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The Efficacy of Integrated Care Protocol on Improving Health-Related Quality of Life among Patients Undergoing Hemodialysis

Furqan Hadi Muslim[1], Diaa Kareem Abd Ali[2]
[1]MSc, Faculty of Nursing, University of Kufa, Najaf, Iraq; furqanhadi94@gmail.com
[2]Prof., University of Al-Ameed, Faculty of Nursing, Karbala, Iraq
University of Kufa, Faculty of Nursing, Najaf, Iraq; dr.diaa@alameed.edu.iq

Abstract

Background*: Hemodialysis is considered the most effective modality for sustaining the lives of patients with end-stage renal disease, as it plays a critical role in replacing essential kidney functions. However, despite its life-saving nature, hemodialysis is associated with a negative impact on various domains of health-related quality of life (HRQoL). Often result in a significant decline across physical, psychological, and social dimensions. Therefore, it is imperative to address these challenges and develop effective strategies, ensuring they can lead a dignified and balanced life through comprehensive care. Evidence supporting the effectiveness of integrated care in improving patient outcomes is weak.*

Study Aim: *To determine the effectiveness of integrated care protocol on improving HRQoL among patients undergoing hemodialysis.*

Methods and Results: *A randomized controlled trial (RCT) was conducted on 70 patients randomly and equally assigned into two groups (experimental and control group); a non-probability (purposive sample) was included in the present study for patients under hemodialysis. The study results indicated the implementation of the integrated care protocol led to significant improvements in HRQoL across multiple domains for the experimental group compared with those participants in the control group. The discussion of the results focused on the implications of the findings for clinical practice.*

Conclusion :*The study has concluded that the integrated care protocol implementation is an effective approach to enhanced HRQoL among patients undergoing hemodialysis. The study recommends future research should continue to explore the efficacy and impact of other protocols on these populations to further inform best nursing practices in the management of negative outcomes of Hemodialysis.*

INTRODUCTION

Hemodialysis is one of the main therapies for patients with end-stage renal disease (1). it is associated with low quality of life (QoL) and a marked decline in functional and psychosocial status despite the life-saving benefits of adequate dialysis, those declines translate into frailty and deteriorating quality of life (2). Quality of life is essential in the management of chronic kidney disease (CKD) patients undergoing hemodialysis. Patients undergoing hemodialysis have the worst quality of life from any long-term condition, and their quality of life is substantially poorer than that of the general population (3). Hospitalizations and mortality are linked to lower quality of life scores (4)Although vital, health-related quality of life is often overlooked in the management of chronic kidney disease (CKD). Patient quality of life serves as a crucial indicator of how well the treatment they get is working, Alongside survival and different kinds of clinical results (5).However, hemodialysis serves to a prolong patient's life, but it has a significant influence on impairing the quality of life (QOL) of these patients, adverse reaction is represented by psychological, physical, financial, and social well-being (6). As mentioned, hemodialysis may adversely react negatively on patients who undergo it through dealing with multifaceted issues like physiological damage as well as lifestyle modifications. Moreover, hemodialysis has an impact on a patient's family life, in addition to their own. It can cause role changes, make it difficult for a patient to work and maintain a job, require transportation, require periodic visits to the healthcare provider, and regrettably, lower their financial situation. Additionally, being chronically ill can lead to low self-esteem and less control over the illness (7). In addition, to physical side effects from hemodialysis which may

include fatigue, activity restriction, severe disability, and impaired functioning status, numerous psychosocial factors and difficulties can face those patients cause them to feel depression, such as changes in how they perceive their bodies and a desire to adhere to particular diet plans when treatment results are not typical (8). Another physical side effect on patients with hemodialysis may have a high burden of symptoms, which includes incapacitating signs like cramping within their muscles, edema in the extremities, decreased appetite, and weariness that impairs their quality of life daily. Major sleep disorders associated with end-stage renal disease (ESRD) are sleep apnea insomnia and restless leg syndrome. Low quality of life and mortality are predicted by poor sleep alone (9). Additionally, there are some techniques for enhancing psychological state that are regarded as essential to a high standard of health using cognitive behavioral therapy (CBT) based interventions by Psychologists have effectively managed depression in patients with hemodialysis (HD), which have also improved secondary outcomes related to self-care (10). Moreover, self-care, the direct involvement of patients in their treatment, is critical for both the physical and psychosocial health of patients on Hemodialysis and involves adherence to prescription medications, dialysis, regimen, regular exercise, monitoring oneself, and follow-up of instruction (11). The WHO defines integrated care (or integrated health services delivery) as "an approach to strengthen people-centered health systems through the promotion of the comprehensive delivery of quality services across the life-course, designed according to the multidimensional needs of the population and the individual and delivered by a coordinated multidisciplinary team of providers working across settings and levels of care. It should be effectively managed to ensure optimal outcomes and the appropriate use of resources based on the best available evidence, with feedback loops to continuously improve performance and to tackle upstream causes of ill health and to promote well-being through intersectoral and multisectoral actions" (12). Implementing integrated care for chronic conditions requires a comprehensive systems perspective, addressing practices, education, research, and policy (13). Integrated care protocols have emerged as a powerful tool in improving the health-related quality of life for hemodialysis patients. By addressing the physical, emotional, and social needs of these patients through comprehensive care plans, care coordination, and patient education, healthcare providers can significantly enhance their overall well-being. The successful implementation of integrated care protocols requires commitment, collaboration, and effective communication among various stakeholders in a hemodialysis center. By prioritizing integrated care, healthcare providers can make a positive impact on the lives of hemodialysis patients, enabling them to lead fulfilling and meaningful lives despite their condition. The study aims to determine the effectiveness of integrated care protocol in improving health-related quality of life among patients undergoing hemodialysis.

METHODS AND MATERIALS

Design of The Study:

A randomized controlled trial (RCT) design was used in the current study to assess the effectiveness of integrated care protocol on improving health-related quality of life among patients undergoing hemodialysis.

Ethical Considerations:

The researcher adhered to the National Research Ethics Committee's standards before conducting the study and obtained approval from the relevant government entity to ensure ethical considerations. After explaining the purpose of the study and informing the patients of their right to voluntarily participate and to withdraw at any time, written informed consent was obtained from the participants.

The Setting of The Study:

The study was conducted at Al-Najaf Al-Ashraf Governorate, Al-Najaf Al-Ashraf Health Directorate, Al-Sadder Medical City, and the Specialized Center for Kidney Diseases and Transplantation's Hemodialysis Unit.

Study Sample and Sampling Technique:

A non-probability purposive sample of 70 patients was selected from those who visited the Hemodialysis Unit at the Specialized Center for Kidney Diseases and Transplantation in Al-Najaf Al-Ashraf for the research.

I. Inclusion criteria of study sample:

1. The age range of all participants is between 19 years old and older because the present study is aimed at adult patients, and CKD is more common in adults than young patients.
2. Patients who are undergoing hemodialysis for at least six months, to ensure they have deterioration in quality of life.

II. Exclusion criteria of study sample:

1. Patients with psychiatric disorders or mental health issues were excluded from the study due to their need for individualized assessments and interventions tailored to their mental health conditions.
2. Cancer patients were excluded from the study due to the complexity of their health conditions and their need for specialized treatment plans and follow-up protocols.
3. Individuals who participate in the study have no history of Hepatitis due to their unique healthcare needs and specialized treatment protocols, which differ from those of the study participants.

STUDY INSTRUMENT:

An assessment tool used to evaluate the health-related quality of life among patients undergoing hemodialysis, the tool included 3 parts:

Part I: Patient's Socio-Demographic Characteristics:

It is measured subjectively and includes six variables age, sex, level of education, socioeconomic status (monthly income), and occupational status, did you educate yourself about improving the quality of life with a disease?

Part II: Clinical parameters:

It is measured subjectively and includes 5 items, Body Mass Index (BMI) contains 2 items height and weight, hemodialysis duration, number of hemodialysis scissions during a week, biochemical parameters during the last month, and comorbidities.

Part III: Health-related quality of life:

Short Form Health Survey-36 Items Scale (Version 1.0) is one of the most widely used tools for measuring health-related quality of life. It consists of 36 items, a scale to evaluate the health-related quality of life pre- and post-implementing integrated care protocol. Panel experts (16 experts) within the specialty of Nursing and Medicine were consulted to assess the validity of the tool (face validity), they agreed to the questionnaire, and some suggested some amendments and additions, all of which were taken into consideration. Since the Short Form Health Survey-36 Items scale is global, there is no modification suggested by the experts. Therefore, the reliability of the scale is not estimated.

- **Data Collection:**

The data collection for this study will involve a survey questionnaire administered to 70 hemodialysis patients. The survey questionnaire will contain three parts: demographic-social data, clinical parameters, and a Short Form Health Survey-36 Items scale. All participants will be asked to complete the survey questionnaire to assess the health-related quality of life without any intervention. The present study conducts face-to-face interviews for the instrument of the study this method is considered a **subjective** response from the participants for the demographical characteristics and health-related quality of life while the data of clinical parameters represent an **objective** response. In order the collected data in the interview depends on the opinion of participants, personal experience, and their explanation. The data collection method started from 17th August 2024 to 8th November 2024. Moreover, in the evaluation of health-related quality of life after the application of integrated care protocol for the study group, the researcher applied two evaluation tests (four weeks and eight weeks after the application of protocol) while the patients were closely monitored by the following established guidelines. For the control group, the researcher used a pre-test and two post-test evaluations without the application of integrated care protocol,

and they still receive management routinely. Furthermore, intending to assess the study group's health-related quality of life after the implementation of the integrated care protocol, the researcher administered two evaluation tests (at the fourth and eighth weeks after the protocol's application), the researcher conducted three types of monitoring to reduce of study threats as the following: closely, direct clinical monitoring of the patients during hemodialysis sessions through comprehensive assessment, verbal reports from nursing team who work in hemodialysis unit about adherence monitoring and follow up response of patient or observed for any side effect on their health, and remote monitoring through direct communication with patient via social media. The control group continues to get routine management, and the researcher uses pre-test and two post-test evaluations at the same time without applying the integrated care procedure.

Blinding: the researcher uses the double-blinded technique in the present study, and it's used between the researcher and the patients for the data collection outcomes. Therefore, the participants and the researcher are unaware of the study and control groups. In addition, both the study and the control group were treated equally after it was randomly assigned (administered the data collection instruments and ethical protocol except for the intervention).

Statistical Analysis: After the data are prepared for statical analysis, the descriptive and inferential statistics are employed for data analysis using the Statical Package of the Social Sciences (SPSS), version (26) as follows:

Descriptive statistics:

- Frequency and percentage tables.
- Mean and standard deviation.

Inferential statistics:

- Used Independent sample t-test
- Paired t-test
- One-way analysis of Variance (ANOVA)

Study Limitations:

In this study, the researcher faced a challenge related to the lack of time available to carry out research procedures, which prevented the possibility of applying more than one therapeutic protocol to patients undergoing hemodialysis. As a result, emphasis has been placed on applying only one sponsorship protocol, to ensure accurate implementation and follow-up, and obtain reliable results within the available time frame.

RESULT OF THE STUDY

Table 1: Study Sample Distribution (Experimental and Control Groups) According to their Socio-Demographic Characteristics

Socio-demographic Characteristics		Experimental Group		Control Group	
		F	%	F	%
Age (years)	20 – 29	6	17.1	7	20.0
	30 – 39	5	14.3	2	5.7
	40 – 49	7	20.0	6	17.1
	50 – 59	7	20.0	9	25.7
	60 and more	10	28.6	11	31.4
	Mean ±SD	47.2 ± 4.24		49.11±6.66	
Sex	Male	18	51.4	21	60.0
	Female	17	48.6	14	40.0
Level of Education	Can't Read and Write	10	28.6	2	5.7
	Read and write	7	20.0	11	31.4
	Primary School Graduated	10	28.6	11	31.4

	Intermediate School Graduated		4	11.4	5	14.3
	Secondary School Graduated		3	8.6	6	17.1
	Diploma		1	2.9	0	0.0
Occupational Status Employee	Own worker or self-employed		1	2.9	2	5.7
	Retired		4	11.4	7	20.0
	Housewife		17	48.6	14	40.0
	Disable		13	37.1	12	34.3
Monthly Income	Enough		7	20.0	4	11.4
	Extent to Some Sufficient Enough		8	22.9	12	34.3
	Not enough		20	57.1	19	54.3
Marital Status	Single		4	11.4	7	20.0
	Married		24	68.6	19	54.3
	Divorced		4	11.4	0	0
	Widow		3	8.6	9	25.7
Did You Educate Yourself About Improve Quality of Life Within Disease?	No		10	28.6	9	25.7
	Yes	Social media، Internet Site	3	8.6	1	2.9
		Nurses	2	5.7	2	5.7
		Nurses، Health Provider، Physician	1	2.9	1	2.9
		Nurses، Internet Site	4	11.4	1	2.9
		Nurses، Physician	7	20.0	17	48.6
		Nurses، Physician، Health Provider	2	5.7	1	2.9
		Physician، Nurses،social media، Internet	3	8.6	1	2.9
		Physician	3	8.6	2	5.7

Sociodemographic Characteristics

Table 1 summarizes the sociodemographic characteristics of the study sample, which included 70 participants divided into experimental (n=35) and control groups (n=35).

The mean age of participants in the experimental group is 47.2 years ±4.24, while the control group has a mean age of 49.11 years ±6.66. As well as, sex distribution, males comprised 51.4% of the experimental group and 60.0% of the control group. Furthermore, educational levels varied, with a notable proportion of participants in the experimental group unable to read and write and the primary school graduated 28.6% compared to 31.4% able to read and write and the primary school graduated in the control group. Besides that, occupational status, a significant percentage of participants in both groups were housewives (48.6% in the experimental group and 40.0% in the control group). In addition, the analysis of monthly income revealed that 57.1% of the experimental group reported insufficient income, compared to 54.3% in the control group. Marital status indicated that the majority of participants in both groups were married (68.6% in the experimental group and 54.3% in the control group). Consequently, the patients responded positively to receiving education aimed at improving their health-related quality of life within the context of their disease. The majority of participants acknowledged the importance of education in managing their condition. However, only 20.0% of participants in the experimental group and 48.6% in the control group reported receiving such educational support from nurses and physicians.

Table 2: Study Sample Distribution (Experimental and Control Groups) According to their Clinical Characteristics

Clinical Characteristics			Groups	
			Experimental F (%)	Control F (%)
Body Mass Index		Underweight (≥18.5)	4(11.4)	3(8.6)
		Normal (18.5-24.9)	18(51.4)	20(57.1)
		Overweight (25-29.9)	7(20.0)	10(28.6)
		Obese (≥30)	6(17.1)	2(5.7)
Number of Hemodialysis Scissions During a Week		Twice times	20(57.1)	27(77.1)
		Three times	15(42.9)	8(22.9)
Hemodialysis Duration (years)		<=1	4(11.4)	2(5.7)
		2 – 3	19(54.3)	18(51.4)
		4+	12(34.3)	15(42.9)
Comorbidities	Yes	No	5(14.3)	4(11.4)
		Diabetes mellitus	18(51.4)	15(42.9)
		Diabetes Mellitus, Heart failure	0(0)	2(5.7)
		Diabetes mellitus, Hypertension	9(25.7)	7(20.0)
		Diabetes mellitus, Hypertension, Heart failure	0(0)	2(5.7)
		Diabetes mellitus, Hypertension, Myocardial infarction	1(2.9)	1(2.9)
		Diabetes mellitus, Stroke	1(2.9)	3(8.6)
		Hypertension	1(2.9)	1(2.9)
Total			35(100)	35(100)

Clinical Characteristics

Table 2 presents the clinical characteristics of the participants. The body mass index (BMI) distribution showed that 51.4% of the experimental group was classified as normal weight, while 57.1% of the control group fell into the same category.

The frequency of hemodialysis sessions revealed that a majority of participants in both groups underwent hemodialysis twice a week (57.1% in the experimental group and 77.1% in the control group). The duration of hemodialysis treatment varied, with 54.3% of the experimental group and 51.4% of the control group having undergone treatment for 2-3 years.

In terms of comorbidities, diabetes mellitus was prevalent in 51.4% of the experimental group and 42.9% in the control group. Other comorbidities included hypertension, heart failure, and stroke.

Table 3: Assessment of Experimental Group Participants' Biochemical Parameters with Significant Comparison Due to the Efficacy of the Study Program (n=35)

Biochemical Parameters	Periods of Measurement	Mean	Std. Deviation	F	P-Value
S. Urea	Pre-test	159.34	28.859	0.849	0.431 NS
	Post-test I	154.20	28.297		
	Post-test II	150.29	30.310		
S. Creatinine	Pre-test	9.143	2.6670	0.865	0.424

	Post-test I	9.131	2.4671		NS
	Post-test II	11.726	16.0643		
Calcium	Pre-test	10.926	17.0970	0.471	0.626 NS
	Post-test I	8.711	.9640		
	Post-test II	9.289	.8794		
Potassium	Pre-test	5.909	1.0628	5.675	0.005 S
	Post-test I	5.520	.6880		
	Post-test II	5.249	.6581		
Sodium	Pre-test	140.51	6.021	6.152	0.003 S
	Post-test I	142.71	3.322		
	Post-test II	144.17	3.249		
Phosphorus	Pre-test	5.426	2.2264	1.803	0.170 NS
	Post-test I	4.874	1.7639		
	Post-test II	4.589	1.5733		
Iron Ferritin	Pre-test	78.94	42.415	2.362	0.099 NS
	Post-test I	87.54	32.611		
	Post-test II	96.49	23.640		
Haemoglobin	Pre-test	9.84(2.3)	2.41	4.848	0.010 S
	Post-test I	10.31(1.7)	1.76		
	Post-test II	10.37(1.6)	1.67		

Biochemical Parameters

The biochemical parameters were assessed before and after the intervention in both groups. (Table-3) illustrates the changes in biochemical parameters for the experimental group. The pre-test mean serum urea level was 159.34 mg/dL (±28.859), which decreased to 150.29 mg/dL (±30.310) by the second post-test. This change was not statistically significant (p=0.431).

However, significant changes were observed in potassium levels, which decreased from a pre-test mean of 5.909 (±1.0628) to 5.249 (±0.6581) in the second post-test (p=0.005). Sodium levels also showed a significant increase from 140.51 (±6.021) to 144.17 (±3.249) (p=0.003). Hemoglobin levels improved significantly from a pre-test mean of 9.84 (±2.41) to 10.37 (±1.67) in the second post-test (p=0.010).

Table-4: Assessment Control Group Participants' Biochemical Parameters with Comparison Due to the Efficacy of Study Program (n=35)

Biochemical Parameters	Periods of Measurement	Mean	Std. Deviation	F	p. value
S. Urea	Pre-test	161.80	43.716	4.15	0.018 S
	Post-test I	180.66	37.725		
	Post-test II	189.91	43.053		
S. Creatinine	Pre-test	9.240	2.7830	0.010	0.990 NS
	Post-test I	9.306	2.8357		
	Post-test II	9.331	2.7376		
Calcium	Pre-test	7.426	1.2171	0.242	0.785 NS
	Post-test I	7.266	1.2146		
	Post-test II	7.454	1.2342		
Potassium	Pre-test	5.611	0.7738	0.890	0.414 NS
	Post-test I	5.826	0.7445		
	Post-test II	5.666	0.5573		
Sodium	Pre-test	139.97	6.883	2.660	0.075

	Post-test I	141.60	6.165		NS
	Post-test II	143.31	4.993		
Phosphorus	Pre-test	5.166	1.6588	0.888	0.415 NS
	Post-test I	5.294	1.6638		
	Post-test II	5.657	1.4688		
Iron Ferritin	Pre-test	67.89	41.314	0.950	0.390 NS
	Post-test I	78.40	47.110		
	Post-test II	81.63	42.198		
Haemoglobin	Pre-test	9.971	1.9640	2.112	0.126 NS
	Post-test I	9.046	2.1999		
	Post-test II	9.117	2.1199		

The biochemical parameters were assessed before and after the intervention in both groups. In the control group, as shown in (Table), serum urea levels increased significantly from a pre-test mean of 161.80 (±43.716) to 189.91 (±43.053) by the second post-test (p=0.018). Other parameters, including serum creatinine, calcium, potassium, sodium, phosphorus, iron ferritin, and hemoglobin, did not show significant changes across the testing periods.

Table 5: Experimental Group Responses Relative to Pre-test, Post-test I, and Post-test II According to the Integrated Care Protocol Program (n=35)

Domain of Scale	Period of Measurement	Mean ± SD	f	p. value
Physical Functioning	Pre-test	31.9 ± 17.4	10.468	0.001
	Post-test I	49.8 ± 20.9		
	Post-test II	52.5 ± 21.7		
Role Limitations Due To Physical Health	Pre-test	3.4 ± 13.5	53.456	0.001
	Post-test I	51.4 ± 26.3		
	Post-test II	52.1 ± 25.2		
Role Limitations Due to Emotional Problems	Pre-test	19.4 ± 38.5	76.135	0.001
	Post-test I	89.5 ± 21.0		
	Post-test II	89.5 ± 21.0		
Energy/ Fatigue	Pre-test	40.5 ± 17.0	25.659	0.001
	Post-test I	68.2 ± 18.8		
	Post-test II	67.4 ± 18.9		
Emotional Well-Being	Pre-test	37.7 ± 16.6	22.492	0.001
	Post-test I	58.2 ± 13.2		
	Post-test II	58.2 ± 13.2		
Social Functioning	Pre-test	40.2 ± 24.4	31.787	0.001
	Post-test I	74.6 ± 18.8		
	Post-test II	74.6 ± 18.8		
Pain	Pre-test	34.0 ± 21.9	17.488	0.001
	Post-test I	59.6 ± 23.5		
	Post-test II	62.7 ± 20.9		
General Health	Pre-test	35.8 ± 16.7	17.488	0.001
	Post-test I	65.5 ± 15.8		
	Post-test II	65.5 ± 15.8		
Total	Pre-test	30.3 ±12.6	38.913	0.001
	Post-test I	64.6 ±14.0		
	Post-test II	65.3 ± 13.8		

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The ANOVA results presented in (Tables-5) indicate significant differences in the efficacy of the integrated care protocol between the experimental and control groups. The experimental group exhibited significant improvements across all domains of HRQoL.

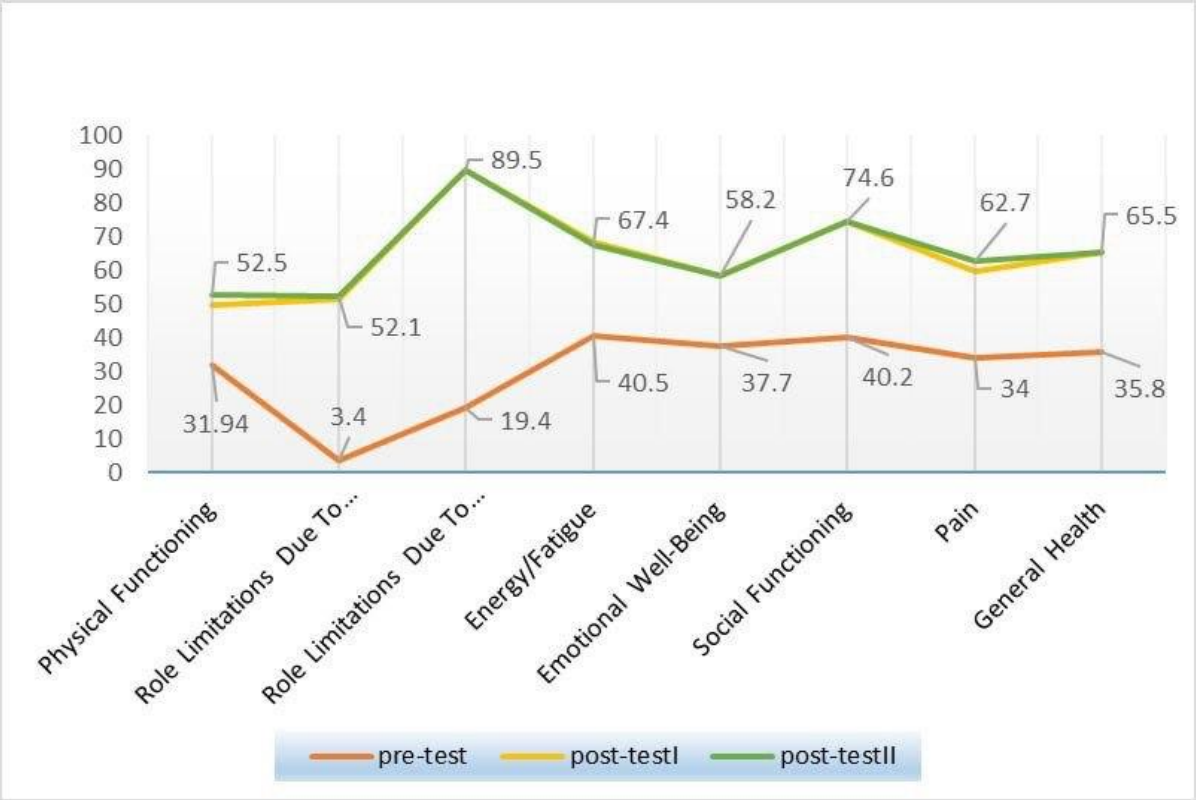

Figure 1: Experimental Group Responses Relative to Pre-test, Post-test I, and Post-test II According to the Integrated Care Protocol Program (n=35).

Table 6: Control Group Responses Relative to Pre-test, Post-test I, and Post-test II According to the Integrated Care Protocol Program (n=35)

Domain of Scale	Period of Measurement	Mean ± SD	F	p. value
Physical Functioning	Pre-test	27.8 ± 23.0	0.258	0.773
	Post-test I	24.8 ± 19.2		
	Post-test II	24.8 ± 19.2		
Role Limitations Due To Physical Health	Pre-test	7.8 ± 19.8	0.684	0.507
	Post-test I	4.2 ± 11.3		
	Post-test II	4.2 ± 11.3		
Role Limitations Due To Emotional Problems	Pre-test	32.3 ± 46.0	0.045	0.956
	Post-test I	35.2 ± 45.6		
	Post-test II	35.2 ± 45.6		
Energy/ Fatigue	Pre-test	32.2 ± 21.1	1.062	0.350
	Post-test I	27.1 ± 15.0		
	Post-test II	27.1 ± 15.0		
Emotional Well-Being	Pre-test	43.6 ± 18.3	0.083	0.920

	Post-test I	42.2 ± 14.5		
	Post-test II	42.4 ± 13.5		
Social Functioning	Pre-test	40.0 ± 24.5	0.020	0.980
	Post-test I	39.2 ± 21.6		
	Post-test II	38.9 ± 21.6		
Pain	Pre-test	32.1 ± 26.0	2.010	0.139
	Post-test I	41.6 ± 22.2		
	Post-test II	41.2 ± 18.1		
General Health	Pre-test	23.2 ± 16.7	3.363	**0.039**
	Post-test I	31.7 ± 15.1		
	Post-test II	31.7 ± 15.1		
Total	Pre-test	29.9 ±16.8	0.038	0.963
	Post-test I	30.8 ± 13.8		
	Post-test II	30.7 ± 13.1		

The ANOVA results presented in (Table 6) indicate significant differences in the efficacy of the integrated care protocol between the experimental and control groups. The control group did not show any significant changes across all domains of HRQoL.

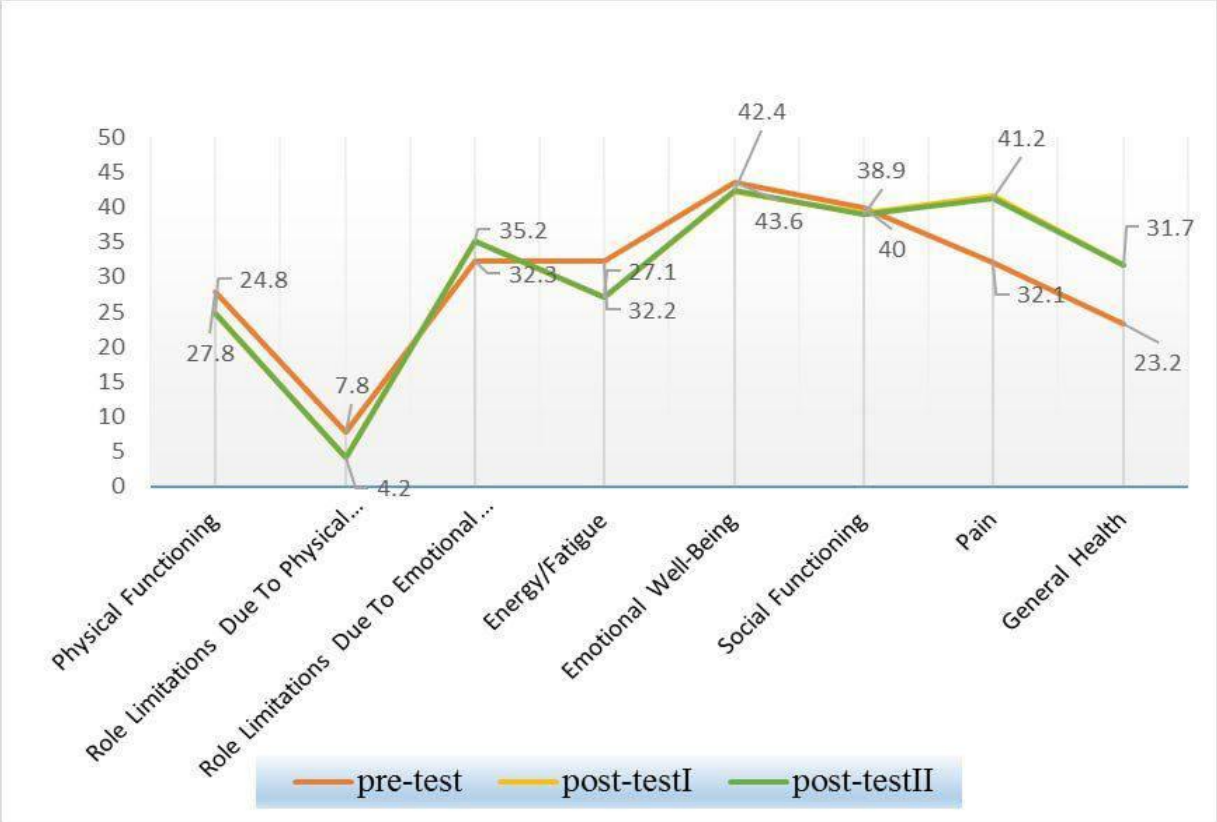

Figure 2: Control Group Responses Relative to Pre-test, Post-test I, and Post-test II According to the Integrated Care Protocol Program (n=35).

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Table-7: Mean Difference (Independent Sample t-Test) Between Experimental and Control Group at Three Periods of Measurements (Pre-Test; Post-Test I; Post-Test II) According to Integrated Care Protocol Program (n=70)

Domain of Scale	Groups	Pre-test Mean ± SD	Independent-Sample t-test d.f=68	Post-test I Mean ± SD	Independent-Sample t-test d.f=68	Post-test II Mean ± SD	Independent-Sample t-test d.f=68
Physical Functioning	Study	31.9 ± 17.4	t. 0.905	49.8 ± 20.9	t 5.201	52.5 ± 21.7	t. 5.824
	Control	27.8 ± 23.0	p.value 0.369	24.8 ± 19.2	p.value **0.001**	24.8 ± 19.2	p.value **0.001**
Role Limitations Due To Physical Health	Study	3.4 ± 13.5	t. 1.048	51.4 ± 26.3	t. 9.713	52.1 ± 25.2	t. 10.237
	Control	7.8 ± 19.8	p.value 0.298	4.2 ± 11.3	p.value **0.001**	4.2 ± 11.3	p.value **0.001**
Role Limitations Due To Emotional Problems	Study	19.4 ± 38.5	t. 1.412	89.5 ± 21.0	t. 6.385	89.5 ± 21.0	t. 6.385
	Control	32.3 ± 46.0	p.value 0.163	35.2 ± 45.6	p.value **0.001**	35.2 ± 45.6	p.value **0.001**
Energy/ Fatigue	Study	40.5 ± 17.0	t. 1.791	68.2 ± 18.8	t. 10.083	67.4 ± 18.9	t. 10.100
	Control	32.2 ± 21.1	p.value 0.078	27.1 ± 15.0	p.value **0.001**	27.1 ± 13.5	p.value **0.001**
Emotional Well-Being	Study	37.7 ± 16.6	t. 1.309	58.2 ± 13.2	t. 4.815	58.2 ± 13.2	t. 4.947
	Control	43.6 ± 18.3	p.value 0.195	42.2 ± 14.5	p.value **0.001**	42.4 ± 14.5	p.value **0.001**
Social Functioning	Study	40.2 ± 24.4	t. 0.000	74.6 ± 18.8	t. 7.288	74.6 ± 18.8	t. 7.377
	Control	40.0 ± 24.5	p.value 1.000	39.2 ± 21.6	p.value **0.001**	39.9 ± 21.6	p.value **0.001**
Pain	Study	34.0 ± 21.9	t. 0.333	59.6 ± 23.5	t. 3.285	62.7 ± 20.9	t. 4.611
	Control	32.1 ± 26.0	p.value 0.740	41.6 ± 22.2	p.value **0.002**	41.2 ± 18.1	p.value **0.001**
General Health	Study	35.8 ± 16.7	t. 3.116	65.5 ± 15.8	t. 9.124	65.5 ± 15.8	t. 9.124
	Control	23.2 ± 16.7	p.value 0.003	31.7 ± 15.1	p.value **0.001**	31.7 ± 15.1	p.value **0.001**
Total	Study	30.3 ±12.6	t. 0.111	64.6 ±14.0	t. 10.162	65.3 ± 13.8	t. 10.74
	Control	29.9 ±16.8	p.value 0.912	30.8 ± 13.8	p.value **0.001**	30.7 ± 13.1	p.value **0.001**

DISCUSSION

The analysis of the mean age of patients undergoing hemodialysis in both the experimental and control groups reveals that the majority of participants belong to the older adult category. This finding aligns with the mean age of participants was an individual aged fifty years, in the study conducted by (14). This indicates that chronic kidney disease and end-stage renal disease are more prevalent among older populations due to the cumulative effects of aging-related comorbidities such as hypertension, diabetes, and cardiovascular diseases. The predominance of male participants in the experimental group and the control group. This agrees with (15) concerning participants' sex more than half of the study group were males more than half could be due to the higher prevalence of the disease among males or differences in healthcare-seeking behavior between genders. Some diseases have a higher prevalence in men due to

biological, lifestyle, or occupational factors (e.g., cardiovascular diseases, lung diseases due to smoking, or workplace exposures). Moreover, in certain cultures, men may be more likely to participate in clinical trials, while women might be underrepresented due to caregiving roles, cultural restrictions, or lower healthcare access. It is notable that a significant portion of participants in both groups had low educational attainment and reported insufficient monthly income, which may impact their overall health literacy and access to healthcare resources. This parallels with previous research indicating that lower socioeconomic status is associated with poorer health outcomes among patients with chronic illnesses. The study conducted by (8) also presents that the majority of the sample are illiterates and primary school graduates. The low education levels in Iraq, with many being either illiterate or only primary school graduates, can be attributed to several factors. Economic hardships force children into labor instead of schooling, while ongoing security issues and past conflicts have damaged infrastructure and displaced families. Additionally, overcrowded schools, limited resources, and weak enforcement of education laws contribute to high dropout rates. Social and cultural factors, such as early marriage and a lack of emphasis on education in some communities, further exacerbate the issue. Lastly, internal displacement and migration have disrupted access to stable education for many children. The housewives-occupied status has the majority participation in both the experimental and control groups in the present study and this is compatible with another study conducted in Iraq by (7) in which a higher percentage of participants in the study are housewives. The reason most participants in the study were housewives can be attributed to social and cultural factors that reinforce traditional gender roles in Iraqi society, where women's primary responsibilities are often seen as family care and child-rearing. Additionally, limited employment opportunities for women contribute to their exclusion from the formal labor market. Economic and educational factors also play a role, as some women may not have completed their education or had the opportunity to enter the workforce due to societal norms or a lack of suitable job opportunities. May indicate a study population with a significant proportion of individuals who are not formally employed. This could reflect cultural or social norms in the study setting, where a considerable number of women might not participate in the workforce. Housewives often rely on their spouse's income, which may impact healthcare access and affordability. This could contribute to financial difficulties in both groups. Both group participants (experimental and control) share a low economic situation. This economic situation coincides with a study conducted in Dhi-Qar governorate, Iraq, where participants were found to have poor economic status (16). The main causes of poverty in Iraq include political instability and security challenges, which have hindered economic growth and development. Additionally, heavy reliance on oil revenues makes the economy vulnerable to price fluctuations, leading to financial crises. High unemployment rates and a lack of economic diversification limit job opportunities, especially for youth and rural populations. Moreover, weak infrastructure and poor public services further deepen social inequalities and hinder progress. This suggests that financial constraints might be a common issue among the study population, potentially affecting access to healthcare, medication adherence, and overall quality of life. Limited financial resources may also contribute to poor health outcomes and reduced healthcare-seeking behaviors. Since most participants are over 60 years old, they are more likely to be married compared to younger individuals. This corresponds with ((17). More than half percent of the total sample were married. Married individuals may be more likely to participate in an RCT because they have spousal support for making healthcare decisions and attending study visits. In many cultures, marriage is a dominant social institution. In addition, married individuals might seek healthcare more frequently, leading to a higher likelihood of being included in studies. The highest percentage of participants received education from nurses and physicians. This is analogous to (18) governments in several countries have undertaken measures to improve health services by enhancing the quality of nursing education. Tele-nursing is one of the methods that rely on information technology Patient education and follow-up care play a key role in rehabilitation after hospital discharge (19). Suggests gaps in the healthcare system, such as time constraints on healthcare professionals, lack of structured patient education programs, resource limitations in hospitals or clinics, and reliance on informal sources of health information.

Part Two: Discussion of Patient's Clinical Characteristics Related to Patients with ESKD and Undergoing Hemodialysis:

The results in four chapters present the clinical characteristics of the participants. The body mass index distribution showed that half of the sample for both (experimental and control) groups are classified as normal weight category, conforming with (20) in which both (interventional and non-interventional groups) fell into the same category. The researcher suggests that caused by malnutrition or loss of appetite due to the accumulation of toxins in the body, resulting in their weight falling within or even below normal weight, or the effect of hemodialysis sessions themselves because dialysis removes excess fluid from the body which can make the apparent weight after the session closer to normal weight.The frequency of hemodialysis sessions revealed that a majority of participants in both groups (the experimental group and the control group) underwent hemodialysis twice a week. The result was equivalent to the study conducted (15) the majority of the study sample had two hemodialysis sessions weekly. Because of the financial burdens associated with transportation, medicines, geographical location, and after the bloody center of hemodialysis from their place of residence, they are forced to reduce the number of sessions as well as lack of health awareness as they believe that two sessions are sufficient to filter the blood appropriately. The disease duration from 2-3 years is the highest percentage for both the experimental group and control group having undergone hemodialysis treatment. This duration resembles a study conducted by (21). The high proportion of patients within a 2–3-year dialysis period has been explained by several factors, including high mortality and health complications after several years, reducing the number of patients continuing to dialysis for longer periods, as well as increased diagnosis of recent renal failure due to the spread of chronic diseases. Some patients also turn to kidney transplants after a while, reducing the numbers of over 3 years in hemodialysis. Also, the sample composition in the study may have influenced this result, as new patients are more represented in medical centers. In terms of comorbidities, diabetes mellitus is prevalent in half the proportion of the experimental group and the control group. Other comorbidities included hypertension, heart failure, and stroke. (22) Indicate the clinical characteristics of the participants also highlighted the prevalence of comorbidities such as diabetes and hypertension, which are known to complicate the management of patients undergoing hemodialysis. Diabetes mellitus is a common comorbidities of hemodialysis patients due to its negative effect on kidney function, causing diabetic nephropathy that leads to deterioration of kidney function. Hypertension associated with diabetes accelerates kidney deterioration and increases the need for dialysis. In addition, weakened immune systems in diabetics contribute to an increased risk of infection and complications affecting the kidneys. These combined factors make diabetes more common among bloody enforcement patients.

Part Three: Discussion of Patients' Biochemical Parameters:

The biochemical parameters are assessed before and after the intervention in both groups and illustrate the changes in biochemical parameters for the experimental group. The mean of the pre-test for serum potassium and Sodium levels decreased by the second post-test. This change is statistically significant. This uniform with (23), carrying out a nutritional education program and found a significant decrease in both potassium and sodium values obtained before and after dialysis. Hemoglobin levels improved significantly from a pre-test mean in the second post-test. (24) showed a significant increase in hemoglobin levels. In the control group, serum urea levels increased significantly from a pre-test mean to the second post-test. Based on the results of the study, it can be justified that the Integrated Care Protocol did not include the administration of new drugs, but focused mainly on adherence to prescribed drugs by physicians. This commitment is an essential part of improving the balance of potassium, sodium, and hemoglobin levels in hemodialysis patients. In addition, the Protocol ensures that patients are directed towards a balanced diet that helps reduce the consumption of potassium and sodium-rich foods, thereby contributing to reduced retention and improved blood levels. By improving adherence to pharmacotherapy and diet regulation, better stability can be achieved in equilibrium and reduce the risks associated with their disorders, enhancing the stability of the general health status of patients and reducing complications resulting from electrolyte imbalances.

Part Four: Discussion of the Effectiveness of Integrated Care Protocol on Improving Health-Related Quality of Life for Patients Undergoing Hemodialysis:

The findings indicated that the experimental group experienced significant improvements in HRQoL across several domains, including physical functioning, role limitations due to physical health, emotional well-being, energy/fatigue, social functioning, pain, and general health.

According to the HRQoL Section Physical Functioning:

The study results indicate a notable improvement in physical functioning within the experimental group over time and based on the statistical means. At baseline, participants exhibited lower levels of physical functioning. However, following the intervention, there was a marked enhancement, which became more evident by the second post-test. This progression suggests that the intervention had a positive impact on the participants' physical capabilities, reflecting a significant improvement in their functional status. This finding is mutually consistent with the work of (25), who emphasized the role of structured interventions in promoting physical activity and mobility among hemodialysis patients. The improvements in physical functioning may be attributed to the comprehensive nature of the integrated care protocol, which likely included tailored exercise regimens, nutritional counseling, and psychosocial support.Additionally, (26) the study concluded that the participating patients had moderate to severe muscle cramps during the hemodialysis procedure. After the application of the stretching exercise program throughout the present study, a significant improvement in the level of muscle cramps has been reported; therefore, the intradialytic stretching exercise is a simple and efficient technique for reducing and preventing muscle cramps among patients undergoing hemodialysis.

Following the HRQoL Section Role Limitations Due to Physical Health:

As previously mentioned in Physical Functioning, the implementation of the integrated care protocol led to a substantial reduction in role limitations associated with physical health. Initially, participants experienced significant restrictions in their ability to perform daily activities due to physical health concerns. However, following the intervention, there was a considerable improvement, indicating that the protocol effectively enhanced their capacity to engage in routine tasks. This positive change suggests that the integrated approach played a crucial role in mitigating physical health-related limitations, contributing to overall functional well-being. This finding suggests that the protocol effectively addressed barriers to participation in daily activities, reinforcing the notion that integrated care can enhance functional independence among hemodialysis patients (27).

Based on the HRQoL Section Role Limitations Due to Emotional Problems:

A significant enhancement in emotional well-being was observed following the implementation of the integrated care protocol. Initially, participants reported lower levels of emotional well-being, indicating the presence of psychological distress. However, after the intervention, there was a marked improvement, suggesting that the protocol was effective in addressing the psychological dimensions of patient care. This positive shift highlights the intervention's role in promoting emotional resilience and overall mental health, reinforcing the importance of comprehensive care strategies in improving patients' well-being. This finding is particularly significant given the high prevalence of depression and anxiety among individuals undergoing hemodialysis (28).

As per the HRQoL Section Energy/Fatigue:

The findings also reveal a significant reduction in fatigue levels following the intervention, emphasizing the effectiveness of a holistic care approach. Initially, participants experienced considerable fatigue, which may have affected their daily functioning and overall quality of life. However, after the implementation of the protocol, there was a noticeable improvement, highlighting the impact of addressing both physical and emotional aspects of health. This improvement underscores the necessity of comprehensive care strategies that integrate multiple dimensions of well-being to enhance patient outcomes. Exercise interventions have shown promising effects in reducing fatigue and improving energy levels in adult hemodialysis patients. Intradialytic exercise, particularly aerobic exercise, has been found to significantly decrease fatigue levels. Additionally, intradialytic aerobic exercise improved dialysis parameters, including blood urea and creatinine levels (29). A systematic review with meta-analysis revealed moderate effects of

exercise interventions on functional capacity and oxygen consumption. Combined aerobic and resistance training demonstrated numerically larger effect sizes compared to either type alone, although the differences were not statistically significant (30). These findings suggest that exercise interventions, especially when combined and sustained over time, can effectively reduce fatigue in hemodialysis patients.

As stated by the HRQoL Section Emotional Well-Being: The study intervention resulted in a significant increase in the measurement levels of the mean (pre-test, post-test I, post-test II) in emotional well-being, indicating a positive impact on the psychological state of the participants. This is similar to (31) The use of interventions intended to promote psycho-emotional well-being and inner strength enables patients to improve coping strategies and resilience when facing adversities, so they find new ways to deal with challenging experiences. The provision of psychosocial support or an improved ability to deal with daily stresses and challenges may be the reason for this improvement. The continued improvement after a period of intervention reflects the sustainability of the impact, meaning that it was not just a temporary change. Raising awareness of the importance of mental health is also likely to play a role in this improvement. This change is statistically significant, it enhances the effectiveness of the study intervention used.

According to the findings of the HRQoL Section Social Functioning: The study intervention resulted in a significant increase in social functioning in health-related quality of life for hemodialysis patients. This is compatible with (32) that perceived social support is associated with a better quality of life in hemodialysis patients. Higher self-efficacy and better social support are independently associated with higher health-related quality of life in hemodialysis patients over time (33) The educational program resulted in a significant increase in social functioning, role-physical, role-emotional, and general health dimensions of health-related quality of life for hemodialysis patients (34).

According to the HRQoL Section Pain: A recent study has demonstrated the positive impact of interventions on pain reduction and quality of life improvement in hemodialysis patients. Additionally, the significant reduction in perceived pain levels, with scores rising from baseline to more than half of the percentage, highlights the integrated care protocol's potential to alleviate discomfort and enhance patients' overall quality of life. This result aligns with a study conducted by (31), which approved intradialytic aerobic exercise program improved frailty, dialysis adequacy, and quality of life in hemodialysis patients. Moreover, intradialytic exercise significantly reduces perceived pain levels and improves HRQoL in hemodialysis patients (35).

According to the HRQoL' Section General Health:

The general health score also exhibited a significant increase, indicating that the integrated care protocol positively influenced patients' perceptions of their overall health status. Similar to the study by (36) research on comprehensive care for chronic conditions highlights its importance in improving health perceptions and outcomes. Studies have identified clusters of illness representations among patients, with some clusters associated with more favorable health outcomes.

Part Five: Discussion of Responses Relative to Pre-test, Post-test I, and Post-test II According to the Integrated Care Protocol Program: The ANOVA results presented indicate significant differences in the efficacy of the integrated care protocol between the experimental and control groups. The experimental group exhibited significant improvements across all domains of HRQoL. Recent studies have demonstrated the positive impact of integrated care protocols on hemodialysis patients' health-related quality of life (HRQoL) and mental health. An integrated self-management program using mobile applications and face-to-face counseling significantly improved self-efficacy and treatment compliance in hemodialysis patients (37). Similarly, a cognitive behavioral intervention combined with a resilience model effectively reduced depression and anxiety symptoms while enhancing quality of life (38). Pharmaceutical care provided by trained pharmacists also showed significant improvements in various HRQoL domains among hemodialysis patients (39). Additionally, a 12-week intradialytic exercise program proved safe and effective in improving HRQoL and reducing depression status without negatively affecting dialytic parameters (40). These findings collectively suggest that integrated care

approaches, including self-management programs, psychological interventions, pharmaceutical care, and exercise regimens, can significantly enhance the overall well-being of hemodialysis patients.

CONCLUSION, RECOMMENDATIONS, AND NURSING IMPLICATIONS

The findings of this study suggest that integrated care protocol enhanced the health-related quality of life of patients receiving hemodialysis, particularly in the physical, social, and emotional dimensions. Statistically significant improvement in these areas was observed in the intervention group compared to the control group. It is recommended that the proposed nursing program be adopted as part of the standard nursing care protocols for hemodialysis patients within Ministry of Health institutions, given its proven effectiveness in enhancing multiple dimensions of quality of life. Future research should also investigate other dimensions of care burden, such as the spiritual dimension. The findings of this study highlight the pivotal role of nurses in enhancing the quality of life for patients undergoing hemodialysis through structured educational and supportive programs. Implementing such nursing interventions within dialysis units can empower patients with knowledge, coping strategies, and self-management skills, ultimately leading to better health outcomes.

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