



The collaborative care model on treatment adherence in patients with chronic kidney failure undergoing hemodialysis: A Randomized clinical trial

Ali, Hassanpour Dehkordi¹, Khodakarm Rahimi², Shahriyar Salehitali^{3*}

¹full professor, School of nursing &midwifery, Community-oriented Nursing Midwifery Research Center, Shahrekord University of Medical Sciences, Shahrekord, Iran

²lecturer, School of nursing &midwifery, Community-oriented Nursing Midwifery Research Center, Shahrekord University of Medical Sciences, Shahrekord, Iran

³Salehitali, Shahriyar, Associate Professor, School of nursing &midwifery, Community-oriented Nursing Midwifery Research Center, Shahrekord University of Medical Sciences, Shahrekord, Iran

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ABSTRACT

Introduction: For individuals with chronic kidney disease requiring hemodialysis, consistent attendance at dialysis sessions, adherence to dietary recommendations, compliance with prescribed medications, and regulation of fluid intake are crucial. These practices not only help manage the illness but also contribute to better health outcomes and improved quality of life. This study investigated the impact of a collaborative care model on treatment adherence among patients with chronic kidney failure undergoing hemodialysis.

Materials and Methods: A randomized clinical trial carried out at Shohada Lordegan Hospital between 2020 and 2021. Sixty-six patients receiving hemodialysis randomly assigned to either an intervention or a control group. The intervention group participated in eight structured educational sessions based on the four-step collaborative care framework motivation, preparation, engagement, and evaluation. Participants monitored for three months following the program. Data were collected using a demographic questionnaire and a treatment adherence scale tailored for hemodialysis patients, administered both before and three months after the intervention. Statistical analysis conducted with SPSS version 22, applying descriptive measures along with Fisher's exact test, independent t-test, and paired t-test.

Results: After three months, the intervention group demonstrated a significant improvement in overall adherence scores and in all four specific domains dialysis attendance, medication compliance, fluid restriction, and dietary adherence compared to both their baseline results and the control group ($P < 0.001$).

Conclusion: Findings suggest that educational programs grounded in collaborative care principles can substantially enhance adherence to treatment regimens. Incorporating this model into nursing practice prioritized, particularly for patients undergoing hemodialysis.

Introduction

Chronic kidney failure represents a major global health challenge, affecting millions of individuals worldwide. Current estimates suggest that approximately 850 million people suffer from

kidney-related disorders, accounting for nearly 10% of the global population.

In the United States, about 15% of adults impacted by chronic kidney disease (CKD) [1-3]. In Iran, more than 4,000 new cases of chronic kidney failure

*Corresponding Author: **Shahriyar Salehitali** (sh_salehitali@yahoo.com - ORCID: 0000-0001-5385-4024)

1 Email: alihassanpouredekordi@gmail.com - ORCID: 0000-0003-4285-8497)

2 Email: karamrahimi95@gmail.com - ORCID: 0000-0002-3114-3122)

reported annually. Although the incidence and prevalence of CKD in Iran have risen considerably in recent years, they remain lower compared to many Western countries [4].

Patients undergoing hemodialysis due to end-stage renal disease (ESRD) face a wide range of physical and psychological complications, including hypotension, muscle cramps, nausea, vomiting, headaches, chest pain, pruritus, fever, and chills [5]. Effective management of ESRD relies on four critical therapeutic dimensions: restriction of fluid intake, adherence to dietary guidelines (such as reduced sodium, potassium, and phosphorus), compliance with prescribed medications, and consistent participation in dialysis sessions. Together, these behaviors form the foundation of adherence in hemodialysis patients [6].

One of the most pressing challenges in this population is poor adherence to treatment regimens [7]. Adherence plays a pivotal role in maintaining health and improving quality of life [8]. Even the most advanced therapeutic strategies fail if patients do not comply, leading to disease progression, complications, and frequent hospitalizations [9]. Non-adherence is particularly common in dietary management, with studies reporting that between 25% and 86% of patients fail to follow prescribed diets [10]. Similarly, nearly half of patients do not comply with fluid restrictions, and 44% neglect dietary recommendations [11]. Such behaviors often result in additional diagnostic procedures, modifications in treatment plans, dosage adjustments, hospital admissions, and increased healthcare expenditures [12].

To address these challenges, nursing models have increasingly utilized to strengthen patient care. These models provide structured frameworks that enhance the effectiveness of interventions. Among them, the Collaborative Care Model developed and evaluated by Mohammadi and colleagues has gained prominence. This model structured around four stages: Motivation, Preparation, Engagement, and Evaluation [13]. Central to the model is the quality of the patient provider relationship, which emphasizes shared responsibility and collaboration rather than unilateral patient compliance [14].

The use of culturally sensitive care models is also vital in improving patient outcomes [15]. Such approaches foster better communication between patients and nurses, thereby enhancing the overall quality of care [16]. In line with the 2009 guidelines issued by the U.S. Centers for Medicare & Medicaid Services, dialysis patients recognized as active members of the healthcare team and are encouraged to participate in self-care. This perspective shifts the focus from traditional notions of “compliance” and “adherence” toward a broader concept of “self-care,” marking a paradigm shift in dialysis management [17].

Aim of the Study: The present study seeks to examine the effectiveness of educational interventions based on the Collaborative Care Model in improving treatment adherence among patients with chronic kidney disease undergoing hemodialysis.

Methods

Study Design and Setting

This randomized clinical trial registered in the Iranian Clinical Trial Registry (IRCT20190303042900N2) and received ethical approval from Shahrekord University of Medical Sciences (Ethics Code: IR. SKMUS.1397.255).

Sample Size and Sampling Method

Based on the data from the Shirazi et al., study on the title effectiveness of psychological rehabilitation, using Dohsa-Hou, on hemodialysis patients' depression, anxiety, stress in Zahdan city, which found a mean stress score difference of 4 and standard deviations of 3 in both groups, and with type I and type II error rates set at 0.01 and 0.05, respectively, the minimum required sample size for each group was calculated as 30 participants [18]. Using the following formula.

$$\frac{(1.96 \pm 1.28)^2 (1.28^2 \pm 1.45^2)}{(10.68 - 9.59)^2} = 33.05.$$

To account for an anticipated 20% dropout rate, five additional participants were included in each group, resulting in a final sample size of 35 per group. Eligible patients undergoing hemodialysis at Shohadaye Lord Egan Hospital, affiliated with Shahrekord University of Medical Sciences (the principal investigator's workplace and research site), were recruited according to the study's inclusion criteria. Participants randomly allocated to either the intervention or the control group using a card-based system. A total of 70 cards were prepared: 35 red cards representing the intervention group (assigned to even-numbered dialysis days) and 35 yellow cards representing the control group (assigned to odd-numbered dialysis days). All cards placed in a container, and each participant drew one at random. The color of the card determined group assignment, and the process continued until all cards had distributed.

Inclusion and Exclusion Criteria

Inclusion Criteria: Participants were required to provide informed and written consent for study participation. They must have undergone at least six months of dialysis with a confirmed final diagnosis and received hemodialysis treatment two to three times per week. Eligible patients were between 18 and 70 years old and did not suffer from advanced underlying conditions such as respiratory failure or malignancy. Additionally, they expected to remain in their service location throughout the educational

intervention and follow-up period without plans to relocate.

Exclusion Criteria: Patients excluded from the study if they withdrew from attending sessions during the study period, expressed unwillingness to continue participation, underwent kidney transplantation, or passed away.

Data Collection

Data gathered using two instruments: a demographic questionnaire and the End-Stage Renal Disease Adherence Questionnaire (ESRD-AQ).

Demographic Questionnaire: This tool captured participant characteristics such as age, gender, marital status, educational background, duration of illness, length of hemodialysis treatment, weekly dialysis frequency, and history of formal education.

ESRD-AQ: Developed by Kim (2009), this self-report measure evaluates adherence behaviors in patients with end-stage renal disease. It contains 46 items across five domains:

- ✓ General Information (5 items)
- ✓ Acceptance of Hemodialysis Treatment (14 items)
- ✓ Acceptance of Medication Treatment (9 items)
- ✓ Fluid Restriction Compliance (10 items)
- ✓ Dietary Adherence (8 items)

The overall adherence score is calculated by summing responses across these domains, ranging from 0 to 1200. Reliability and validity were established through content validation and test-retest methods, yielding a Cronbach's alpha of 0.98 and a correlation coefficient of $r=0.850$. Higher scores reflect stronger adherence. According to Kim's classification, scores within ± 1 SD of the mean indicate moderate adherence, values below -1 SD represent poor adherence, and scores above $+1$ SD denote good adherence [19-20].

Intervention

After obtaining approval from Shahrekord University of Medical Sciences and relevant authorities, the researcher initiated the study. Participants first completed the demographic and adherence questionnaires. The experimental group then received an educational program based on the collaborative care model, delivered in four phases: motivation, preparation, engagement, and evaluation over eight sessions, followed by a three-month follow-up.

Motivation Phase

In week one, a 60-minute session held to assess patient needs and enhance motivation. Results of the preliminary evaluation shared and discussed with participants.

Preparation Phase

During week two, care planning tailored to meet the specific needs of each patient. Participants organized into subgroups of 8-10 individuals, with each subgroup attending a one-hour session scheduled in coordination with their availability.

Engagement Phase

This stage included both educational and follow-up activities:

Educational sessions: Three 60-minute meetings in one week covered disease characteristics, treatment options, complications, and adherence factors. Each session emphasized practical strategies and interactive discussions.

Follow-up sessions: Conducted in weeks seven and eight, these 30-minute meetings reviewed patient progress, challenges, and prior learning. The research and treatment teams jointly provided feedback and guidance.

Educational content delivered in clear, accessible language, primarily through lectures. Participants also received supplementary materials such as booklets and pamphlets.

Evaluation Phase

At the end of the three months, the adherence questionnaire re-administered to both groups to assess intervention effectiveness. Sessions held in the hospital's dialysis unit and training facilities. To prevent cross-group influence, dialysis schedules separated: the intervention group attended on even-numbered days, while the control group scheduled on odd-numbered days.

Data Analysis

Data analysis employed both descriptive and inferential statistics. Means and standard deviations were calculated, while independent t-tests, paired t-tests, and Fisher's exact tests were used for comparisons. Statistical significance was set at $p<0.05$.

Results

The intervention group had a mean age of 55.15 ± 9.06 years, while the control group averaged 57.09 ± 14.35 years. The mean duration of hemodialysis was 5.73 ± 2.11 years in the intervention group compared with 4.06 ± 1.93 years in the control group. Likewise, the average length of illness was 5.82 ± 2.17 years for participants in the intervention group and 4.18 ± 1.94 years for those in the control group. Results from independent samples t-tests indicated that these differences in age, dialysis duration, and disease duration were not statistically significant (see Table 1)

Table 1. Mean and Standard Deviation of Age, Duration of Hemodialysis Treatment, and Duration of Disease in the Intervention and Control Groups

Variable	Group s		In a dependent t-test
	control	Intervention	
	Mean ± SD	Mean ± SD	
Age (years)	57.09 ± 14.35	55/15±9/06	p < 0.157
Duration of Hemodialysis Treatment	4.06 ± 1.93	5.73 ± 2.11	p < 0.143
Duration of Disease (years)	4.18 ± 1.94	5.82 ± 2.169	p < 0.153

In the control group, 60.6% of participants were male, compared with 54.5% in the intervention group. Educational attainment was generally low, with 94% of the control group and 78.8% of the intervention group lacking a high school diploma. Marital status showed little variation between groups: 72.7% of the control group and 75.8% of the intervention group were married. Hemodialysis frequency was slightly higher in the intervention

group, where 69.7% received treatment three times per week, compared with 57.6% in the control

group. Formal training history was absent in 87.9% of the control group and 78.8% of the intervention group. Fisher's exact tests confirmed that none of these differences gender, education, marital status, or training history were statistically significant (Table 2)

Table 2. Demographic characteristics of research units

Variable		Control group		Intervention group		p-value
		Percentage	count	Percentage	count	
Sex	male	60.6	20	54.5	18	8.0/p>*
	Female	39.4	13	45.5	15	
Education level	Below Diploma	94	31	78.8	26	p> /329*
	Diploma	3	1	15.2	5	
	University	3	1	6.1	2	
Marital Status	Single	24.2	8	15.2	5	p> /337*
	Married	72.7	24	75.8	25	
	Divorce	3	1	9.1	3	
Hemodialysis Sessions per Week	Twice	42.4	14	30.3	10	p> /337*
	Three time	57.6	19	69.7	23	
Previous Formal Training	Trained	12.1	4	21.2	7	p> /124*
	Non Trained	87.9	29	78.8	26	
Total		100	33	100	33	

*Fisher's exact test
The findings revealed significant improvements in the intervention group across multiple domains,

including adherence to hemodialysis sessions, medication compliance, fluid restriction, dietary adherence, and overall treatment adherence. These

changes, observed before and after the intervention, highlight the effectiveness of the educational program. In contrast, the control group showed no

statistically significant differences in any of these areas (Table 3).

Table 3. "Comparison of Mean and Standard Deviation of treatment Adherence Dimensions Before vs. After Intervention in Each Research Group

Treatment Adherence Domain	Case group		Control group	
	Before Intervention	After Intervention	Before Intervention	After Intervention
Hemodialysis Adherence	456.81 ± 129.64	523.48 ± 68.73	500.00 ± 99.41	487.88 ± 89.48
Paired t-test	P< 0.003		P> 0.3	
Medication Adherence	139.39 ± 34.82	180.30 ± 24.81	128.79 ± 35.42	136.36 ± 31.31
Paired t-test	P < 0.001		P> 0.12	
Fluid Restriction Adherence	137.88 ± 37.56	150.00 ± 30.62	109.09 ± 38.43	101.52 ± 26.47
Paired t-test	P< 0.01		P> 0.22	
Dietary Regimen Adherence	107.58 ± 37.75	125.76 ± 33.36	109.09 ± 38.43	103.03 ± 27.78
Paired t-test	P<0.01		P>0.24	
Total Treatment Adherence Score	840.15 ± 175.32	975.00 ± 102.88	866.67 ± 115.18	768.79 ± 111.07
Paired t-test	P < 0.001		P> 0.2	

Before the intervention, no significant differences were observed between the intervention and control groups across any adherence domains, including hemodialysis compliance, medication adherence, fluid restriction, dietary adherence, or the overall

adherence score. Following the intervention, however, statistically significant improvements emerged in the intervention group, with higher scores recorded in the overall adherence measure as well as in each individual domain (Table 4).

Table 4. Comparison of the mean and standard deviation of the scores for dimensions of treatment adherence and the total treatment adherence score in the intervention group compared to the control group before and after the intervention.

Adherence domination	Stage	(Control) Mean ± SD	(Intervention) Mean ± SD	P-value *
Hemodialysis Adherence	Before	500.00 ± 99.41	456.81 ± 129.64	0.134*
	After	427.88 ± 89.487	523.48 ± 68.733	0.01*
Medication Adherence	Before	128.79 ± 35.422	139.39 ± 34.816	0.224
	After	136.36 ± 31.307	180.30 ± 24.810	0.001
Fluid Restriction Adherence	Before	125.76 ± 41.686	137.88 ± 37.563	0.219
	After	101.52 ± 26.472	150.00 ± 30.619	0.01
Dietary Adherence	Before	109.09 ± 38.435	107.58 ± 37.752	0.872
	After	103.03 ± 27.781	125.76 ± 33.357	0.004
Total Treatment Adherence Score	Before	866.67 ± 115.18	840.15 ± 175.32	0.470
	After	768.79 ± 111.067	975.00 ± 102.88	0.001

Discussion

The present study demonstrates that educational interventions grounded in a participatory care model effectively improved all dimensions of treatment adherence among patients undergoing hemodialysis. These interventions significantly enhanced adherence levels, underscoring their importance in patient care strategies.

The findings are consistent with prior research. For example, Tayebi et al. reported that the follow-up care model improved adherence to dietary restrictions, fluid management, dialysis attendance, and medication compliance, establishing a strong link between follow-up care and treatment adherence [21]. Similarly, Mahmoudi et al. found that although adherence levels initially differed between groups, individualized multi-stage care led to significant improvements in the intervention group compared with controls by the end of their trial [22].

Other studies also support the effectiveness of participatory and model-based interventions. Lashkari et al. showed that the participatory care model reduced fatigue severity in hemodialysis patients ($p=0.036$) [23]. Özdemir and Unsar, applying the Roy Adaptation Model, demonstrated improvements in fluid control, symptom management, and quality of life, recommending systematic use of this approach by hemodialysis nurses [24]. Likewise, Arad et al. (2021) found that patient education combined with nurse-led telephone follow-up enhanced adherence across four domains: dialysis attendance, medication use, fluid restriction, and dietary compliance [25].

The results of the current study confirm these findings, highlighting that participatory care not only improves adherence but also positively influences patient outcomes such as fatigue. Collectively, these studies suggest that nurse-led, model-based interventions can play a vital role in improving the health of patients with chronic kidney disease, with adherence serving as a key determinant of overall well-being.

Kana et al. (2018) further emphasized the importance of patient knowledge in adherence, noting higher knowledge levels and lower non-adherence rates in Japan compared with the U.S. However, the unexpected finding of 100% adherence in Japan limited cross-country comparisons, pointing to the need for further investigation into cultural and systemic factors influencing adherence [26]. While the present study acknowledges that education and knowledge alone cannot fully explain adherence behaviors, it reinforces that nursing care models provide a holistic framework. These models extend beyond knowledge transfer, integrating motivation, support, and patient engagement to foster sustainable adherence and improved health outcomes. The study by Salehi et al. indicates that religious beliefs and

social values serve as powerful tools for accepting one's current situation and adhering to defined conditions. Therefore, in nursing model-based interventions, emphasizing these values is essential [27].

Conclusion

This study highlights that educational interventions structured around the collaborative care model can markedly improve treatment adherence among hemodialysis patients. Enhanced adherence contributes to better clinical outcomes, fewer complications, and greater patient acceptance of their condition. These findings underscore the value of incorporating the collaborative care model into routine nursing practice as a strategic approach to elevating the quality of care for individuals with chronic illnesses.

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Disclosure Statement

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Authors' Contributions

All authors contributed to data analysis, drafting, and revising of the paper and agreed to be responsible for all the aspects of this work.

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