Dietary Education Intervention with Wechat Model Will Impact on Dietary Protein Intake in Patient Treated With Peritoneal Dialysis

NCT: 02426580

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Study Design

Study Type: (select one)

√☐   Clinical Interventional   ☐   Clinical Interventional

☐   Non-clinical (i.e., benchwork, in-vitro, animal model)   ☐   Other (explain):

Does the proposed research require an Investigational New Drug (IND)/Investigational Device Exemption (IDE) application (US), a Clinical Trial Application (CTA) (Canada and EU), and/or any other similar regulatory filing?

☐ Yes   √ ☐   No   Explain the basis for your determination: we have cell phones and free download software of wechat

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Pathology, disease state, or condition to be treated/studied and incidence:

End-stage renal disease (ESRD) patients were treated with peritoneal dialysis. The peritoneal dialysis prescription: 3-4 daily exchanges of 2L dialysate, 16-24 hours a day. Dialysate: 1.5% or 2.5% glucose in dialysate and the concentration of calcium in dialysate is 1.25mmol/L.

Study Population (ages, gender, relevant disease states):

Age of 18 to 65 years and no limitation of sex. The patients were diagnosed as ESRD.

Key Inclusion Criteria: 1. All patients followed at the PD center that successful completed training and have received treatment for at least 1 month. 2. The life expectancy will be more than one year. 3. All patients will provide written informed consent. (1) Aged between 18 and 65 years old; (2) had been on PD for more than one month in medically stable condition; (3) no peritonitis within one month;(4) All the participants or their family members were required to own a Smartphone and to be able to correctly complete the follow up consultations either on Wechat or on phone calls.

Key Exclusion Criteria: 1.the patients will be severe ill status and unlikely to survive for 12 months.

Duration of subject participation: 1st December 2014 – 31st December 2017

                   Prospective : April 2015 to April 2017

                   Retrospective: January 2014 to January 2015

Total number of subjects to be enrolled: We will enrolled 140 PD patients from the Stern peritoneal dialysis unit in the Third People's Hospital of Chengdu affiliated with Chongqing Medical University

Number of study or comparison groups: All patients will be assigned into two groups according to their willing.

                   Intervention group: N=70

                   Controlled group: N=70

Specific details of Treatment/Intervention: (prescription and/or therapy, devices, equipment, solutions, product to be used in conducting study):

This will be a 12-month, A combined prospective and retrospective study of dietary education intervention with comprehensive peritoneal dialysis education with emphasis on egg whites based optimal protein intake on Wechat platform compared with a conventional clinic visit education model. At enrollment, patients will be educated with the conventional education model including operation of dialysate, the catheter exit care, complications of PD, record of ultrafiltration and urine volume, basic protein intake (egg white will be added as a

suitable kind of protein intake) and calorie intake. And then they will be randomly assigned into one of two parallel groups: (1) Control group: Intervention with conventional education every 1-3 months during routing clinical visit ;(2) Intervention group: wechat delivery of dietary education:

Intervention with conventional education will occur every 3 months during routing clinical visit and wechat model of dietary education will occur every 1 month by cellphone. The control group will also receive monthly cell phone calls but without the wechat intervention. The wechat model will provide information on protein, calcium, phosphorus and sodium intake, suggested by the current KDIGO/ KDOQI guideline. The wechat model will include pictures, words, video and voice. Furthermore, we will emphasize the use of egg white protein which may be effective dietary component lowering serum phosphorus without risking malnutrition.

The baseline characteristics included the following variables : age, sex, diabetes, cause of kidney disease if known, medication list, comorbid condition list, smoking history, body weight (kilograms), blood pressure , PCR, serum albumin, serum total protein, C-react protein(CRP)、white blood cell count(WBC), hemoglobin, serum phosphorus, serum calcium, serum sodium, serum magnesium, serum uric acid, intact parathyroid hormone (iPTH), vitamin D, bicarbonate, KT/V, WCC. The study period will be 12 months, with the patients returning every 3 months for measurement of parameters, peritoneal equilibration test (PET), calculation of KT/V and WCC by software, dietary interviews and 3 day dietary recall and conventional education of PD. And we will record the incidence of peritonitis, readmission and switching to hemodialysis and mortality rate. During the course of study, the dose and types of medication could be changed if medically necessary in the view of the treating physician.

Efficacy Assessments (What data will be collected/utilized?):

Wechat is available and convenient for all kinds of platforms with a little network traffic fee (less than 10 RMB per month); enjoy group chat and private chat; support voice, photo, video and text messages. Baidu search found that at present 600 million people had registered wechat in China. We will use the software of wechat to send message to our PD patients with the Nutrition knowledge of protein, phosphorus, calcium and sodium. And the messages will be picture or/and video of food model with voice or/and words notes. Egg whites are tasty and readily available with a low phosphorus content and could be a good source for additional protein intake for the PD patients. The outcomes of our   may be the following:(1) The protein intake of PD patients will achieve or be close to the target of 1.2g/kg/d in intervention with wechat group; (2) Changes in parameters of primary endpoints from baseline to last evaluation may be show significant difference between the intervention with wechat group and the control group; (3) The incidence of peritonitis, readmission, switching to hemodialysis and mortality rate may be lower in the intervention with wechat group compared with the control group. Furthermore the limitations of our study are the single center design.

Statistical Methods (for analyzing primary & secondary endpoints):

Continuous variables are reported as mean±SD. Categorical variables are reported as frequency and percentage. Comparisons between values of intervention with wechat group and values of controlled group at every time points of study will be made. Continuous variables with normal distribution will use analysis of t-test. Continuous variables with abnormal distribution will use analysis of rank-sum test. Categorical variables will use analysis of covariance. Regression analysis will be performed to comparing the levels of primary endpoints, with PCR being the independent variable. Logistic regression analysis will be performed within the secondary endpoints. All statistical tests were conducted at a significance level of $\alpha = 0.05$. All the statistical analyses will be conducted with Empower Stats.

Is the study sufficiently powered (adequate sample size) to answer the research question? Explain:
We tested a sample population of 10 patients treated at the PD center who successfully completed training and were on therapy for at least 3 months. At the time of the first clinic visit, we collected data and calculated mean $\pm$ SD of PCRs as 0.834 ± 0.154 using SPSS (version1.6). According to sample size counting formula $N = 2*[(\alpha+\beta)*\sigma/\delta]^2$, we calculated that a total sample size of 50 patients in each group will be needed to detect an significant difference ($P<0.05$) in PCR of $+0.090$ g/(kg.d) from baseline to last measurement during the study between the wechat group and control group. The sample size (assuming a 20% dropout rate) was estimated at 60 patients in each group. So we think this study is sufficiently powered to answer the research question.

Statistical Analysis Plan (SAP)
1. Analysis of baseline parameters, including: age, sex body weight (kilograms), nPCR, serum albumin, hemoglobin,
serum phosphorus, serum calcium, intact parathyroid hormone (iPTH), KT/V, WCC, dietary protein intake(DPI), dietary energy intake(DEI) and the protein provided by the egg white.
2. Analysis of parameters after 12 months, including: body weight (kilograms), nPCR, serum albumin, hemoglobin,
serum phosphorus, serum calcium, intact parathyroid hormone (iPTH), KT/V, WCC, dietary protein intake(DPI), dietary energy intake(DEI) and the protein provided by the egg white.
3. Analysis of the difference of the incidence of peritonitis, readmission and switching to hemodialysis or renal transplant and lost follow-up.