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Original article

New strategies to empower patients with chronic kidney disease in phosphorus control (empower-PHOS)

Nuevas estrategias para empoderar a los pacientes con enfermedad renal cronica en el control de p (Empower-PHOS)

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ABSTRACT

Introduction: Serum phosphorus (P) control in hemodialysis (HD) remains a major challenge, largely influenced by phosphate binder adherence and patient engagement. Structured educational strategies may enhance self-care and improve clinical outcomes.

Objective: To evaluate the effectiveness of a patient-centered educational intervention for phosphorus control in hemodialysis.

Material and methods: Multicenter, prospective, randomized clinical trial including patients with hyperphosphatemia or high binder requirements, allocated to an intervention group (structured education + Empower-PHOS tool) or a control group (standard care). Serum P, binder dose, and adherence (SMAQ) were assessed at baseline and at 3, 6, and 12 months.

Results: Both groups were comparable at baseline. A total of 122 patients from 14 centers were enrolled. The intervention group achieved significant reductions in serum P at 3 months (from 6.1 to 5.4 mg/dl; $p < .001$) and at 12 months (from 6.2 to 5.2 mg/dl; $p = .010$), without changes in the number of pills or daily binder dose. Improvements were observed in both adherent and non-adherent patients, with particularly notable reductions among the latter (from 6.4 ± 1.2 to 5.8 ± 1.2 mg/dl; $p = .015$). Adherence according to SMAQ did not change significantly.

Conclusions: A structured, patient-centered educational intervention improved phosphorus control in hemodialysis, even among patients with low baseline adherence, without increasing the pharmacological burden. These findings support the integration of personalized educational strategies as a key component in the comprehensive management of hyperphosphatemia in routine hemodialysis practice.

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Palabras clave:
Hemodiálisis
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Autogestión
Enfermedad renal crónica
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Intervención centrada en el paciente

RESUMEN

Introducción: El control del fósforo (P) sérico en hemodiálisis (HD) sigue siendo un reto, condicionado por la adherencia a los captores y la implicación del paciente. Estrategias educativas estructuradas pueden mejorar el autocuidado y optimizar los resultados clínicos.
Objetivo: Evaluar la eficacia de una intervención educativa centrada en el paciente para el control del P en HD.
Material y métodos: Ensayo clínico multicéntrico, prospectivo y aleatorizado en los pacientes con hiperfosfatemia o altas dosis de captores, asignados a intervención (educación estructurada + herramienta Empower-PHOS) o control (manejo habitual). Se midieron P sérico, dosis de captores y adherencia (SMAQ) a 0, 3, 6 y 12 meses.
Resultados: Ambos grupos fueron comparables al inicio. Se incluyeron 122 pacientes de 14 centros. El grupo intervención logró reducciones significativas del P a los 3 meses (de 6,1 a 5,4 mg/dl; $p < 0,001$) y a los 12 meses (de 6,2 a 5,2 mg/dl; $p = 0,010$), sin cambios en el número de comprimidos ni en la dosis diaria. La mejora se observó tanto en los pacientes adherentes como en no adherentes, con reducciones especialmente relevantes en estos últimos (de 6,4 ± 1,2 a 5,8 ± 1,2 mg/dl; $p = 0,015$). La adherencia según SMAQ no varió significativamente.
Conclusiones: Una intervención educativa estructurada centrada en el paciente mejora el control del P en HD, incluso en los pacientes con baja adherencia, sin aumentar la carga farmacológica. Estos resultados respaldan el uso de estrategias educativas personalizadas como complemento clave en el manejo integral de la hiperfosfatemia que pueden integrarse en la práctica clínica habitual de las unidades de HD.

Introduction

Despite the broad therapeutic arsenal available, serum phosphorus (P) control continues to represent a relevant clinical challenge in nephrology practice.[1,2] Adherence to phosphate binder therapy and long-term persistence are essential determinants of this goal, yet they are conditioned by multiple factors such as the complexity of the therapeutic regimen, pill burden, adverse effects, and individual patient characteristics.[3–5] Despite the emergence of new strategies for P control,[6] fostering patient autonomy and active involvement in self-care constitutes a fundamental strategy for improving clinical outcomes.[7,8] Furthermore, the variability observed in the COSMOS study[2] reinforces the need for standardized interventions that promote active patient participation and equity in outcomes.

In addition to pharmacological treatments, recent literature highlights the importance of structured educational strategies that combine tailored information, visual tools, and health literacy techniques. These interventions not only aim to convey knowledge but also to empower patients to apply information in their daily lives, facilitating shared decision-making and improving therapeutic adherence. Empowerment, understood as the patient's capacity to actively participate in the management of their disease, is associated with better biochemical and clinical outcomes in chronic kidney disease (CKD).[4]

In this context, we developed a specific educational tool called "Patient Empowerment in Phosphorus Control (Empower-PHOS)," designed to help patients understand the approximate P content of foods and autonomously adjust binder doses according to actual intake. This approach integrates simple visual education, active patient participation, and a therapeutic self-management model aimed at improving P management without increasing the pharmacological burden. Empower-PHOS was conceived as an intervention applicable in routine clinical practice and potentially useful in units with limited resources.

The aim of this study is to analyze the efficacy of a hyperphosphatemia treatment model that actively involves the hemodialysis (HD) patient in their own care, providing structured tools to assume a responsible role in collaboration with the healthcare team, in the context of P control in HD patients. The primary objective was to evaluate the impact of a structured, patient-centered educational intervention on serum P control, and the secondary objective was to analyze changes in binder dose and number, as well as treatment adherence.

Material and methods

Study design

Multicenter, prospective, interventional study in HD patients with follow-up at 0, 3, 6, and 12 months.

Study population

Adult patients undergoing HD treatment for at least 3 months prior to inclusion who had suboptimal P control were included, defined as serum P levels > 5.5 mg/dl (> 1.78 mmol/l) at the start of the study, or controlled P levels (< 5.5 mg/dl) but requiring high doses of phosphate binders, defined as > 7 pills/day.

Additionally, patients had to be able to comply with the study protocol, which involved following the instructions for phosphate binder administration (without changing the type of binder throughout the study) and attending follow-up visits, as well as completing the required questionnaires. Finally, all participating patients signed an informed consent form to participate in the study.

Intervention group and control group

The study included an intervention group and a control group. Patients were randomly assigned to one of these 2 groups. Patient allocation to the study groups was performed in a randomized manner by research personnel external to the participating centers, with no involvement in patient recruitment or in the application of the intervention at each center. Allocation was consecutive and balanced, ensuring a similar number of patients in the intervention and control groups at each center. No losses occurred after initial assignment. Patients in the intervention group received educational tools specifically designed to improve patient self-care and autonomy, enabling them to assume a more active role in managing their phosphate binder treatment, while the control group did not receive any additional educational intervention and continued with usual management of their treatment.

The educational intervention consisted of a single structured initial interview, conducted by the patient's attending nephrologist following a prior training session aimed at the participating professionals. During this interview, the basic principles of P content and bioavailability in foods were explained, as well as the use of the tool to adjust binder administration according to intake.

No systematic follow-up educational reinforcement program was established, and no other healthcare professionals (nurses or dietitians) were involved in the direct application of the intervention, with the aim of evaluating its feasibility and reproducibility in routine clinical practice in HD units.

As part of the educational tool, patients had access to an explanatory video, which they could view autonomously as many times as they deemed necessary, facilitating the repetition and consolidation of the content.

Patients assigned to the control group continued with the usual P management at each center, without receiving additional structured educational intervention. This management was carried out according to the usual clinical practice of each HD unit, with potential inter-center variations in aspects such as the availability of dietary support or the type of phosphate binder prescribed.

Both cohorts were followed for the same period and the results were compared in terms of P control, number of pills and dose of phosphate binders, and treatment adherence between the 2 groups.

Variables collected

Various demographic, clinical, and treatment variables were collected. Regarding demographic variables, basic data such as age, sex, CKD etiology, time since HD initiation, type of dialysis used, as well as the presence of diabetes mellitus and vascular access type (arteriovenous fistula or catheter) were recorded.

Laboratory variables were measured at several time points during the study (baseline, 1, 3, 6, and 12 months) and included parameters such as mean Kt/V or KT index, serum P, calcium, parathyroid hormone (PTH), vitamin D, albumin, C-reactive protein, and hemoglobin. These variables allowed the evaluation of P control and other key factors in the treatment of HD patients. All laboratory determinations were performed on pre-dialysis samples corresponding to the short interdialytic period, following the standard procedures of each center and in accordance with standard clinical practice in HD.

Data on the pharmacological treatment patients were receiving were also collected, including the administration of vitamin D (cholecalciferol, calcifediol), calcimimetics (etelcalcetide or cinacalcet), paricalcitol, calcitriol, alfacalcidol, rocaltrol, and denosumab. Likewise, erythropoietin (EPO) doses and the daily amount of phosphate binders, as well as the frequency of their use and the type of binder used, were recorded.

Measurement variables

The variables used to analyze the effectiveness of the model included serum P levels, which were used to evaluate P control in patients. Secondary variables included the number of pills and daily milligrams of phosphate binder taken. Monitoring of phosphate binder use was performed through a "last week reminder," which patients completed by recording daily doses and the foods with which they took the binders.

Overall pharmacological treatment compliance was measured using the Simplified Medication Adherence Questionnaire (SMAQ), a validated tool for assessing pharmacological adherence in patients with chronic diseases, including CKD and the HD population.[9,10] The SMAQ consists of 6 questions that allow patients to be classified as adherent or non-adherent based on their responses. Adherence to phosphate binder treatment was assessed using the SMAQ questionnaire at each scheduled visit (0, 3, 6, and 12 months). Given its dichotomous nature, any response indicative of non-compliance classified the patient as non-adherent.

The response alternatives are dichotomous; any response in the direction of non-compliance is considered non-adherence to treatment.

Intervention

A training session was held for the participating nephrologists, addressing communication skills and instructions for using the tool. The importance of the different sources of P (organic and inorganic) and their bioavailability was emphasized, in order to train nephrologists to convey this information to patients and empower them in managing their disease.

Each nephrologist conducted an interview with the patients, during which the tool was delivered and explained. This tool included figures designed for individualized treatment and to promote patient empowerment, providing guidance on how to take phosphate binders in relation to the foods consumed, adjusting doses according to the type of meal, and including intermediate snacks (Fig. 1).

Intervention tool

The educational intervention was based on a tool developed specifically for this study, called "Patient Empowerment in Phosphorus Control (Empower-PHOS)," aimed at facilitating the understanding of P content in foods and the autonomous adjustment of binders according to intake. The "Empower-PHOS" tool consisted of a series of materials with illustrations about the P content of different foods and practical information serving as a guide on how to dose binders according to intake at each meal, adjusting the dose in relation to the amount and type of foods consumed during both main meals and intermediate snacks. The materials delivered to patients consisted of: (1) an A4-sized magnet with information to optimize the administration of the prescribed binders (Fig. 2A) (2) a business card-sized foldable accordion card with synthesized information (for the patient to always carry with them when eating outside the home) (Fig. 2B), and (3) an explanatory video of the materials.

Satisfaction assessment with the tool

The satisfaction assessment was carried out through structured questionnaires, which included items on overall perception, usefulness of the materials, and care experience, differentiated for patients and healthcare professionals.

Ethical aspects

The study was approved by the Ethics Committee of Fundación Jiménez Díaz (reference code: PIC007-22_FJD). All patients signed written informed consent before inclusion.

Statistics

Sample size calculation: According to published data, approximately 75% of HD patients have low adherence to phosphate binders. It was estimated that the educational intervention could reduce the proportion of non-adherent patients by 20%. Considering a significance level of 5%, a power of 80%, and an estimated loss of 15%, it was calculated that 174 patients (87 per group) would be needed to detect differences between groups. The final number of included patients was conditioned by the actual availability of participants at the centers.

Qualitative variables were expressed as absolute frequencies and percentages and compared using the chi-squared test. The distribution of quantitative variables was assessed using the Shapiro-Wilk test. Quantitative variables were described as mean and standard deviation (SD) if they followed a normal distribution, or as median and interquartile range (IQR: 25th–75th percentile) otherwise. For baseline comparison between the control and intervention groups, Student's *t*-test for independent samples or the Mann–Whitney U test for independent samples was used for non-normally distributed data.

Fig. 1. Images of the materials delivered to patients. A) Information from the A4-sized magnet. B) Image of the foldable accordion card (business card size).

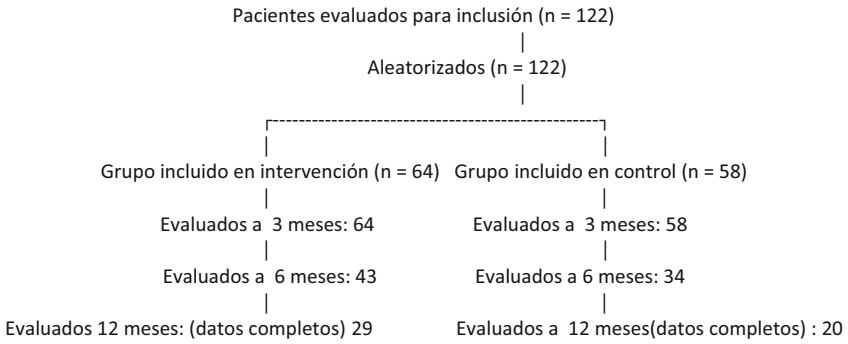

Fig. 2. Flowchart of patient inclusion, randomization, and follow-up. Of the 122 patients included and randomized, all were evaluated at 3 months. The number of patients evaluated decreased progressively at 6 and 12 months due to follow-up losses inherent to the hemodialysis population. The number of patients with complete data available for analysis at 12 months is indicated in each group.

Cochran's Q test was applied to assess possible changes in treatment adherence across the 4 study time points (0, 3, 6, and 12 months). Comparisons at 0, 3, 6, and 12 months were performed using Student's *t*-test for paired samples or the Wilcoxon signed-rank test, as appropriate. These tests were applied both to the intra-group analysis (intervention and control) and to the subgroups defined by treatment adherence within each group (according to the second SMAQ questionnaire measurement in each pairwise comparison).

Due to the pragmatic nature of the study and the progressive loss of follow-up during the 6- and 12-month evaluations, an analysis based on intra-group pairwise comparisons at each time point was chosen, in order to use the available information from patients evaluated at each visit. Although linear mixed models could have allowed a more complete longitudinal analysis, their application was limited by the variability in the number of patients available at the different follow-up time points.

A p value ≤ 0.05 was considered statistically significant. The analysis was performed using IBM SPSS® Statistics v29.0, and graphical representations were created with Microsoft Excel® 2021.

Results

A total of 122 patients from 14 HD centers were included. At baseline, 82 (67.2%) had serum p > 5.5 mg/dl and 57 (46.7%) required > 7 phosphate binder pills per day. Of the total patients, 64 (52.5%) were assigned to the intervention group and 58 (47.5%) to the control group. Of the 122 patients included, all completed the baseline evaluation and the 3-month visit. However, some patients did not have complete data for all analyzed variables, which is why the number of cases included in certain analyses is lower. At 6 months, 68 patients attended the visit, but only 59 had complete data for all variables included in the analysis. At 12 months, 49 patients had complete laboratory and adherence data. Losses to follow-up were similar between groups and were mainly due to death, kidney transplant, or transfer to other centers.

The process of inclusion, randomization, follow-up, and analysis is shown in Fig. 2.

Baseline characteristics of both groups are shown in Table 1. No significant differences were found in demographic and clinical parameters. Baseline P levels were slightly higher in the intervention group (median: 6.0 mg/dl; IQR: 5.3–7.1) compared with the control group (5.7 mg/dl; IQR: 5.1–6.8), without statistical significance. Adherence according to SMAQ was similar (43.9 vs. 37.7%; p = 0.514).

Overall comparison between groups

In the intervention group, P levels decreased significantly at 3 months ($p \leq 0.001$) and at 12 months (p = 0.010), without changes in the number of pills or daily dose (Table 2). In the control group, there were no significant changes in P; only a reduction in the number of pills (p = 0.029) and dose (p = 0.021) was observed at 12 months. Additionally, the percentage of patients with serum P levels < 5.5 mg/dl was analyzed at each time interval. In the control group, the percentages of patients with controlled P were 34.5% at baseline, 37.0% at 3 months, 38.2% at 6 months, and 40.0% at 12 months. In the intervention group, these percentages were 31.3% at baseline, 50.0% at 3 months, 45.3% at 6 months, and 51.7% at 12 months. Overall, the intervention group showed a higher percentage of patients with controlled serum P (<5.5 mg/dl) at all time points after study initiation.

Although the main analysis focused on intra-group changes throughout follow-up, no statistically significant inter-group differences were observed in absolute serum P values or total binder dose at the different time points. Nevertheless, serum P decreases without concomitant dose increases were more consistent in the intervention group.

Adherence according to SMAQ

Adherence assessed by the SMAQ questionnaire did not show significant changes throughout follow-up in either group (Cochran's Q: control group p = 0.153; intervention group p = 0.112). The proportion of adherent and non-adherent patients remained stable across all time point evaluations, with no relevant differences between groups.

Adherence did not show significant changes throughout the study in either group (Cochran's Q: control p = 0.153; intervention p = 0.112).

Adherent patients

Both groups showed a significant reduction in P, more marked and sustained in the intervention group (Table 3). In the intervention group, the median baseline value went from 5.7 to 4.8 mg/dl at 3 months (p = 0.005); 4.8 ± 1.9 mg/dl at 6 months (p = 0.013); 5.3 ± 1.1 at 12 months (p = 0.004). In the control group, the median went from 5.7 to 5.1 mg/dl at 3 months (p = 0.004); from 6.0 ± 1.5 to 5.0 ± 1.2 at 12 months (p = 0.023).

Among adherent patients in the intervention group, there were no changes in the number or dose of binders, whereas in the control group both parameters decreased significantly at 12 months (Table 3).

Non-adherent patients

Only the intervention group showed a significant reduction in P at 12 months (6.4 ± 1.2 → 5.8 ± 1.2 mg/dl; p = 0.015). In the control group, P levels remained elevated without significant changes at any time point (Table 3).

Table 1
Baseline characteristics (0 months) of the intervention group and the control group.

Characteristic	N	Intervention group	N	Control group	p-Value
Time on HD (months)	63	59.6 (43.8–106.0)	56	64.6 (46.7–107.9)	0.580
Age (years)	64	55.2 ± 13.1	57	55.9 ± 12.3	0.165
Sex: Male	64	44 (68.8%)	58	41 (70.7%)	0.816
Sex: Female		20 (31.3%)		17 (29.3%)	
Serum phosphorus (mg/dl)	64	6.0 (5.3–7.1)	58	5.7 (5.1–6.8)	0.823
P qualitative 1: < 5 mg/dl	64	11 (17.2%)	58	10 (17.2%)	0.994
P ≥ 5 mg/dl		53 (82.8%)		48 (82.8%)	
P qualitative 2: < 5.5 mg/dl	64	20 (31.3%)	58	20 (34.5%)	0.704
P ≥ 5.5 mg/dl		44 (68.8%)		38 (65.5%)	
Calcium	64	8.7 (8.2–9.2)	58	8.6 (8.1–9.2)	0.490
PTH	63	360.0 (187.0–589.0)	57	360.2 (255.9–549.0)	0.475
Vitamin D	53	23.0 (14.0–36.0)	51	22.0 (12.8–32.1)	0.378
Albumin	64	4.0 (3.8–4.3)	58	3.9 (3.7–4.3)	0.300
C-reactive protein	62	1.7 (0.7–4.0)	56	2.0 (0.5–4.5)	0.792
Hemoglobin	64	11.7 (11.0–12.9)	58	11.8 (11.1–12.4)	0.977
Native vitamin D: No	64	31 (48.4%)	58	31 (53.4%)	0.580
Native vitamin D: Yes		33 (51.6%)		27 (46.6%)	
Native vitamin D dose (μg/month)	33	52,000.0 (52,000.0–52,000.0)	27	52,000.0 (42,700.0–76,600.0)	0.969
Calcimimetics: Cinacalcet	35	19 (54.3%)	29	13 (44.8%)	0.451
Calcimimetics: Etelcalcetide		16 (45.7%)		16 (55.2%)	
Calcimimetic dose (mg/week): Cinacalcet	19	12.0 (90.0–210.0)	13	180.0 (90.0–210.0)	0.791
Etelcalcetide	16	15,000 (7500–21,250)	16	7500 (7500–15,000)	0.468
Active vitamin D: No	64	30 (46.9%)	58	39 (67.2%)	0.023
Active vitamin D: Yes		34 (53.1%)		19 (32.8%)	
Active vitamin D dose (μg/month)	34	4.5 (4.0–6.0)	19	6.0 (4.0–12.0)	0.094
EPO type: Erythropoietin	55	35 (63.6%)	49	39 (79.6%)	0.073
EPO type: Darbepoetin		20 (36.4%)		10 (20.4%)	
EPO dose (u/week): Erythropoietin	34	8500.0 (4000.0–12,000.0)	38	6000.0 (3000.0–12,000.0)	0.751
Darbepoetin (u/week)	20	30.0 (20.0–45.0)	10	50.0 (30.0–100.0)	0.109
No. phosphate binder pills	64	6.0 (3.0–9.0)	58	7.0 (3.0–12.0)	0.184
Phosphate binder dose (mg)	64	4625.0 (2400.0–6825.0)	58	4500.0 (2175.0–8700.0)	0.231
Dry weight	64	73.8 (66.3–88.5)	58	77.0 (67.5–88.5)	0.532
SMAQ: Adherent	57	25 (43.9%)	53	20 (37.7%)	0.514
SMAQ: Non-adherent		32 (56.1%)		33 (62.3%)	

SD: standard deviation; PTH: parathyroid hormone; SMAQ: Simplified Medication Adherence Questionnaire.

Regarding treatment, among non-adherent patients in the intervention group, there was a significant reduction between 0 and 3 months in both the number of pills (p = 0.043) and the dose (p = 0.037), remaining stable thereafter. In the control group, there were no changes.

Overall, adherent patients in both groups had lower P levels than non-adherent patients, although differences in binder use were more pronounced in the control group.

Tool assessment

The overall patient rating was high, with a mean of 8.2/10, participation 8.5/10, and willingness to recommend the intervention also 8.5/10. The materials were perceived as easy to use (4/5) and useful for remembering and understanding the information (3.6–3.8/5).

Responses were obtained from 20 of 27 professionals (74%), who rated the strategy as effective (3.9/5) and easy to implement (4/5), although they rated its impact on improving adherence more modestly (2.8/5). Overall satisfaction with the intervention was high (8.6/10). In qualitative comments, professionals noted initial difficulties in adjusting the dose and explaining to the patient how to match binders to meals; however, once the regimen was internalized, the simplification of the process proved beneficial. They also emphasized that the intervention is especially useful for reinforcing and consolidating adherence in already-adherent patients, but less effective for modifying behaviors in those with low baseline adherence.

Discussion

Hyperphosphatemia control in HD patients remains a clinical challenge. Its management depends not only on binder dose but also on adherence, education, and the patient's ability to adjust medication according to their diet. These factors, linked to active patient involvement, support the use of structured educational interventions that promote empowerment and shared decision-making. This study demonstrates that a structured educational intervention can significantly improve P control in HD patients, both in adherent and non-adherent patients, without the need to increase the pharmacological burden.

Compared with previously published educational interventions, Empower-PHOS contributes several novel elements. First, it introduces a model for autonomous binder dose adjustment based on actual intake, using a simple visual tool that allows the patient to identify the approximate P content of each food and adjust the dose without increasing the total pharmacological burden. Second, it is a pragmatic intervention based on a single structured interview supplemented with audiovisual material that the patient can review autonomously as many times as needed, without requiring intensive periodic reinforcements. This approach facilitates its implementation in units with limited resources and contributes to its potential reproducibility in routine clinical practice.

These differentiating elements allow adequate contextualization of the results observed in the intervention group throughout follow-up. In the intervention group, serum levels decreased at 3 and 12 months, with the dose and number of pills remaining stable. This result suggests, consistent with other studies, a more efficient use of treatment, likely mediated by improvements in patient knowledge, motivation, and behavior.[11,12] The transition from a paternalistic approach to P binder management to a model in which the patient assumes a leading role in their management may have promoted a greater degree of engagement,[13–15] and the incorporation of the patient's beliefs, expectations, and preferences improves clinical effectiveness and treatment sustainability in the medium and long term in other studies.[16,17]

Table 2
Comparisons at 0, 3, 6, and 12 months within the intervention group and the control group.

0 vs. 3 months					
Group	Characteristic	N	Baseline Mean ± SD Median (p25–75) Frequency (%)	3 months	p-Value
Control	Phosphorus	54	5.7 (5.3–6.7)	5.6 (4.6–6.8)	0.106
Control	% p < 5.5 mg/dl	54	34.5%	37.0%	0.506
Control	No. binder pills	52	7.0 (4.0–12.0)	7.0 (3.5–12.0)	0.430
Control	Binder dose (mg)	52	4650.0 (2400.0–8602.5)	4800.0 (2500.0–8852.5)	0.978
Intervention	Phosphorus	60	6.1 (5.3–7.2)	5.4 (4.4–6.0)	<0.001
Intervention	% p < 5.5 mg/dl	60	31.3%	50.0%	0.009
Intervention	No. binder pills	57	6.0 (3.0–9.0)	6.0 (3.0–9.0)	0.249
Intervention	Binder dose (mg)	57	4750.0 (2400.0–6750.0)	4305.0 (2100.0–6300.0)	0.158
0 vs. 6 months					
Group	Characteristic	N	Baseline Mean ± SD Median (p25–75) Frequency (%)	6 months	p-Value
Control	Phosphorus	34	5.7 (5.4–6.5)	5.9 (4.6–6.6)	0.401
Control	% p < 5.5 mg/dl	34	34.5%	38.2%	0.290
Control	No. binder pills	34	7.0 (4.0–12.0)	6.0 (3.0–12.0)	0.396
Control	Binder dose (mg)	34	4650.0 (2175.0–8700.0)	4100.0 (2400.0–8700.0)	0.423
Intervention	Phosphorus	43	6.0 (5.3–7.2)	5.7 (4.2–6.9)	0.188
Intervention	% p < 5.5 mg/dl	43	31.3 %	45.3 %	0.148
Intervention	No. binder pills	43	7.1 ± 3.9	7.6 ± 4.0	0.178
Intervention	Binder dose (mg)	43	4800.0 (2400.0–6575.0)	4800.0 (2400.0–7200.0)	0.624
0 vs. 12 months					
Group	Characteristic	N	Baseline Mean ± SD Median (p25–75) Frequency (%)	12 months	p-Value
Control	Phosphorus	20	5.8 (5.3–6.5)	5.4 (4.4–6.5)	0.227
Control	% p < 5.5 mg/dl	20	34.5 %	40.0 %	0.192
Control	No. binder pills	23	8.7 ± 6.0	6.8 ± 5.4	0.029
Control	Binder dose (mg)	23	5839.6 ± 3,966.2	4281.3 ± 3516.9	0.021
Intervention	Phosphorus	29	6.2 (5.4–7.2)	5.2 (4.5–6.3)	0.010
Intervention	% p < 5.5 mg/dl	29	31.3 %	51.0 %	0.115
Intervention	No. binder pills	31	7.3 ± 4.3	6.8 ± 3.9	0.253
Intervention	Binder dose (mg)	31	4788.2 ± 2945.5	4453.3 ± 2756.9	0.255

SD: standard deviation.

The absence of statistically significant inter-group differences should be interpreted considering that the study was not powered for this objective; however, the consistency of the changes observed in the intervention group suggests a clinically relevant impact of the educational intervention.

A possible explanation for the improvement in results in the intervention group is the individualized adjustment of medication according to the P content of foods by the patient, as promoted by the educational tool. Although this was not directly measured, it may have contributed to the biochemical improvement without increasing the dose. In the control group, however, the reduction in binders was not associated with clinical improvements, especially in non-adherent patients, which reinforces the insufficiency of isolated pharmacological treatment.[13–17] Given that P absorption varies according to its origin, it is essential that professionals and patients know its content and bioavailability and apply binder dose adjustments to adequately individualize binder use taking this into account.[18]

This pattern is consistent with Ferezin et al.,[19] who describe a direct relationship between the number of pills and elevated P levels. This paradox—prescribing more without obtaining better results—likely reflects clinical attempts to compensate for the lack of adherence without evident clinical success and suggests that pharmacological treatment, without educational strategies, may not be sufficient to achieve sustained control. Taken together, our data reinforce the idea that the way medication is administered—particularly its adjustment according to dietary intake—may be more determinant for therapeutic effectiveness than the total amount of binders prescribed.

The analysis by adherence status confirms the effectiveness of the structured intervention. In both groups, the decrease in P implies a change in patient behavior, but only in the intervention group was this improvement achieved without modifying the dose—indicating more efficient adherence—, while in the control group, the P reduction led the medical team to lower the dose, mixing the behavioral effect with a subsequent clinical adjustment.

In non-adherent patients, the intervention was decisive: only the intervention group achieved a significant reduction in P levels, while in the control group they remained elevated or even worsened, despite pharmacological adjustments. These findings reinforce the hypothesis that the educational intervention can be effective even in higher-risk profiles or those with poorer adherence, and moreover in the long term (during 12 months of follow-up), acting on behavioral determinants that go beyond medication. This is also suggested by Karamanidou et al.,[4] who highlight the value of simplifying management, reinforcing education, and facilitating the integration of treatment into the patient's daily life.

This study, unlike other works focused on the type of binder,[14,17] demonstrates that it is possible to achieve similar benefits by acting on cognitive and behavioral factors, without the need to modify the medication.

Table 3
Comparisons at 0, 3, 6, and 12 months in subgroups of adherent and non-adherent patients, by control and intervention group.

Adherent patients — 0 vs. 3 months					
Group	Characteristic	N	Baseline Mean ± SD Median (p25–75) Frequency (%)	3 months	p-Value
Control	Phosphorus	25	5.7 (5.1–6.4)	5.1 (4.4–5.6)	0.004
Control	No. binder pills	25	6.0 (2.0–9.0)	5.0 (2.0–9.0)	0.080
Control	Binder dose (mg)	25	3600.0 (1500.0–7200.0)	3250.0 (1500.0–7200.0)	0.179
Intervention	Phosphorus	34	5.7 (4.5–6.3)	4.8 (4.1–5.8)	0.005
Intervention	No. binder pills	32	6.3 ± 3.5	6.7 ± 4.0	0.248
Intervention	Binder dose (mg)	32	4330.8 ± 2524.1	4592.7 ± 3013.1	0.280
Adherent patients — 0 vs. 6 months					
Group	Characteristic	N	Baseline Mean ± SD Median (p25–75) Frequency (%)	6 months	p-Value
Control	Phosphorus	17	5.7 (5.1–6.2)	5.1 (3.8–5.9)	0.070
Control	No. binder pills	16	6.0 (2.0–10.0)	4.0 (3.0–9.0)	0.507
Control	Binder dose (mg)	16	3750.0 (1250.0–7335.0)	3000.0 (1500.0–6550.0)	0.591
Intervention	Phosphorus	27	5.4 ± 2.0	4.8 ± 1.9	0.013
Intervention	No. binder pills	27	6.2 ± 3.6	7.2 ± 4.1	0.075
Intervention	Binder dose (mg)	27	4303.0 ± 2559.6	4922.0 ± 2863.1	0.081
Adherent patients — 0 vs. 12 months					
Group	Characteristic	N	Baseline Mean ± SD Median (p25–75) Frequency (%)	12 months	p-Value
Control	Phosphorus	11	6.0 ± 1.5	5.0 ± 1.2	0.023
Control	No. binder pills	10	7.3 ± 5.0	4.8 ± 3.6	0.036
Control	Binder dose (mg)	10	4980.0 ± 3628.2	3140.0 ± 2580.4	0.035
Intervention	Phosphorus	15	6.5 ± 1.1	5.3 ± 1.1	0.004
Intervention	No. binder pills	15	8.3 ± 3.7	6.9 ± 3.5	0.109
Intervention	Binder dose (mg)	15	5257.3 ± 2572.0	4400.7 ± 2335.6	0.160
Non-adherent patients — 0 vs. 3 months					
Group	Characteristic	N	Baseline Mean ± SD Median (p25–75) Frequency (%)	3 months	p-Value
Control	Phosphorus	23	5.9 (5.4–7.7)	6.6 (5.4–8.0)	0.867
Control	No. binder pills	22	10.5 (6.0–15.0)	10.5 (6.0–15.0)	0.832
Control	Binder dose (mg)	22	7350.0 (3400.0–9800.0)	6800.0 (4000.0–10,200.0)	0.385
Intervention	Phosphorus	16	7.2 (6.1–7.5)	5.9 (5.5–7.2)	0.408
Intervention	No. binder pills	16	8.5 ± 4.1	6.8 ± 3.9	0.043
Intervention	Binder dose (mg)	16	5181.3 ± 2695.7	4303.1 ± 2285.0	0.037
Non-adherent patients — 0 vs. 6 months					
Group	Characteristic	N	Baseline Mean ± SD Median (p25–75) Frequency (%)	6 months	p-Value
Control	Phosphorus	17	6.0 (5.4–7.3)	6.5 (5.8–9.0)	0.492
Control	No. binder pills	17	11.0 (6.0–15.0)	12.0 (5.0–15.0)	0.875
Control	Binder dose (mg)	17	7691.8 ± 4514.8	7707.9 ± 5555.6	0.492
Intervention	Phosphorus	14	6.5 ± 1.1	6.9 ± 1.7	0.194
Intervention	No. binder pills	14	9.4 ± 3.7	8.9 ± 3.7	0.283
Intervention	Binder dose (mg)	14	5828.9 ± 2536.4	5474.3 ± 2534.4	0.269
Non-adherent patients — 0 vs. 12 months					
Group	Characteristic	N	Baseline Mean ± SD Median (p25–75) Frequency (%)	12 months	p-Value
Control	Phosphorus	8	5.9 (5.5–6.7)	6.7 (5.4–8.1)	0.779
Control	No. binder pills	8	11.6 ± 6.9	9.4 ± 6.1	0.180
Control	Binder dose (mg)	8	7738.8 ± 4132.9	5546.3 ± 3867.6	0.125
Intervention	Phosphorus	8	6.4 ± 1.2	5.8 ± 1.2	0.015
Intervention	No. binder pills	8	9.3 ± 4.6	9.4 ± 4.3	0.446
Intervention	Binder dose (mg)	8	6413.1 ± 2995.5	6334.0 ± 3163.5	0.443

SD: standard deviation.

On the other hand, the improvements observed in the control group could be explained by the observational effect, the closer clinical monitoring resulting from study participation, and the possible influence of indirect knowledge acquisition motivated by study participation cannot be ruled out, as reported in the literature.[20]

In the control group, greater differences in prescribed treatment were observed between adherent and non-adherent patients, especially in the total number of pills and daily dose of phosphate binders. These differences reflect compensatory clinical adjustments made by the medical team, such as increasing the dose in patients with poor control or reducing it when P improves. In contrast, in the intervention group, the binder regimen was more uniform between adherent and non-adherent patients, suggesting that the intervention facilitated more effective self-management of treatment, improved medication organization, and correct adaptation to intake without the need to increase or decrease doses. Taken together, these results show that adherence depends not only on the medical prescription but also on the patient's ability to understand and correctly apply their treatment in daily life.

In this study, the SMAQ questionnaire did not detect overall changes, suggesting limitations in its sensitivity to capture subtle behavioral improvements. As noted by Horne et al.[13] and Fisher et al.,[21] adherence is dynamic and multidimensional, and may not have been fully captured by this tool. This finding is consistent with the aim of the intervention, which was not to modify adherence in dichotomous terms but to improve treatment efficiency through a more appropriate adjustment of binders according to intake, even in patients previously classified as non-adherent.

Our results support the empowerment model proposed by Náfrádi et al.[16] and the recommendations of NICE[15] and other authors[22], which promote active patient involvement. Recent studies indicate that improving functional and communicative literacy (the ability to understand and use health information in daily practice) is essential for integrating treatment into daily life.[23]

The assessment by patients and professionals is consistent with our findings: patients highlighted the usefulness of the intervention for understanding and managing medication, and professionals considered it effective and simple, emphasizing that its role is not to improve adherence but to support already-adherent patients in more efficient use of binders.

Among the limitations, patient loss, the lack of qualitative tools to explore motivation, knowledge, or practical application, and the exclusive use of the SMAQ, which may have limited the detection of subtle improvements in adherence, stand out, as well as the absence of analysis of clinical endpoints. Another limitation of the study is that the estimated sample size in the design (174 patients) was not reached, due to the actual availability of participants at the participating centers. Ultimately, 122 patients were included. This reduction in the planned sample size may have decreased statistical power, especially in the 6- and 12-month analyses, and should be considered when interpreting the results. Likewise, the use of pairwise comparisons instead of longitudinal mixed models constitutes a methodological limitation that should be taken into account, especially in long-term analyses, and could be addressed in future studies with more complete follow-up. However, the randomized, multicenter design, and the structured, patient-centered approach provide robustness and applicability to the results.

In conclusion, a structured educational intervention improves P control in HD patients, even in profiles with low adherence, without increasing the pharmacological burden. It reinforces the importance of incorporating educational, motivational, and patient-centered strategies as an essential complement to conventional treatment of P management in advanced CKD. The implementation of educational strategies such as "Empower-PHOS" could be easily integrated into HD units and contribute to improving clinical outcomes.

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