Effectiveness of the CDK-SMS nursing intervention for adults with chronic kidney disease

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Scope and justification of the proposal

Chronic kidney disease is a complex pathology, where the person who suffers from it is faced with unexpected changes in their customs and lifestyles, in addition to complying with a strict therapeutic regimen, because from its diagnosis it seeks to delay progress of this, and the prevention of complications derived from its development (1). Within the disease management guidelines at the European level ,which were necessary for the Colombian context, they recommend that the factors associated with disease progression should be addressed, which include: "the cause of the disease, the level of the glomerular filtration rate, the level of albuminuria, age, sex, race / ethnicity, elevated blood pressure, hyperglycemia, dyslipidemia, smoking, obesity, history of cardiovascular disease, continued exposure to nephrotoxic agents and others"(2–4), most of which are modifiable, through self-management interventions.

Self-management interventions aimed at adults with CKD in early stages contribute to improving the quality of life, self-management behaviors and self-efficacy, but above all in the prevention of complications derived from the disease. Preventing a person with CKD from progressing to advanced stages or terminal management phases leads to lower health care costs by delaying the start of specialized treatments (renal replacement therapies) that require high technology and preventing complications that can lead to an increased mortality in the population. Results that have been considered within health policies and therefore have become a premise that justifies the relevance of the nursing intervention in self-management (5–9).

The nursing intervention in self-management implies advancing in approaches where adults with early-stage CKD are active agents in managing their own care towards awareness and responsibility for the daily care of the disease (5,10). Today there is a nursing intervention in self-management the CKD SMS, designed specifically for the population object of this study, which has been administered in two countries where there are different socio-economic and cultural characteristics (Vietnam and Australia), demonstrating feasibility in its implementation and acceptability by the participants, in addition to being effective in promoting self-management behaviors, a comprehensive and novel construct (8,11–14), which is achieved through the manipulation of self-efficacy.

In the present proposal, therapeutic adherence is a central concept since it is expected that when performing the nursing intervention in self-management, adherence to the therapeutic regimen will increase, evidenced in the exercise of healthy habits, such as the intake of a diet in accordance with its condition and the reduction of risk factors inherent to the disease, also translated into the impact of these factors on clinical control variables such as: improving blood pressure control, glycosylated hemoglobin levels, but also an important impact in delaying the progression of the disease, which is evidenced not only by not requiring renal replacement therapies, but also by maintaining or improving the

glomerular filtration rate, which is beneficial for both the person and for the health system (15–17).

The nursing professional plays an important role in the execution of self-management interventions such as the CKD SMS, since it is who within the health team has the responsibility of imparting education and monitoring people, in the investigations found in most of the Regarding the interventions that have been carried out, the participation of the nursing professional has been fundamental since it is the one who is in constant interaction with the person.

Research contributions to public policies

Chronic kidney disease (CKD) represents a catastrophic public health problem that is growing worldwide, affecting 10% of the world's adult population (18). In Colombia, the high-cost account reported a prevalence of 3.5 cases per 1,000 inhabitants (19), ages ranging from 50 to 80 years. 90% of cases are in primary stages (stages 1,2,3 and 4), which do not require renal replacement therapies and in these stages, there is a window of opportunity to promote changes in lifestyles, adherence Therapeutic and self-management as intervention measures that can contribute to the prevention of disease progression, complications derived from it, and these variables have so far not been considered comprehensively in previous studies.

In response to this problem, the World Health Organization calls attention to a comprehensive approach to chronic kidney disease, which should be aimed at improving the understanding, measurement, prevention and even treatment of it, also affirming that said approaches will contribute to the social appropriation of knowledge and the reduction of the burden of this disease in the future. The National Kidney Foundation (NKF), in its work to support the formulation of public policies, has reported the importance of health education and primary care, for the benefit of people's well-being and quality of life (20).

At the national level, in addition to the clinical practice guide where care is framed and self-management is mentioned as an approach tool, there are important regulations from the current health model, this has special strategies within which it must be addressed the care of people with CKD and makes explicit the importance of management from the early stages. Said strategies (19) are: primary health care that seeks to provide comprehensive care where disease prevention, diagnosis, treatment, and rehabilitation are found.

Within primary care, there is a relevant strategy in the management of CKD, called health risk management, which is transversal within the comprehensive health care policy, this strategy is based on the articulation and interaction of the system agents in order to "identify, measure, intervene from prevention to palliation and carry out follow-up, monitoring and evaluation of risks to the health of people, families and communities, aimed at achieving results in health and well-being of the population "(2).

Derived from this strategy, resolution 2565 of 2007 (21) was created, in which chronic kidney disease is defined as a high-cost disease, translated into mandatory notification of both the disease and also those precursor pathologies such as hypertension and diabetes ; Following the path of risk management, the high cost account in 2016 in its circular 0038 (22), determines the adoption of the 4X4 strategy proposed by the WHO, which emphasizes the work for the implementation of interventions that are effective based on evidence to reduce risk factors and reduce the prevalence and mortality of non-communicable diseases, which for this case specifically is CKD.

A tool that implements all the guidelines in the approach to the disease is the acquisition of self-management behaviors in people with CKD in early stages, which allows them to have a participation in the control of their health, making correct and informed decisions, but above all with the conviction in himself of being able to maintain his state of health, control and achieve objectives in relation to his disease, through the stimulation of self-efficacy.

Research question

How effective is the CKD SMS self-management nursing intervention on self-management behaviors, self-efficacy, and adherence in adults with early-stage CKD compared to usual care?

General objective

To determine the effectiveness of the self-management nursing intervention (CKD SMS) on self-management behaviors, self-efficacy, and therapeutic adherence in people with CKD in early stages compared to usual care.

Specific objectives

1. Describe the sociodemographic and clinical characteristics of the control group and the experimental group.
2. Establish the level of self-efficacy, self-management behaviors and therapeutic adherence as a baseline in people with chronic kidney disease in early stages.
3. To evaluate the changes in self-management behaviors, self-efficacy, and therapeutic adherence post-intervention and in the control group at 16 weeks.

Hypothesis:

- Establish that the CKD SMS intervention has a positive effect on self-efficacy and therapeutic adherence in people with early-stage CKD compared to usual care.
- Establish the effectiveness of the CKD SMS intervention in improving self-management behaviors compared to the usual intervention in people with CKD in early stages.

METHODOLOGY

This is a quantitative investigation, with a pragmatic randomized clinical trial (pRCT) design, parallel experimental type, given the one-to-one allocation in two parallel groups with repeated pre-test and post-test measures, considering that this type of study it is useful for evaluating interventions in usual care (23). In CKD, the use of a pRCT enables a broader range of patients to be included to test an intervention applicable to patient care and to measure relevant patient-centered outcomes, thus improving external validity and translation of the results into the clinical care (24).

Where the outcome variables are: Self-management behaviors (primary), self-efficacy and therapeutic adherence (secondary). The population will be adult men and women with chronic kidney disease in stages 1-4, who attend control of their disease or belong to the BBraun Avitum Prevenser program.

Relevance of effectiveness measurement:
Assuming that effectiveness refers to "the effects of an activity and its final results, benefits and consequences for a population in relation to the established objectives" (25), it is pertinent to measure this within the present study, since it is sought to really determine that the CKD SMS intervention improves the self-management behaviors of people with CKD in their real context, hence this measurement is the objective even of pragmatic clinical trials. And it differs from the efficacy that is more related to randomized clinical trials since they look for the “degree to which the intervention produces the hypothetical effects under ideal conditions” (26).

POPULATION

Target population: Adult men and women with chronic kidney disease in stages 1-4, with different characteristics such as educational level, socioeconomic status, and marital status. Taking into account that the definition of early stages through the criteria demarcated by the Colombian clinical practice guideline, where the glomerular filtration rate (GFR) is the indicator for stratification as follows: stage 1 people with a GFR less than or equal to 90 (ml (min / 1.73 m2), stage 2 people with GFR between 60-89 (ml (min / 1.73 m2), stage 3 people with GFR between 30-59 (ml (min / 1.73 m2)) and stage 4 people with GFR between 15-30 (ml (min / 1.73 m2) who attend kidney protection programs of the Renal Units in Colombia.

Accessible population: Adult population men and women with chronic kidney disease in stages 1-4, with different characteristics such as educational level, socioeconomic status, marital status, those who attend control of their disease or belong to the Prevenser program of the BBraun Avitum, in Colombia, which can be found in the databases provided by Prevenser program.

Sampling frame: Database provided by Prevenser program population: It will be those participants who meet the inclusion and exclusion criteria, which are:

Inclusion criteria

- Adults, of legal age for Colombia (18 years), with a diagnosis of chronic kidney disease in stages 1-4, without renal replacement therapy according to the Kdigo guidelines.
- People without comorbidity and with non-decompensated or exacerbated chronic comorbidities.
- People in use of their mental and communication faculties.

Exclusion criteria

- People who are under the effect of some substance that alters the mental state.
- People under 18 years of age.
- Being receiving renal replacement therapy or being in a terminal stage.
- Illiterate people.
- People who are participating in another educational intervention different from the usual care.

SAMPLE

Sample design: The sample size was calculated through probability sampling, since individuals have the same probability of being chosen. On the other hand, of the comparison of means in independent groups, assuming a power of 80%, a confidence level of 95%, an expected mean difference of 18.13 in the improvement of self-management, reported by previous studies (6,27).

Sample size: A total of 82 participants (41 per group), in addition, a mortality of 20% of the participants is expected, so a total sample of 100 participants (50 per group) will be assumed. made in the Epidat 3.1 program.

Randomization: Participants will be randomized into two groups, using sequentially numbered opaque sealed envelopes, where the investigator and participants will be blinded to the allocation of each group. For the generation of the randomization sequence, it will be developed by the investigator by means of the realization of a table of random numbers in the Epidat 3.1 program to eliminate the selection bias, in the same way, said table will be verified to guarantee balance between the number of participants assigned to each group (control and intervention).

Blinding: In view of the need to minimize bias, both the participants and the recruitment research assistant will be blinded until allocation. The Result Research Assistant will not have access to the allocation base, nor to the allocation codes. On the other hand, it is

declared that the intervention will be given by the researcher and that the main researcher will also participate in statistical analysis, therefore, the study is classified as single blind.

STUDY VARIABLES

Among the variables that are available for the present study are:

- Independent Variables: Sociodemographic characteristics, related to the disease or clinical condition and the CKD intervention.
- Dependent variables: Self-management behaviors, therapeutic adherence, and self-efficacy.

Within the mediating, shaping or confounding variables, the following are found according to what is established in the literature: age, gender, level of education, time of diagnosis and other comorbidities, which are initially considered independent variables and will be measured. In the study, for its management, strategies such as randomization will be used, the differences between the crude estimates of an association and those adjusted considering a confounding variable will be identified and its adjustment is responsible for at least 10% in the magnitude of the difference.

PHASES OF THE STUDY

The phases of the study will be pre-pilot phase in which the CKD SMS intervention will be adapted to the Colombian context, considering the evaluation by experts in the management of people with CKD in early stages. Pilot phase will be carried out the exploration of the field, followed by adjustments regarding the application time in the handling of the instruments and the training in these aspects for the research assistant. And the main phase of the study where the intervention will be implemented and the data will be collected, the latter by means of the instruments: characterization sheet, Self-management instrument in early-stage chronic kidney disease CKD SM, EAT therapeutic adherence scale, Self-efficacy scale general. The intervention is planned to be implemented both in person and digitally assisted.

INTERVENTIONS

- **CKD SMS intervention**

CKD SMS (Chronic Kidney Disease Self-Management Support) intervention (6,27), guided by the Social Cognitive Theory, through the manipulation of self-efficacy, is educational for the adult with CKD in early stages where a primer will be used which contains a primer that explains the functions of the kidneys, the first signs and symptoms of CKD and the strategies to control or delay the progression of CKD, such as the benefits of maintaining a healthy lifestyle and adherence to treatment. Also, a diary for participants to record side effects of

medications, monitor their clinical data, treatment plan and questions for medical appointments.

All the materials of the intervention will be prepared for an appropriate reading level for the participants and will be delivered in physical or digital format, the intervention will be provided by the researcher who is a nurse, a master's degree in nursing with an emphasis on chronic patient care and with experience of 12 years, of which 7 have been in the management of people with CKD in the different stages and in renal replacement therapies such as hemodialysis, peritoneal dialysis and kidney transplantation.

The intervention begins with a face-to-face or digitally assisted session, entry into improving the knowledge and self-management of CKD through, using the four sources of manipulation of self-efficacy (achievement of performance, indirect experience, verbal persuasion, and self-evaluation). In this session, participants will be asked to identify their problems related to CKD and establish, based on these two goals, that they are real and achievable according to their priorities. These goals will be recorded in the monitoring format and will be monitored in the telephone or WhatsApp follow-ups. This using the performance achievement manipulation source, said session lasts 60 minutes, as does the final session at week 16 (6,27).

For the use of vicarious or indirect experience, images will be used that demonstrate what should or should not be done within the educational material, in addition to the use of videos of successful experiences. Verbal persuasion will be used through providing verbal advice and suggestions to each participant. Self-assessment will be used to encourage participants to identify where they have been successful in the management of CKD and therapeutic adherence, in addition to expressing difficulties and concerns in managing their disease (6,27).

The continuation of the intervention will be carried out through 2 follow-ups by phone or via WhatsApp with a duration of 20 to 30 minutes per week 4 and 12, where the research nurse will reinforce the self-management action plan and monitor progress towards the goals set; Therefore, the focus will be to identify improvements and encourage participants to continue with the change in behavior through positive reinforcement, in addition, discussion processes will be carried out according to the information given through the educational material given to the participant. The participant will be encouraged to seek family and social support to achieve long-term behavior changes, in addition to raising their concerns, doubts or concerns that arise during the intervention in each follow-up to be able to respond or, failing that, manage the resolution of these (6,27).

The intervention is carried out individually, digitally assisted both for the meetings and for the follow-up, always trying to promote a quiet environment, free of noise and in the time agreed with the participant to give the intervention.

- Conventional intervention

The conventional intervention corresponds to the protocol established in the Prevenser program of the renal unit (BBraun Avitum) for the management of people with CKD in early stages.

BIAS CONTROL

Internal validity

- **Selection and performance bias:** to avoid this bias, random selection will be carried out by delimiting the population and defining the sampling frame in detail, being adequate for the study design; in addition to the generation of a list of the patients who attend the controls, for the assignment of random numbers and the appropriate method for this by means of a software. On the other hand, allocation concealment will be carried out with sealed envelopes containing the allocation number; Within the calculation of the sample, an additional 20% is initially added as prevention of losses in the groups, additionally the intervention protocol will be carried out faithfully and the largest portion of the contact data of the participants will be taken in order not to lose the contact and their participation in the follow-up.
- **Performance and arrest bias:** A single-blind study will be carried out in which the allocation to the participants will be blinded, since the intervention and the analysis of the results will probably have to be developed by the main investigator and therefore this cannot be blinded. But to have faithful results, the data collection (application of the instruments) will be supported by a research assistant who will also be blinded to the assignment of the participants to the control group or experimental group.
- **Attrition bias:** The collection of the information will be meticulous in order not to lose any data, and, in addition, a percentage addition will be made in the calculation of the sample to predict the mortality of the participants.
- **Reporting bias:** The delivery of the results without missing the expected results in accordance with the methodological approach, in the same way, will be its publication.

External validity

- **Impossibility of replicating the treatments:** the intervention is described in detail and aims to address a problem in clinical practice.
- **Effects of the experimenter:** the research assistant in charge of collecting the data will be masked.
- **Reactive effects of the treatments:** as mentioned in the intervention protocol, this will be developed initially in the context of the health institution and will continue in the normal context of the participant with prior agreement.

- **Interference from multiple treatments:** within the exclusion criteria those who are participating in another research with an educational component different from the usual care are considered.

Measurement instruments

The information collection process will be carried out from the design of a form for the collection of sociodemographic data and clinical conditions of the participants and the application of the instruments for measuring both primary and secondary results:

- Self-management instrument in early stages CKD SM chronic kidney disease: 30 items, 4 factors (self-integration, problem solving, seeking social support and adherence to the recommended regimen), Cronbach's alpha of 0.95; English, Vietnamese, Taiwanese, and Mandarin languages. Likert scale evaluation, possible score from 29 to 116 (28).
- Therapeutic adherence scale EAT: 21 items, 3 factors (control over the intake of drugs and food, medical-behavioral monitoring, and self-efficacy); Cronbach's alpha of 0.92, evaluation on a scale from 0 to 100; Spanish language (29).
- General Self-efficacy Scale: 10 items, Cronbach's alpha of 0.87, in English and Spanish languages (30).

APPROACH TO THE ANALYSIS FRAMEWORK

To respond to specific objectives 1 and 2, a statistical analysis will be carried out through descriptive statistics. Subsequently, a normality test will be carried out, to identify how the data distribution is presented, in addition, it is carried out to determine the tests to be used, whether parametric or non-parametric in the inferential analysis, bivariate and multivariate analysis. A bivariate analysis, to compare the sociodemographic and clinical characteristics between the groups.

To respond to specific objective 3, Inferential statistics will be carried out, which will be carried out to accept or reject the null or alternative hypothesis, which are proposed as:

- H1: The CKD SMS intervention in self-management in people with CKD in early stages is effective on self-management behaviors, self-efficacy, and therapeutic adherence. (H1: G1> G2; $p < 0.05$)
- H0: The CKD SMS intervention in people with CKD in early stages is not effective on self-management behaviors, self-efficacy, and therapeutic adherence. (H0: G1 = G2; $p > 0.05$)

But it is also used multivariate analysis, to determine the individual relationship but also the relationship of the possible variables that intervene on the results, a simple logistic regression model will be built and adjusted according to the possible confounding variables.

ETHICAL CONSIDERATIONS

For this research, the ethical aspects of research in human beings are considered, for which national regulations and recommendations are considered, such as resolution 8430 of October 4, 1993 (31), issued by the Ministry of Health and establishes the scientific, technical, and administrative standards for health research. Taking into account these regulations, the research declares will be carried out with the authorization of the participant for which it will have informed consent, in addition to being carried out by a researcher with knowledge and experience in the subject and will have the approval of the ethics committee of the Faculty of Nursing of the National University of Colombia, will also have approval by the participating institution and authorization for the use of data collection instruments.

On the other hand, the classification of the research is of risk greater than the minimum, since it includes the performance of an intervention; but it is proposed to improve the provision and the health status of the participants (31). This research contributes to the knowledge of an intervention that can be recommended and used in the future, which is included in the provision of services specifically in the care of people with chronic kidney disease in early stages and this type of research is already being considered that there is no other way to respond to the phenomenon studied.

Informed consent will be in accordance with the criteria outlined in the resolution, which will explain the nature of the research, objectives, and in this process, emphasis will be placed on data confidentiality and voluntary participation. The prior signature and ratification of said knowledge will be the starting point for data collection, in this procedure sensitive data will not be included in order not to generate discrimination such as racial or ethnic origin, political orientation, religious or philosophical convictions, the data personnel to be recorded will be those strictly necessary and relevant for the completion of the investigation.

In addition to the above, this research will guarantee and consider in all the guidelines for its development the ethical principles framed in the deontological code of Nursing (32), such as:

- Respect: In this research, the use of informed consent by the participant will be guaranteed. In addition to other measures regarding the collection of data for which the participant will be identified with a code to safeguard their privacy and confidentiality, in this way their rights will be respected, and their dignity will be maintained, said number will be used in the instruments for collecting and analyzing information.

- Beneficence and non-maleficence: For this research, an exhaustive critical review of the best available evidence was carried out, which made it possible to select the intervention proposed by Havas et al. (27) and later by Nguyent et al. (19), in people with disease chronic

kidney disease in early stages. In addition, there are systematic reviews and meta-analyzes of experimental studies that have demonstrated the benefits of interventions in self-management, on the other hand, if any risk condition is identified in the participant, the interdisciplinary treating group will be notified for its respective management.

- Confidentiality and Privacy: It will be safeguarded through the management of the information where the data will be supervised, controlled, and processed by the researcher and the identity of the participants will be assigned a code for their identification. The information will not be transferred to people who are not part of the investigation team.

- Veracity and Fidelity: It will be respected through the presentation of the research findings, where no type of manipulation will be carried out to obtain results.

Additionally, the bioethical principle of reciprocity, meanwhile, the general findings of the research once completed, will be presented at the institution and participants. Likewise, the principle of justice, since the participants of the control group will receive feedback on their condition in the variables (self-efficacy, self-management behaviors and therapeutic adherence), in addition to specific recommendations to improve each of these and the delivery of educational material prepared in reciprocity for a transfer and social appropriation of knowledge to all participants. This study will comply with the provisions of the Declaration of Helsinki regarding the registration of experimental studies, as this according to the World Health Organization guarantees that the actors who participate in decision-making regarding health care have access A complete vision of the research, in addition, will constitute a resource that improves the transparency in the research, the validity and the value of the scientific databases, as well as it will also facilitate the identification of gaps in scientific research (33).

Also, it will comply with Agreement 035 of 2003 of the National University of Colombia (34), in all matters concerning respect for intellectual property, through proper management of the institutional image, since if resources such as the institutional image are required for the generation of documents and pieces as in the case of educational material, the pertinent authorizations will be requested for this purpose.

Environmental considerations: Regarding the environmental considerations that will be considered in this study, we have: The bibliographic references that will be used to give theoretical and conceptual support to the study during development will be obtained from systematized databases and that are within the resources of the University. On the other hand, environmental sustainability will be sought, using digital formats.

Schedule

Months / Activities	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Participating institution permit request																								
Endorsement request from the Faculty Ethics Committee																								
Pre pilot phase																								
Adaptation of the intervention to the Colombian context																								
Creation of educational and monitoring material for the intervention																								
Adaptation and psychometric tests of the self-management instrument in people with CKD (CDK SM) in the Colombian context																								
Pilot test																								
Field exploration																								
Data collection time adjustments																								
Research assistant training																								
Training in the delivery of the intervention																								
Main phase of the Study																								
Recruitment of participants and pretest application																								
Delivery of the Intervention																								
Posttest application																								
Analysis of data																								
Preparation of final report																								
Socialization of Results																								

EXPECTED RESULTS

Among the expected results derived from the research, the presentation at an international scientific event and the production of a scientific article are planned.

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