# The impact of a nutrition intervention program targeting elderly people with chronic kidney disease

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> Abstract Chronic kidney disease (CKD) is recognized as a complex disease that requires multiple approaches to its treatment. The aim of this study was to evaluate the impact of a nutritional intervention program on the nutritional status and quality of life of elderly pre-dialysis CKD patients. A prospective cohort study was carried out involving 64 elderly stage 3 CKD patients receiving treatment at a Primary Care Center in the Municipality of Diadema in the State of São Paulo, Brazil. The nutritional intervention consisted of one individual and three group meetings. Nutritional status was assessed using anthropometric variables and classified according to Body Mass Index (BMI). Cardiovascular risk was classified according to Waist Circumference (WC). Quality of life was assessed using the WHOQOL-BREF. The data was analyzed adopting a significance level of 5%. Mean age was  $73.95 \pm 7.84$  years and the majority of the sample were women, had a low level of schooling, and low monthly income. With respect to nutritional status, 21.9% of the sample were underweight, 32.8% overweight, and 62.6% were at a high or very high risk of developing cardiovascular disease. The nutritional intervention program had a positive impact on nutritional status, leading to a decline in BMI and WC, reduction in risk of developing heart disease, increased satisfaction with current state of health, and improved quality of life. Key words Chronic Kidney Disease. Aging. Food and Nutrition Education

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#### Introduction

Chronic kidney disease (CKD) is defined by structural or functional abnormalities of the kidney for three months or longer with implications for health<sup>1</sup>. The main causes of kidney failure are underlying diseases such as diabetes mellitus and high blood pressure<sup>2</sup>.

Apart from pathological abnormalities, the natural aging process has a notable influence on all the components of the kidney, leading to morphological changes and reduced kidney function, which can be aggravated by comorbities<sup>3</sup>. Population studies carried out in different countries show that the estimated prevalence of CKD is up to 7.2% in adults over the age of 30 and 23 to 36% in people aged over 64 years<sup>4</sup>.

In Brazil, there is insufficient data to estimate the prevalence of CKD. If the situation in North America, where prevalence is 10%, is taken as a basis, approximately 20 million Brazilians have the disease<sup>4</sup>.

Since CKD is a generally "silent disease", early detection and treatment are critical to delay the disease, reduce progression to kidney failure and thus slow the decline in quality of life and reduce health care costs<sup>5</sup>.

In this respect, by providing access to information and addressing subjective issues related to eating, food and nutrition education is able to contribute towards improving the quality of life of CKD patients. Nutrition interventions tailored to a specific group of patients may encourage compliance with dietary guidelines and therefore help to slow the progression of CKD.

The present study therefore aims to assess the impact of a nutrition intervention program on nutritional status and quality of life among elderly pre-dialysis CKD patients.

### Methods

#### **Participants**

A prospective cohort study was carried out involving 64 elderly stage 3 CKD patients aged 60 years and over receiving treatment in a Primary Care Center (*Unidade Básica de Saúde* - UBS) in the municipality of Diadema in the State of São Paulo. The sample members were monitored over a period of nine months, between August 2012 and May 2013.

#### Recruitment and selection

Sample members were initially selected from the Arterial Hypertension and Diabetes Management System (*Sistema de Gestão Clínica da Hipertensão Arterial e Diabetes* - HIPERDIA) which registers and enables the monitoring of patients with high blood pressure and/or diabetes mellitus receiving treatment through the Unified Health System's (*Sistema Único de Saúde* - SUS) outpatient network<sup>6</sup>.

The information provided by HIPERDIA includes serum creatinine levels used to calculate estimated glomerular filtration rate (GFR).

The classification of the stages of CKD was based on the level of estimated GFR calculated using the Cockcroft-Gault equation, whereby a GFR of 30 - 59ml/min/1.73m<sup>2</sup> is classified as stage three<sup>7,8</sup>.

Using the information contained in the patients' records on the HIPERDIA for 2010 and 2012, the sample members were selected in accordance with the following inclusion criteria: aged 60 years and over; stage 3 CKD patients.

A total of 146 elderly people who met the inclusion criteria were invited in writing to take part in the study through a letter delivered to their home by a Community Health Agent (Agente Comunitário de Saúde). A total of 98 patients accepted the invite and were part of the initial sample and 64 patients remained until the end of the monitoring period.

The invitation process and first contact with the sample members took place only after the project was granted approval by the Research Ethics Committee. Prospective sample members were informed of the risks and benefits of participating in the study and of the following exclusion criteria: stage 3 CKD patient fails to attend individual treatment sessions or attendance frequency is less than 75%. Those patients who agreed to participate in the study signed an informed consent form.

#### The nutrition intervention

Three group meetings and one individual meeting were held with the sample members. It is important to note that, to avoid excessive losses throughout the study period, patients who would otherwise have been excluded from the study because they failed to attend individual treatment sessions were followed up before advancing to the next stage of the program.

The group interventions consisted of three meetings, each with a maximum of 15 patients and lasting approximately one hour (Chart 1), and addressed the following main nutrition-related topics: eating small meals throughout the day; fluid intake; potassium content within the group of fruits and vegetables; and information on how to moderate protein, fat and sodium intake.

Individual meetings were held after the first group meeting to define personalized diet plans. These plans were elaborated based on information obtained from a 24-hour dietary recall, food preferences and aversions, and dietary guidelines for non-dialysis CKD patients (energy, carbohydrates, proteins, lipids, fibers, and micronutrients). After defining the nutrition goals for each patient, the diet plans nutrition goals were established using the AVANUTRI nutritional assessment and prescription software, version 4.0.

It is important to note that, to measure progress towards the achievement of expected results, an overall assessment was undertaken rather than a specific assessment for each strategy of the intervention program<sup>9</sup>. To this end, the nutrition intervention was assessed at the end of the process by comparing the study variables (anthropometric variables and quality of life) before and after the intervention.

## Sociodemographic profile, anthropometric variables, and quality of life

Sociodemographic data (sex, age, level of schooling, and monthly family income) was obtained using interviews conducted by the nutritionist/researcher before the nutrition intervention.

Anthropometric measurements (weight, height, and waist circumference) were taken using standard techniques before and after the nutrition intervention program. Body weight was measured using a digital scale with a capacity and accuracy of 200 kg and 50 g, respectively. The patient stood upright with feet together in the middle of the scale with minimal clothing, shoes removed and arms hanging directly alongside the torso. The patient remained still until the weight appeared on the display<sup>10</sup>.

Height was measured to the nearest 0.5 cm using a stadiometer attached to the scale with a maximum extension of 2 m. Patients were asked to stand upright with their shoes removed, heels together and weight evenly distributed between the feet, and with their head free of any hair ornament looking straight ahead at a fixed point at the level of the eyes<sup>10</sup>.

The patient's weight and height was used to calculate Body Mass Index (BMI) and classify

<b>Chart 1</b> . Description of	group interver	ntion strategies in	plemented with th	he elderly	pre-dialysi	is CKD patients.

Topic	Objectives	Teaching strategy
Understanding	Introduce the concept and functions of the kidney,	■ Presentation: verbal
the kidney and	showing its importance for body balance.	communication between the
its functions	Explain the relationship between aging and kidney	researcher and group, allowing
	functioning.	for questions at all times.
	■ Introduce the definition and classification of CKD and	<ul> <li>Resources: digital projector.</li> </ul>
	the principal causes that lead to its development.	
Diet for people	Reinforce nutritional guidelines for Pre-dialysis CKD	<ul> <li>Conversation circle: creation</li> </ul>
with CKD	patients.	of opportunities for group
	Discuss and reflect on the main difficulties and ease	dialogue where group members
	of compliance with a prescribed diet plan (individual	are able to express themselves
	meeting).	and, above all, listen to others
		and themselves, thus promoting
		experience sharing.
CKD	• Revisit the classification of CKD and present treatment	<ul> <li>Oral presentation about types</li> </ul>
treatment	provided as the disease progresses to more advanced	of treatment in the advanced
	stages (dialysis).	stages of CKD, enabling the
		group members to clear up
		doubts.
		Resources: poster.

nutritional status into the following categories: underweight – BMI < 23 kg/m<sup>2</sup>; normal weight – BMI  $\ge 23$  and < 28 kg/m<sup>2</sup>; overweight – BMI  $\ge 28$  and < 3.0 kg/m<sup>2</sup>; and obese – BMI  $\ge 30$  kg/m<sup>2</sup> <sup>11</sup>.

Waist circumference (WC) was measured using an inelastic fiber glass tape measure. Patients were asked to stand upright with their legs slightly separated, weight evenly distributed between the feet, and arms hanging directly alongside the torso. The tape was positioned horizontally at the midpoint between the lower edge of the last rib and the top of the iliac crest. The patient was then asked to breathe in and breathe out fully to take the measurement<sup>10,12</sup>.

The cut-off points adopted for this study are those set by the World Health Organization (WHO) for adults, since there are no specific parameters for the elderly. Based on this, women with a WC of  $\geq$  80 cm and men with a WC of  $\geq$  94 cm were regarded as being at a high risk of developing cardiovascular disease (CVD), while women with a WC of  $\geq$  88 cm and men with a WC of  $\geq$  102 cm were considered at very high risk of developing CVD<sup>13</sup>.

The World Health Organization Quality of Life Questionnaire (WHOQOL-BREF) was used to evaluate patients' subjective perceptions of quality of life. This tool was used since it has been shown to be useful for measuring quality of life among CKD patients<sup>14</sup>. The questionnaire comprises 26 items grouped into four domains (physical, psychological, social, and environmental), including the first two questions that address the patient's general self-perception of quality of life and satisfaction with current state of health<sup>15</sup>.

The WHOQOL-BREF was used to assess quality of life before and after the nutrition intervention. The questionnaire was administered through face-to-face interviews, to account for the fact that sample members may have suffered from visual acuity loss and/or have had a low level of education.

Each domain and question was scored on a scale of zero to five. There are no cut-off points for higher or lower quality of life. The overall score ranges from zero to 100, where 100 indicates high quality of life and zero suggests low quality of life.

#### Data analysis

The data was analyzed using the Statistical Package for Social Science (SPSS), version 21, adopting a significance level of 5% (p  $\leq$  0.05), while paired sample Student's t-Test was used to

compare average BMI and WC, the scores for the domains and questions addressing the patient's general self-perception of quality of life and satisfaction with current state of health, and the overall WHOQOL-BREF score before and after the intervention program.

#### Results

The average age of the sample was  $73.95 \pm 7.84$  years across a range of 60 to 91 years. Age distribution among those aged < 75 years was similar to that among those aged  $\geq$  75 years. The majority of the sample were women (65.6%), had not completed elementary school or not provided information on their level of education (92.2%), and had a monthly family income of up to three minimum salaries (76.6%) (Table 1).

With respect to nutritional status, the majority of the sample were of normal weight, while 21.9% were underweight and 32.8% were overweight or obese. The prevalence of overweight was greater among women and 62.6% of the sample were at a high or very high risk of developing CVD based on WC. The prevalence of very high risk of developing CVD based on WC was greater among men (Table 2).

The mean and standard deviation of BMI and WC by sex before and after the nutrition intervention are shown in Table 3. A statistically significant reduction in BMI and WC in both sexes was observed after the nutrition interven-

**Table 1.** Sociodemographic characteristics of elderly pre-dialysis CKD patients.

Sociodemographic variables	n	%
Sex		
Male	22	34.4
Female	42	65.6
Age group		
< 75 years	33	51.6
≥ 75 years	31	48.4
Level of schooling		
No schooling	20	31.3
Did not complete elementary school	39	60.9
Completed elementary school	05	7.8
Monthly family income		
Up to 3 minimum salaries	49	76.6
≥ 3 minimum salaries	15	23.4

tion program. However, despite the reduction in WC, the risk of CVD among women remained high.

With respect to quality of life, it was observed that the highest scores were attained for the social domain social, which addresses satisfaction with personal relationships and sexual activity, while the lowest scores were achieved for the environmental domain, which encompasses feelings of physical safety and security, leisure opportunities, living conditions, access to health services, transport, and financial situation (Table 4).

The findings show that there were no gains or losses after the nutrition intervention with respect to the scores for each of the domains, the question addressing self-perception of quality of life, and the overall WHOQOL-BREF score. However, there was a statistically significant increase in satisfaction with current state of health among the sample members after the intervention, demonstrated by the average scores for the second question "How satisfied are you with your health?" (Table 4).

Table 2. Nutritional status and cardiovascular risk among elderly pre-dialysis CKD patients.

Health status	Classification	Male (n = 22)	Female (n = 42)	Total (n = 64)
NT 4 24 Table	Underweight	6 (27.3%)	8 (19.0%)	14 <b>(21.9%)</b>
	Normal	11 (50.0%)	18 (42.5%)	29 (45.3%)
Nutritional status	Overweight	1 (4.5%)	7 (16.7%)	8 (12.5%)
	Obese	4 (18.5%)	9 (21.4%)	13 (20.3%)
Cardiovascular Risk	No risk	6 (27.3%)	18 (42.9%)	24 (37.5%)
	High risk	3 (13.6%)	17 (40.5%)	20 (31.3%)
	Very high risk	13 (59.1%)	7 (16.7%)	20 (31.3%)

**Table 3.** Mean and standard deviation of BMI and WC among elderly pre-dialysis CKD patients by sex, and pre and post intervention.

C		Pre	Post	
Sex		Mean ± SD	Mean ± SD	p
Men (n = 42)	BMI	$26.75 \pm 3.72$	$26.23 \pm 3.67$	0.015
	WC	$85.68 \pm 8.04$	$83.62 \pm 8.00$	0.003
Women $(n = 22)$	BMI	$25.59 \pm 3.82$	$24.99 \pm 3.76$	0.001
	WC	$89.71 \pm 10.70$	$87.91 \pm 10.96$	0.001

**Table 4**. Mean and standard deviation of scores for domains, questions addressing the patients' general self-perception of quality of life and satisfaction with current state of health, and the overall WHOQOL-BREF score among elderly pre-dialysis CKD patients, pre and post intervention.

Variable –	Pre	Post	р
variable –	Mean ± SD	Mean ± SD	
Physical domain	$59.43 \pm 13.67$	$59.77 \pm 14.39$	0.845
Psychological domain	$61.07 \pm 13.01$	$62.70 \pm 15.31$	0.292
Social domain	$70.83 \pm 12.24$	$71.61 \pm 12.75$	0.682
Environmental domain	$56.01 \pm 10.10$	$55.42 \pm 10.64$	0.729
Self-perception of quality of life	$64.84 \pm 19.27$	$62.11 \pm 18.36$	0.311
Satisfaction with state of health	$56.64 \pm 22.82$	$62.89 \pm 20.89$	0.035
Overall score	$60.17 \pm 8.76$	$60.68 \pm 9.61$	0.633

#### Discussion

By understanding the profile of CKD patients and ensuring the early tailor-made treatment of the disease, it is possible to slow its progression and avoid complications and thus improve patient quality of life and reduce treatment costs<sup>16</sup>. With this in mind, strategies aimed at encouraging adherence to dietary guidelines, such as the planning, implementation and evaluation of nutrition education programs are warranted<sup>17</sup>. The present study therefore intended to assess the impact of a nutrition intervention program targeting elderly pre-dialysis CKD patients by comparing anthropometric variables and quality of life before and after the intervention.

Regarding nutritional status, the BMI results were similar to those of a cross-sectional study conducted by Martin et al. <sup>18</sup> in São Paulo with elderly men and women, which showed that over half of the sample were of normal weight, 14.3% undernourished, and 21.4% overweight. A study of elderly CKD patients conducted by Rembold et al. <sup>16</sup> showed that 6.9% and 54.1% of patients were underweight and overweight, respectively, and that prevalence of poor nutritional status was relatively high among both patients diagnosed with CKD and those who did not have the disease.

CKD patients are susceptible to malnutrition and, given that this condition is a marker of poor prognosis of CKD, the assessment of nutritional status aims to determine whether the patient is malnourished or at risk of malnutrition<sup>19</sup>. Although malnutrition is common among patients with kidney problems, there has been relatively little research into its prevalence in pre-dialysis CKD patients<sup>20</sup>. Furthermore, prevalence of malnutrition depends on the diagnostic criteria used (biochemical: albumin and creatinine; anthropometric: arm circumference and BMW; and nutritional: subjective global assessment)21. For example, the diagnosis of malnutrition based on hypoalbuminemia resulted in prevalence rates of between 20 and 45%, while diagnoses using subjective global assessment resulted in rates ranging between 18 and 20%<sup>20</sup>. These prevalence rates are in line with the underweight results found by the present study (21.9%) using anthropometric indicators (BMI). It is important to diagnose malnutrition in CKD patients since the condition is associated with an increased risk of infection, hospitalization and mortality, inflammation and reduced quality of life21.

Despite the high prevalence of malnutrition found in CKD patients, it has been shown that

overweight and obesity are common nutritional disorders among this group8. Studies show that around 50 to 60% of pre-dialysis CKD patients are overweight or obese according to BMI<sup>22</sup>. The present study showed that overweight was more prevalent in women (38.1%) than in men (23%). Similar findings were reported by the "Health, Well-being and Aging" (Saúde, bem-estar e envelhecimento - SABE) study conducted by the Pan American Health Organization (PAHO) with older adults living in urban areas in the Municipality of São Paulo, which showed that the prevalence of overweight and obesity among women was 40.5% as compared to 21.7% in men. This situation seems to reflect, among other factors, a larger amount of body fat, since women have a lower body mass index and are generally shorter in stature than men. This occurs in all ages, mainly due to the fact that fat is approximately four times greater in women<sup>23</sup>.

These findings show that there is no one single profile of nutritional status among CKD patients. Thus, equal attention should be given to both malnutrition and overweight, since obesity is an important risk factor for hypertension and type 2 diabetes, which, when concomitant, aggravate kidney damage<sup>24</sup>. Apart from being associated with the development of CKD, these conditions also play a role in the progression of the disease to more advanced stages and in mortality associated with kidney disease<sup>25</sup>. The majority of treatments and approaches that seek to ameliorate the complications of CKD in obese patients focus on management of associated risk factors, such as hypertension, diabetes and hyperlipidemia using strategies like nutritional counseling, pharmacological interference, and, in certain cases, surgery<sup>24</sup>. In this sense, normal-weight patients should avoid gaining weight, while overweight patients should lose weight, in view of the benefits associated with the control of blood pressure and blood sugar levels<sup>25</sup>.

With respect to risk of developing CVD based on WC, the findings show that men have a significantly larger visceral fat area than women. These findings are similar to those of a study carried out by Sanches et al.<sup>26</sup> with 122 adult pre-dialysis CKD patients aged between 27 and 79 years.

These results emphasize the fact that abdominal fat is a factor that favors the occurrence of cardiovascular events. Furthermore, it is notable that the prevalence of CVD is greater among CKD patients, including pre-dialysis patients, than in the general population, and constitutes the main cause of morbidity and mortality

among this group, especially among patients undergoing dialysis<sup>27</sup>.

The assessment of the impact of the nutrition intervention showed that there was a statistically significant reduction in average BMI and WC among both men and women after the intervention.

Similarly, a prospective randomized controlled trial with pre-dialysis CKD patients with an average age of  $63.4 \pm 11.0$  years showed that there was a statistically significant reduction in average BMI at the end of the program in both the intervention and control group and a statistically significant reduction in WC among men from the intervention group and in women from the control group<sup>17</sup>. The program therefore had an important impact considering that reducing body weight and WC can slow the progression of CKD and in view of the fact that overweight and cardiovascular events are among the main cause of morbidity and mortality in CKD patients.

In a study involving 38 obese CKD patients that explored the influence of dietary intervention and physical exercise, Wang et al.<sup>28</sup> observed that after a two-month life-style intervention program patients who managed to control body weight showed a significant improvement in the control of blood pressure, lipid profile, serum creatinine levels, estimated glomerular filtration rate, and proteinuria. These results show that a combination of dietary interventions and physical exercise is associated with the amelioration of cardiovascular risk factors and CKD in obese CKD patients.

It is important to mention that reductions in BMI should be assessed individually and with caution in CKD patients, especially in older adults, given the possible negative effects related to malnutrition. Ricardo et al.29 assessed the association between healthy life-styles and lower risk of death among CKD patients participating in the Third National Health and Nutrition Examination Survey (NHANES III). The researchers reported that risk of mortality increased by 30% among patients with a BMI of between 18.5 and 22 kg/m<sup>2</sup>, suggesting that avoiding low BMI may improve patient survival. Although general obesity may play a protective role against catabolic events that affect CKD patients, abdominal obesity is also a risk factor that negatively affects survival in these patients<sup>30</sup>, thus showing the importance of reducing WC and BMI. However, the effects of BMI among pre-dialysis CKD patients have been less studied, suggesting that further research is required to obtain a better understanding and determine the ideal BMI for this group<sup>29</sup>.

Although BMI is used as a tool for assessing nutritional status in epidemiological studies, such a measure may be considered inappropriate in routine clinical practice for monitoring body fat or nutritional status, particularly for patients with CKD, due to certain limitations such as its inability to differentiate between body compartments like fat mass and lean muscle mass31,32 and the tendency to "mask" nutritional status in cases of water retention, a common symptom among CKD patients<sup>33</sup>, especially in more advanced stages of the disease. An examination to detect edema was not conducted under the present study. However, it is important to highlight that patients that participated in this study were not in the advanced stage of CKD.

Given the importance of body composition in the prognosis of CKD patients, BMI and WC should not be used in isolation in routine clinical practice, but rather with other methods and tools for assessing nutritional status and body composition in order to adequately assess nutritional status<sup>34</sup>.

With respect to quality of life, there was a statistically significant increase in satisfaction with current state of health after the intervention, which may be considered a positive impact, given that CKD is not a curable disease and therefore the primary goal of treatment should be improve patient satisfaction and well-being<sup>14</sup>.

Using the Kidney Disease Quality of Life Short Form and Short Form-36 (SF-36) with a specific module adapted to assess kidney disease Campbell et al.<sup>35</sup> assessed the impact of a nutrition intervention on the quality of life of pre-dialysis CKD patients divided into intervention and control groups and observed a statistically significant difference between average scores for symptoms of kidney disease, cognitive functioning, and vitality in favor of the intervention group.

In an assessment of the impact of an interdisciplinary program on the quality of life of pre-dialysis CKD patients using the Medical Outcomes Study Questionnaire 36 – Item Short Form Health Survey (SF-36), Santos et al.<sup>36</sup> observed that, after a year participating in the program, there was a statistically significant increase in the scores obtained by the intervention group in five of the eight domains, while in the control group there was no improvement in the quality of life parameters assessed by the study.

Little research has been carried out into the quality of life of pre-dialysis CKD patients. Furthermore, most studies focus on physical and lab-

oratory-based assessments, rather than psychological and quality of life parameters<sup>36</sup>. Despite the fact that different instruments were used to assess quality of life, the findings of the present study and the other studies mentioned above show the importance of early nutrition-based interdisciplinary interventions for pre-dialysis patients that are aimed at improving the quality of life of this group from diagnosis up to the commencement of renal replacement therapy.

In this respect, it is important to highlight that, given the complex nature of CKD and the clinical problems associated with aging, an interdisciplinary approach that includes nutritionists and food and nutrition education is the most effective way of delivering adequate care to elderly CKD patients since it enables a multidimensional evaluation of the patient<sup>37</sup>.

The limitations of the study include the use of non-probability sampling methods and the absence of a control group. As a result, the findings should be interpreted with caution and should not be generalized to elderly CKD patients as a whole. Other limitations include the use of the 24-hour dietary recall to assess food intake, given that the quality of the information provided by this method depends on, among other factors, memory, patient cooperation, and age. The latter may affect the ability of the patient to accurately remember food intake, and extremely old patients may require someone to help relay the information<sup>38</sup>.

Finally, it is suggested that further prospective randomized controlled studies focusing on the planning, implementation, and evaluation of nutrition education interventions with elderly CKD patients should be carried out.

#### **Conclusions**

The findings show that the nutrition intervention program had a positive impact on nutritional status, reduced the risk of developing cardiovascular disease, and led to an increase in satisfaction with current state of health, thus resulting in improved quality of life. This was probably due to the nutrition intervention, which provided information on the disease and nutritional care, thus improving treatment adherence among pa-

Despite its limitations and considering the scarcity of literature on nutrition interventions with pre-dialysis CKD patients, particularly among older patients, this study is an important contribution to research in this area and provides helpful insights into education-based nutritional care aimed at improving patient compliance with dietary guidelines.

Furthermore, the benefits associated with the educational component of the nutrition intervention emphasize the need to create public policies aimed promoting food and nutrition education in primary health care through cost-effective actions focusing on the prevention of CKD among patients suffering from high blood pressure and diabetes - those most affected by kidney disease - and on slowing the progression of CKD in the early stages of the disease in order to improve quality of life and reduce the health care costs generated by dialysis.

#### **Collaborations**

FG Magalhães participated in study conception, data collection and interpretation, and in the drafting of this article; RMM Goulart participated in study conception, the critical review of this article, and the final approval of the version to be published; LC Prearo participated in data analysis and in the final approval of the version to be published.

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