Study Protocol

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KIDNEY RESEARCH AND CLINICAL PRACTICE

Shared Decision Making for Choosing renAl Replacement Therapy in Chronic Kidney Disease Patients (SDM-ART trial): study protocol for randomized clinical trial

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Background: Patients with chronic kidney disease (CKD) should be educated about their condition so that they can initiate dialysis at the optimal time and make an informed choice between dialysis modalities. Shared decision-making (SDM) empowers patients to select their own treatment and improves patient outcomes. This study aimed to evaluate whether SDM affects the choice of renal replacement therapy among CKD patients.

Methods: This is a multicenter, open-label, randomized, pragmatic clinical trial. A total of 1,194 participants with CKD who are considering renal replacement therapy were enrolled. The participants will be randomized into three groups in a 1:1:1 ratio: the conventional group, extensive informed decision-making group, and SDM group. Participants will be educated twice at months 0 and 2. Videos and leaflets will be provided to all patients. Patients in the conventional group will receive 5 minutes of education at each visit. The extensive informed decision-making group will receive more informed and detailed education using intensive learning materials for 10 minutes each visit. Patients in the SDM group will be educated for 10 minutes each visit according to illness perception and item-based analysis. The primary endpoint is the ratio of hemodialysis to peritoneal dialysis and kidney transplantation among the groups. Secondary outcomes include unplanned dialysis, economic efficiency, patient satisfaction, patient evaluation of the process, and patient adherence.

Discussion: The SDM-ART is an ongoing clinical study to investigate the effect of SDM on the choice of renal replacement therapy in patients with CKD.

Keywords: Chronic renal insufficiency, Peritoneal dialysis, Renal dialysis, Shared decision making

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Introduction

The number of patients with chronic kidney disease (CKD) and kidney failure with replacement therapy (KFRT) is rapidly increasing due to longer life expectancy and a higher prevalence of chronic diseases including diabetes and hypertension [1,2]. CKD progression heavily increases socioeconomic burden [3]. When CKD patients approach KFRT, they must choose a renal replacement therapy (RRT) that usually includes dialysis or kidney transplantation (KT). KT provides superior survival outcomes and long-term cost-effectiveness compared to dialysis [4]. However, lack of available donated kidneys in addition to socioeconomic limitations can lead patients to choose dialysis treatment, of which there are two types: hemodialysis (HD) and peritoneal dialysis (PD).

HD and PD are complementary and have several advantages and disadvantages. When patients choose a dialysis modality, various medical and socioeconomic factors should be considered, and the decision to go with one modality over another should be made on a patient-centered basis. In Korea, the proportion of HD patients is increasing while the proportion of PD patients is decreasing, and most KFRT patients have recently undergone HD [2]. In particular, the percentage of patients who selected HD as their initial RRT increased from <70% before 2008 to >80% after 2014 [2]. However, improvements in PD patient survival have led to similar mortality rates between PD and HD in Korea [2,5]. In other countries, PD mortality rates were lower than those of HD prior to 2000, but the survival rates between the two groups are similar now [6–8]. Quality of life is also comparable between the PD and HD groups [9,10].

Shared decision-making (SDM) is an approach in which clinicians and patients make decisions together using the best available evidence [11]. An understanding of treatment goals, advantages and disadvantages of treatment options, and the likelihood of achieving desired outcomes are all important to patients [12]. Additionally, SDM increases patients' quality of life and maintains their autonomy [13]. International guidelines recommend that all patients with CKD be educated at the predialysis stage to improve their knowledge and understanding of their own condition, and to make an informed choice among the RRT options [12,14–16]. SDM is a recommended model to follow when choosing the preferred treatment for patients with advanced CKD [12,14–16]. Despite these recommendations, many patients feel unprepared and ill-informed about the initiation of dialysis and available treatment options [17]. This may lead to a situation where the patient loses the opportunity to make their own choices, resulting in emergency dialysis or a dialysis modality that is not suitable.

CKD patients have the right to choose RRT modalities that are appropriate for them through sufficient communication with clinicians, but how to guide the patient through the decision-making process is not well-established. Therefore, this study aims to evaluate whether SDM has an effect on RRT choice among CKD patients.

Methods

Study design

This study is an investigator-initiated, multicenter, open-label, randomized, pragmatic clinical trial occurring over a 12-month period. Patients with CKD who have not received RRT will be screened to participate, and those who meet all inclusion and exclusion criteria will be eligible for enrollment. After participants provide written informed consent and are enrolled, they will be randomized into the three study arms. Participants will receive education twice during months 0 and 2, and clinical follow-up will be performed at months 4, 6, 8, 10, and 12 (Fig. 1).

Study participants

Participants will be recruited from the following 19 tertiary university hospitals in Korea: Seoul National University Bundang Hospital, Seoul National University Hospital, Seoul National University Boramae Medical Center, Severance Hospital, The Catholic University of Korea Seoul St. Mary's Hospital, Ewha Woman's University Seoul Hospital, Samsung Medical Center, The Catholic University of Korea Eunpyeong St. Mary's Hospital, Korea University Guro Hospital, Kyung Hee University Hospital at Gangdong, Dongguk University Ilsan Hospital, Gachon University Gil Medical Center, Yonsei University Wonju Severance Christian Hospital, Daejeon Eulji Medical Center, Ulsan University Hospital, Kyungpook National University Hospital, Pusan National University Hospital, Chonnam National

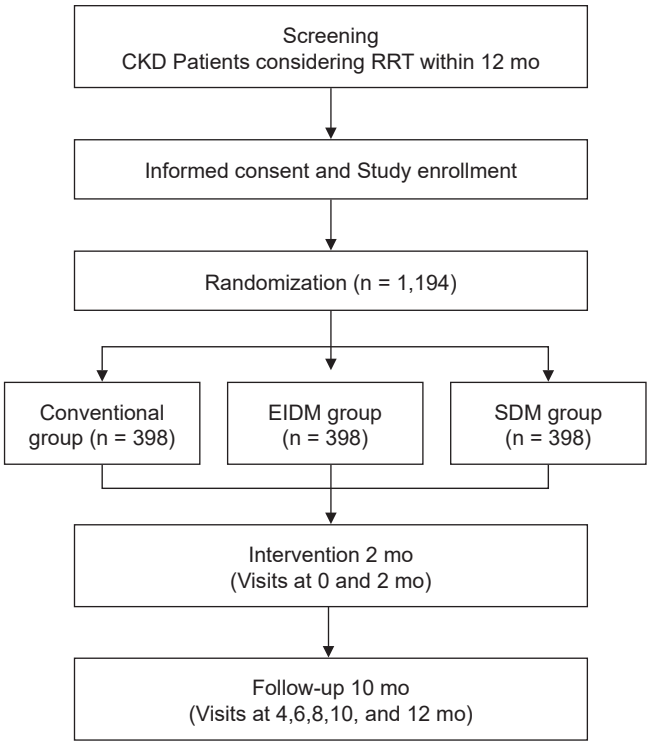

Figure 1. Overview flow chart of the SDM-ART (Shared Decision Making for Choosing renAl Replacement Therapy in Chronic Kidney Disease Patients) trial.
CKD, chronic kidney disease; RRT, renal replacement therapy; EIDM, extensive informed decision-making; SDM, shared decision-making.

Table 1. Inclusion and exclusion criteria

Inclusion criteria	1. Patients with chronic kidney disease whose nephrologist predicts initiation of renal replacement therapy within 12 months: a) Patients with stage 5 chronic kidney disease (defined as a creatinine-based eGFR of <15 mL/dL/1.73 m^2 at least two times at intervals of 2 weeks or longer) b) Patients with cystatin-C–based eGFR of <15 mL/dL/1.73 m^2 at least once if the creatinine-based eGFR does not accurately evaluate patient kidney function due to patient characteristics c) Patients whose nephrologist requires renal replacement therapy within 12 months due to the patient's comorbidities even when eGFR is ≥15 mL/dL/1.73 m^2 2. Patients between 19 and 80 years old 3. Patients who understand the study 4. Patients who have no permanent access device for long-term maintenance dialysis
Exclusion criteria	1. Patients who have a contraindication to perform peritoneal dialysis due to abdominal surgery 2. Patients whose life expectancy is less than 6 months due to underlying diseases 3. Patients who have enrolled in other clinical trials within 3 months or plan to participate in other clinical trials during this clinical trial period 4. Patients judged by the investigator to be inappropriate for participation in this clinical trial

eGFR, estimated glomerular filtration rate.

University Hospital, and Kyungpook National University Chilgok Hospital. The inclusion and exclusion criteria are presented in Table 1. The estimated glomerular filtration rate (eGFR) was calculated using the four-variable Modification of Diet in Renal Disease equation as follows [18]: eGFR (mL/min per 1.73 m^2) = 175 × [serum creatinine (mg/dL)]$^{-1.154}$ × [age]$^{-0.203}$ × [0.742 if female] × [1.212 if black].

Ethics approval and consent to participate

All participants provided informed consent prior to enrollment. This study obtained the approval from Institutional Review Board (IRB) at all 19 participating sites (Additional information). The trial protocol was registered at ClinicalTrials.gov (http://www.clinicaltrials.gov; NCT04976166) on July 26, 2021. Recruitment began in March 2021 and 215 patients were randomized by December 2021. Recruitment in this study is ongoing. The protocol version number is 3.1 dated December 2021.

Randomization

The randomization process is conducted using a web-based program. A list of random numbers will be generated by a computerized random allocation system operated by the Medical Research Collaborating Center at Seoul National University Hospital. Eligible participants will be randomized into three groups in a 1:1:1 ratio: the conventional group, extensive informed decision-making (EIDM) group, and SDM group. Randomization will be stratified based on the institution and diabetes status. All patients are provided with an educational leaflet and a QR code to view a 12-minute video describing the importance of informed decision-making when choosing dialysis therapy, and the advantages and disadvantages of the dialysis modalities. Participants will receive education twice, once during

month 0 and once during month 2 and will then decide on their preferred dialysis modality. Dialysis education will be provided by the doctors at each hospital. Patients in the conventional group will receive education as usual in the form of leaflets for 5 minutes at months 0 and 2. Patients in the EIDM group will be provided with education consisting of intensive learning materials for more than 10 minutes at months 0 and 2. Patients in the SDM group will receive education using a self-developed counseling calendar (Supplementary Fig. 1, available online) for more than 10 minutes and will complete self-assessment items and illness perception at month 0 [19]. Self-assessment consists of 35 items in three categories: dialysis environment, health, and lifestyle (Supplementary Table 1, available online). Illness perception is a 10-item questionnaire using a scale from 1 to 5 (Supplementary Table 2, available online). Then, patients will be educated for more than 10 minutes according to their values and preferences through illness perception and items-based analysis at month 2 (Fig. 2).

Primary endpoint

The primary endpoint is the proportion of HD versus non-HD (PD and KT) treatments among the groups. HD is defined as dialysis via arteriovenous fistula (AVF) or arteriovenous graft (AVG), or 8 weeks after arteriovenous vascular surgery. PD is defined as starting PD or 4 weeks after PD catheter insertion. KT is defined as a KT operation.

Secondary endpoints

The secondary endpoints include unplanned dialysis, economic efficiency, patient satisfaction, patients' evaluation of the SDM process, and patient adherence.

Unplanned dialysis events will be compared to planned dialysis. Planned dialysis is defined as starting dialysis if the patient has a permanent access device such as AVF/AVG and PD catheter already in place. If dialysis is started 4 weeks after PD catheter insertion or 8 weeks after arteriovenous vascular surgery, planned dialysis should be re-

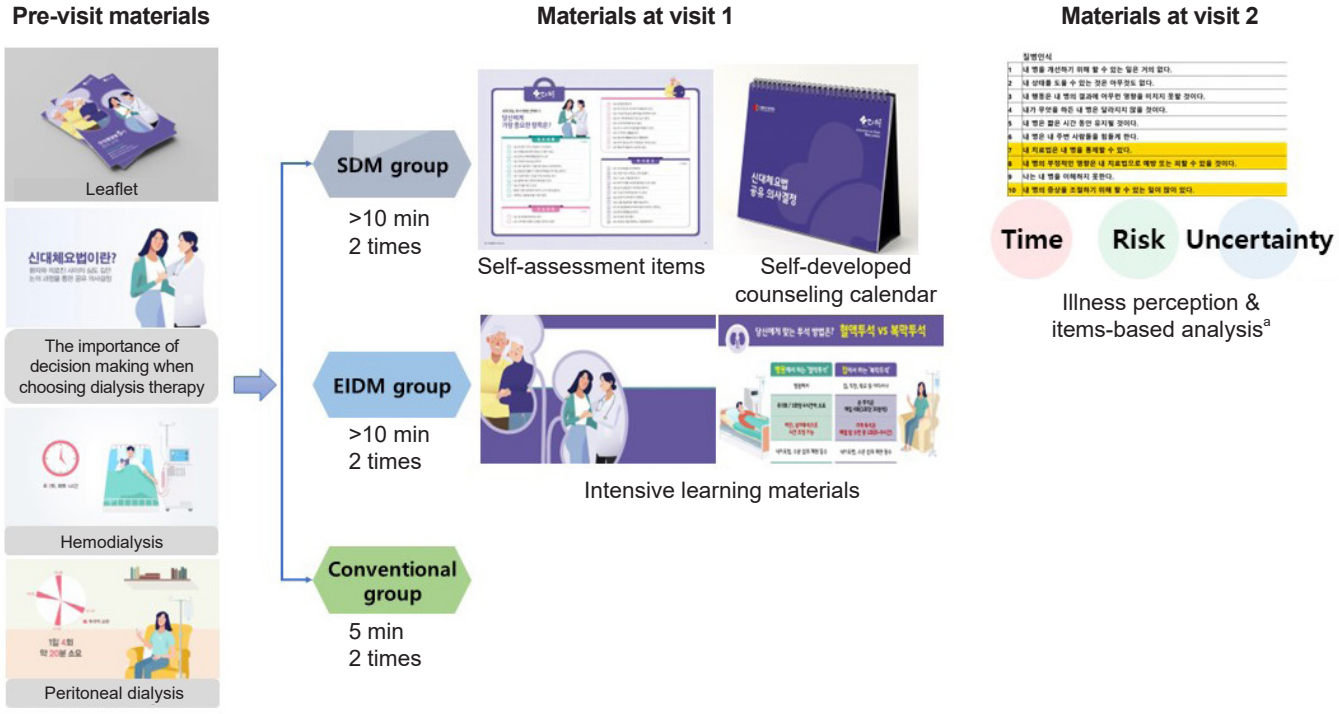

Figure 2. Education methods and materials provided to each group.
EIDM, extensive informed decision-making; SDM, shared decision-making.
[a]Patients filled out illness perception and self-assessment items at month 0 and were educated according to illness perception and item-based analysis at month 2.

corded regardless of the use of a permanent access device.

Economic efficiency will be assessed using a cost-utility analysis from a healthcare sector perspective. Healthcare, patient, and family costs are tallied using a survey at months 2 and 12. Healthcare costs include the medical costs for CKD treatment. Additionally, patient and family costs include a caregiver and transportation, among others. For utility, study participants will be asked to fill out the 5-level EQ-5D version (EQ-5D-5L) of the EuroQol group and the Korean Health-Related Quality of Life Instrument with 8 items (HINT-8) [20] at months 0, 2, and 12. We will calculate quality-adjusted life year (QALY) by multiplying the EQ-5D index by the follow-up duration in each arm. Finally, the incremental cost-utility ratio for SDM groups is calculated as the ratio of differences in costs and utilities among the three groups.

Patient satisfaction will be assessed using the patient satisfaction questionnaire (ZUF-8) at months 0, 2, and 12 [21]. The ZUF-8 questionnaire, "Fragebogen zur Patientenzufriedenheit," is an eight-item questionnaire that assesses patient satisfaction using a scale from 1 to 4. Originally, ZUF-8 used a 4-point scale, but in this study, we further extended the scoring system of this questionnaire from four to five incremental stages of perceived satisfaction ranging from 1 to 5 [22]. The minimum and maximum values were 8 and 40, respectively. Higher scores indicated better outcomes.

Patients' evaluation of the SDM process will be assessed using the nine-item Shared Decision Making Questionnaire (SDM-Q-9) at months 0, 2, and 12 [23]. The original instrument (SDM-Q) consisted of 26 items with items rated on a 4-point scale. The SDM-Q-9 is a major revision from the original wherein the response scale was adjusted from 4-point to 6-point ratings to include greater extremes ("completely disagree" and "completely agree") to counter high ceiling effects [24]. In this study, six response options are converted into five incremental stages ranging from 1 to 5. To calculate the total scale score, items are summed, resulting in total a range from 9 to 45. Higher scores reflect a patient's level of participation in SDM regarding their treatment. The translated version of SDM-Q-9 reported excellent reliability and validity [24–26].

Patient adherence will be assessed using the eight-item Morisky Medication Adherence Scale (MMAS-8) at months 0, 2, and 12 [27]. The MMAS-8 is an eight-item questionnaire and the scale includes seven items with yes/no response options and one item with a 5-point Likert scale option [28]. The cumulative score based on eight items is used to obtain a final adherence score ranging from 0 to 8. Adherence is defined as low (score 0–5), medium (score 6–7), or high (score 8).

Participants will visit the outpatient clinic or receive a phone call for a survey on economic efficiency, patient satisfaction, and patient adherence 12 months after the end of the study.

Clinical and laboratory evaluations

A physical examination, comorbidity assessment, and medication review will be performed, including the following laboratory evaluations: complete blood count (hemoglobin, hematocrit, white blood cells, and platelets), sodium, potassium, chloride, total CO_2, glucose, protein, albumin, aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase, gamma-glutamyl transferase, blood urea nitrogen (BUN), creatinine, calcium, phosphorous, total bilirubin, uric acid, total cholesterol, low-density lipoprotein cholesterol triglyceride, and eGFR. Complete blood count, sodium, potassium, chloride, protein, albumin, AST, ALT, BUN, creatinine, calcium, phosphorous, and eGFR evaluations will be conducted every 2 months during the study. The self-assessment questionnaire will be completed by the SDM group only at month 0 and in all groups at month 12. The study schedule is shown in Fig. 3. Participants will visit the outpatient clinic or receive a phone call for a survey on "illness perception" 12 months after the end of the study.

Sample size calculations

We estimated a 10% increase in the proportion of non-HD patients in the EIDM or SDM groups compared with those in the conventional group. It is estimated that the proportion of non-HD patients in the conventional group will be 15% and 25% in the EIDM or SDM groups. We calculated the required sample size for a two-sided level of significance of $\alpha = 0.05$, a power of 90%, and one interim analysis. The number of participants required was 358 per group. Based on the assumption of a dropout rate of 10%, a total of 1,194 participants were included in the analysis. Interim

Period	Screening	Assessment periods						
Visit	0	1	2	3	4	5	6	7
Study month	–3 to 0	0	2	4	6	8	10	12
Informed consent	×							
Eligibility screen	×							
Allocation		×						
Medical history/family history/demographic data	×							
Physical examination	×							
Blood pressure and heart rate	×	×	×	×	×	×	×	×
Height, body mass index	×							
Body weight	×	×	×	×	×	×	×	×
Chest X-ray, ECG	×							
Routine laboratory data[a]	×	×	×	×	×	×	×	×
Intervention (education)		×	×					
Adverse events monitoring		×	×	×	×	×	×	×
Medications	×	×	×	×	×	×	×	×
Questionnaire								
Economic efficiency			×					×
Patient satisfaction		×	×					×
Patient adherence		×	×					×
Patients' evaluation		×	×					×
Quality of life[b]		×	×					×
Doctor satisfaction		×	×					×
Illness perception		×						×
Self-assessment items[c]		×						×
Decision of dialysis modality			×					

Figure 3. Timeline of study procedures and outcome assessments.
ECG, electrocardiogram.
[a]Screening visit: Complete blood count (hemoglobin, hematocrit, white blood cells, and platelets), sodium, potassium, chloride, total CO_2, protein, albumin, aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase, gamma-glutamyl transferase, blood urea nitrogen (BUN), creatinine, calcium, phosphorus, uric acid, glucose, total bilirubin, total cholesterol, low-density lipoprotein cholesterol, triglyceride, and estimated glomerular filtration rate (eGFR). Visit 1–7: Complete blood count, sodium, potassium, chloride, protein, albumin, AST, ALT, BUN, creatinine, calcium, phosphorous, and eGFR. [b]EQ-5D-5L (the 5-level EQ-5D version of the EuroQol group) and HINT-8 (the Korean Health-Related Quality of Life Instrument with 8 items). [c]Only the shared decision-making group at visit 1 and all groups at visit 7.

analysis will be performed at 50% study progress, and the significance levels used in the interim analysis will be p = 0.003. The final analysis will be completed after the last participant's treatment. The O'Brien-Fleming alpha spending function will be used to test the primary outcomes in the interim analysis and final analysis.

Safety issues and adverse events

The trial itself is not expected to pose any medical risk to the participants. The safety assessments include laboratory tests (hematology and blood chemistry), blood pressure, heart rate, and body weight. Any adverse events (AEs) will be assessed every visit after randomization. All AEs will be summarized and presented according to their severity and outcome.

Data collection and management

All participants' information will be recorded by the investigators and clinical research coordinators (CRCs) at the participating hospital using electronic case report forms

(eCRF) from a web-based database (Korea National Institute of Health; http://icreat.nih.go.kr). Records will only be accessed by authorized personnel to ensure confidentiality. The data will be handled confidentially and anonymously. Study participants will only be recognized by their study ID, and their personal identifiers will not be recorded or stored. Investigators and CRCs at the participating hospitals will monitor the completeness of the eCRF. An independent data management team separate from the investigators will conduct data management. A data validation plan will be prepared to review the consistency, validity, and completeness of the eCRF data. Through this iterative process, the data will be cleaned and the final database will be locked. All database backups of the eCRF will be performed in real time. A data monitoring committee board is not needed because this study is a minimal-risk study.

To modify protocols, approval will be required during an investigator meeting. Any planned amendments in this trial will be communicated to the trial site staff in person and reported to the IRB and sponsor. The investigators will also update the protocol in the clinical trial registry.

Statistical analyses

All primary and secondary endpoints and serious AEs will be analyzed by investigators at participating hospitals. The differences among the groups will be analyzed using one-way analysis of variance and Kruskal-Wallis rank sum tests for continuous variables, and chi-square and Fisher exact tests for categorical variables. Repeated measures data will be compared using a mixed model. The primary endpoint, HD versus non-HD, was analyzed using a logistic regression model among the groups. A logistic regression model was used to analyze stratification factors (institutions and diabetes) and factors with a standardized difference of 10% or more because of randomization. For the secondary endpoints, a mixed model will be used to analyze whether there is a difference over time among groups, or if there is a different pattern among groups according to time by correcting for stratification factors (institutions and diabetes) and factors with a standardized difference of 10% or more because of randomization. If the measurement data are not repeated, logistic regression analysis or linear regression analysis will be used according to stratification factors and covariates.

The statistical analyses will be conducted on an intention-to-treat (ITT) and per-protocol (PP) basis. For the ITT analysis, all participants who are enrolled and randomized to one of the three groups and who complete the first visit will be included. For PP analysis, all participants who complete the study will be included to evaluate the primary and secondary outcomes.

The final dataset will be available for researchers who are interested in related topics after the research team has disseminated the main findings of the research aims. Permission from the primary investigator is required for all publications and dissemination efforts.

Dissemination plans

The research progress will be regularly reported to the National Evidence-based Healthcare Collaborating Agency and will be presented at the Korean Society of Nephrology conference. We will also disseminate the study results at national and international conferences and in scientific peer-reviewed journals.

Discussion

This study compares RRT choice among patients with CKD according to the level of SDM. It also compares the differences in unplanned dialysis, economic efficiency, patient satisfaction, patients' evaluation of the process, and patient adherence.

SDM is an important component of patient-centered care. The physician provides quality information about treatment options, the patient provides his or her values and preferences, and together they make the best decision [29]. SDM increases the quality of decision-making and acceptability of patients during the treatment process because they feel a responsibility for their own treatment. In the past, patients relied on physician judgment and decisions alone when deciding on a treatment plan [30]. However, in recent years due to improvements in medical care, various treatments for the same disease have been made available, and communication technology has facilitated easy acquisition of health and medical information. The patient has a right to know their treatment options and the associated risks and benefits, which often means more in-depth information is required. However, extensive

information can be exhausting and distressing for patients, many of whom ultimately end up on dialysis without feeling they have actually made an appropriate decision [30]. Moreover, some comorbidities are related to the choice of dialysis modality, and this choice might not lead to the best outcomes in the real-world [31]. Therefore, patients are changing the way they participate in the treatment decision-making process.

This study divides patients into three groups according to education method and decision aids. The differences among the groups are the quality and quantity of information provided and the extent to which patients and doctors share their opinions. In the conventional group, the necessity of starting dialysis and the advantages and disadvantages of the dialysis methods are briefly explained twice within 5-minute sessions, after which the patient decides on the start date and dialysis method. The EIDM group receives more information, including intensive learning materials, and the patient undergoes a session that is 5 minutes longer than the conventional group's education. However, while KFRT patients prefer to receive information, this does not always translate into active involvement in decision-making [32]. Thus, in the SDM group, the doctor explains the necessity of starting dialysis and describes the different dialysis methods to the patient, and then refers to the self-assessment responses. The patient is then educated according to their answers to the self-assessment items, with a particular focus on patient illness perceptions. Afterward, the patient makes a treatment decision based on the doctor's recommendations as well as their values and preferences.

Illness perceptions are the organized beliefs patients have about their disease and are defined by identity, cause, timeline, consequences, control, and emotional responses [33,34]. Within KFRT, illness perceptions have been shown to be related to a variety of health outcomes including quality of life [35], depression [36,37], and mortality [38,39]. In this respect, an investigation into the illness perceptions of people with kidney disease is important and may serve as an interventional target for treatment engagement, adherence, and health outcomes [40]. A recent study showed that understanding the illness perception of CKD patients was crucial in the SDM communication process [19]. The illness perception of HD and PD patients was different, and it affected patients' perception and satisfaction with SDM [19]. When patients report that they have participated in SDM, they are likely to enjoy better affective-cognitive outcomes such as improved satisfaction and less decisional conflict [41]. The challenging point is that it is not clear what leads a patient to report a decision as having been shared. Thus, to foster SDM and its associated benefits in practice, more effort should be given to finding links between SDM and patient behavioral and health outcomes.

The primary endpoint in this study is the proportion of HD versus non-HD treatments. It is very important to choose long-term RRT for KFRT patients. KT is the best choice for RRT, but lack of available donated kidneys or poor socioeconomic status can lead a patient to choose HD or PD. The reason why "8 weeks after vascular surgery" was added to the definition is that 8 weeks is the period during which the patient can be considered to have decided on their dialysis method through HD, and they are ready to start HD. This means that they have no chance to change their dialysis modality. Also, the reason why "4 weeks after PD catheter insertion" was added to the definition is that 4 weeks is the period during which the patient can be considered to have decided on their dialysis method through PD. Various medical and socioeconomic factors influence decisions regarding dialysis modality selection. The importance of health and dialysis environmental factors is more emphasized in HD patients, while lifestyle factors may be considered more important in PD patients [19]. PD patients were found to have been provided with sufficient information and were more informed about dialysis modalities than HD patients [42,43]. A recent study reported that SDM implementation for long-term RRT led to more KFRT patients receiving living KT and entering PD rather than HD [44]. The incidence of HD patients is increasing to >80% in Korea [2]. The sample size in this study was calculated assuming that the ratio of non-HD patients increased by 10%.

The secondary endpoints are unplanned dialysis, economic efficiency, patient satisfaction, patient evaluation of the SDM process, and patient adherence. Implementing SDM and providing sufficient information on RRT may lead to a situation in which the patient has the ability to make an informed choice. This results in more planned dialysis treatments and increases patient satisfaction and adherence. This study also compares the differences in economic efficiency. Control and treatment of CKD and RRT impose a large economic burden on the healthcare system and its

patients. Korea has higher HD costs than PD costs—5-year costs were $16,335 and $12,398 for HD and PD, respectively [3]. The cost per QALY gained was RM (Malaysian ringgit) 46,595 for HD and RM41,527 for PD in Malaysia, and increasing PD as the initial dialysis modality would be more cost-effective [45]. With regard to medication adherence, a recent study in China reported that patient adherence was positively correlated with perceived necessity and negatively correlated with concern [46]. Among 283 PD hypertensive patients who completed the MMAS-8 questionnaire, the proportion of medium-to-high drug adherence to anti-hypertensive therapy was 89.8% [47].

In summary, the SDM-ART study is a multicenter, open-label, randomized, pragmatic trial to evaluate the effect of SDM on RRT choice in patients with CKD. The results of this trial could help better equip patients to choose the right RRT modality and could be useful in reducing unplanned dialysis, decreasing economic burden, and increasing overall patient satisfaction and adherence.

Additional information

The approval numbers from the Institutional Review Boards of all 19 participating sites are as follows: Gachon University Gil Medical Center, GAIRB2021-122; Seoul National University Bundang Hospital, B-2103/672-405; Seoul National University Hospital, H-2011-164-1176; Seoul National University Boramae Medical Center, 20-2021-31; Severance Hospital, 4-2021-0459; The Catholic University of Korea Seoul St. Mary's Hospital, XC21EIDI0046; Ewha Woman's University Seoul Hospital, SEUMC 2021-03-007-008; Samsung Medical Center, SMC 2021-02-040-005; The Catholic University of Korea Eunpyeong St. Mary's Hospital, XC21EIDI0046; Korea University Guro Hospital, 2021GR0188; Kyung Hee University Hospital at Gangdong, KHNMC 2021-03-003-001; Dongguk University Ilsan Hospital, DUIH2021-03-034-007; Yonsei University Wonju Severance Christian Hospital, CR320200; Daejeon Eulji Medical Center, EMC 2021-03-001-001; Ulsan University Hospital, UUH 2021-05-009; Kyungpook National University Hospital, KNUH 2021-02-027-001; Pusan National University Hospital, 2103-022-101; Chonnam National University Hospital, BTMP-2021-063; and Kyungpook National University Chilgok Hospital, KNUCH2021-03-021-002.

Conflicts of interest

All authors have no conflicts of interest to declare.

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Data sharing statement

The data presented in this study are available on request from the corresponding author.

Authors' contributions

Conceptualization, Data curation, Formal analysis, Methodology: YCK, Soojin K, MWJ, Sejoong K
Funding acquisition: Sejoong K
Investigation, Methodology, Resources: JHC, SHS, Soojin K, MWJ, Sejoong K
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References

1. Ji E, Kim YS. Prevalence of chronic kidney disease defined by using CKD-EPI equation and albumin-to-creatinine ratio in the Korean adult population. *Korean J Intern Med* 2016;31:1120–1130.
2. Hong YA, Ban TH, Kang CY, et al. Trends in epidemiologic characteristics of end-stage renal disease from 2019 Korean Renal Data System (KORDS). *Kidney Res Clin Pract* 2021;40:52–61.
3. Kim SH, Jo MW, Go DS, Ryu DR, Park J. Economic burden of chronic kidney disease in Korea using national sample cohort. *J Nephrol* 2017;30:787–793.
4. Wong G, Howard K, Chapman JR, et al. Comparative survival and economic benefits of deceased donor kidney transplantation and dialysis in people with varying ages and co-morbidities. *PLoS One* 2012;7:e29591.
5. Lee SW, Lee NR, Son SK, et al. Comparative study of peritoneal dialysis versus hemodialysis on the clinical outcomes in Korea: a population-based approach. *Sci Rep* 2019;9:5905.
6. Mehrotra R, Chiu YW, Kalantar-Zadeh K, Bargman J, Vonesh E. Similar outcomes with hemodialysis and peritoneal dialysis in patients with end-stage renal disease. *Arch Intern Med* 2011;171:110–118.
7. Yeates K, Zhu N, Vonesh E, Trpeski L, Blake P, Fenton S. Hemodialysis and peritoneal dialysis are associated with similar outcomes for end-stage renal disease treatment in Canada. *Nephrol Dial Transplant* 2012;27:3568–3575.
8. Chang YK, Hsu CC, Hwang SJ, et al. A comparative assessment of survival between propensity score-matched patients with peritoneal dialysis and hemodialysis in Taiwan. *Medicine (Baltimore)* 2012;91:144–151.
9. Zazzeroni L, Pasquinelli G, Nanni E, Cremonini V, Rubbi I. Comparison of quality of life in patients undergoing hemodialysis and peritoneal dialysis: a systematic review and meta-analysis. *Kidney Blood Press Res* 2017;42:717–727.
10. Purnell TS, Auguste P, Crews DC, et al. Comparison of life participation activities among adults treated by hemodialysis, peritoneal dialysis, and kidney transplantation: a systematic review. *Am J Kidney Dis* 2013;62:953–973.
11. Elwyn G, Laitner S, Coulter A, Walker E, Watson P, Thomson R. Implementing shared decision making in the NHS. *BMJ* 2010;341:c5146.
12. Davison SN, Levin A, Moss AH, et al. Executive summary of the KDIGO Controversies Conference on Supportive Care in Chronic Kidney Disease: developing a roadmap to improving quality care. *Kidney Int* 2015;88:447–459.
13. Santema TB, Stubenrouch FE, Koelemay MJ, et al. Shared decision making in vascular surgery: an exploratory study. *Eur J Vasc Endovasc Surg* 2016;51:587–593.
14. Farrington K, Warwick G. Renal Association Clinical Practice Guideline on planning, initiating and withdrawal of renal replacement therapy. *Nephron Clin Pract* 2011;118 Suppl 1:c189–c208.
15. Galla JH. Clinical practice guideline on shared decision-making in the appropriate initiation of and withdrawal from dialysis. The Renal Physicians Association and the American Society of Nephrology. *J Am Soc Nephrol* 2000;11:1340–1342.
16. Farrington K, Covic A, Aucella F, et al. Clinical Practice Guideline on management of older patients with chronic kidney disease stage 3b or higher (eGFR <45 mL/min/1.73 m2). *Nephrol Dial Transplant* 2016;31:ii1–ii66.
17. Song MK, Lin FC, Gilet CA, Arnold RM, Bridgman JC, Ward SE. Patient perspectives on informed decision-making surrounding dialysis initiation. *Nephrol Dial Transplant* 2013;28:2815–2823.
18. Levey AS, Coresh J, Greene T, et al. Using standardized serum creatinine values in the modification of diet in renal disease study equation for estimating glomerular filtration rate. *Ann Intern Med* 2006;145:247–254.
19. Kim S, Park JT, Shin SJ, et al. Evaluating a shared decision-making intervention regarding dialysis modality: development and validation of self-assessment items for patients with chronic kidney disease. *Kidney Res Clin Pract* 2022;41:175–187.
20. Lee H, Jo M, Choi S, Kim Y, Oh K. Development and psychometric evaluation of measurement instrument for Korean health-related quality of life. *Public Health Wkly Rep* 2016;9:447–454.
21. Schmidt J, Lamprecht F, Wittmann WW. Satisfaction with inpatient management. Development of a questionnaire and initial validity studies. *Psychother Psychosom Med Psychol* 1989;39:248–255.

22. Züllich D, Zimmering M, Keil T, Querfeld U. Migration background and patient satisfaction in a pediatric nephrology outpatient clinic. *Pediatr Nephrol* 2012;27:1309–1316.
23. Kriston L, Scholl I, Hölzel L, Simon D, Loh A, Härter M. The 9-item Shared Decision Making Questionnaire (SDM-Q-9): development and psychometric properties in a primary care sample. *Patient Educ Couns* 2010;80:94–99.
24. Doherr H, Christalle E, Kriston L, Härter M, Scholl I. Use of the 9-item Shared Decision Making Questionnaire (SDM-Q-9 and SDM-Q-Doc) in intervention studies: a systematic review. *PLoS One* 2017;12:e0173904.
25. Alvarado-Villa GE, Moncayo-Rizzo JD, Gallardo-Rumbea JA. Spanish validation endorsement of SDM-Q-9, a new approach. *BMC Public Health* 2019;19:106.
26. Rencz F, Tamási B, Brodszky V, Gulácsi L, Weszl M, Péntek M. Validity and reliability of the 9-item Shared Decision Making Questionnaire (SDM-Q-9) in a national survey in Hungary. *Eur J Health Econ* 2019;20:43–55.
27. Morisky DE, Ang A, Krousel-Wood M, Ward HJ. Predictive validity of a medication adherence measure in an outpatient setting. *J Clin Hypertens (Greenwich)* 2008;10:348–354.
28. Ahlawat R, Tiwari P, D'Cruz S. Prevalence and predictors of medication non-adherence in patients of chronic kidney disease: evidence from a cross sectional study. *J Pharma Care Health Syst* 2016;3:1.
29. Schrager SB, Phillips G, Burnside E. A simple approach to shared decision making in cancer screening. *Fam Pract Manag* 2017;24:5–10.
30. Davis JL, Davison SN. Hard choices, better outcomes: a review of shared decision-making and patient decision aids around dialysis initiation and conservative kidney management. *Curr Opin Nephrol Hypertens* 2017;26:205–213.
31. Kim HJ, Park JT, Han SH, et al. The pattern of choosing dialysis modality and related mortality outcomes in Korea: a national population-based study. *Korean J Intern Med* 2017;32:699–710.
32. Jayanti A, Neuvonen M, Wearden A, et al. Healthcare decision-making in end stage renal disease: patient preferences and clinical correlates. *BMC Nephrol* 2015;16:189.
33. Leventhal H, Phillips LA, Burns E. The Common-Sense Model of Self-Regulation (CSM): a dynamic framework for understanding illness self-management. *J Behav Med* 2016;39:935–946.
34. Diefenbach MA, Leventhal H. The common-sense model of illness representation: theoretical and practical considerations. *J Soc Distress Homeless* 1996;5:11–38.
35. Griva K, Jayasena D, Davenport A, Harrison M, Newman SP. Illness and treatment cognitions and health related quality of life in end stage renal disease. *Br J Health Psychol* 2009;14:17–34.
36. Chilcot J, Wellsted D, Davenport A, Farrington K. Illness representations and concurrent depression symptoms in haemodialysis patients. *J Health Psychol* 2011;16:1127–1137.
37. Chilcot J, Norton S, Wellsted D, Davenport A, Firth J, Farrington K. Distinct depression symptom trajectories over the first year of dialysis: associations with illness perceptions. *Ann Behav Med* 2013;45:78–88.
38. Chilcot J, Wellsted D, Farrington K. Illness perceptions predict survival in haemodialysis patients. *Am J Nephrol* 2011;33:358–363.
39. Parfeni M, Nistor I, Covic A. A systematic review regarding the association of illness perception and survival among end-stage renal disease patients. *Nephrol Dial Transplant* 2013;28:2407–2414.
40. Rees J, Chilcot J, Donnellan W, Soulsby L. Exploring the nature of illness perceptions in people with end-stage kidney disease. *J Ren Care* 2018;44:19–29.
41. Shay LA, Lafata JE. Where is the evidence?: a systematic review of shared decision making and patient outcomes. *Med Decis Making* 2015;35:114–131.
42. Ghodsian S, Ghafourifard M, Ghahramanian A. Comparison of shared decision making in patients undergoing hemodialysis and peritoneal dialysis for choosing a dialysis modality. *BMC Nephrol* 2021;22:67.
43. Balzer MS, Clajus C, Eden G, et al. Patient perspectives on renal replacement therapy modality choice: a multicenter questionnaire study on bioethical dimensions. *Perit Dial Int* 2019;39:519–526.
44. Lee CT, Cheng CY, Yu TM, et al. Shared decision making increases living kidney transplantation and peritoneal dialysis. *Transplant Proc* 2019;51:1321–1324.
45. Surendra NK, Abdul Manaf MR, Hooi LS, et al. Cost utility analysis of end stage renal disease treatment in Ministry of Health dialysis centres, Malaysia: hemodialysis versus continuous ambulatory peritoneal dialysis. *PLoS One* 2019;14:e0218422.
46. Bai HH, Nie XJ, Chen XL, Liang NJ, Peng LR, Yao YQ. Beliefs about medication and their association with adherence in Chinese patients with non-dialysis chronic kidney disease stages 3-5. *Medicine (Baltimore)* 2022;101:e28491.
47. Li D, Huo Z, Liu D, et al. Current apparent treatment-resistant hypertension in patients undergoing peritoneal dialysis: a multi-center cross-sectional study. *J Clin Hypertens (Greenwich)* 2022;24:493–501.