Effects of Intensive Dietary Counseling versus Standard Dietary Counseling in Chronic Kidney Disease Patients: The Pilot Study

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Abstract

Background: Chronic kidney disease (CKD) is a major public health problem worldwide, particularly in Thailand. Several studies have recommended limiting protein and sodium intake with the benefit of delaying kidney deterioration. Hence, dietary counseling is recommended for CKD patients. We aimed to explore and compare the effects of intensive dietary counseling (In-counseling) and standard dietary counseling (Sd-counselling) for controlling protein and sodium intake.

Methods: The present study was an open-labeled randomized control trial. The participants were stage III – IV CKD patients who were stable on their current treatment. The Id-counseling group received 30-minute monthly lessons with advice on dietary intake. The Sd-counseling group received the usual standard of care. The outcomes were daily protein intake (DPI) and 24-hour urinary sodium (UNa) at two months.

Results: Twenty CKD patients were divided into two groups of 10 participants each. Baseline characteristics were similar in both groups, except there were more CKD stage 4 patients in Sd-counselling group (3 vs 1 participant). The three most common comorbidities were hypertension (80%), dyslipidemia (70%) and diabetes mellitus (50%). Baseline DPI and 24-hour UNa were similar in both groups. After 2 months, the DPI of the In-counseling group achieved greater target-control than Sd-counseling. There was a trend to decrease 24-hour UNa between before and after counseling in In-counseling group. However, the DPI and 24-hour UNa at the end of the study was not statistically significant.

Conclusion: Although our study did not show significant benefit from In-counselling, it might be due to a small sample size and short time period. There was, however, some trend showing a benefit of In-counselling. A larger scale randomized controlled trial should be conducted to explore this benefit.

Keywords: intensive dietary counseling, chronic kidney disease, dietary protein intake, sodium intake.

โครงการศึกษานำร่องทางคลินิกแบบสุ่มเปรียบเทียบประสิทธิภาพของการให้ความรู้และคำแนะนำด้านโภชนาการแบบเข้มข้นเทียบกับแบบปกติในผู้ป่วยโรคไตเรื้อรัง

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บทคัดย่อ

บทนำ: โรคไตวายเรื้อรัง เป็นโรคที่พบบ่อยและเป็นปัญหาด้านสาธารณสุขที่สำคัญของโลกโดยเฉพาะในประเทศไทย เป็นโรคเรื้อรังที่รักษาไม่หายขาด จำเป็นต้องได้รับการรักษาต่อเนื่อง มีการศึกษาหลายการศึกษาโดยเฉพาะในคนไข้โรคไตเรื้อรังระยะก่อนบำบัดทดแทนไต ได้ศึกษาถึงความสำคัญของการจำกัดสารอาหารประเภทโปรตีนและโซเดียม ได้ประโยชน์ช่วยชะลอการเสื่อมของไตได้ ผู้วิจัยได้ศึกษาความสัมพันธ์เปรียบเทียบประสิทธิภาพของการให้ความรู้และแนะนำด้านโภชนาการ ในผู้ป่วยโรคไตเรื้อรังแบบเข้มข้นแบบตัวต่อตัวเทียบกับแบบปกติทั่วไป โดยวัดค่าโปรตีนที่ได้รับในแต่ละวัน

วิธีการดำเนินการศึกษา: การศึกษานี้ได้ศึกษาแบบ open – labeled, randomized control trial โดยใช้ระบบคอมพิวเตอร์ โดยกลุ่มที่ได้รับความรู้ทางด้านโภชนาการแบบเข้มข้นตัวต่อตัว (intensive nutritional counseling) จะได้รับคำแนะนำจากนักโภชนาการ 30 นาทีในทุกเดือน ส่วนในกลุ่มที่ได้รับความรู้ทางด้านโภชนาการแบบมาตรฐานในแผนกผู้ป่วยนอก (standard nutritional counseling) การวัดค่าโปรตีนที่ได้รับในแต่ละวัน (dietary protein intake) จะเก็บยูเรียในปัสสาวะ 24 ชั่วโมง และ ผู้วิจัยประเมินปริมาณโซเดียมที่ได้รับในแต่ละวันจากค่าโซเดียมในปัสสาวะ 24 ชั่วโมง โดยเปรียบเทียบผู้เข้าร่วมวิจัยในแต่ละวิธีการ ให้คำแนะนำและความรู้ด้านโภชนาการ วัดค่าผลลัพธ์หลัก คือ ค่าโปรตีนที่ได้ในแต่ละวัน ที่ 2 เดือน ปริมาณโซเดียมในปัสสาวะ การทำงานของไต ไขมันในเลือด ฟอสฟอรัสและค่าเกลือแร่ในร่างกาย

ผลการศึกษา: ผู้วิจัยได้รวบรวมผู้เข้าร่วมโครงการวิจัย 20 คน เป็นคนไข้ไตวายเรื้อรัง (แบ่งเป็นได้รับความรู้ทางโภชนาการแบบเข้มข้นตัวต่อตัว 10 คน และได้รับความรู้ทางโภชนาการแบบทั่วไป 10 คน) เก็บระหว่าง เดือนมกราคม 2561 ถึง ตุลาคม 2561 โดยลักษณะพื้นฐานทั้งสองกลุ่มไม่แตกต่างกันอย่างมีนัยสำคัญ โรคประจำตัวที่พบบ่อย 3 โรค ได้แก่ โรคความดันโลหิตสูงคิดเป็นร้อยละ 80 ไขมันในเลือดสูง ร้อยละ 70 และเบาหวานร้อยละ 50 ปริมาณค่าโปรตีนที่ได้ต่อวันก่อนเข้าโครงการทั้งสองกลุ่มไม่แตกต่างกัน คิดเป็นค่าเฉลี่ยที่ 0.77 กรัม/กิโลกรัม/วัน ในกลุ่มเข้มข้นตัวต่อตัว และ 0.80 กรัม/กิโลกรัม/วัน ในกลุ่มมาตรฐาน ค่าโซเดียมในปัสสาวะ 24 ชั่วโมงมีแนวโน้มลดลงในกลุ่มเข้มข้นตัวต่อตัว แต่ไม่มีนัยสำคัญทางสถิติ

สรุป: ถึงแม้ว่าการศึกษาของเราจะไม่แสดงความแตกต่างอย่างมีนัยสำคัญในการให้ความรู้และคำแนะนำด้านโภชนการในผู้ป่วยโรคไตเรื้อรังด้วยการประเมินค่าบริโภคโปรตีนในแต่ละวัน แต่ก็มีแนวโน้มว่าการคุมการรับประทานเกลือจะดีขึ้นในกลุ่มที่ได้รับความรู้ทางโภชนาการแบบเข้มข้นตัวต่อตัว ดังนั้นการศึกษาที่มีขนาดตัวอย่างเพิ่มขึ้นน่าจะแสดงประสิทธิภาพของการได้ความรู้ทางโภชนาการแบบเข้มข้นตัวต่อตัวได้

คำสำคัญ: ประสิทธิภาพของการให้ความรู้, โรคไตเรื้อรัง, การวัดค่าโปรตีนที่ได้รับในแต่ละวัน, ปริมาณโซเดียม

Introduction

Chronic Kidney Disease (CKD) is a significant problem in Thailand and the prevalence of CKD is on the rise[1]. If CKD is not properly treated, the disease will worsen until it becomes end-stage renal failure requiring dialysis, which is increasing in prevalence and incidence in Thailand[2]. Several studies have found dietary control contributes to delaying kidney deterioration, particularly dietary control aimed at limiting protein and sodium intake. The recommendation of the Nephrology Society of Thailand in 2015 on limiting protein for Stage 3 Chronic Kidney Disease (CKD) patients was not to limit protein, but not to exceed protein intake of 1.3 grams per kilogram of the patient's recommended weight and to consume high-quality protein or complete amino acids. For CKD at the stage where estimated glomerular filtration rate (eGFR) is less than 30 ml/min/1.73m^2 patients are advised to limit protein intake to less than 0.8 grams per kilogram of the patient's recommended weight. Many previous studies have recommended intensive or individual dietary counseling as being more useful and yielding better outcomes than practical or standard counseling in patients on dialysis, CKD patients[3]. diabetes mellitus patients[4]. and patients with malnutrition[5].

Hence, this study aimed to explore the effects of intensive dietary counseling versus standard counseling in CKD patients.

Material and methods

Study design and population

This was an open-labeled randomized control study. We enrolled participants between July 1st, 2018 and October 31st, 2018 at a university hospital. The patients who visit the nephrology clinic were invited to participate. The eligibility criteria were age between 18 – 70 years, diagnosed stage 3 – 4 CKD, and treatment with maximum, or tolerated dose, of renin-angiotensin-aldosterone system (RAAS) inhibitor for 2 months. The exclusion criteria were: (1) current treatment with dialysis, (2) active infection, (3) pregnancy, (4) active malignancy, (5) malnutrition with serum albumin below 3.5 mg/dL, and (6) declined to participate.

Randomization

When participants had been screened and met the inclusion criteria for enrollment in the study, they were randomized into the following two groups with a computer-based randomization system: the group offered intensive dietary counseling (Id-counseling) and the group offered standard dietary counseling (Sd-counseling).

Treatment

For the Id-counseling group, the participants received individual dietary counseling directly from a nutritionist for 30 to 45 minutes in a CKD clinic. They were advised to make proper adjustments tailored to each individual, including interactions aimed at helping the patients gain understanding and improve their knowledge. For example, key points were emphasized by providing information sheets, following up, and providing advice every month. The participants in Sd-counseling group received standard or routine counseling, which had been individual counseling at regular visits to the nephrology clinic. During the study period, RAAS inhibitors were maintained at the same doses as they were at enrollment.

Data collection

After enrollment in the study, the participants were interviewed on their respective backgrounds, diagnosis of diseases, weight, height and waist circumference. They were then given physical examinations and baseline laboratory tests for Blood Urea Nitrogen (BUN), creatinine (Cr), electrolyte, albumin, blood sugar, hemoglobin A1c (HbA1c), calcium, magnesium, phosphate, lipid profile and 24-hour urine for urea, sodium, and protein. The urinary samples were taken at 24 hours by having the patients urinate as usual immediately after awakening. Then, the patients provided urine samples all day until the next morning with the last sample being given after the patients awoke the next day.

We assessed daily protein intake (DPI) based on the normalized protein equivalent of nitrogen appearance (nPNA) by calculating based on urinary samples taken at 24 hours to test for urea and protein, and then calculated as follows:

nPNA = ([(UUN + (0.031 x BW)) x 6.25] + Up) / BW

nPNA, normalized protein equivalent of total nitrogen appearance (g/day); UUN, 24-hour urinary urea nitrogen (g/day); Up, 24-hour urinary protein (g/day); and BW, body weight.

For the DPI-targeted, we assigned subjects based on the stage of CKD: CKD stage III, 0.8 – 1 g/kg/day and CKD stage IV, 0.6 – 0.8 g/kg/day. We assessed the sodium intake by taking urine samples at 24 hours to test for sodium.

Outcomes

The primary outcome was to compare the efficiency of protein control by the methods of Id-counseling versus Sd-counseling in CKD patients. The secondary outcome was to compare the efficiency of controlling sodium intake between both groups, including follow-up by comparing the changes in cholesterol levels, blood glucose levels and phosphorous levels.

Statistical analysis

The sample size was not calculated as this was a pilot study. Continuous variables are presented as mean and Standard Deviation (SD) or median (Interquartile range (IQR)), depending on distribution. Categorical variables are presented as proportions. For comparisons, independent t-test was used when data were normally distributed and Mann–Whitney U test when data were not normally distributed. Additionally, chi-squared and Fisher's exact tests were used for comparing categorical variables. The statistical analysis was performed by using the R version 3.4.4 program (R Foundation for Statistical Computing, Vienna, Austria) for analyzing the results with statistical significance set at P-value <0.05.

Ethical Considerations

The present study was certified by the Institutional Review Board (COA 113/60) for considering ethics in research involving human subjects (Research Promotion Department, Faculty of Medicine, Navamindradhiraj University, Bangkok, Thailand).

Results

Baseline characteristics

Twenty-four patients met eligibility criteria and four patients declined participation in the study. Ten of the participants were randomized to Id counseling group and the other ten participants received Sd-counseling (Figure 1). The general baseline characteristics of the patients in both groups had no statistically significant differences (Table 1).

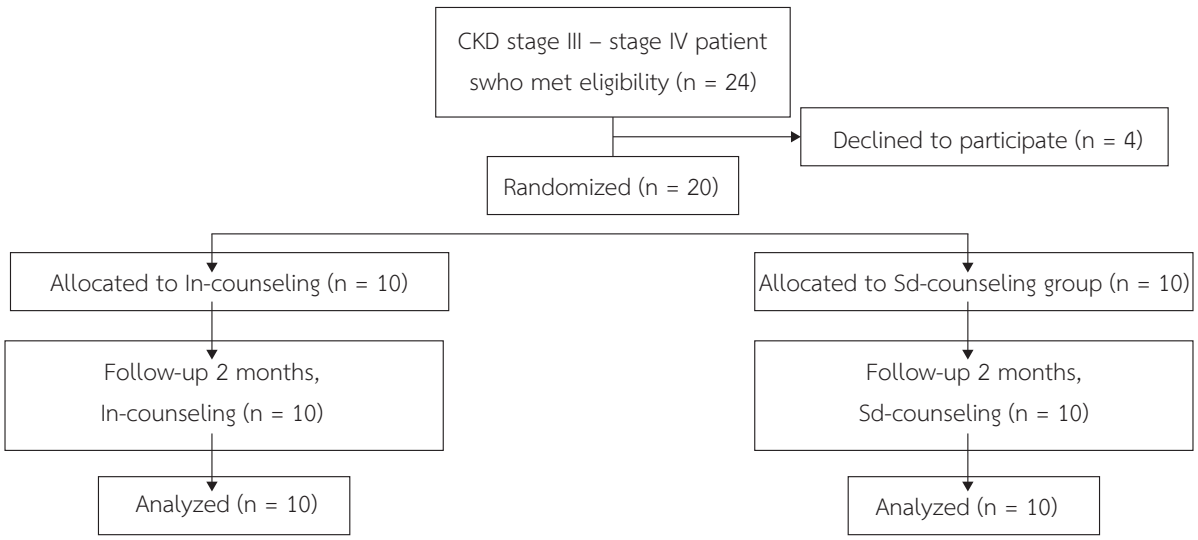

Figure 1: Flowchart of the participants in randomized control of nutritional intervention in the study. Abbreviation: CKD, Chronic Kidney Disease; In-counselling, intensive counselling; n, numbers; Sd-counselling, standard counselling.

Table 1:

The baseline characteristics and laboratory results of participants

Characteristic	In-counseling (n = 10)	Sd-counseling (n = 10)	p–value
Age, years	67 (63.5, 69.0)	64 (62.2, 66.7)	0.268
Gender: male, n (%)	5 (50)	5 (50)	1.000
CKD stage, n (%)			0.582
- III	9 (90)	7 (70)	
- IV	1 (10)	3 (30)	
Type 2 DM, n (%)	6 (60)	4 (40)	0.654
Hypertension, no (%)	8 (80)	9 (90)	0.453
Dyslipidemia, no (%)	5 (50)	9 (90)	0.104
Drug, n (%)			
- RAAS inhibitor	9 (80)	10 (10)	
- Lipid lowering	8 (80)	8 (80)	
- Diuretics	0	0	
Cr, mg/dl	1.4 ± 0.3	1.5 ± 0.6	0.593
eGFR, ml/min/1.73 m^2	52 ± 6	48 ± 8	0.643
Blood sugar, mg/dl	139.0 ± 49.3	118.7 ± 25.4	0.267
HbA1C, %	6.1 (5.2, 6.9)	6.2 (5.9, 7.1)	0.910
Cholesterol, mg/dl	181.7 ± 43.5	220.2 ± 32.1	0.311
Phosphorus, mg/dl	4.4 ± 1.3	3.9 ± 0.9	0.427
Serum albumin, mg/dl	3.7 (3.3, 4.0)	3.8 (3.6, 4.0)	0.648
DPI, g/kg/day	0.7 (0.6, 0.8)	0.8 (0.7, 0.9)	0.599
Target DPI, n (%)	10 (100)	8 (80)	0.456
24- hour UNa, mmol/d	142.7 ± 44.5	151.5 ± 47.6	0.674

Abbreviations: CKD, chronic kidney disease; Cr, creatinine; DM, diabetes mellitus; DPI, daily protein intake; eGFR, estimated glomerular filtration rate; HbA1C, hemoglobin A1C; In-counseling, intensive counseling; LDL, low density lipoprotein; n, numbers; RAAS, renin-angiotensin-aldosterone system; Sd-counselling, standard counseling; Una, urinary sodium.

The median age was 65 years and 50 percent of the subjects were male. The chronic diseases reported by the subjects were diabetes mellitus, hypertension, and high blood cholesterol at 60, 80 and 50 percent, respectively. The laboratory test results were similar for the two groups in terms of Cr, HbA1c, blood sugar, cholesterol, LDL, phosphorus and albumin. The RAAS inhibitor was prescribed in similar proportions to both groups.

The DPI at the beginning of In-counseling and Sd-counseling was similar [0.77 (0.67 – 0.81) vs. 0.80 (0.72 – 0.90) mg/kg/day; p-value = 0.599]. The DPI for individual subjects was within a range of 10/10 (100%) for subjects in the In-counseling group versus 9/10 (90%) for subjects in the Sd-counseling group (p-value = 0.456). Furthermore, 24-hour urine sodium values were also similar at the beginning of the study at 142.7 mmol per day in the Id-counseling group and 151.5 mmol in the Sd-counseling group (p-value = 0.674). there was no dropout and all participants in Id-counseling group visited CKD clinic regularly.

Outcomes

At two months after the completion of the study, the DPI between both groups were similar (p-value = 0.241) (table 2). The In-counseling group had more individual DPI values within a target based on CKD staging of 9/10 (90%) than the Sd-counseling with 6/10 (60%) subjects, but with no statistical significance (p-value = 0.303). The individual and overall DPI changes of both groups at 2 months are shown in Figure 2. The 24-hour urine sodium at 2 months equaled 136.1 (42.3) mmol/day for the In-counseling group versus 153.2 (47.1) mmol/day for Sd-counselling group. The In-counseling group tended to have lower 24-hour urine sodium than the Sd-counseling group (Table 2 and Figure 2); however, they were not statistically significant.

There were no statistically significant differences between the two groups for cholesterol, HbA1c, phosphate and bicarbonate levels at two months. Nevertheless, the potassium level in the In-counseling group indicated better control than the Sd-counseling group with statistical significance (p-value = 0.034). However, no patient developed hyperkalemia.

Discussion

The present study showed that In-counseling could be set up in a chronic kidney disease clinic. The participants had good compliance with regularly visits to the In-counseling nutritionist. There was a tendency for Sd-counselling not to control DPI. The DPI after 2 months of Sd-counselling group was higher than at enrollment time (p-value = 0.064). However, the DPI was still at target level in both groups. There was no statistical difference for controlled sodium intake between both groups.

When patients ingest higher amounts of protein, it increases endogenous acid production. Recent studies have reported an association between endogenous acid production and CKD progression[6-8]. A high salt diet is associated with high blood pressure and fluid retention, which subsequently increase cardiovascular death[9-11]. Numerous studies have shown limiting protein intake and lowering dietary sodium could slow the progression of CKD[11-13]. The implementation of dietary knowledge for CKD patients was recommended. However, there are many and various obstacles such as lack of time for counseling by physician, the complexity of dietary advice, or suboptimal knowledge of basic nutrition for specific diseases.

Table 2:

Outcome of patients between intensive nutritional counseling group and standard nutritional counseling group

Outcomes	In-counseling	Sd-counseling	p–value
2-month DPI, g/kg/day	0.7 (0.6, 0.7)	0.8 (0.7, 0.9)	0.241
Difference of DPI†, g/kg/day	-0.017 (-0.092, 0.165)	-0.053 (-0.079, -0.026)	0.545
2-month target DPI, n (%)	9 (90)	6 (60)	0.303
24-hour UNa, mmol/day	136.1 ± 42.3	153.2 ± 47.1	0.404
Difference of 24-hour Una‡, mmol/day	6.5 (1.25, 11.75)	-2.5 (-4.00, 2.25)	0.240
Cholesterol, mg/dl	188.6 ± 42.8	224.4 ± 58.0	0.324
HbA1c, %	7.1 ± 2.4	6.4 ± 0.8	0.399
Phosphate, mg/dl	3.7 ± 0.96	3.8 ± 0.7	0.675
Potassium, mg/dl	3.8 ± 0.2	4.3 ± 0.6	0.034
HCO_3, mg/dl	27.1 ± 3.8	27.3 ± 3.8	0.908

†DPI at pre-study minus DPI at 2 months. ‡ 24-hour Una at pre-study minus 24-hour Una at 2 months. Abbreviations: CKD, Chronic Kidney Disease; DPI, Daily Protein Intake; HbA1C, hemoglobin A1C; HCO_3, serum bicarbonate; In-counseling, intensive counseling; n, numbers; Sd-counseling, standard counseling; UNa, urinary sodium.

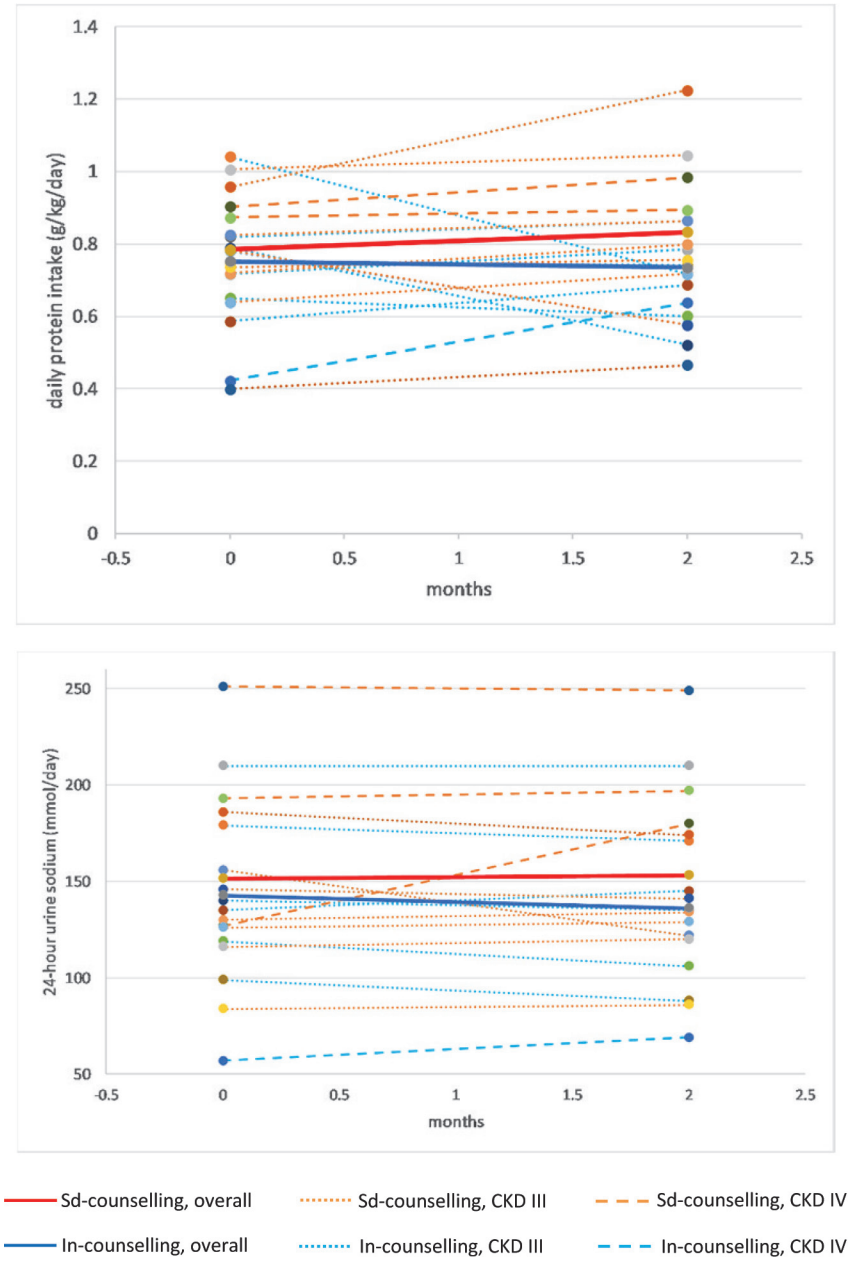

Figure 2: The scatter plot between outcomes and treatments.
The top figure shows DPI at pre-study and the end of the study. The bottom figure shows 24-hour Una at pre-study and the end of the study. These results were plotted by individual participants and median of overall participants classified by treatment group. The plots were also classified by CKD staging. Abbreviations: CKD, Chronic Kidney Disease; DPI; Daily Protein Intake; In-counseling, intensive counseling; Sd-counseling, standard counseling; UNa, urinary sodium.

A study from Brazil reported that implementation of a nutrition education program in the CKD clinic for 6 months could significantly lower dietary protein intake[14]. However, our study's baseline DPI in both groups were nearly achieved the target level; it could because of our results that show the DPI reduction in Sd-counselling group.

Our study had some limitations. The sample size was too small to show statistical significance. The follow-up period was short. If patients were in In-counseling and followed up over a longer period of time, it may increase patients' knowledge resulting in better controlled protein and salt intake, or it may cause patient fatigue leading to poor compliance clinic with visits. Our study showed the feasibility of an intensive nutritional counseling program provided by a nutritionist at CKD clinic over a short-term period. Hence, the challenge is how to develop a nutritional counseling program that our patients would be able to visit regularly.

Conclusion

Intensive dietary counseling with regular monitoring of CKD patients at stages 3-4 can effectively decrease daily dietary protein intake and reduce sodium in the urine. However, the decrease was not statistically significant when compared to standard dietary counseling. To confirm our finding, future studies with larger populations and longer follow-up periods are required.

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