

EPIC Trial: education programme impact on serum phosphorous control in CKD 5D patients on hemodialysis

Ensaio EPIC: impacto do programa de educação no controle de fósforo sérico em pacientes com DRC 5D em hemodiálise

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Submitted on: 11/21/2016.

Approved on: 03/03/2017.

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DOI: 10.5935/0101-2800.20170072

ABSTRACT

Introduction: In stage 5D chronic kidney disease (CKD 5D) patients, the encouragement of treatment adherence by health professionals is a significant clinical challenge. **Objectives:** This study evaluates the impact of a nutritional education programme on hyperphosphatemia, utilizing the transtheoretical model of behavior change (TMBC). **Subjects and Methods:** A prospective interventional study comprising 179 CKD 5D patients with hypophosphatemia. The 4-month educational programme took place during dialysis sessions. Demographic and laboratory data were evaluated, whilst the TMBC was utilized both pre- and post-intervention. **Results:** 132 patients showed a positive change and significant reduction in phosphate levels, whilst 47 patients showed a negative change and little reduction in phosphate levels. Positive changes were identified at different levels of literacy. 117/179 participants had ongoing treatment with sevelamer throughout the trial period. 61 patients with intact parathyroid hormone (iPTH) < 300pg/ml showed phosphate level reductions, whilst 118 patients with iPTH > 300 pg/ml also showed a decrease in phosphate levels. **Conclusions:** Nutritional education programmes can achieve excellent results when appropriately applied. An education programme may be effective across different literacy levels.

Keywords: education; hyperphosphatemia; renal dialysis.

RESUMO

Introdução: nos pacientes com insuficiência renal crônica no estágio 5D (DRC 5D), o incentivo à adesão ao tratamento pelos profissionais de saúde é um desafio clínico significativo. **Objetivos:** Este estudo avalia o impacto de um programa de educação nutricional em hiperfosfatemia, utilizando o modelo transteórico de mudança de comportamento (TMBC). **Casística e métodos:** estudo prospectivo de intervenção que incluiu 179 pacientes com DRC 5D com hipofosfatemia. O programa educacional de 4 meses ocorreu durante as sessões de diálise. Os dados demográficos e laboratoriais foram avaliados, enquanto o TMBC foi utilizado tanto antes, quanto após a intervenção. **Resultados:** 132 pacientes apresentaram variação positiva e redução significativa nos níveis de fosfato, enquanto 47 pacientes apresentaram variação negativa e pouca redução nos níveis de fosfato. Mudanças positivas foram identificadas em diferentes níveis de alfabetização. 117/179 participantes foram submetidos a tratamento contínuo com sevelamer ao longo do estudo. Tivemos 61 pacientes com hormônio paratireoideiano intacto (iPTH) < 300 pg/ml que apresentaram redução do nível de fosfato, enquanto 118 pacientes com iPTH > 300 pg/ml também mostraram uma diminuição nos níveis de fosfato. **Conclusões:** os programas de educação nutricional podem produzir excelentes resultados quando adequadamente empregados. Um programa de educação pode ser efetivo em diferentes níveis de alfabetização.

Palavras-chave: educação; hemodiálise; hiperfosfatemia.

INTRODUCTION

Stage 5D chronic kidney disease (CKD 5D) is highly prevalent worldwide and significantly decreases both life expectancy and quality of life of CKD patients.^{1,2} Among the CKD 5D patient's complications, high serum phosphorus levels contribute to the high mortality from cardiovascular disorders, vascular disorders and bone calcification as well as complications associated with mineral metabolism.³

Due to their clinical relevance, increased serum phosphorus levels may be indicative of poor nutritional and pharmaceutical adherence in CKD 5D patients. Kutner et al. showed that phosphorus levels above 7.5 mg/dl indicate a lack of adherence.⁴ Saran *et al.*⁵ also showed non-adherence to treatment in CKD 5D patients to be associated with higher mortality and a high rate of hyperphosphatemia-related hospital admissions, as well as more missed hemodialysis sessions.

Nutritional education is therefore an important aspect of clinical management that encourages a continuous and interactive process that looks to improve the patient's lifestyle and thereby prevent the CKD 5D-related complications that decrease the patient's quality of life.⁶⁻⁸ Providing elementary concepts in nutrition allows patients to consciously adopt healthier behavior and achieve positive clinical outcomes. Nutritional education is also an important tool to highlight fallacies about food as well as facilitating appropriate nutritional behaviors.^{8,9}

Despite the many available strategies for the provision of nutritional education, encouraging patients to adopt health behaviors still remains a great challenge. Among these strategies, the transtheoretical model of behavior change (TMBC) empowers patients through providing them with an appropriate knowledge base in regard to their behavior, whilst also encouraging their active participation in their own self-care. The TMBC model proposes behavior to change in five dynamic stages (pre-contemplation, contemplation, preparation, action and maintenance), with each stage corresponding to a different temporal dimension of behavior. In addition, the TMBC model also takes into consideration lack of adherence and treatment relapse.¹⁰

In this study, the utility of the TMBC model is investigated in CKD 5D patients, including its impact on serum phosphorous levels. Results indicate that this approach has significant clinical utility.

SUBJECTS AND METHODS

179/180 CKD 5D patients completed this prospective clinical trial. All patients were on high-flux hemodialysis (blood flow = 350 ml/min, dialysate flow = 500 ml/min, three times per week, 4-hour session).

Inclusion Criteria: All CKD 5D patients were aged 18 years or older, being of both sexes and with serum phosphorus levels higher than 5.5 mg/dl, as determined by three consecutive measurements over the previous three months, prior to the beginning of the trial.

Exclusion Criteria: patients not freely providing consent, pregnant women and patients whose serum phosphorous levels were lower than, or equal to, 5.5 mg/dl in the last three months.

Data Collection: dry weight, height, body mass index (BMI), gender, age, schooling, serum calcium levels, serum phosphorus levels, intact parathyroid hormone (iPTH) level, the coefficient of hemodialysis adequacy (Kt/V) were analyzed pre- and post- nutritional intervention.

Sevelamer treatment: over the previous three months prior to trial initiation, patients were on a standardized oral dose of sevelamer, 800 mg, three times a day, which was not modified during the study. Sevelamer was the only phosphate-binder prescribed during the follow-up period.

Calcitriol treatment: patients with iPTH > 300 pg/ml were treated using a standardized 1 mcg i.v. dose of calcitriol at each hemodialysis session. Patients were administered this dose over the previous three months, prior to study initiation, and it was not modified during the course of the study. Calcitriol was the only drug used. Calcimimetics were not used over this 4 month period.

Pre-Intervention: The transtheoretical model of behavior change (TMBC) was initiated pre-intervention in order to plan the nutritional approach. The TMBC was applied according to the questionnaire described in Appendix 1. The answers given by the participants were used to identify their stage in the process of behavioral change, which were defined as follows:

- Stage 1 (Pre-contemplation): patients do not acknowledge they have a disease and they are not willing to change their behavior. The nutritional intervention consists of providing patients with information regarding their problem.
- Stage 2 (Contemplation): patients acknowledge the disease and contemplate making changes. The nutritional intervention involves the identification of positive features and establishment of what changes the patient believes should be made.
- Stage 3 (Preparation): patients are ready to make changes, but they need nutritional advice in order to make a cost-benefit assessment. At this stage, an individualized nutritional intervention is carried out in order to identify possible alternatives and improve the patients' self-esteem.
- Stage 4 (Action): the patients express their desire to change as well as initiating changes. However, at this stage such change is stressful, and they are in need of support. The nutritional intervention must provide support and motivation to reinforce the advantages of change.
- Stage 5 (Maintenance): the patients have complied with the suggested changes for more than six months; nevertheless, nutritional intervention is needed to enhance self-control, thereby better enabling the patient to overcome any challenges that may arise.
- Stage 6 (Relapse): patients discontinue the recommended diet and medication. Nutritional intervention at this stage must act to reinforce progress previously attained, thereby stimulating future behavior changes.

Intervention: each patient's nutritional education intervention was carried out for four months during hemodialysis sessions. The intervention consisted of one lecture about nutrition and three nutritionist-patients interaction sessions. Ten-minute lectures were given using an illustrative flip chart placed in the dialysis room, presenting pictures about food, phosphate-binder and its mechanism of action, as well as the digestive system, which aimed to increase patient understanding about the importance of nutrition for CKD 5D patients on hemodialysis. At the end of the lectures, the patients were given brochures

with explanatory text and illustrations, allowing the patient and caregiver(s) to have ready access to this information at home.

The nutritionist-patients interaction sessions were also carried out during the dialysis sessions, including traffic light, ready-made meal and self-service interactions.

The traffic light session utilized photographs of foods and two large paper rectangles, colored red or yellow, which represented traffic lights. The nutritionist presented photographs of foods, and the participants had to decide whether to place each picture on the yellow rectangle, corresponding to foods that may be consumed with moderation, or on the red rectangle, corresponding to foods that must be avoided. The consequences of inappropriate food consumption choices were discussed and advice reiterated.

The ready-made meal session comprised photographs of full meals (breakfast, lunch, snack and dinner), representing both adequate and inadequate dietary selections. Each meal was individually shown to the participants and they were asked to vote on whether the meal's composition was adequate or not, which foods would require phosphate binders and how they should be used.

When the majority of participants agreed that a meal was inadequate, the participants who had rated it as adequate were asked to justify their choice and to make suggestions as to how the meal should be changed to achieve adequacy. These proposed adjustments were made by nutritionist. All illustrative meals were displayed and discussed according to this process.

The self-service session was also carried out using photographs or drawings of foods. Before the onset of the dialysis session, patients were divided into groups and each group was asked to plan a meal (breakfast, lunch, snack or dinner) that they judged to be healthy, using the provided food images. The adequacy of the meals devised by each group was discussed during the dialysis session.

Post-Intervention: The TMBC was also applied after the nutritional intervention to plan the nutritional approach.

To analyze the results of the TMBC, the pre- and post-intervention findings were divided in two groups: one comprised those patients showing a positive shift and the other included those patients showing a negative stage shift, namely a relapse or a backward move

to an earlier stage. The criteria employed to define these groups are described in Table 1.

STATISTICAL ANALYSIS

Data was analyzed using the software *Statistical Product for Service Solutions*, SPSS, version 15.0, for Windows (IBM, USA). The continuous variables were compared using the Student's t-test. The categorical variables and groups were analyzed using contingency tables, with the chi-squared test and Fisher's exact test being applied when appropriate. Statistical significance was established for p values < 0.05 .

RESULTS

The overall characteristics of the patients assessed in this study are described in Table 2. Of the 179 patients, 98 (54.8%) were female, indicating no statistical differences between the sexes ($p = 0.23$). The patient mean age was 52 ± 15 years.

Mean time on hemodialysis was 2 ± 0.63 years and the coefficient of hemodialysis adequacy (Kt/V) was 1 ± 0.27 , pre- and post-intervention, indicating there was no changes in the hemodialysis prescription over the trial.

Using BMI classification (eutrophic, overweight or obese), 90 (50.3%) patients were regarded as eutrophic, 50 (27.9%) patients were regarded as overweight whilst 39 (21.8%) were regarded as obese, indicating similar proportions between eutrophic patients and patients with nutritional disorders ($p = 1.0$).

Regarding years of schooling, 58 (32.4%) patients completed 0-4-years, 57 completed 5-8-years, 64 patients completed 9 or more year. Such data highlights that only elementary education was typically achieved, as well as the reasons for the low levels of literacy. Similar proportion of years in school are evident between the two groups.

As regards the phosphate-binder treatment, 117 (65.4%) patients were on sevelamer hydrochloride (Renagel) and 62 (34.6%) patients were without phosphate-binder treatment. No other kind of phosphate-binder drug was prescribed in this patient sample.

After the nutritional intervention, a statistically significant decrease was evident in the serum phosphorus level of patients who were on sevelamer treatment ($n = 117/179$), from 6.8 ± 1.06 mg/dl to 5.6 ± 1.5

TABLE 1 CRITERIA FOR THE 6 STAGES OF THE TMBC

Pre-Nutritional Intervention Result	Positive shift Post-Nutritional intervention result	Negative shift Post-Nutritional Intervention Result
Precontemplation	Contemplation Preparation Action Maintenance	Precontemplation Relapse
Contemplation	Preparation Action Maintenance	Contemplation Relapse
Preparation	Action Maintenance	Precontemplation Contemplation Preparation
Action	Action Maintenance	Precontemplation Contemplation Preparation Relapse
Maintenance	Maintenance	Precontemplation Contemplation Preparation Action Relapse
Relapse	Precontemplation Contemplation Preparation Action Maintenance	Relapse

TABLE 2 OVERALL CHARACTERISTICS OF THE ASSESSED PATIENTS

Variables	
Gender	[n/total (%)]
Female	98/179 (54.7%)
Age (years)	Mean (SD)
Age	52 ± 15
Time on hemodialysis (years)	2.0 ± 0.63
Body Mass Index (BMI)	[n/total (%)]
Eutrophic	90/179 (50.3%)
Overweight	50/179 (27.9%)
Obesity	39/179 (21.8%)
Kt/V	1.0 ± 0.27
Sevelamer Treatment	[n/total (%)]
Yes	117/179 (65.4%)
No	62/179 (34.6%)
Calcitriol Treatment	[n/total (%)]
Yes (iPTH > 300 pg/ml; Ca < 9.5 mg/dl)	61/179 (34.1%)
No (iPTH < 300 pg/ml; Ca < 9.5 mg/dl)	118/179 (65.9%)
Schooling	n/total (%)
0-4 years	58/179 (32.4%)
5-8 years	57/179 (31.8%)
9 or more years	64/179 (35.8%)

mg/dl ($p < 0.05$), as well as in those not on sevelamer treatment ($n = 62/179$) from 6.6 ± 1.0 mg/dl to 6.1 ± 1.6 mg/dl ($p < 0.05$), indicating a greater reduction among patients on sevelamer treatment (Table 3).

Additionally, a statistically significant decrease in the serum phosphorus level of patients with iPTH < 300 pg/ml and Calcium < 9.5 mg/dl ($n = 61/179$), from 6.7 ± 1.20 mg/dl to 5.5 ± 1.5 mg/dl ($p < 0.05$), was evident. A statistically significant decrease in the serum phosphorus level among patients with iPTH > 300 pg/ml and Calcium < 9.5 mg/ml ($n = 118/179$), from 6.8 ± 1.0 mg/dl to 5.9 ± 1.6 mg/dl ($p < 0.05$), was also evident. Such data indicates a greater reduction in serum phosphorus levels among patients not on calcitriol treatment (Table 4).

The comparison of schooling level and phosphate levels indicated a significant decrease in phosphate levels across the three total-schooling-years groups. In the 0-4 year range, a statistically significant decrease in the serum phosphorus level was evident, from 6.7 ± 1.0 mg/dl to 5.5 ± 1.5 mg/dl ($p < 0.05$). In the 5-8 year range, the serum phosphorus level reduced from

TABLE 3 SERUM PHOSPHATE (MG/DL) CONCENTRATIONS IN PATIENTS CLASSIFIED ON THE BASIS OF PHOSPHATE BINDER PRESCRIPTION, PRE- AND POST-INTERVENTION

Patients on sevelamer treatment (117/179)		
Pre-intervention	6.8 ± 1.06	$p < 0.05$
Post-intervention	5.6 ± 1.5	
Patients not on sevelamer treatment (62/179)		
Pre-intervention	6.6 ± 1.0	$p < 0.05$
Post-intervention	6.1 ± 1.6	

TABLE 4 SERUM PHOSPHATE CONCENTRATIONS IN PATIENTS CLASSIFIED ON THE BASIS OF IPTH LEVELS, PRE- AND POST-INTERVENTION

Patients with iPTH < 300 pg/ml ($n = 61/179$)		
Pre-intervention	6.7 ± 1.2	$p < 0.05$
Post-intervention	5.5 ± 1.5	
Patients with iPTH ≥ 300 pg/mL (118/179)		
Pre-intervention	6.8 ± 1.0	$p < 0.05$
Post-intervention	5.9 ± 1.6	

6.7 ± 1.10 mg/dl to 5.5 ± 1.4 mg/dl ($p < 0.05$). In the 9 or more year range, the serum phosphate level reduction was from 6.8 ± 1.1 mg/dl to 5.9 ± 1.3 mg/dl ($p < 0.05$). Such data indicates a greater reduction among patients not on calcitriol treatment (Table 5).

As regards the behavioral changes after intervention, positive shifts were identified in 51 (28.4%) patients, whilst 13 (7.2%) patients showed little progress and 68 (37.9%) patients stayed in the action or maintenance stages, indicating that 132 (73.7%) patients derived benefits from the nutritional intervention. The patients that benefited from the intervention showed a serum phosphate level reduction from 6.8 ± 1.1 mg/dl to 5.5 ± 1.3 mg/dl ($p < 0.05$). On the other hand, 47 (26.3%) relapsed or regressed patients showed only a small serum phosphate level reduction from 6.8 ± 1.5 mg/dl to 6.5 ± 1.7 mg/dl ($p > 0.05$), indicating a statistically significant difference between the groups ($p < 0.05$ - Table 6).

The Chi-square analysis of the outcomes of the TMBC and the serum phosphorus levels by category (lower or equal 5.5 mg/dl and higher than 5.5 mg/dl) showed that most patients exhibiting serum phosphorus levels over 5.5 mg/dl (85.1% $n = 40/47$) were in the Negative outcome group ($n = 47$) (Figure 1). Additionally, few patients in the Negative outcome group exhibited serum phosphate levels below 5.5 mg/dl ($n = 7/47$).

TABLE 5 SERUM PHOSPHATE LEVELS IN PATIENTS CLASSIFIED ON THE BASIS OF LITERACY LEVEL

0-4 year range of schooling		
Pre-intervention	6.7 ± 1.0	$p < 0.05$
Post-intervention	5.5 ± 1.5	
5-8 year range of schooling		
Pre-intervention	6.7 ± 1.1	$p < 0.05$
Post-intervention	5.5 ± 1.4	
9 or more years range of schooling		
Pre-intervention	6.8 ± 1.1	$p < 0.05$
Post-intervention	5.9 ± 1.3	

The Chi-square analysis of the outcomes of the TMBC and schooling levels by category showed similar proportions (> 70%) of positive and negative shift changes (< 30%) across years of schooling (Figure 2).

DISCUSSION

This trial highlights important and clinically relevant findings regarding the outcomes of a nutrition education program utilizing TMBC. This approach was shown to effectively improve the short-term control of serum phosphate level in most study participants (73.7%). These results are in concordance with previous studies on the effectiveness of nutritional education programs.^{11,12}

Both sevelamer treatment and no sevelamer treatment groups showed a statistically significant reduction in serum phosphorus levels, indicating the clinical utility of this educational programme, irrespective of treatment with sevelamer. The relevance of the educational programme is highlighted by the data showing that in the three consecutive months before the trial, patients of both groups had shown high levels of phosphate, even when taking calcitriol and sevelamer. Such data corroborates previous reports.¹³ Deus *et al.*¹³ showed that nutrition educational programmes are more effective when added to treatment with phosphate binder medication. At this point, it may be inferred that a quicker control of hyperphosphatemia can be achieved with a combination of diet change and phosphate-binder drug.

Reduced serum phosphate levels were independent of gender and iPTH levels. It is also of note that none of the patients missed sessions over the course of the study, highlighting the study's perceived usefulness and the value of a TMBC approach.

In comparison to many clinical investigations, the participants of this study showed a low level of schooling years. 32.4% of patients had 0-4 years of schooling, 31.8% of patients had 5-8 years of schooling and 35.8% had 9 or more years of schooling. Despite the low schooling level, it was possible to reduce phosphate levels in most patients. This highlights the utility of this approach, including as derived from the use of images and audiovisual resources in the didactic materials, as well as the brochures that patients took home, which enabled information to be constantly available to them and their caregivers.

In addition, the way of teaching (group dynamics, information access and group discussions on daily dietary situations), during hemodialysis sessions, improved the likelihood of the patient's active participation, at least in part by clarify questions as to what, why, when and how, regarding dietary management of their clinical condition. Such detail and personal involvement improves both knowledge and compliance. The nutritional counseling focused on enabling the patients to translate the nutritional information into practical, everyday food choices.¹⁴

Treatment adherence is multifactorial, and not only related to the teaching approach. Many factors may influence treatment outcome, including situation perception and the deployment of different strategies in the face of everyday challenges, as well as external factors (personal, social and economic problems and social networks). The present study, although limited to results in a short-term period, indicates the utility of nutritional interventions, with short-term effects that may reinforce habits that drive long-term changes in eating behavior.¹⁵

As an approach to driving change, the TMBC is shown to be feasible and effective in CKD 5D patients in a short-term period. After the nutritional intervention, the number of patients in the preparation and action stages increased, and most patients exhibited positive outcomes. Negative stage shifts, relapse and stage regression, were more highly correlated with increased serum phosphorus levels, indicating that these patients must be closely monitored and may benefit from other clinical interventions.

TABLE 6 SHIFT CHANGES DURING THE TRIAL

Change	[n/total (%)]	Phosphate level Pre-intervention	Phosphate level Post-intervention	p-value
Positive	132/179 (73.7%)	6.8 ± 1.1	5,5 ± 1,3	p < 0.05
Negative	47/179 (26.3%)	6.8 ± 1.5	6,5 ± 1,7	

Figure 1. Positive or negative outcomes in the transtheoretical model of behavior change in CKD 5D patients on hemodialysis at the end of nutritional education programme. Positive Outcome: positive shift, patient in action stage or maintenance stage (n = 132). Negative outcome: relapsed patient or patient who moved back to an earlier stage (n = 47). Chi-square test, 95% confidence interval: $p < 0.05$.

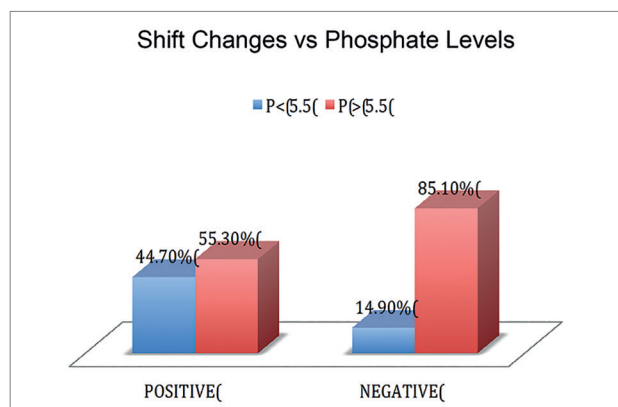
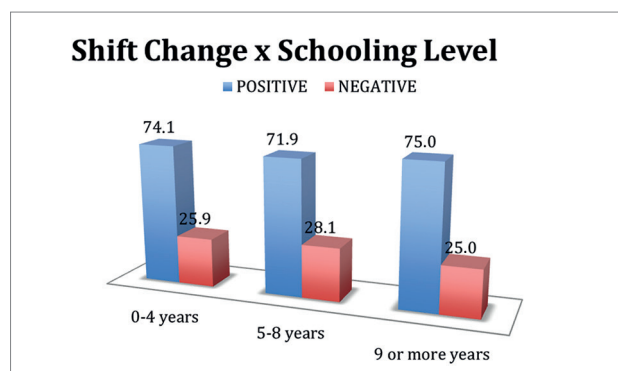


Figure 2. Comparison between Shift Changes (Positive or Negative) and Schooling Levels. Chi square test (Confidence Interval: 95%). Comparison among schooling levels: $p > 0,05$.



CONCLUSIONS

In conclusion, this study showed that a nutritional intervention programme is effective in the short term. Educational programmes are cheap and easy to implement, with TMBC showing that positive outcomes can be achieved, with this utility interacting with serum phosphate levels in CKD 5D patients on chronic hemodialysis.

The results of this study highlight how a simple and cheap educational programme can increase motivation and clinical outcomes, irrespective of years of schooling and literacy levels.

ACKNOWLEDGMENTS

The authors thank the staff of the Association of Juvenile Diabetes of São Paulo/Brazil and the support of the dialysis clinic in this study.

CONFLICT OF INTEREST STATEMENT

There is no conflict of interest in this trial.

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