Dietary Strategies for Hyperphosphatemia: A Randomized Controlled Study on the Effectiveness of Phosphate-Specific Interventions in Reducing Serum Phosphate Levels in Hemodialysis Patients in a Dialysis Center

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Date: 9 /11/ 2025

Abstract

Background: Hyperphosphatemia is a dangerous complication of chronic kidney disease (CKD), especially in hemodialysis (HD) patients, lead to major complications, including cardiovascular disease, secondary hyperparathyroidism, and CKD-mineral and bone disorders (CKD-MBD), which increase morbidity and mortality. Effective management requires phosphate binders, phosphorus-restricted diet, and dialysis. These are challenging due to complex dietary choices, burden of multiple medications, and lack of awareness. That underscoring the need for patient education to avoid foods rich in phosphorus and increase adherence to low phosphorus diet.

Aim: Evaluate success of phosphorus-specific dietary intervention with education and counseling in improving dietary adherence, knowledge, and serum phosphorus levels among HD patients.

Methods: A randomized controlled interventional study performed at the Dialysis Unit in the Department of Nephrology at Al-Sader Medical Teaching Hospital (Najaf, Iraq), involved 200 patients,195 completing the study. Patients randomly grouped into the intervention group, received individual dietary plans, educational materials, and weekly follow-ups for a four-month period. The control group not received dietary attention. Monthly measurements were taken of the serum levels of parathyroid hormone (PTH), calcium (Ca), and phosphorus. Validated questionnaires were used to collect data, assessing dietary habits, phosphorus knowledge, and adherence.

Results: A significant reduction occurred in the serum phosphorus level of intervention group (6.26 to 3.79 mg/dL, $P < 0.001$). Ca and PTH levels were (8.02 mg/dL to 9.26 mg/dL, $P < 0.001$ and 405.07 pg/mL to 234.75 pg/mL, $P < 0.001$, respectively).

Conclusion: The results showed that supporting individualized nutrition plans and increasing awareness of foods rich in phosphorus are essential elements of routine care. By incorporating these strategies into clinical practice can improve patient management and outcomes.

Keywords: Hyperphosphatemia, Dietary intervention, Patient education, chronic kidney disease (CKD), Serum Phosphorus.

1. Introduction

Hyperphosphatemia is a major problem in chronic kidney disease patients (CKD), in particular those on Hemodialysis (HD). Capacity of the kidneys to eliminate phosphorus diminished when kidney functions declined, which will lead to buildup of phosphorus in the bloodstream. Severe complications such as cardiovascular disease, soft tissue calcification, secondary hyperparathyroidism (SHPT), and renal osteodystrophy can result from high phosphorus levels in blood, and they increase morbidity and mortality risks (1). Dietary restriction of phosphorus is necessary in control hyperphosphatemia, correcting SHPT and preventing cardiovascular problems. However, complex renal diets can be difficult to follow, so there is a need for useful teaching methods to improve adherence and health outcomes. The researchers concluded that the most effective way to encourage improved phosphorus management is to select an educational intervention that supports the style of the patient (2).

1.1 Pathophysiology of Hyperphosphatemia in CKD Patients

When renal excretion declines, ability of body to maintain phosphorus balance is impaired, lead to hyperphosphatemia (3). In early stage of CKD, in order to compensate this decline, the body attempts to increase secretion of parathyroid hormone (PTH). This hormone enhances removal of phosphorus by blocking its reabsorption in kidney tubules (4). These compensating mechanisms are insufficient as CKD worsens, resulting in chronic phosphorus load and related metabolic disorders (5). The occurrence of SHPT, a disorder marked by the chronic excessive production of PTH lead to bone loss and renal osteodystrophy, is greatly influenced by hyperphosphatemia in CKD. phosphorus buildup contributes to vascular calcification, which raises the risk of plaque buildup, cardiovascular diseases, arterial stiffness, left ventricular hypertrophy, and death (6).

1.2 Management of Hyperphosphatemia

management include many strategies to control phosphorus levels and lower health risks. Include dietary modification by reduction of phosphate-rich food additives, processed meats, soft drinks, use of phosphate binders, and increase dialysis times. These interventions together are important to the complete control of phosphorus levels and support general patient health and reduce complications (7).

1.2.1 Dietary Phosphorus Restriction

Diet restriction is critical part in management of hyperphosphatemia and its complications (8). According to the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (KDOQI) CKD patients in stages 3-5 with hyperphosphatemia should limit dietary phosphorus intake to between (800-1,000 mg) per day (9). It is challenging to achieve proper phosphorus levels due to many factors. So, dietary intervention is a cornerstone in managing hyperphosphatemia. poor adherence to phosphate binders and reduced efficacy when phosphate intake is high because phosphate binders are most effective when phosphate intake below 1000mg/ day, their efficacy decrease when higher intake of more than 1500 mg/day, and this contributes to hyperphosphatemia (10). Poor adherence to HD sessions contributes to phosphorus buildup. Because of HD remove 600-1200 mg per session and phosphate binder removes 200-300 mg per day there is need to dietary phosphorus restriction to maintain phosphorus level below 5.5mg per dl (11). many patients have trouble to be educated and make decision because they are unaware enough about foods high in phosphorus. availability of low phosphorus food alternatives is limited, and adherence to low phosphate diet is difficult because of food preferences and dietary restrictions (12). Renal diet is naturally complex and requires careful

nutrient monitoring, especially balancing between phosphorus restriction and maintain adequate protein intake. Another problem is that processed foods contain large amounts of phosphorus that are not labeled by manufacturer, thereby it hard to patients to monitor their intake (13). These factors contribute to difficulty in dietary compliance. So, there is need to dietary intervention as a critical part of CKD management. Giving patients complete education about phosphorus sources and dietary changes can improve the ability to make decisions that will promote phosphorus regulation and general health outcomes (13).

1.2.2 Phosphorus Food Sources

It is important to identify differences in phosphorus sources and absorption rate for developing effective dietary strategies (11). Two forms available: organic and inorganic phosphorus (14). About 45% of phosphate taken comes from inorganic sources (processed food for example: cheese, cakes, soft drinks, and pies). In contrast, about 20% of dietary phosphorus is from organic sources, including chicken, milk, grains, and eggs. Bioavailability of organic form ranging from 60% to 80%, whereas inorganic phosphorus is absorbed at a significantly higher rate 90% or more (11). A major concern in dietary management is the extensive use of phosphorus additives in processed foods, including restructured meats, processed cheese, instant products, refrigerated bakery items, and beverages. These additives contribute to 100% phosphorus absorption, often without the patient's awareness (15). By focusing on fresh, natural foods and reducing the consumption of processed foods that contain phosphorus additives, patients can better control their phosphorus levels and improve overall health outcomes (2). Studies shown that reduction of phosphate additives achieved by patient education to read ingredients and avoiding products with phosphate additives. A study reported decrease of 0.6mg \ dl in phosphorus level among HD patients by this intervention (16). Recent guidelines confirm importance of check sources and

forms of phosphorus when nutritional education is given (15). Importantly, one of the aspects of this study is to increase awareness regarding phosphate additives and their dietary sources. Through targeted educational interventions, potentially leading to the control of phosphorus levels.

New Developments in Dietary Interventions for Hyperphosphatemia Worldwide: Consequences and Prospects for Regional Studies in Iraq

Dietary interventions, nutritional education, and creative techniques are vital global efforts made to deal with hyperphosphatemia. These efforts indicate the importance of developing individual plans to lower phosphorus intake while maintaining sufficient nutritional status. Use of low-phosphorus dietary alternatives, and continuous nutritional education are crucial for managing hyperphosphatemia, according to recent American recommendations (2024). The importance of a multidisciplinary medical team in enhancing quality of life of patients is also highlighted in the guidelines (17).

This study aims to assess effects of a phosphorus-specific diet intervention through education and direct consultations on dietary compliance, knowledge scores, and serum phosphorus, and its association with phosphate binder agents in managing phosphorus levels

There is a notable lack of data addressing dietary phosphate management in CKD patients within Iraq. Cultural dietary practices, socioeconomic constraints, and limited access to healthcare resources create unique patient barriers. This study fills gap by providing evidence-based insights to the Iraqi population. By incorporating locally available food options, culturally appropriate nutritional plans, and accessible educational tools like WhatsApp and phone calls, the study presents a realistic model for phosphorus management in resource-limited settings.

2.Methods

2.1 Study Design

A randomized controlled interventional study, involving patients on HD at stage 5 CKD. patients are enrolled in a dietary program with a specific phosphate content for three months. This study occurred from October 2024 to January 2025 at the Hemodialysis Unit in the Department of Nephrology at Al-Sader Medical Teaching Hospital.

2.2 Ethical Approval

This study received approval from Scientific Committee at College of Pharmacy/University of Kufa, and from the Nephrology Center at Al-Sader Teaching Medical City. Written informed consent was also obtained from patients before initiation of the study **[Appendix 1]**.

2.3 Sample size calculation

The sample size for this randomized controlled interventional study was determined based on previous clinical trials evaluating dietary phosphate control in patients undergoing HD. Using an estimated medium effect size (Cohen's d = 0.5), a power of 80%, and a confidence level of 95%, the minimum required sample size was calculated using G*Power software to be approximately 64 participants per group. To enhance statistical power and account for potential dropouts, the final sample size was increased to 100 patients in each group, for a total of 200 participants.

2.4 Patients of the Study

After screening and exclusion criteria, a random sample of 200 patients HD was selected. They divided equally into two groups (control and intervention), 100 patients in each group. During the trial, five patients were lost: one opted out, two withdrew due to difficulties complying with the prescribed diet, one was removed while awaiting transplantation, and one succumbed to an infection caused by mucormycosis. Thus, 195 volunteers successfully completed the study trial **(Figure 2.1).**

Inclusion criteria were the following:

- Males and females aged ≥ 18 and ≤ 60 years old.
- Diagnosis: Patients with stage 5 CKD undergoing hemodialysis.
- Dialysis Duration: Receiving at least two weekly dialysis sessions for at least 2 months.
- Phosphate Binder Use: Sevelamer (the only available in the nephrology center).
- Informed agreement: patients agreed to provide written informed consent.
- Language competence: patients or caregivers able to read, write, and speak Arabic.

Exclusion criteria were the following:

- Be younger than 18 or older than 60.
- Getting less than two sessions per week or less than two months of hemodialysis.
- The inability or refusal to give written informed consent.
- A history of severe mental illnesses or cognitive impairment that limits participation.
- Acute illness, an ongoing infection, or hospitalization during the hiring process.

- A history of malabsorption conditions that could impact phosphate metabolism or gastrointestinal surgery.
- Noncompliance with medication or dialysis regimens.

2.5 Sampling method

A list of all eligible patients who met inclusion criteria was created. patients selected by a simple random sampling method. This method involved that eligible patients in the list were assigned a unique identification number. Then randomly selected by a random number generator tool (Excel). A total of 200 patients were selected to participate in the study.

2.5.1 Randomization process

Selected patients randomly assigned to either control or intervention group using a fair randomization method to ensure equal distribution of patients in study groups. The researcher flips a fair coin for each patient joined the study. If coin showed image face, the patient entered in control group. If it was the writing face, the patient entered intervention group, which involve receiving dietary counselling according to study protocol.

2.5.2 Data collection

Data were collected using two questionnaires, Medication Adherence Reporting Scale-5 (MARS-5) and knowledge about phosphate questionnaire **[Appendix 2]**. They are validated in the study of *Falah et al. 2021* (18), they assessed awareness, dietary habits, and phosphate management. They covered demographic data (age, gender, and educational level), dietary behaviors, and chronic conditions history. Baseline phosphorus, PTH, and calcium (Ca) levels were measured. The study evaluated knowledge of phosphate-rich foods, prior education, and ability to identify

high phosphate foods. Awareness of phosphate content in dairy products, canned foods, grains, nuts, and processed meats was evaluated. Participants rated their knowledge, their phosphate intake monitoring. challenges in reducing phosphate intake (lack of knowledge, food availability, and cost) also assessed. also reported whether they received dietary guidance and its clarity. Lastly, the study assessed their perceptions of phosphate management, including its importance in preventing complications and confidence in controlling phosphate levels.

Regular follow-ups were conducted during each dialysis session to monitor adherence. Then, they adjusted weekly. serum phosphate and Ca were measured monthly. October 2024 was baseline. November, December, and January 2025 were follow-up times, respectively. control group underwent only baseline data without intervention. Intervention included counselling and education for phosphate-specific diet for each patient according to their food preferences and eating behavior and maintained a balanced diet in limited amounts of phosphorus (800-1000 mg/day), and education about phosphate and Ca physiology in simple patient-friendly language, risks of hyperphosphatemia, and high phosphate foods. Brochures handed out to patients **[Appendix 3]** included risks of hyperphosphatemia and foods with high and low phosphate content, and additives. Another sheet contained amount of phosphorus allowed to be taken daily or weekly for each type of food, how to regulate phosphorus level, and importance of adherence to phosphate binders **[Appendix 3]**. we utilized WhatsApp and telephone calls to stay connected with patients, address their inquiries, and ensure they received all necessary information. This approach allowed us to maintain continuous communication, provide ongoing support, and monitor progress and challenges throughout the intervention period. As part of the program, food preferences and dietary habits were assessed before meal plans were assigned. primary goal was to ensure that daily phosphorus intake remained within 800- 1000 mg/day while maintaining a

balanced nutrition. **(Table 2.1)** summarizes the modified Dietary Plan with Iraqi Meals designed for patients, ensuring phosphorus intake remains within the recommended range (19), (20).

2.6 Statistical analysis

All statistical analysis were performed using statistical package for social sciences (SPSS) version 30. First, we checked if the Data were normally distributed. Descriptive statistics were presented as mean, standard deviation (SD), median, frequencies, and simple percentages. The comparison between the two groups (intervention and control) was done using the independent t-test. For within-group comparisons (pre- and post-intervention), the paired t-test was used. A p-value less than 0.05 was considered statistically significant.

3.Results

In intervention group 50% aged 31–50, 40% were 51-60, and 10% were 18-3. 60% was females. Hypertension and diabetes mellitus were major chronic conditions (70% and 80% respectively). In control group, 30% were aged 18-30, 50% were 31-50, 20% were 51-60. 60% was males. Major chronic conditions (40% hypertension, 50% Diabetes mellitus) **(Table 3.1)**. Total of 99 participants responded to questionnaire **(Table 3.2)**. 36% not received prior phosphate education, 73% were unable to list phosphate-rich foods. Main barriers to phosphate restriction included lack of knowledge (37%), cost of low-phosphate foods (30%), and limited alternatives (25%). At baseline serum phosphorus levels were for intervention and control groups (6.26 ± 1.72 mg/dL, 5.84 ± 1.79 mg/dL; $P = 0.089$, respectively)**,** on November intervention group showed a reduction to 4.93 ± 1.37 mg/dL. On December and January declined to 4.29 ± 1.13 mg/dL and 3.79 ± 1.51 mg/dL, respectively **(Table 3.3), Figure 3.1**. The intervention group showed significant reductions in serum phosphorus levels over time. The mean level decreased from 6.26 ±

1.72 mg/dL at baseline to 4.93± 1.37 mg/dL in November (P < 0.001). Further reductions occurred in December (4.29 ± 1.13 mg/dL) and January (3.79 ± 1.51 mg/dL), with all pairwise comparisons being significant (P < 0.001). **Table 3.4, Figure 3.2** presents within-group comparisons at different time points, paired t-tests confirmed significant mean score reductions, indicating the intervention's effectiveness. Mean Ca levels increased from 8.02 at baseline to 9.26 in January (P < 0.001) and PTH levels decreased from 405.07 at baseline to 234.75 in December (P < 0.001) **(Table 3.5).**

4. Discussion

dietary restriction is a foundational component that poses challenges in patient adherence and long-term implementation. This study sought to assess how structured dietary interventions and continuous patient education and support could influence serum phosphorus levels and overall phosphorus management. One of the distinguishing aspects of this research lies in its context-specific contribution. Results of this study demonstrated a significant reduction in serum phosphorus of intervention group 6.26 ± 1.72 mg/dL at baseline to 3.79 ± 1.51 mg/dL after three months, nearly a 40% decline. In contrast, increased progressively in the control group. These findings underline the effectiveness of combining targeted dietary modifications with ongoing education and personalized support to improve phosphorus control. Several previous studies corroborate current findings. A 2022 study in Qatar showed decline in phosphorus from (~7.2 to 5.2 mg/dL), p < 0.05, but did not include a strong educational aspect (21). In contrast, the present study provided structured education and ongoing support, likely contributed to better adherence. A 2025 Chinese study with 8.8% reduction (6.35 to 5.79 mg/d, p-value 0.048), the smaller reduction may be due to the lack of continuous education and follow-up support (22), which were key elements in the current study's approach. A 2021 Egyptian study showed 13.8 ± 21.41%

reduction in serum phosphorus levels ($p = 0.02$) following a 12-week educational program (23). This highlights the benefit of patient education in phosphorus management, but modest reduction compared to the current study suggests that combining education with practical dietary planning and regular follow-up as done in the current research yields better outcomes. A 2023 Californian study showed education in phosphorus levels after a 30-day educational intervention ($p = .001$), not detailed but emphasizing short-term effectiveness, also supported the effectiveness of continuous education, digital support tools, and individualized plans in achieving positive outcomes (12). A 2012 Spanish study reported a six-month dietary intervention, decreasing phosphorus levels by 1.67 mg/dl, ($p = 0.003$) (24). These results align closely with the current study, reinforcing the importance of structured and sustained dietary interventions. The Chinese study emphasized diet but excluded education, likely limiting behavioral change. The Egyptian study involved education but no dietary follow-up or monitoring. The Qatari study focused on counseling without in-depth education on phosphorus risks. These variations emphasize that success in phosphorus management hinges on a holistic, personalized approach combining education, culturally adapted diets, and consistent patient engagement strategies all central to this study. The implications of this study are far-reaching. It not only validates the effectiveness of phosphate restriction but also the value of education and cultural adaptation in enhancing adherence. The proposed model can serve as a blueprint form future dietary management program in Iraq and similar low-resource environments. It highlights the importance of patient empowerment, continuous monitoring, and practical, context-aware solutions. This study paves the way for further research exploring long-term adherence, technology's role in dietary counseling, and the cost- effectiveness of such interventions. Additionally, it underscores the need for national dietary guidelines and educational campaigns targeting both patients and healthcare providers. Future initiatives should consider leveraging community-based

interventions and digital platforms to expand the reach and sustainability of phosphorus control strategies. This study has important aspects, but it also lacks some features. The short follow-up period of 3 months is a limitation because it does not allow for the evaluation of long-term sustainability. Also, adherence to diet and phosphate binders use were self-reported, which may introduce some biases. Finally, because the study was conducted at a single center, external generalizability of the study findings could be limited.

Conclusion

The results showed that supporting individualized nutrition plans and increasing awareness of foods rich in phosphorus are essential elements of routine care. By incorporating these strategies into clinical practice can improve patient management and outcomes.

Recommendations

1. It is recommended that larger multicenter studies be conducted to assess the broader applicability of their findings and to identify the most significant components of dietary practices education.

2. Exploring the effects of dietary education on clinical outcomes like cardiovascular events, hospital admissions, and mortality, both short-term and long-term, should be evaluated.

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Table 2.1. Dietary Plans with Iraqi Meals.

Meal	Food items	Phosphorus content (mg)
Breakfast	Bread (1 piece) + Boiled egg (1) + Cucumber (½ cup)	120mg
	Bread (¼ piece) + White cheese (2 tbsp) + Tomato slices (½ cup)	110 mg
	Labneh (2 tbsp) + Bread (¼ piece) + Olive oil (1 tsp) + Mint leaves	100mg
	Semolina porridge (½ cup) + Low-fat milk (½ cup) + Cinnamon (1 tsp)	115mg
Snack	Low-fat yogurt drink (½ cup) + Cucumber (½ cup)	90mg
	Bread (¼ piece) + Low fat white cheese (2 tbsp)	100mg
Lunch	White rice (½ cup) + Grilled chicken tikka (85g) + Okra stew (without meat) (½ cup)	280mg
	Red kidney bean stew (without meat) (½ cup) + Bread (¼ piece) + Tomato & cucumber salad (½ cup)	260mg

	Grilled masgouf fish (85g) + White rice (½ cup) + Grilled vegetables (½ cup)	310mg
	Lentil stew (without meat) (½ cup) + Bread (¼ piece) + Green salad (½ cup)	270mg
	Oven-roasted chicken (85g) + Vermicelli rice (½ cup) + Light lentil soup (½ cup)	290mg
	Grilled eggplant stew (without meat) (½ cup) + Bread (¼ piece) + Tomato & cucumber salad (½ cup)	280mg
	Grilled dolma (without meat) (½ cup) + Low-fat yogurt (½ cup) + Bread (¼ piece)	270mg
Snack	Date (1 piece) + Bread (¼ piece) + Unsweetened tea	95mg
	Unsalted biscuits (4 pieces) + Honey (1 tsp)	100mg

	Unsalted popcorn (1 cup) + Unsalted nuts (1 tbsp)	120mg
	Fresh orange juice (½ cup) + Unsalted tea biscuits (3 pieces)	115mg
	Sliced apple (½ piece) + Unsalted walnuts (1 tbsp)	95mg
	Pomegranate seeds (¼ cup) + Low-fat yogurt (½ cup)	115mg
	Dates (1 piece) + Low fat milk (½ cup) + Cardamom for flavour	125mg
Dinner	Boiled egg (1) + Bread (¼ piece) + Cucumber (½ cup)	120mg
	White rice (½ cup) + Light chicken soup (½ cup) + Cucumber & tomato salad	140mg

	Grilled kofta (85g) + Light lentil soup (½ cup) + Low-fat yogurt (½ cup)	145mg
	Mashed chickpeas (without tahini) (2 tbsp) + Bread (¼ piece) + Olive oil (1 tsp)	130mg
	Lentil stew (without meat) (½ cup) + Thin flatbread (¼ piece) + Fresh vegetable salad	120mg
	Vermicelli rice (½ cup) + Grilled chicken (85g) + Low-fat yogurt (½ cup)	155mg
	Grilled fish (85g) + Roasted potatoes (½ cup) + Bread (¼ piece)	150mg

Table 3.1. Demographic Data

	Group 1 n= 100	Group 2 n= 100
	No	No
Age Group		
Years 18-30	10	30
Years 31-50	50	50
Years 51-60	40	20
Gender		
Male	40	60
Female	60	40
Chronic Conditions		
Hypertension	70	40
Diabetes	80	50
Obesity	30	10
Heart Disease	15	5
Epilepsy/ seizures	10	5

Table 3.2 Response to Questionnaires

	Total (n=99)	%
Knowledge of phosphate		
Educated about Phosphate	64	64%
Not Educated	35	36%
Ability to list phosphate- rich foods		
Can list	27	27%
Cannot list	72	73%
Attention to phosphate intake		
Pay Attention	41	41%
Not pay Attention	58	59%
Reduction of phosphate- rich foods		
Reduced based on advice	41	41%
Did not reduce	58	59%
Use phosphate binder		
Yes	57	58%
No	42	42%
Awareness of blood phosphorus level		
Aware	43	43%
Unaware	56	57%

Barriers to reducing phosphate intake		
Lack of knowledge	37	37%
Cost of low phosphorus foods	*30*	30%
Difficult finding alternatives	25	25%
Guidance on low phosphate diet		
Received guidance	53	53%
Did not received	46	46%
Ease of understanding information		
Easy	45	45%
Maybe	31	31%
Difficult	24	24%
Importance of controlling phosphate		
Very important	23	23%
Important	48	48%
Somewhat important	26	26%
Not important	2	2%
Confidence in managing phosphate		
Confident	67	68%
Unsure	24	24%
Not confident	8	8%

Table 3.3 Comparison of Mean Scores Between Intervention and Control Groups Over Time

Groups	Intervention (100)	Control (n=100)	P-Value	95% Confidence Interval of the Difference	
	Mean±S.D	Mean±S.D		Lower	Upper
Baseline	6.26±1.72	5.84±1.79	0.089	0.235	1.216
Nov.	4.93±1.37	5.87±1.51	<0.001	-1.335	-0.530
Dec.	4.29±1.13	6.35±1.86	<0.001	-2.485	-1.625
Jan.	3.79±1.51	7.24±2.22	<0.001	-3.973	-2.911

Table 3.5 Calcium and PTH levels distribution.

Category	Ca (Mean ± SD)	P- value	PTH (Mean ± SD)	P- value
Baseline	8.02 ± 1.13	<0.001	405.07 ± 269.73	<0.001
Nov.	8.35 ± 0.97			
Dec.	8.82 ± 0.79		234.75 ± 182.55	
Jan.	9.26 ± 0.90			

Appendices

Appendix 1: Written consent form

Informed Consent Form

Study Title: Dietary Strategies for Hyperphosphatemia: A Randomized Controlled Study on the Effectiveness of Phosphate-Specific Interventions in Reducing Serum Phosphate Levels in Hemodialysis Patients in a dialysis center.

Principal Investigator: Shaima Alaa Abdulhafidh

Institution: College of Pharmacy, University of Kufa

Introduction: This study is a clinical trial, conducted to evaluate effectiveness of specific dietary intervention in reducing serum phosphorus levels in hemodialysis patients. Before you decide to participate, please read the following information carefully.

Purpose of the Study: The purpose of this study is to assess whether targeted dietary counselling and education can help lower phosphate levels in patients with end-stage kidney disease undergoing hemodialysis.

Procedures: If you agree to participate, you will receive dietary counselling, educational materials, and regular follow-ups over a 3-month period. Your blood levels of phosphate, calcium, and PTH will be measured periodically as part of your routine care.

Risks and Benefits: There are no anticipated risks beyond routine care. You may benefit from improved dietary understanding and phosphate control.

Voluntary Participation: Participation is entirely voluntary. You may withdraw at any time without affecting your treatment or medical care.

Confidentiality: All data collected will be kept confidential. Your identity will not be revealed in any publication resulting from this study.

By signing below, you indicate that you have read and understood the information provided and voluntarily consent to participate in this research study.

Participant's Signature: _____

Appendix 2: study questionaries

A- English validated version of MARS-5 questionnaire

Patient Demographics

1. Age: What is your age?

2. Gender: What is your gender?

3. Medical History: Do you have any chronic conditions?)(

4. Current Treatment:

Knowledge of Phosphate-Rich Foods:

1.Understanding of Phosphate:

Have you ever been educated about the role of phosphate in your diet? (Yes/No)

Can you list any foods you know are high in phosphate?

4. Awareness of Phosphate Content in Foods:

How would you rate your knowledge of which foods contain high levels of phosphate? (Poor/Fair/Good/Excellent)

5. Food Groups:

Do you think dairy products are rich in phosphate? (Yes/No/Not Sure)

Are you aware that processed foods (e.g., canned meats, soft drinks) often contain added phosphates? (Yes/No/Not Sure)

Do you know that whole grains, nuts, and certain types of meat are high in phosphate? (Yes/No/Not Sure)

Dietary Habits:

1. Phosphate-Rich Food Consumption:

How often do you consume dairy products (e.g., milk, cheese, yogurt)? (Daily/Weekly/Rarely/Never)

How often do you eat processed or fast foods? (Daily/Weekly/Rarely/Never)

2. Phosphate Intake Management:

Have you ever reduced your intake of phosphate-rich foods based on advice from a healthcare professional? (Yes/No) If yes, what changes have you made in your diet?

3. Use of Phosphate Binders:

Are you currently taking any phosphate binders to help control your phosphate levels? (Yes/No)

Perceived Barriers to Dietary Changes:

1. Challenges in Reducing Phosphate-Rich Foods:

What are the main challenges you face in reducing phosphate-rich foods from your diet? (Select all that apply):

- **Lack of knowledge**
- **Difficulty finding alternative foods**
- **Expense of low-phosphate foods**
- **Other (please specify)**

2. Education on diet:

Have you received educational materials or counseling about a lowphosphate diet? (Yes/No)

Was this information easy to understand and apply to your daily life? (Yes/No/Somewhat)

Patient Attitudes and Beliefs:

1. **Perception of Importance:**

How important do you think it is to control phosphate levels in your diet to avoid complications like hyperphosphatemia? (Not important/Somewhat important/Very important)

2.Confidence in Managing Phosphate Levels:

How confident are you in your ability to manage phosphate levels in your diet? (Not confident/Somewhat confident/Very confident)

B- English version of Phosphate Knowledge Questionnaire

Please note the following before answering the Questionnaire:

a. Mark the answer you find to be correct.

b. There may be several answers to one question.

c. The questionnaire has two pages with a total of eight questions.

1. For what condition do you receive phosphate binder?

a. High blood pressure

b. Diabetes

c. High serum phosphate

d. Low serum phosphate

e. I do not know

2. How does the phosphate binder work?

a. Lower the blood pressure

b. Lower the blood sugar level

c. Lower the serum phosphate level

d. Increase the serum phosphate level

e. I do not know

3. What would you want to prevent by using phosphate binder?

a. Itches of the skin

b. Red eyes

c. Development of diabetes

d. Heart attack

e. I do not know

4. When should you take your phosphate binder?

a. In the evening

b. In the morning

c. For each meal

d. It does not matter

e. I do not know

5. How you take the phosphate binder tablet?

a. before meal

b. after meal

c. during meal

d. after meal by half hour

e. I do not know

6. The phosphate binder may affect the uptake of the following medicine?

a. Medicines against heart burn

b. Blood pressure medicines

c. Some antibiotics

d. Diuretics

e. I do not know

7. What should you do if you have forgotten to take phosphate binder?

a. take double dose with next meal

b. take the next dose as normal with a meal

c. it does not matter if you forget a dose

d. I do not know

e. Take half dose with next meal

8. What might the symptoms of side effects of the phosphate binder?

a. Nausea

b. Vomiting

c. Constipation

d. Headache

e. I do not know

Appendix 3: Educational materials

A- Brochures

The Risk of High Phosphorus in Kidney Patients

Although phosphorus is one of the most important minerals that the body needs continuously, its danger lies in the fact that it accumulates in kidney patients. This accumulation and increase can cause significant harm, especially in patients with chronic kidney failure undergoing dialysis. It is therefore essential for dialysis patients to maintain their blood phosphorus levels within safe limits. This may require limiting foods rich in phosphorus to about **800–1000 mg per day**.

Table: Phosphorus in Foods

High- Phosphorus Foods	Low- Phosphorus Foods
Meat, poultry, fish	Fresh fruits and vegetables
Whole grains and legumes	Refined grains and white rice
Dairy products	Rice milk (without phosphate additives)
Soft drinks (cola)	Lemonade and clear sodas
Nuts and seeds	White bread, pasta, and crackers
Peanut butter	Unsalted popcorns

Examples of Foods with Added Phosphorus

Processed meats (such as sausages and canned meats), processed foods, fast foods, frozen foods, soft drinks (especially cola), and processed cheeses. Phosphorus additives are also found in instant products such as cake mixes, instant soups, powdered creamers, and some chocolate spreads.


What Happens if Phosphorus Exceeds the Normal Range?

Consuming foods high in phosphorus increases its level in the blood and dialysis can't completely remove it. This leads to calcium withdrawal from the bones to balance the excess phosphorus, causing bone fragility and increasing fracture risk. High phosphorus can also cause skin itching, red eyes, and calcification of calcium-phosphate deposits in the joints, muscles, skin, blood vessels, and heart. This may result in serious complications such as heart disease, stroke, and other organ damage.



B- Sheets

Foods Kidney Patients Should Pay Attention To:

Grains and Bread

If there is no restriction on calorie intake or carbohydrate consumption for diabetes control, grains and bread are an important source of energy. Most individuals need 6–11 servings daily.

One-quarter to one-third of a loaf of bread equals one serving for each of:

- ½ cup cooked rice or pasta.
- ½ cup of cooked grains.
- 4 unsalted biscuits.
- 3 cups of unsalted popcorn.

Avoid whole grains and bran cereals as they are high in phosphorus.

Milk and Dairy

Limit milk, yogurt, and cheese to ½ cup or 30–40 g per day because dairy products are high in phosphorus. The phosphorus content is the same for all types of milk (fat-free, low-fat, and whole). If phosphorus is high in the blood, limit all types of dairy. Phosphate binders may be prescribed to be taken with meals.

Fruits and Fruit Juice

Consume 2–3 servings daily of low-potassium fruits (Apples, pears, pineapple, strawberries, mandarin oranges).

One serving equals: ½ cup juice or 1 small fruit.

Vegetables

Consume 2–3 servings daily of low-potassium vegetables such as (cabbage, cauliflower, corn, cucumber, green beans, lettuce, okra, onion, peas, radish).

One serving equals: ½ cup or cup of cooked or raw vegetables.

Managing Phosphorus Levels in the Blood

- Control portion sizes of high-phosphorus foods.
- The presence of phosphorus in these foods does not mean avoiding them completely, as they contain protein essential for the body. Therefore, we provide you with dietary plans to determine the permitted amounts.
- Limit milk to 2 servings daily (½ cup per serving).
- Eat fish once a week only.
- Avoid inorganic phosphorus found in canned foods and soft drinks as much as possible.
- Take phosphate binder medication regularly with meals.

References:

- Academy of Nutrition and Dietetics (Nutrition Care Manual), 2021–2022.
- National Kidney Foundation (2015): Dietary guidelines for adults starting on hemodialysis.