment aimed at minimizing morbidity and mortality in ESRD (such as intensifying dialysis) is often ineffective; therefore, focusing on HRQOL is an important therapeutic objective because a close relationship exists between HRQOL, morbidity, and mortality. Allen et al. [32], McCarley [33], Wang and Chiou [34] suggested that these patients want to be treated as whole persons and respected as knowledgeable partners in the management of a complex illness that is experienced in not only a body but in a unique life-world. Health professionals' medical expertise should be combined on a case-by-case basis with the patient's knowledge about their own body and life in a way that leads to genuine cooperation and concordant care of the whole person [32]. The body of research on this topic seems to support the notion that patients who learn about their disease and its treatment and who are able to self-manage their health care may experience improved functioning and an increased overall quality of life. In particular, cognitive-behavioral therapy (CBT) appears to have potential and could be an important component of an empowerment program that can be tailored to the specific problems of ESRD patients [4]. Cukor et al. [14] studied the effects of CBT on the reduction of depression in hemodialysis patients with elevated depressive affect and found that it led to marked improvements in depression, QOL, and treatment compliance.

Studies taking into account both physiological and psychosocial variables are useful for understanding the effects of therapeutic patient education programs [35] Therefore, we evaluated the efficacy of an empowerment program that combines disease-specific education with cognitive- behavioral training

(CBT), in promoting compliance, reducing symptom burden, and improving QOL in patients with chronic ESRD receiving HDT.

Objectives

The objectives of the current study were to:

- A. Develop an empowerment program for ESRD.
- B. To evaluate the outcomes of the empowerment program through the following:
 - Compare dietary and fluid intake compliance between the empowerment and control groups at baseline and at the 6-week follow-up; as measured by levels of serum phosphorus, calcium, potassium and blood urea nitrogen (BUN), blood pressure, and interdialytic weight gain (IWG).
 - Compare symptom burden in terms of prevalence and severity between the empowerment and control groups at baseline and at 6-week follow-up.
 - Compare QOL between the empowerment and control groups at baseline and 6-week follow-up.
 - Examine the relationship between compliance, symptom burden and QOL among ESRD patients.

Materials and Methods

Study Setting

The study was conducted at the dialysis unit of King Abdulaziz Medical City, Kingdom of Saudi Arabia.

Study Participants

Seventy-two patients with ESRD, on maintenance HDT, were recruited for this randomized controlled study. Sample size was calculated assuming a level of significance of 5%, a power of 80% and an effect size of 0.35. Exclusion criteria were disinterest in the study intervention or refusal to consent; infection with HIV; and acute renal failure. Patients were randomly assigned to either empowerment or control group. Twelve patients were excluded due to either withdrawal from the study or lost to follow up, resulting in final data analysis of 60 patients.

Study Design

An experimental study design was used. The experimental (intervention) group received empowerment program training, whereas the control group received only routine care provided by the dialysis unit.

Data Collection Instruments

Data was collected using the following instruments:

Socio-Demographic and Medical Data Sheet: This instrument elicited data related to age, sex, marital status, employment status, comorbidities, and duration of dialysis.

Dialysis Symptom Index (DSI): This index, ass developed by Weisbord et al. [36], is widely used to assess physical and

emotional symptom burden among patients with ESRD. It comprises 30 items, each of which assesses a specific physical or emotional symptom on a five-point Likert scale. The Arabic version of the modified DSI demonstrates good psychometric properties, measures the multidimensional nature of symptoms, and canbe used to assess symptom burden at different stages of chronic kidney disease. The DSI was able to discriminate between non-dialysis and dialysis groups ($p < 0.001$) and demonstrated convergent validity with domains of the Kidney Disease Quality of Life short form. Excellent test-retest and internal consistency reliability (Cronbach's $\alpha = 0.91$) were also demonstrated [37].

Dietary and Fluid Compliance: Compliance was measured according to the following health indicators: serum phosphorus, serum calcium, serum potassium, serum albumin, Urea Reduction Ratio (URR), Dialysis Adequacy (Kt/V), interdialytic weight gain (IWG), and mean pre-dialysis blood pressure. IWG is the weight gained between the end of one dialysis session and the beginning of the next. This is a validated marker of compliance to fluid restriction and/or regulation. Serum phosphate level is used to assess patient's compliance with prescribed oral phosphate binder medications and dietary phosphate restriction.

The URR was calculated by dividing the post treatment blood urea nitrogen (BUN) by the pre BUN, this provides a measure of the percentage by which BUN (and thus uremia) was reduced following treatment [38]. Kt/V is the gold standard for measuring the adequacy of dialysis. Computation of this value is based on the reduction in BUN during dialysis treatment, using a formula that also includes the time spent on the machine, the amount of fluid removed, and the patient's weight. The National Kidney Foundation Dialysis Outcomes and Quality Improvement (NKF/DOQI) guidelines state that the minimum Kt/V should be 1.2, with lower values associated with patient's morbidity and mortality.

Kidney Disease Quality of Life-Short Form (KDQOL-SF): This is a self-report measure developed for patients with kidney disease who are receiving dialysis [39,40]. The KDQOL-SF focus on health-related concerns of patients; namely, symptoms and/or problems, effects of disease on daily life, burden of disease, work status, cognitive function, quality of social interaction, sexual function, and sleep. Also included are three additional QOL scales: social support, encouragement by the dialysis staff, and patient satisfaction. Validity and reliability of the scale is well supported in the literature [41,42].

Beck Depression Inventory (BDI): The BDI is a self-rating questionnaire that measures cognitive-affective symptoms and attitudes, impaired performance, and somatic symptoms. Several studies have validated the BDI as a simple depression-screening test among dialysis population. It comprises a 21-item scale that measures the severity of depression. Scores range from 0 to 63, with higher scores indicating more severe depression [43]. Research evidence supports the reliability and validity of the BDI for use with the general population [44,45].

Data Collection Procedure

After necessary ethical and administrative approval by the hospital ethical committee and approval of the medical director of the concerned dialysis-ward, the researchers contacted the potential participants. The purpose and rationale of the study were explained and participants were assured that confidentiality and anonymity of their data would be maintained throughout the study. Immediately after the written consent was secured, random assignment of participants to either of the study groups was carried out. Patients in the empowerment program group received the empowerment program in addition to routine care, and patients in the control group received the routine care provided in the dialysis ward.

Following the collection of baseline data, including patients' sociodemographic background, symptom burden, and information regarding compliance and QOL; empowerment intervention training was initiated. Empowerment intervention was based on individual as well as small-group discussions. Dividing the empowerment group into small subgroups allowed many opportunities for questions and role-playing. Participants in the empowerment program took part in twice-weekly small group sessions (four or five individuals per group) over a 6-week period and a bi-monthly post-program follow-up to help them to develop self-care skills, improve compliance, cope with stressors, and maintain good QOL. Each session lasted approximately 45-60 minutes.

The goal of the empowerment training program was to increase patients' sense of competence and mastery and, subsequently, to reinforce the development of constructive coping strategies. The empowerment program was based on assessment of the participants' needs and an extensive literature review. It was divided into cognitive and psychological empowerment components. The major cognitive content areas of the program were: reasons for HDT; fluid and diet restrictions; and potentials complications associated with excess fluids, protein, sodium and salt intake. The cognitive training also covered the need for weight gain control; the required medications and heed for compliance.

A booklet was developed and distributed to all study participants to be used as backup support and reminder at home. All participants were encouraged to share its content with family members and all social support networks at home. This was done in the tenet that this might encourage significant people at home to support patients' efforts for compliance with diet and fluid recommendations. The psychological component of the empowerment-training program was based on CBT, which have

given rise to strategies for helping patients to cope with stress and adapt with their chronic illness. Stress management was an integral part; its aim was to control the stress response through cognitive restructuring of stressors and various relaxation techniques. A variety of methods was implemented, including mental imagery and progressive muscular relaxation. The investigators led the group in one of these techniques for the first 10-15 minutes of each session. Patients were encouraged to practice at home every day, and they provided feedback about the effectiveness of the techniques used in managing their stress.

A major theme and its objectives were planned for each weekly session. These were related to patient self-management training for self-care, symptom control and management, follow-up monitoring and treatment, stressors recognition and stress management, seeking support, problem solving, and rehearsing coping strategies. There was a strong emphasis on managing food choice, dealing with thirst, fatigue or sleep alterations, weight control, and compliance with treatment. In each session, the plan was to reflect on the previous session and on what the patients had experienced and ascertained since the previous session. Researchers supported the patients in problem solving, making plans and setting goals, and discussing strengths and barriers to making behavioral changes.

Lastly, the study outcome measures were re-assessed for all study participants at 6 weeks following program implementation. Data were collected during 2013-2014.

Statistical Analysis

Data management and data analysis were performed using SPSS Version 20. Descriptive statistics, parametric and non-parametric inferential statistical were performed to compare scores before and after the intervention. Comparison of outcomes for pre- and post- summed scores helped to test the study program's effects on producing the desired outcomes. A p-value of less than 0.05 was considered statistically significant in all analyses.

Results

Socio-demographic characteristics of the participants are shown in Table 1. The empowerment groups comprised of 30 patients with a mean age of 48.7±16.3 years while the control group had 30 patients with a mean age of 58.5±17.7 years. Significant difference was shown between groups concerning sex and employment status (p=0.001, p= 0.007; respectively). Majority of the participants in empowerment group were females and not employed.

Table 1: Socio-demographic Characteristics of Study Participants^a.

Characteristic	T-Test	Control Group Mean (SD)	Empowerment Group Mean (SD)	Subgroup	Characteristic
Age (years)	48.7 (16.3)	58.5 (17.7)	0.05	0.83	
Dialysis Duration (years)	8.7 (5.2)	6.15 (6.9)	0.36	0.55	

		Control Group N (%)	Empowerment Group N (%)	Chi	P-Value
Sex	Male	7 (23.3)	21 (70.0)	13.125	0.00
	Female	23 (76.7)	9 (30.0)		
Marital Status	Single	6 (20.0)	5 (16.7)	3.5	0.32
	Married	19 (63.3)	22 (73.3)		
	Divorced	2 (06.7)	3 (10.0)		
	Widow	3 (10.0)	0 (00.0)		
Educational Status	Illiterate	12 (40.0)	9 (30.0)	3.739	0.44
	Primary	13 (43.3)	16 (53.3)		
	Secondary	2 (06.7)	2 (6.7)		
	Diploma	0 (00.0)	2 (6.7)		
	University	3 (10.0)	1 (3.3)		
Employment	Do not Work	23 (76.7)	13 (43.3)	9.921	0.01
	Work	5 (16.7)	5 (16.7)		
	Retired	2 (06.7)	12 (40.0)		
Co-morbidities	None	10 (33.3)	11 (36.7)	7.73	0.36
	One	11 (36.7)	8 (26.7)		
	Two	6 (20.0)	6 (20.0)		
	Three or more	3 (10.0)	5 (16.7)		

Between-groups comparisons of dietary and fluid intake compliance at baseline and 6-week follow-up were investigated using ANOVA while ANCOVA was conducted in cases where significant baseline differences were detected between the two study groups. Measures of compliance are shown in Table 2. As shown, the majority of the measured parameters were not

significantly different between the two groups at pre-program or at 6 weeks after the program, with the exception of URR, Kt/V (significantly lower for the control group at baseline only) (p=0.02, p= 0.01; respectively) and albumin (significantly higher for the empowerment group at both baseline and post-program) (p=0.001, p= 0.02; respectively).

Table 2: Pre-Program and Post-Program Laboratory Profile and Clinical Indices for Empowerment and Control Groups.

Measure	Time Point	Empowerment Group Mean (SD)	Control Group Mean (SD)	Mean Difference(95% CI)	P-Value
Hb	Pre-Program	10.50 (2.06)	10.95 (1.17)	-0.45 (-1.31 to 0.41)	0.3
	Post-Program	11.10 (1.30)	10.88 (1.42)	0.22 (-0.49 to 0.93)	0.53
Hct	Pre-Program	33.24 (5.21)	33.95 (3.81)	-0.72 (-3.08 to 1.64)	0.55
	Post-Program	33.64 (4.07)	33.45 (4.87)	0.19 (-2.13 to 2.50)	0.87
BUN	Pre-Program	26.9 (7.79)	25.72 (7.37)	1.20 (-2.72 to 5.12)	0.54
	Post-Program	25.18 (4.49)	23.52 (7.51)	1.66 (-1.54 to 4.86)	0.3
K+	Pre-Program	4.89 (0.78)	4.94 (0.84)	-0.05 (-0.46 to 0.37)	0.82
	Post-Program	4.74 (0.67)	4.62 (0.98)	0.13 (-0.31 to 0.56)	0.56
Ca ²⁺	Pre-Program	2.16 (0.22)	2.11 (0.17)	0.05 (-0.06 to 0.15)	0.37
	Post-Program	2.15 (0.22)	2.11 (0.20)	0.04 (-0.07 to 0.15)	0.49
PO ₄	Pre-Program	1.80 (0.68)	1.61 (0.40)	0.19 (-0.10 to 0.48)	0.2
	Post-Program	1.80 (0.63)	1.70 (0.61)	0.11 (-0.23 to 0.43)	0.52

URR	Pre-Program	75.61 (7.34)	71.19 (6.37)	4.42 (0.87 to 7.97)	0.02
	Post-Program	74.86 (13.29)	74.17 (4.68)	0.71 (-4.44 to 5.85)	0.82*
Kt/V	Pre-Program	1.60 (0.32)	1.40 (0.25)	0.20 (0.06 to 0.35)	0.01
	Post-Program	1.62 (0.42)	1.51 (0.21)	0.11 (-0.06 to 0.28)	0.73*
Alb	Pre-Program	35.69 (3.26)	32.77 (3.22)	2.87 (1.20 to 4.53)	0.001
	Post-Program	33.67 (3.62)	31.97 (3.54)	1.70 (0.09 to 3.31)	0.02*

Hb, Hemoglobin; Hct, Hematocrit; BUN, Blood urea nitrogen; K⁺, Potassium; Ca²⁺, Calcium; PO₄, Phosphorus; URR, Urea Reduction Ratio, Kt/V, Dialysis Adequacy, Alb, Albumin.

*ANCOVA analysis carried out to control for baseline differences.

Compliance was also tested using measures of IWG and BP (Table 3). No significant between-group difference was found at baseline. However, the empowerment group had a significantly lower mean systolic BP and a significantly lower mean IWG at the 6-week follow-up (p=0.02, p< 0.001; respectively).

Table 3: Fluid Adherence Profile among Study Participants.

Measure	Time Point	Empowerment Group Mean (SD)	Control Group Mean (SD)	Mean Difference(95% CI)	P-Value
Pre-Dialysis Systolic BP	Pre-Program	137.27 (22.98)	135.76 (21.31)	2.43 (-9.08 to 13.95)	0.67
	Post-Program	126.69 (24.10)	140.67 (17.58)	-13.9 (-25.29 to -2.67)	0.02
Pre-Dialysis Diastolic BP	Pre-Program	70.80 (15.52)	65.31 (14.27)	5.67 (-1.99 to 13.32)	0.14
	Post-Program	66.77 (13.49)	64.20 (14.69)	2.57 (-4.72 to 9.86)	0.48
Interdialytic Weight Gain	Pre-Program	1.66 (0.99)	1.52 (0.95)	0.14 (-0.37 to 0.65)	0.6
	Post-Program	1.34 (0.72)	2.46 (1.89)	-1.12 (-1.86 to -0.38)	0.00

Analysis of group differences in QOL, depression, and symptom burden (DSI) at baseline and at follow-up are shown in Table 4. The empowerment group had a significantly higher DSI prevalence at baseline and significantly lower DSI prevalence post-program compared to the control group (p=0.02, p< 0.001; respectively). Similarly, the empowerment group had significantly higher DSI severity than the control group at baseline, and significantly lower DSI severity post-program (p=0.05, p< 0.001; respectively).

Table 4: DSI, KDQOL-SF and Beck Depression Profile among Study Participants.

Measure	Time Point	Empowerment Group Mean (SD)	Control Group Mean (SD)	Mean Difference(95% CI)	P-Value
DSI Prevalence	Pre-Program	17.30 (5.35)	13.27 (7.67)	4.03 (0.61 to 7.45)	0.02
	Post-Program	12.73 (6.73)	14.70 (8.38)	-1.97 (-5.89 to 1.96)	0.00*
DSI Severity	Pre-Program	56.17 (21.47)	42.97 (28.46)	13.20 (0.17 to 26.23)	0.05
	Post-Program	33.17 (17.76)	48.70 (32.43)	-15.53 (-29.05 to -2.02)	0.00*
KDQOL-SF	Pre-Program	53.03 (8.47)	60.52 (11.87)	-7.49 (-13.09 to -1.89)	0.01
	Post-Program	64.03 (9.13)	55.96 (11.20)	7.61 (1.68 to 13.54)	0.00*
BDI	Pre-Program	16.77 (11.89)	15.76 (8.68)	1.0 (-4.38 to 6.38)	0.71
	Post-Program	11.53 (9.99)	17.77 (13.39)	-6.23 (-12.34 to -0.13)	0.04

DSI, Dialysis Symptom Index; KDQOL-SF, Kidney Disease Quality of Life-Short Form; BDI, Beck Depression Inventory.

*ANCOVA analysis carried out to control for baseline differences.

The DSI prevalence and severity of each symptom are shown in Table 5. For DSI prevalence, there was significantly more worrying, trouble falling asleep, irritability, nervousness, and complaints of nausea and vomiting in the empowerment group at baseline. At 6 weeks, the higher prevalence among empowerment

group tended to show lower trends similar to those shown by the control group. For DSI severity, the empowerment group showed improved control of symptom at 6 week despite that items of feeling tired or a lack of energy, headache, diarrhea and vomiting, were worst among the empowerment group at baseline (Table 6).

Table 5: DSI, Prevalence of Symptoms among Study Participants.

Symptom	Pre-Program			Post-Program		
	Empowerment Group	Control Group	P-Value a	Empowerment Group	Control Group	P value a
Feeling tired or lack of energy	28 (93.3)	23 (76.7)	0.15	19 (63.3)	22 (73.3)	0.58
Worrying	24 (80.0)	15 (50.0)	0.03	16 (53.3)	19 (63.3)	0.6
Dry skin	21 (70.0)	21 (70.0)	1	19 (63.3)	18 (60.0)	1
Itching	22 (73.3)	19 (63.3)	0.58	20 (66.7)	20 (66.7)	1
Trouble staying asleep	18 (60.0)	13 (43.3)	0.3	16 (53.3)	19 (63.3)	0.6
Trouble falling asleep	20 (66.7)	11 (36.7)	0.04	17 (56.7)	15 (50.0)	0.79
Feeling sad	18 (60.0)	14 (46.7)	0.44	13 (43.3)	13 (43.3)	1
Feeling irritable	26 (86.7)	18 (60.0)	0.04	21 (70.0)	20 (66.7)	1
Difficulty becoming sexually aroused	7 (23.3)	7 (23.3)	1	5 (16.7)	9 (30.0)	0.36
Bone or joint pain	23 (76.7)	16 (53.3)	0.1	20 (66.7)	16 (53.3)	0.43
Muscle cramps	16 (53.3)	13 (43.3)	0.61	8 (26.7)	13 (43.3)	0.28
Feeling anxious	19 (63.3)	15 (50.0)	0.44	16 (53.3)	18 (60.0)	0.79
Decreased interest in sex	10 (33.3)	9 (30.0)	1	8 (26.7)	10 (33.3)	0.78
Dry mouth	11 (36.7)	14 (46.7)	0.6	14 (46.7)	15 (50.0)	1
Constipation	20 (66.7)	17 (56.7)	0.59	14 (46.7)	14 (46.7)	1
Swelling in legs	12 (40.0)	10 (33.3)	0.79	4 (13.3)	8 (26.7)	0.33
Restless legs	8 (26.7)	11 (36.7)	0.58	4 (13.3)	10 (33.3)	0.13
Feeling nervous	28 (93.3)	18 (60.0)	0.01	22 (73.3)	21 (70.0)	1
Headache	21 (70.0)	18 (60.0)	0.59	12 (40.0)	15 (50.0)	0.6
Diarrhea	13 (43.3)	7 (23.3)	0.17	6 (20.0)	9 (30.0)	0.55
Decreased appetite	15 (50.0)	13 (43.3)	0.79	14 (46.7)	16 (53.3)	0.79
Cough	13 (43.3)	12 (40.0)	1	7 (23.3)	16 (53.3)	0.03
Muscle soreness	13 (43.3)	11 (36.7)	0.79	6 (20.0)	16 (53.3)	0.02
Nausea	21 (70.0)	9 (30.0)	0	8 (26.7)	15 (50.0)	0.11
Lightheadedness or dizziness	16 (53.3)	14 (46.7)	0.79	15 (30.0)	18 (60.0)	0.6
Shortness of breath	16 (53.3)	11 (36.7)	0.29	10 (33.3)	12 (40.0)	0.79
Difficulty concentrating	15 (50.0)	9 (30.0)	0.19	14 (46.7)	10 (33.3)	0.43
Numbness or tingling in feet	20 (66.7)	15 (50.0)	0.29	17 (56.7)	15 (50.0)	0.79
Vomiting	13 (43.3)	5 (16.7)	0.04	7 (23.3)	7 (23.3)	1
Chest pain	12 (40.0)	10 (33.3)	0.79	10 (33.3)	12 (40.0)	0.79

DSI, Dialysis Symptom Index;

*All P values are Pre-Bonferroni corrections.

Table 6: DSI, Severity of Symptoms among the Study Participants.

Symptom	Pre Program			Post Program		
	Empowerment Group	Control Group	P value	Empowerment Group	Control Group	P value
Feeling tired or lack of energy	2.97 (1.25)	2.47 (1.68)	0.03	1.63 (1.35)	2.50 (1.74)	0.25
Worrying	2.50 (1.63)	1.67 (1.83)	0.09	1.37 (1.45)	2.17 (1.86)	0.07
Dry skin	2.47 (1.91)	2.03 (1.56)	0.07	1.77 (1.55)	2.07 (1.89)	0.08
Itching	2.53 (1.85)	2.30 (2.02)	0.35	1.77 (1.52)	2.40 (1.98)	0.02
Trouble staying asleep	2.20 (2.04)	1.40 (1.79)	0.29	1.57 (1.72)	2.23 (1.92)	0.28
Trouble falling asleep	2.47 (2.03)	1.17 (1.72)	0.21	1.60 (1.63)	1.73 (1.87)	0.07
Feeling sad	1.73 (1.66)	1.63 (1.92)	0.09	1.10 (1.35)	1.47 (1.81)	0.01
Feeling irritable	3.30 (1.75)	2.13 (2.05)	0.25	2.17 (1.70)	2.47 (1.94)	0.13
Difficulty becoming sexually aroused	0.80 (1.56)	0.90 (1.77)	0.56	0.40 (0.93)	1.20 (1.96)	0
Bone or joint pain	2.50 (1.72)	1.63 (1.69)	0.56	1.80 (1.54)	1.97 (2.03)	0.01
Muscle cramps	1.67 (1.79)	1.50 (1.89)	0.49	0.57 (0.97)	1.37 (1.73)	0
Feeling anxious	2.07 (1.86)	1.57 (1.76)	0.93	1.47 (1.59)	2.03 (1.90)	0.23
Decreased interest in sex	1.17 (1.89)	1.03 (1.79)	0.67	0.77 (1.41)	1.20 (1.88)	0.04
Dry mouth	1.07 (1.53)	1.53 (1.80)	0.11	1.17 (1.42)	1.67 (1.81)	0.01
Constipation	2.33 (1.89)	1.90 (1.88)	0.99	1.47 (1.70)	1.60 (1.87)	0.39
Swelling in legs	1.23 (1.65)	1.00 (1.60)	0.46	0.33 (0.88)	0.70 (1.21)	0.01
Restless legs	0.77 (1.36)	1.13 (1.63)	0.11	0.27 (0.69)	1.03 (1.59)	0
Feeling nervous	3.40 (1.48)	1.97 (1.90)	0.15	2.17 (1.62)	2.47 (1.87)	0.13
Headache	1.93 (1.53)	2.03 (1.79)	0.03	0.90 (1.16)	1.47 (1.59)	0
Diarrhea	1.30 (1.64)	0.57 (1.07)	0	0.47 (0.97)	0.80 (1.30)	0.02
Decreased appetite	1.50 (1.66)	1.37 (1.73)	0.78	1.00 (1.11)	1.80 (1.86)	0
Cough	1.33 (1.71)	1.37 (1.83)	0.51	0.47 (0.86)	1.50 (1.50)	0
Muscle soreness	1.37 (1.79)	1.10 (1.56)	0.43	0.50 (1.04)	1.57 (1.63)	0
Nausea	2.03 (1.54)	1.00 (1.66)	0.47	0.67 (1.16)	1.53 (1.74)	0
Lightheadedness or dizziness	1.67 (1.69)	1.53 (1.80)	0.63	1.10 (1.16)	1.90 (1.81)	0.02
Shortness of breath	1.67 (1.75)	1.10 (1.56)	0.37	0.80 (1.21)	1.23 (1.72)	0.03
Difficulty concentrating	1.40 (1.59)	1.00 (1.64)	1	1.10 (1.32)	1.03 (1.63)	0.27
Numbness or tingling in feet	2.20 (1.75)	1.63 (1.85)	0.59	1.40 (1.35)	1.77 (1.96)	0
Vomiting	1.33 (1.65)	0.47 (1.17)	0	0.63 (1.19)	0.80 (1.58)	0.24
Chest Pain	1.27 (1.70)	0.83 (1.26)	0.02	0.77 (1.14)	1.03 (1.35)	0.08

DSI, Dialysis Symptom Index;

*All P values are Pre-Bonferroni corrections.

The empowerment group had a significantly lower QOL at baseline and a significantly higher QOL score post-program compared to the control group ($p=0.01$, $p< 0.001$; respectively). Depression, as measured by the BDI, did not differ between the two groups at baseline, but the empowerment group was significantly less depressed than the control group post-program ($p=0.71$, $p= 0.04$; respectively). Further analysis of QOL dimensions in

both study groups is shown in Table 7. It should be noted that for KDQOL-SF scores, a higher number reflects a more favorable health state. The empowerment group showed significantly higher post-program scores for several Kidney Disease-Targeted scales including, symptoms, effects of kidney disease, burden of kidney disease, cognitive function, quality of social interaction, and patient satisfaction.

Table 7: KDQOL-SF™ Dimensions' Profile among Study Participants.

	Time Point	Empowerment Group Mean (SD)	Control Group Mean (SD)	Mean Difference (95% CI)	P-Value
Kidney Disease-Targeted Scales					
Symptoms and/or Problems	Pre-Program	57.78 (19.53)	67.92 (20.23)	-10.14 (-20.41 to 0.14)	0.05
	Post-Program	77.36 (13.54)	61.46 (24.66)	15.90 (5.62 to 26.19)	0.00*
Effect of Kidney Disease	Pre-Program	53.54 (15.57)	63.44 (22.54)	-9.89 (-19.91 to 0.11)	0.05
	Post-Program	69.58 (17.98)	60.10 (24.68)	9.48 (-1.68 to 20.64)	0.00*
Burden of Kidney Disease	Pre-Program	47.92 (22.47)	45.63 (25.65)	2.29 (-10.17 to 14.75)	0.71
	Post-Program	54.79 (20.68)	34.17 (29.30)	20.63 (7.52 to 33.73)	0
Work Status	Pre-Program	73.33 (36.52)	75.00 (34.11)	-1.67 (-19.93 to 16.59)	0.86
	Post-Program	68.33 (38.25)	78.33 (33.95)	-10.00 (-28.69 to 8.69)	0.29
Cognitive Function	Pre-Program	69.11 (20.75)	74.44 (20.50)	-5.33 (-15.99 to 5.33)	0.32
	Post-Program	79.11 (14.41)	64.22 (24.35)	14.89 (4.55 to 25.23)	0.01
Quality of Social Interaction	Pre-Program	64.89 (20.11)	70.00 (25.48)	-5.11(-16.97 to 6.75)	0.39
	Post-Program	76.22 (17.99)	64.44 (24.15)	11.78 (0.77 to 22.79)	0.04
Sexual Function	Pre-Program	75.00 (36.98)	73.21 (22.16)	1.79 (-32.25 to 35.82)	0.91
	Post-Program	83.93 (20.05)	58.33 (35.06)	25.60 (-8.56 to 59.75)	0.13
Sleep	Pre-Program	56.67 (13.62)	62.25 (23.16)	-5.58 (-15.40 to 4.24)	0.26
	Post-Program	59.42 (16.37)	57.92 (19.90)	1.50 (-7.92 to 10.92)	0.75
Social Support	Pre-Program	18.89 (22.63)	16.11 (24.94)	2.78 (-9.53 to 15.09)	0.65
	Post-Program	06.67 (12.83)	19.44 (22.78)	-12.78 (-22.33 to -3.22)	0.01
Dialysis Staff Encouragement	Pre-Program	84.58 (25.36)	89.58 (13.96)	-5.00 (-15.58 to 5.58)	0.35
	Post-Program	87.50 (21.53)	87.50 (20.76)	0.00 (-10.93 to 10.93)	1
Dialysis Staff Encouragement	Pre-Program	71.11 (29.01)	70.56 (25.78)	0.56 (-13.63 to 14.74)	0.94
	Post-Program	78.33 (21.51)	65.00 (26.02)	13.33 (0.99 to 25.67)	0.03
36-Item Health Survey Scales					
Physical functioning	Pre-Program	42.67 (24.70)	38.83 (30.11)	3.83 (-10.40 to 18.06)	0.59
	Post-Program	65.00 (26.56)	36.03 (28.04)	28.97 (14.73 to 43.20)	0
Role-Physical	Pre-Program	20.00 (26.59)	38.33 (36.98)	-18.33 (-34.98 to -1.69)	0.03
	Post-Program	38.33 (35.80)	28.33 (27.65)	10.00 (-6.53 to 26.53)	0.01*
Bodily Pain	Pre-Program	41.75 (26.82)	55.17 (30.30)	-13.42 (-28.20 to 1.37)	0.08
	Post-Program	64.42 (27.06)	53.17 (32.24)	11.25 (-4.13 to 26.63)	0.15
General Health Perceptions	Pre-Program	44.17 (11.60)	39.83 (14.05)	4.33 (-2.33 to 10.99)	0.19
	Post-Program	62.50 (17.36)	38.83 (19.81)	23.67 (14.04 to 33.29)	0
Emotional Well-being	Pre-Program	62.40 (15.78)	66.93 (22.18)	-4.53 (-14.48 to 5.42)	0.37
	Post-Program	69.20 (20.93)	58.00 (23.17)	11.20 (-0.21 to 22.61)	0.045
Role-Emotional	Pre-Program	18.89 (31.18)	52.22 (41.69)	-33.33 (-52.36 to -14.3)	0.00
	Post-Program	46.67 (36.72)	33.33 (36.09)	13.33 (-5.49 to 32.15)	0.00*
Social Function	Pre-Program	48.75 (28.11)	55.42 (31.43)	-6.67 (-22.09 to 8.75)	0.39
	Post-Program	65.00 (21.63)	49.58 (34.97)	15.42 (0.39 to 30.44)	0.04
Energy/Fatigue	Pre-Program	45.00 (19.56)	52.17 (22.69)	-7.17 (-18.12 to 3.78)	0
	Post-Program	61.00 (22.26)	44.83 (22.76)	16.17 (4.53 to 27.80)	0.01

Change in Health	Pre-Program	51.67 (27.80)	64.17 (31.95)	-12.50 (-27.98 to 2.98)	0.11
	Post-Program	71.67 (27.65)	52.50 (32.40)	19.17 (3.60 to 34.73)	0.02
Overall Health Rating	Pre-Program	59.67 (22.97)	62.67 (28.15)	-3.00 (-16.28 to 10.28)	0.65
	Post-Program	66.00 (20.94)	55.00 (29.10)	11.00 (-2.10 to 24.10)	0.09

KDQOL-SF, Kidney Disease Quality of Life-Short Form;

*ANCOVA analysis carried out to control for baseline differences.

A Pearson correlation of the study outcomes at baseline and post-program is shown in Table 8. Symptom burden, symptom severity, and depression scores were significantly associated with each other at both study time points. Increased QOL was

significantly associated with decreased symptom burden, symptom severity and depression scores at both time points. Participants' age was significantly associated with post-program symptom severity and QOL.

Table 8: Correlations between Age, Dialysis Duration, Weight Gain, DSI, QOL, and BDI.

		1	2	3	4	5	6	7	8	9	10	
1	Age		-									
2	Dialysis Duration		0.07	-								
3	Weight Gain	^a Pre	-0.04	0.1	-							
4		^b Post	0	-0.25	0.06	-						
5	*DSI Burden	^a Pre	0.16	0.11	-0.06	-0.39**	-					
6		^b Post	0.25	-0.01	-0.09	-0.27*	0.71**	-				
7	*DSI Severity	^a Pre	0.24	0.19	-0.07	-0.34**	0.94**	0.67**	-			
8		^b Post	0.33*	0.02	-0.12	-0.2	0.63**	0.92**	0.65**	-		
9	**QOL	^a Pre	-0.14	-0.18	-0.02	0.27	-0.73**	-0.47**	-0.73**	-0.45**	-	
10		^b Post	-0.31*	0.04	-0.04	-0.03	-0.49**	-0.64**	-0.47**	-0.71**	0.57**	-
11	***BDI	^a Pre	0.02	0.06	0.08	-0.19	0.50**	0.47**	0.52**	0.47**	-0.62**	-0.56**
12		^b Post	0.18	-0.04	0.04	-0.08	0.45**	0.60**	0.46**	0.70**	-0.47**	-0.67**

^aPre, Pre Program; ^bPost Program; *DSI, Dialysis Symptom Index; **KDQOL-SF, Kidney Disease Quality of Life-Short Form; ***BDI, Beck Depression Inventory.

Discussion

The current study investigated the efficacy of an empowerment program in promoting compliance, reducing symptom burden, and improving QOL among patients with chronic ESRD receiving HDT. Our findings clearly demonstrated that the 6-week empowerment program substantially improved the outcomes for patients. Patients in the empowerment group were required to make major lifestyle changes and to exert control over their lives by self-managing their illness. The empowerment program was based on the belief that individuals are naturally motivated to improve their own clinical outcomes, and thereby it aimed at enhancing patient self-confidence to carry out the desired behaviors [15]. Mc Carley [33], Piper [21] agreed that behavioral changes and adherence to therapies could not be achieved unless patients internalize the need for self-change, experience-improved self-esteem, confidence and an ability to exercise choice, and accept responsibility for their health.

More specifically, the current study revealed a positive effect of empowerment on patients' compliance, symptom burden, and QOL. Our findings are congruent with intervention studies

conducted over shorter (less than 6 weeks) periods of time [46,47]. In a systematic review of the impact of therapeutic patient education programs in hemodialysis, Indier [35] found that educational programs have become more numerous and efficient. Tang [47] reported that an empowerment-based approach to self-management of diabetes mellitus is promising for improving and/or sustaining diabetes-related health outcomes.

Possible explanations for the positive influence of current study program might include the extensive knowledge building through the twelve planned sessions, the use of a booklet as a reminder for patients at home, the use of audiovisual material, and the problem solving and cognitive-behavioral approaches that were developed and adopted for use in the study. Wang and Chiou [34] found that participants with insufficient knowledge were incapable of completely achieving or comprehending routine self-care and were affected by powerlessness. The authors therefore considered patient's empowerment a crucial element in enhancing patient knowledge of treatment recommendations and need for life style changes to remain in control of their lives. This is in line with findings of Heikkinen et al. [19] which showed that improvement in the level and sufficiency of knowledge of

patients had in turn led to an increase in cognitive empowerment. Indeed, Allen et al. [32], Henry [20], Wan et al. [23] emphasized that treating patients as knowledgeable partners in the management of a complex illness is considered an important aspect in patient empowerment. In concordance, Hain and Sandy [24], Anderson and Funnell [16], Wan et al. [23] contended that patient enablement as fundamental element of the empowerment process involves changing from a paternalistic approach to one of a partnership to sustain behavioral change, which allows patients to take responsibility and to control self-care behaviors. Therefore, the empowerment education program in the present study enabled the patients to be in a better position to reflect on their lives with ESRD, to set appropriate goals and make decisions for managing their disease.

In addition, some factors embedded in the plan for current study, might have detrimentally contributed to improved patients' adherence to the scheduled program sessions. The empowerment sessions were planned to start 30 minutes prior to patients' scheduled dialysis session to avoid placing an extra burden on them, specifically, transport issues, and the accompanying financial demands. Many patients, particularly the females, were transported through hospital facilities for their scheduled sessions. These arrangements minimized many of the possible concerns that might affect patients' program completion.

Participants' Compliance

Concerning compliance, patients are classified as dietary compliant if serum potassium, calcium, phosphate, albumin, and BUN levels were within acceptable reference limits. Accordingly, the empowerment group participants showed dietary compliance for the majority of laboratory parameters at post-test compared with their baseline tests. Moreover, majority of the measured dietary parameters were not significantly different between the study groups at either pre-program or 6 weeks after the program, with the exception of the albumin level, URR and Kt/V. Albumin levels were substantially higher for the empowerment group at both time points, with the lower value being at post-program which was attributed to patients' increased compliance with protein restrictions.

The empowerment group showed a significantly higher level of URR and Kt/V at baseline. Interestingly, this group difference was maintained at 6 weeks but was not more statistically significant. Considering the importance of these measures in assessing potential health problems and risk of death, it would seem that the capacity of patient empowerment programs to have an effect on these values is an important health benefit. It could also be indicative of the improved patient-carer relationship in the empowerment group. Indeed, Kt/V values have been related to patient-nurse relationships [38].

Further to compliance data, the study did not show any differences in BUN, either at pre- nor at post-program for both study groups. This could be explained in light of patients' Saudi cultural and social dietary habits, which make it difficult for patient

to reduce intake of high-protein foods, such as meat, fish, eggs, and dairy products. Indeed, many patients found dietary restrictions to be the most challenging part of treatment. However, with regard to fluid compliance, the empowerment group had significantly lower levels of IWG and mean systolic blood pressure than the control group at the 6-week follow-up. According to Holmberg and Stegmay [48], to lower the risk of volume overload between thrice-weekly dialysis, IWG should be less than 2.5 kg or 3.5% of dry body weight. This level was achieved in the empowerment group, whereas the IWG of the control group was borderline. IWG is thought to reflect fluid and sodium intake compliance and has been suggested to be a better objective measure of compliance than phosphorus (SPO4) concentration [49]. As explained by [27], high values of predialysis systolic, diastolic, and mean arterial BP are usually associated with increased IWG; thus, we suggest that the improvement in fluid compliance of patients in the empowerment group contributed to the resulting decrease in their blood pressure.

One major factor that might have influenced patients' compliance is their knowledge. Patient's knowledge and beliefs about their disease and self-management were the major factors that might have positively influenced participants' compliance. Baraz et al. [28] showed that an increased level of patient education in their hemodialysis teaching groups might strengthen the relationship between knowledge and compliance. Castner [51] emphasized that patient education and support are integral aspects of the fluid management. More generally, increasing awareness of benefits of adherence increases the likelihood that patients will perform the desired behavior [52]. Chilcot et al. [29] demonstrated the important effect of consequence perceptions in patient fluid adherence—specifically, that lowered consequence perceptions increased the odds of nonadherence in patients with ESRD group. Also important are individual patient beliefs. Indeed, addressing patients' personal beliefs regarding the effectiveness of treatment can provide a powerful tool that could influence the extent to which they feel motivated to regulate their illness and adhere to treatment [30].

Symptom Burden

It was found that ESRD symptoms were highly prevalent and more severe at baseline among the empowerment group, whereas at post-program empowerment group had better recovery than the control group. The fact that, Danquah et al. [53] reported higher incidence for the different symptom dimensions among females than males and that higher burden of symptoms has also been reported among women [54], might explain the greater symptom prevalence and severity in the empowerment group at baseline. Indeed, the majority of participants from empowerment group were females, whereas the majority of participants from the control group were males.

Among the reported symptoms; tiredness, irritability, nervousness, itching dry skin, difficulty falling asleep, numbness, pain, constipation, and headache; were the most frequent and

severe. These findings were similar to those reported by Murtagh [8], who found a weighted high mean prevalence for the following symptoms: fatigue/tiredness, pruritus, constipation, pain, sleeps disturbance, anxiety, anorexia, restless leg syndrome, and depression. Similarly, Harwood et al. [55] identified fatigue, sleep problems, peripheral neuropathy, muscle cramps, and restless legs as the five stressors most frequently reported by patients with CKD. Consistent with these findings, Yu et al. [56] reported that the three most common symptoms among 117 Taiwanese dialysis patients were, in order of decreasing frequency, tiredness, dry mouth, and lack of vitality.

The variations in symptom severity observed in these studies could be attributed to the fact that severity is considered a subjective sensation that is affected by culture, personality, differences in symptom definition, and period of prevalence [8,56]. Also Murtagh et al. [8] emphasized the marked impact that cultural differences can have on the perception of symptom severity by patients undergoing HDT. Actually, our study participants' reports of symptom severity however high but considered lower compared to previous studies, and would be explained in light of their strong religious beliefs that their illness is a test from God and people should show their faith by accepting and avoiding complains.

Reasons for patients' symptom experiences are however numerous. Symptoms such as joint pain, arrhythmia, and numbness experienced by patients might be related to the disturbance of potassium ions [56]. Whereas tiredness and muscle weakness, energy and sensory discomfort might be associated with anemia, which could have been caused by insufficient erythropoietin, inhibition of erythropoiesis, decreasing erythrocyte lifespan, or blood loss during the procedure. In addition, serum albumin concentration has been identified as an important factor associated with physical activity and energy expenditure [57] affecting 18% to 75% of patients on dialysis [51]. Chertow et al. [58] demonstrated that low levels of pre-albumin and albumin are markers for protein-energy malnutrition and are linked to poor clinical outcomes in terms of symptom index among patients receiving HDT. In current study, serum albumin was significantly higher in empowerment group and similarly physical functioning was higher among participants in empowerment group than the control group.

Kidney Disease Quality of Life

The current results are suggestive of an improvement in QOL in the empowerment group post-program compared to the control group. Scores for several Kidney Disease-Targeted Scales were significantly better in the empowerment group, including symptoms/problems, effect of kidney disease, burden of kidney disease, cognitive function, and quality of social interaction, social support and patient satisfaction. These findings are in line with Chan et al. [59] findings that revealed appreciable improvements in physical clinical measurements, QOL, and aspects of self-management skills following self-management program for hemodialysis patients.

Additionally, majority of QOL dimensions improved relative to pre program scores, including physical function, physical role, bodily pain, general health, vitality, social function, mental health, and emotional role. An extensive body of literature supports the efficacy of empowerment and educational interventions in improving the different dimensions of QOL for patients with chronic diseases [60]. Aujoulat et al. [61] showed that empowerment-based approaches are patient-centered and based on focused development of self-care skills. The design of the empowerment intervention in present study was based on individual and small-group discussions. Wong & colleagues [62] emphasized that patients' involvement in effective self-care management is important for maintaining QOL and bringing about positive clinical outcomes. Dividing the empowerment group into small subgroups allowed ample opportunity for questions and role-playing using different techniques that have been shown to play a key part in improving self-care and QOL in HD patients [63,64].

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