Research Article

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Preliminary Efficacy of an Integrated Cognitive and Self-Management Training Program in Hemodialysis Patients

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Abstract

Background: Hemodialysis (HD) serves as the primary mode of renal replacement therapy for the majority of these patients, yet it simultaneously introduces significant physiological and psychological stressors [(1,2)]. **Objectives:** This pilot randomized controlled study aimed to examine the feasibility and preliminary efficacy of an Integrated Cognitive and Self-Management Training (ICST) program to improve cognitive function and self-management behaviors among patients with end-stage kidney disease (ESKD) undergoing hemodialysis (HD). **Methods:** ESKD patients who met the inclusion criteria (n = 20) were randomly assigned to either the experimental group (n = 10) or control group (n = 10). The experimental group received usual care plus the ICST program, comprising 16 sessions (60 minutes each, twice weekly) delivered over 8 weeks during the one-hour pre-dialysis waiting period. Cognitive function and self-management behaviors were assessed using the Montreal Cognitive Assessment-Basic (MoCA-B) and the Self-Management Behavior Questionnaire (SMBQ) at baseline and post-intervention (Week 8). Qualitative feedback on program acceptability was also collected from experimental-group participants through brief open-ended questionnaire items conducted by the research assistant at the final session. Demographic data were summarized using descriptive statistics. Between-group differences were assessed using independent-samples *t*-tests, while within-group pre–post changes in the intervention group were examined using paired-samples *t*-tests. **Results:** The ICST program demonstrated excellent feasibility with a 100% participant retention and attendance rate, and zero adverse events. At post-intervention, the experimental group achieved significantly higher scores than the control group in both cognitive function (26.20 $\pm$ 0.63

vs. 25.10 ± 0.57; t = 4.09, p < .001, 95% CI [0.54, 1.67], Cohen's d = 1.83) and self-management behaviors (173.00 ± 10.38 vs. 136.60 ± 26.38; t = 4.06, p < .001, 95% CI [17.56, 55.24], Cohen's d = 1.82). Within-group analysis (experimental group only, n=10) confirmed significant pre- to post-intervention improvements in cognitive function (t_9 = 6.71, p < .001) and self-management behaviors (t_9 = 7.11, p < .001). Qualitative feedback confirmed high acceptability; participants described the program as "clear, practical, and easy to complete." **Conclusions:** The ICST program was feasible, highly acceptable, and demonstrated large preliminary effects on both cognitive function and self-management behaviors for HD patients. These findings warrant larger-scale randomized controlled trials with longer follow-up periods to confirm long-term clinical benefits and further studies exploring the feasibility of broader clinical implementation across hemodialysis settings.

Keywords: End-stage kidney disease, Hemodialysis, Integrated cognitive and self-management training, Cognitive function, Self-management behavior, Pilot randomized controlled trial.

What was Known

- Cognitive deficits and poor self-management affect HD patients' health and their quality of life.
- Existing interventions often target either patients' cognitive function or self-management behaviors in isolation. An integrated intervention that simultaneously enhances cognitive function and self-management is therefore needed.

What's New and Next

- This integrated program showed promising preliminary potential for improving both cognitive function and self-management behaviors among these patients.
- Delivery during waiting time revealed high acceptance and feasibility of the program.
- More robust randomized controlled trials are warranted to further establish program's effectiveness.

Introduction

Patients with end-stage kidney disease (ESKD) constitute a rapidly expanding global demographic, primarily driven by aging populations and rising rates of chronic comorbidities such as hypertension and diabetes. Among these, cognitive impairment (CI) is a major clinical concern, demonstrating an alarmingly high prevalence in this population; recent meta-analyses estimate rates between 51% and 55%, with particularly severe deficits observed in executive functions, memory, and attention [3,4,5]. Clinically, these deficits are frequently underrecognized, and up to

one-third of HD patients may progress from mild cognitive impairment (MCI) to dementia, thereby intensifying the healthcare burden on both individuals and families [6,7].

The pathogenesis of cognitive decline in HD patients is multifactorial, involving mechanisms such as uremic toxin retention, recurrent cerebral ischemia, chronic inflammation, and hemodynamic instability during dialysis sessions [3]. This cognitive deterioration profoundly hinders patients' capacity to comprehend medical instructions, adhere to complex treatment regimens, and maintain functional independence [2,6,7,8], and is strongly associated with increased hospitalization, mortality, and reduced quality of life [2,8]. Because effective self-management encompassing disease-related knowledge, medication and dietary adherence, symptom monitoring, and timely response to complications [9] fundamentally depends on intact cognitive abilities, impaired cognition directly undermines these self-management skills, leading to poorer disease control and diminished treatment outcomes [10]. Consistent with this, lower self-efficacy and self-management capability have been associated with more severe cognitive complaints and increased adverse clinical events among HD patients [1,9,10,11].

Despite this well-established interdependence, current interventions typically target either cognitive function or self-management behaviors in isolation [9]. Cognitive training programs alone may enhance attention, memory, or problem-solving, but do not equip patients with the practical skills needed to translate improved cognition into disease-specific self-care actions. Conversely, self-management education alone may be insufficient for patients with underlying cognitive deficits, who may struggle to comprehend, retain, and apply the information taught [9,10]. Existing home-based and intradialytic cognitive or exercise training programs have demonstrated only short-term gains, and more rigorous evaluations of interventions that simultaneously target both domains remain lacking [4,12]. This represents a clear and clinically important research gap: an integrated intervention that concurrently trains cognitive skills and reinforces their direct application to self-management tasks, rather than addressing either domain alone, is needed to produce synergistic and more sustainable benefits for HD patients.

The Integrated Cognitive and Self-Management Training (ICST) program was specifically developed to fill this clinical gap. Administered during the underutilized one-hour waiting period prior to HD sessions, it successfully addresses major participation barriers such as time constraints and post-dialysis fatigue [7]. To evaluate this novel approach, this pilot randomized controlled trial was conducted. The primary overarching aim of this study was to assess the feasibility, acceptability,

and preliminary efficacy of the ICST program in ESKD patients undergoing HD. Specifically, the feasibility aims were to evaluate participant retention rates, session attendance, safety profiles, and qualitative acceptability. The preliminary efficacy aims were to examine the short-term effects of the ICST program on improving cognitive function and self-management behaviors. This study addressed two central research questions: (1) Is the ICST program feasible and acceptable within a pre-dialysis environment? and (2) Does the ICST program demonstrate preliminary efficacy in improving cognitive function and self-management behaviors compared to usual care? We hypothesized that the ICST program would demonstrate excellent feasibility metrics and that patients receiving the ICST program would achieve significantly higher post-intervention scores in both cognitive function and self-management behaviors compared to those receiving usual care. The findings will provide essential information for designing a future adequately powered randomized controlled trial.

Materials and Methods

1. Research Design

This study was a randomized controlled pilot trial adopting a parallel-group, pretest–posttest design, conducted and reported in strict accordance with the CONSORT extension for pilot and feasibility trials [13]. As a pilot trial, the primary focus was to evaluate specific feasibility indicators to determine the progression criteria for a future definitive trial. Feasibility was evaluated using five pre-specified indicators, consistent with recommendations for pilot and feasibility trials [13]: recruitment rate (proportion of eligible patients who consented to participate); (2) retention rate (proportion of enrolled participants completing the 8-weeks); (3) adherence (proportion of the 16 scheduled intervention sessions attended); (4) acceptability (participants' subjective experience of the program, assessed through post-intervention qualitative feedback); and (5) safety (occurrence of any adverse events during program participation). A priori, the ICST program was considered feasible if retention and attendance rates exceeded 80%, consistent with common feasibility thresholds for pilot trials. Secondary objectives focused on evaluating the preliminary efficacy of the program on cognitive function and self-management behaviors.

2. Population and sample

The study population comprised patients with ESKD undergoing maintenance HD at a specialized HD center in Chanthaburi province, Thailand. A convenience sample of 20 patients was enrolled. This sample size is justified for a pilot trial to evaluate operational feasibility and estimate

effect sizes, aligning with established methodological recommendations suggesting 10 to 12 participants per group for pilot experiments [14].

Participants were included if they met the following criteria: (1) aged 40 to 65 years; (2) undergoing maintenance HD for 1-3 months with a stable vascular access; (3) possessed no overt cognitive impairment, defined as a Mini-Mental State Examination Thai (MMSE-Thai 2002) score > 22. This threshold was selected to exclude patients with overt dementia who might be unable to meaningfully engage in the structured cognitive and self-management exercises, while still permitting inclusion of patients with milder, subclinical cognitive impairment. Because the MMSE is a relatively coarse screening tool, the more sensitive Montreal Cognitive Assessment-Basic (MoCA-B) was subsequently used as the primary outcome measure to detect and quantify milder cognitive deficits and change over time; (4) maintained functional independence in activities of daily living (Modified Barthel ADL Index [BAI] > 12); and (5) were able to effectively read, write, and speak the Thai language. Exclusion criteria included lived alone or relying entirely on paid caregivers; possessing major neurological or medical co-morbidities that could confound cognitive scores (e.g., prior stroke, acute myocardial infarction); or experiencing a critical illness requiring acute hospitalization during the study period.

Following baseline screening, the 20 eligible participants were randomly allocated into either the experimental group (n=10) or the control group (n=10) in a 1:1 ratio. To minimize selection bias, block randomization with a fixed block size of 4 was executed. The randomization sequence was generated by an independent statistician using a computer-generated random number table.

To ensure rigorous allocation concealment, the generated sequence was securely sealed within sequentially numbered, opaque, sealed envelopes (SNOSE). The envelopes were maintained by an independent clinic nurse (RA2) who was not involved in participant recruitment. Once a participant signed the informed consent form, the trained research assistant (RA1) contacted the independent nurse (RA2), who then opened the next envelope in the sequence to reveal the group assignment.

Regarding blinding, due to the active behavioral nature of the nursing intervention, it was impossible to blind the participants or the interventionist nurses. However, strict single-blinding was successfully maintained for outcomes. The data collector (a trained research nurse who administered the pre- and post-test questionnaires) was entirely blinded to the group assignments. Furthermore, the statistical data analyst was completely blinded, receiving a masked dataset with anonymized

group codes (e.g., Group A and Group B). The flow diagram of the selection procedure is presented in Figure 1.

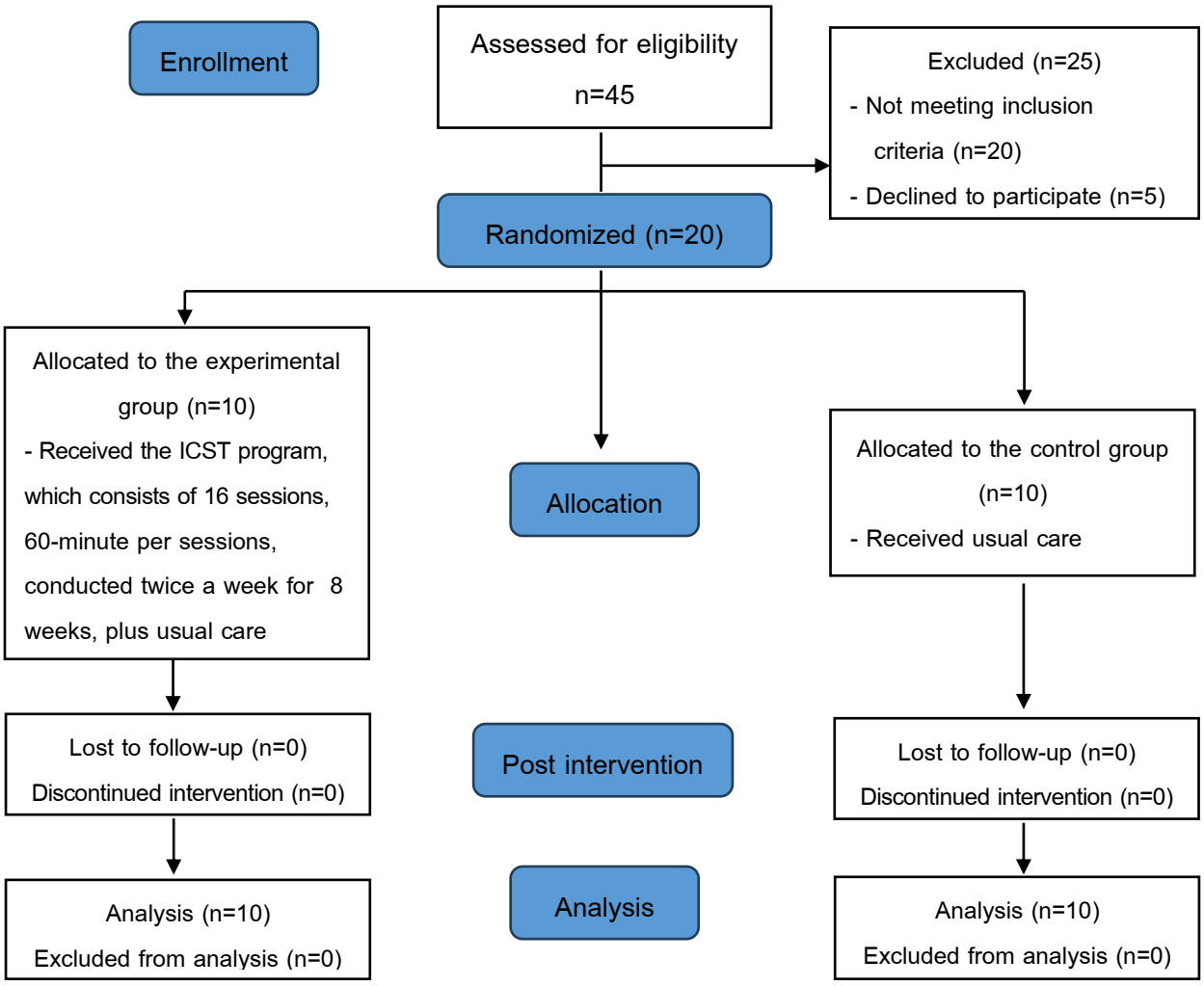

Figure 1 Flow diagram of the selection procedure

3. Instruments

The instruments were divided into two parts: 1) Instruments for data collection, and 2) Instruments for the program.

1) Instruments for data collection:

1.1 Demographic and Clinical Questionnaire: Developed by the researchers to record general characteristics (gender, age, marital status, education level, medical care entitlements, and income) and clinical parameters extracted from medical records (duration on HD, serum blood urea nitrogen, serum creatinine, hemoglobin, blood glucose, K, Na, P, and Kt/V).

1.2 Montreal Cognitive Assessment-Basic (MoCA-B; Thai Version): Originally developed by Nasreddine et al. [15], and translated into Thai by Julayanont et al. [16], the MoCA-B is a highly sensitive instrument used to detect mild cognitive deficits across diverse educational levels. It evaluates domains including attention, executive functions, memory, and language. Scores range from 0–30, with scores ≥25 indicating normal cognitive function (adjusted for education level) and scores <25 indicating cognitive impairment, demonstrating high sensitivity (81%) and specificity (86%) [16]. Inter-rater reliability between the researcher and three research assistants in this study was 0.98 and 0.99.

1.3 Self-Management Behavior Questionnaire (SMBQ; Thai Version): Developed by Curtin et al. [17,18] and translated into the Thai by Sritarapipat et al. [19], the SMBQ captures self-care across 37 items across five dimensions: self-care activities, medication adherence, communication, self-advocacy, and partnership in care. Responses are scored on a 5-point Likert scale (1=never to 5=always), with cumulative scores ranging from 37 to 185. Higher scores indicate superior self-management. The original subscale reliability coefficients ranged from 0.70–0.84 [17], Cronbach's alpha for this sample was 0.96.

2) Instruments for the program:

The ICST program was a structured nursing intervention theoretically grounded in Meleis' Transition Theory [20] aimed to promote patient's illness adaptation, Cognitive Training Principles [21] (focusing on structured attention, memory, and problem-solving), and Self-Management Frameworks [17] (focusing on patient empowerment and illness management).

The content validity of the ICST program was rigorously reviewed and validated by a panel of five independent experts: one nephrologist, one neurologist, one specializing in Advanced Practice Nursing (APN) in medical-surgical nursing, and two nursing professors in areas of adult or elderly nursing. The resulting Item Objective Congruence (IOC) was 0.97, confirming excellent clinical and theoretical validity.

4. Implementation Process

The ICST program comprised a total of 16 scheduled sessions delivered twice weekly over an 8-week period. Each session lasted exactly 60 minutes and was administered on a one-on-one basis by a trained research nurse. To systematically eliminate participation barriers such as post-dialysis fatigue or severe time constraints, all sessions were carried out during the underutilized 1-hour waiting period prior to the patient's scheduled HD session.

The weekly structure was organized as follows:

Week 0: Pre-intervention baseline assessment.

Week 1 (Session 1): Building relationships to establish trust and a supportive atmosphere.

Week 1 (Session 2): Assessing readiness for transition.

Week 2 (Session 3): Preparing for transition and role supplementation.

Week 2-8 (Session 4-15): Cognitive and self-management training and its application in participants' own practice.

Week 8 (Session 16): Post-intervention assessment and qualitative feedback collection.

The control group concurrently received standard usual care provided by the dialysis unit, which included routine medical check-ups and standard verbal nursing instructions.

5. Data collection

Data collection was executed at baseline (Week 0) and post-intervention (Week 8) by the blinded data collector. Prior to commencement, the researcher provided comprehensive explanations regarding study objectives and guaranteed absolute data confidentiality. Written informed consent was voluntarily obtained from all participants. The completion of the structured questionnaires required approximately 60 minutes per participant. At Week 8, qualitative acceptability feedback was gathered from the experimental group via brief semi-structured, open-ended face-to-face interviews lasting 10–15 minutes, focusing on their perceptions of the program's utility and ease of completion.

6. Data analysis

Quantitative data were analyzed using SPSS statistical software program version 26, and the statistical significance level was set at $p < .05$. Descriptive statistics (frequencies, percentages, means, and standard deviations) summarized demographic and clinical profiles. The chi-square test, Fisher's exact test, and independent *t*-test were employed to determine the differences in demographic characteristics between these two groups.

The mathematical assumptions for parametric testing were carefully verified. Normality of the continuous outcome scores (MoCA-B and SMBQ) was assessed using the Shapiro-Wilk test alongside skewness and kurtosis analyses, with all parameters falling well within acceptable ranges (skewness/kurtosis values between $\pm$ 1.5), justifying the use of *t*-tests. Within-group changes from pre- to post-intervention were evaluated using paired-samples *t*-tests, while between-group differences at post-intervention were evaluated via independent-samples *t*-tests. To determine the

magnitude of the clinical effects, Cohen's *d* effect sizes and corresponding 95% confidence intervals (CI) were computed.

Data analysis strictly adhered to the Intention-to-Treat (ITT) framework. Missing data was planned to be handled via multiple imputations; however, no dropouts or missing data points occurred during this pilot study (n = 20 retained).

For the qualitative feedback, interview transcripts were analyzed using inductive content analysis to extract key themes regarding the program's acceptability and operational feasibility.

Results

1. Demographic and Clinical Characteristics of Participants

A total of 20 patients undergoing maintenance HD successfully completed the study, with 10 participants allocated to the experimental group and 10 to the control group. Data completeness was 100% due to a zero-dropout rate; therefore, no missing data imputation methods were required. As shown in Table 1 and Table 2, baseline demographic profiles were highly homogeneous between the two groups. The mean age was 54.80 $\pm$ 6.84 years for the experimental group and 57.30 $\pm$ 8.40 years for the control group (p=.475). Across both groups, the majority of participants were male (60% in the experimental group and 70% in the control group) and married (60% in both groups). The highest proportion in both groups having completed only primary school (60% and 50%, respectively), and most participants reported a monthly income between 5,001 and 10,000 Thai Baht per month (60% in both groups), with the Universal Coverage Scheme (UCS) being the predominant medical entitlement (70% and 80%, respectively). These data suggest a generally homogeneous sample characterized by middle age, low educational attainment, and reliance on public healthcare coverage, reflecting a typical demographic profile of ESKD patients in this setting. No statistically significant difference in demographic characteristics were found between groups (p > .05 for all comparisons). The details are shown in Table 1.

Table 1 Description of the general information of participants

Characteristics	Experimental group (n = 10)		Control group (n = 10)		Test	*p*-value
	n	%	n	%		
Gender					χ^2 = .639	.220
Male	6	60	7	70		
Female	4	40	3	30		

Table 1 Description of the general information of participants (Cont.)

Characteristics	Experimental group (n = 10)		Control group (n = 10)		Test	*p*-value
	n	%	n	%		
Age (year)					t = -.730	.475
Range	46-65		41-65			
M ± *SD*	54.80 ± 6.84		57.30 ± 8.40			
Marital status					χ^2 = .766	.533
Single	3	30	2	20		
Married	6	60	6	60		
Widowed/Divorced	1	10	2	20		
Education level					χ^2 = .865	.291
No formal education	0	0	0	0		
Primary school	6	60	5	50		
Secondary school	2	20	3	30		
Higher	2	20	2	20		
Medical care entitlements					χ^2 = .606	.267
Civil Servant Medical Benefit Scheme (CSMBS)	0	0	0	0		
Universal Coverage Scheme (UCS)	7	70	8	80		
Social Security Scheme (SSS)	3	30	2	20		
Income (Baht/ month)					χ^2 = .766	.533
≤ 5,000	2	20	1	10		
5,001-10,000	6	60	6	60		
> 10,000	2	20	3	30		

t = Independent t-test, χ^2 = Chi-squared test

The study involved two groups of ESKD patients undergoing HD. Baseline demographic data indicated comparable disease chronicity, with the experimental group having a mean ESKD diagnosis duration of 6.30 months (*SD* = 3.13) and a mean HD duration of 2.60 months (*SD* = 0.67), while the control group showed similar figures (7.30 months for ESKD duration, *SD* = 4.22; 2.40 months for HD duration, *SD* = 0.84). Both groups demonstrated adequate dialysis efficacy with similar mean Kt/V values (Experimental: 1.76 ± 0.05; Control: 1.77 ± 0.05). However, clinical indicators of kidney failure and related complications were evident across both groups. A significant baseline metabolic imbalance was observed in serum creatinine levels, which were significantly higher in the experimental group (11.53 ± 2.60 mg/dl, p = .003) compared to the control group (7.63 ± 2.56 mg/dl) and blood urea nitrogen, alongside persistent anemia reflected by mean hemoglobin levels around 10.13 g/dl. Electrolyte and metabolic parameters, such as sodium, potassium, phosphate, and blood glucose, were generally consistent between the groups, with mean values reflecting the typical challenges of metabolic management in patients on maintenance hemodialysis. No statistically significant difference were found between groups for most health indicators ($p > .05$), except serum creatinine ($p < .05$). The details are shown in Table 2.

Tables 2 Descriptions of health information of the participants

Characteristics	Experimental group (n = 10)		Control group (n = 10)		Test	*p*-value
	n	%	n	%		
Duration of ESKD diagnosis (month)					*t* = -.602	.555
Range	2-11		1-15			
M ± *SD*	6.30 ± 3.13		7.30 ± 4.22			
Duration on HD (month)					*t* = .577	.571
Range	1-3		1-3			
M ± *SD*	2.60 ± 0.70		2.40 ± 0.84			
Serum blood urea nitrogen (mg/dl)					*t* = 1.837	.083
Range	27.10-88.80		26.50-99.40			
M ± *SD*	64.12 ± 18.82		46.41 ± 23.99			
Serum creatinine (mg/dl)					*t* = 3.380	.003*
Range	8.48-15.97		4.70-12.40			
M ± *SD*	11.53 ± 2.60		7.63 ± 2.56			
Hemoglobin (g/dl)					*t* = .004	.997
Range	7.20-14.40		6.40-14.06			
M ± *SD*	10.13 ± 2.08		10.13 ± 2.58			
Blood glucose (mg/dl)					*t* = -.852	.406
Range	95-155		83-158			
M ± *SD*	122.20 ± 22.42		130.40 ± 20.59			
Potassium (mEq/L)					*t* = 1.196	.247
Range	3.97-5.23		3.10-5.04			
M ± SD	4.50 ± 0.39		4.24 ± 0.56			
Sodium (mEq/L)						
Range	132.90-143.80		135.00-141.20			
M ± *SD*	138.07 ± 3.10		136.75 ± 2.20			

Tables 2 Descriptions of health information of the participants (Cont.)

Characteristics	Experimental group (n = 10)		Control group (n = 10)		Test	*p*-value
	n	%	n	%		
Phosphate (mg/dL)					*t* = -.383	.706
Range	3.10-7.20		2.10-9.90			
M ± *SD*	5.06 ± 1.24		5.38 ± 2.33			
Kt/V (3 time/week)					*t* = -.447	.660
Range	1.7-1.8		1.7-1.8			
M ± *SD*	1.76 ± 0.05		1.77 ± 0.05			

t = Independent t-test, χ^2 = Chi-squared test, *p < .05

2. Comparison of outcome variables between the control and experimental groups, and within the experimental group before and after receiving the ICST program

At baseline, mean scores for cognitive function and self-management behaviors did not differ significantly between the experimental and control groups (independent *t*-test: t_{18} = 0.00, p = 1.000 and t_{18} = 0.57, p = .576, respectively), confirming baseline comparability between groups on these outcomes.

Following this baseline equivalence, at post-intervention (Week 8), the experimental group showed significantly higher mean scores than the control group for both cognitive function (t_{18} = 4.09, p < .001, 95% CI [0.54, 1.67], Cohen's d = 1.83) and self-management behaviors (t_{18} = 4.06, p < .001, 95% CI [17.56, 55.24], Cohen's d = 1.82), indicating a significantly greater improvement in the experimental group relative to usual care.

Within the experimental group, paired-samples *t*-tests confirmed significant improvements from pre- to post-intervention in both cognitive function (t_9 = 6.71, p < .001, 95% CI [0.99, 2.01], dz = 2.12) and self-management behaviors (t_9 = 7.11, p < .001, 95% CI [30.07, 58.13], dz = 2.25), demonstrating that participants who received the ICST program showed significant improvement over the 8-week study period.

Tables 3 Comparison of outcome variables between the control and experimental groups, and within the experimental group before and after receiving the ICST program (n = 20)

Outcome variables	Experimental group (n = 10)		Control group (n=10)		t_1	*p*-value	MD. (95% CI)	Cohen's *d*
	Mean	*SD*	Mean	*SD*				
Cognitive functions								
Pre-intervention	24.700	.675	24.700	.675	0.000	1.000	0.00(-0.63, 0.63)	0.00
Post-intervention	26.200	.632	25.100	.568	4.093	<.001*	1.10(0.54, 1.67)	1.83**
t_2	6.708						1.50(0.99, 2.01)	2.12^{+}
p-value	<.001*							
Self-management behaviors								
Pre-intervention	128.900	18.412	123.900	20.819	0.569	.576	5.00(-13.46, 23.46)	0.25
Post-intervention	173.000	10.382	136.600	26.383	4.060	<.001*	36.40(17.56, 55.24)	1.82**
t_2	7.112						44.10(30.07, 58.13)	2.25^{+}
p-value	<.001*							

t_1 = Between-group analysis utilized independent-samples *t*-test (*df*=18), t_2 = Within-group analysis utilized paired-samples *t*-test (*df*=9), 95% CI = 95% Confidence Interval of the mean difference between groups, *p < .05, **Cohen's *d* (between-group, pooled SD); $^{+}$ Cohen's *dz* (within-group, based on SD of the difference scores) effect size thresholds: <0.2=small; 0.2–0.8=medium; >0.8 = large.

MD. = Mean difference

Feasibility

Among the 20 randomized participants, all provided voluntary informed consent and were retained throughout the study, resulting in a 100% retention rate. All participants in the experimental group completed all 16 assigned sessions (100% attendance), and no adverse events were reported, suggesting favorable safety in this pilot sample. Qualitative feedback indicated high acceptability: participants described the program as "clear, practical, and easy to complete," and many requested take-home exercises to continue practicing independently.

Discussion

The results of this pilot randomized controlled trial provide promising preliminary evidence regarding the feasibility, acceptability, and short-term efficacy of the ICST program for patients with ESKD undergoing maintenance HD. Notably, the 100% participant retention and attendance rates, combined with zero reported intervention-related adverse events, indicate that executing a structured behavioral and cognitive intervention during the pre-dialysis waiting period is highly feasible and operationally safe within the Thai healthcare context, as detailed in the following discussion.

Cognitive Functions

The findings of this pilot study provide preliminary evidence suggesting that the ICST program may enhance cognitive function in patients with ESKD undergoing HD. Participants in the experimental group achieved significantly higher mean scores on cognitive function than those in the control group at post-intervention (week 8). These findings suggest that the improvements may be attributable to the ICST program rather than the natural course of time or usual care alone, although this interpretation should be confirmed in an adequately powered trial. Consequently, these preliminary findings highlight the potential importance of structured, multi-dimensional interventions in addressing both cognitive function and self-management to help slow cognitive decline in patients with ESKD undergoing HD.

These results are broadly consistent with prior research demonstrating that cognitive training interventions can improve cognitive function such as memory, attention, and executive functioning in patients with chronic illnesses [22,23,24,25]. Likewise, studies specifically focusing on patients undergoing HD have shown that targeted approaches focusing on cognitive stimulation and self-regulation contribute to the maintenance of cognitive abilities [26,27]. Such improvements observed in this study are noteworthy given that cognitive impairment is a common and debilitating complication among patients with ESKD, frequently associated with reduced quality of life and increased morbidity [3,23,28,29].

The within-group analysis revealed that cognitive function scores in the experimental group improved significantly from pre-intervention to post-intervention. These preliminary findings suggest that the ICST program may not only help prevent further cognitive decline but also promote measurable short-term improvements in cognitive function; whether these gains are sustained beyond the 8-week study period could not be determined in this pilot trial and warrants longer-term follow-up in future research.

The observed enhancement is plausibly attributable to the integrative design of the ICST program, which combined evidence-based cognitive training, self-management skill development, and reinforcement strategies. This multifaceted approach may have created synergistic effects by promoting neuroplasticity, fostering patient engagement, and strengthening self-regulation. Previous research has suggested that combining cognitive and self-management interventions may be more effective than using either approach in isolation, as it simultaneously addresses neurocognitive processes and behavioral adaptation [25,30].

The findings may also carry implications for clinical practice. Cognitive impairment in patients undergoing HD remains under-recognized despite its substantial impacts on treatment adherence, decision-making, and quality of life. The present pilot study suggests the potential of structured, nurse-led interventions such as ICST as feasible and possibly effective non-pharmacological strategies to help preserve and improve cognitive health in this vulnerable population; however, this potential requires confirmation in a larger, adequately powered trial.

Furthermore, the self-management component of the ICST program may have indirectly contributed to improvements in cognitive function. By equipping patients with the skills to better manage diet, fluid intake, medication adherence, and disease understanding, the program may have promoted improved metabolic control and hemodynamic stability. Reductions in uremic burden and blood pressure fluctuations are known to benefit cerebral health, thereby potentially creating a more favorable physiological environment for cognitive functioning [28,30]. This dual mechanism directly training cognitive processes while simultaneously optimizing systemic conditions is one plausible explanation for the large effect sizes observed; however, given the small sample size, these effect size estimates should be interpreted with caution and confirmed in a larger trial. Although research on combined cognitive and self-management programs in HD populations remains limited, these findings are broadly consistent with studies in other chronic conditions, such as heart failure and diabetes, where multicomponent interventions have been shown to improve both clinical outcomes and cognitive performance [11,31,32,33,34].

It is important to note that not all prior studies of cognitive or combined interventions in HD populations have reported consistent benefits. For instance, some intradialytic cognitive stimulation trials have shown improvements limited to specific cognitive domains (e.g., attention) without generalized gains across all domains [26], and effects have sometimes diminished once the intervention ended, raising questions about durability [4,12]. Differences in intervention intensity,

delivery setting (intradialytic vs. pre-dialysis waiting period), and participants' baseline cognitive status (studies including patients with more severe impairment vs. this study's relatively cognitively intact sample, MMSE-Thai >22) may partly explain these discrepancies and should be considered when generalizing the present findings to broader HD populations.

Self-management Behaviors

The findings of this pilot study provide preliminary evidence suggesting that the ICST program may enhance self-management behaviors among patients with ESKD undergoing HD. Participants in the experimental group demonstrated significantly higher mean scores of self-management behaviors compared to those in the control group at post-intervention. These findings suggest that the improvements may be attributable to the ICST intervention, though causal inference is limited by the small sample size. These preliminary findings highlight the potential value of structured, nurse-led interventions in empowering patients and enhancing their capacity to manage the complexities of their illness.

Importantly, these findings are broadly consistent with prior research emphasizing the importance of self-management interventions in patients with CKD and ESKD. Previous studies have demonstrated that educational and behavioral programs focusing on self-care can improve adherence to fluid and dietary restrictions, medication regimens, and dialysis treatment protocols [33,35,36,37,38]. Moreover, self-management interventions have been associated with favorable clinical outcomes, including reduced hospitalization, improved treatment adherence, and enhanced quality of life [27,39,40,41,42,43]. The present pilot study adds to this body of evidence by exploring whether an integrative approach, combining cognitive and self-management strategies, can achieve short-term improvements in self-management behaviors; confirmation of sustained, longer-term benefit requires further research.

The within-group analysis revealed that self-management behavior scores in the experimental group improved significantly from pre-intervention to post-intervention. This finding suggests that the ICST program may enhanced patients' knowledge and behavioral skills within the 8-week study period; however, without longer-term follow-up, whether these gains are maintained over time cannot be confirmed.

Consistent with previous research, interventions that integrate cognitive-behavioral strategies with self-management education have been shown to foster greater patient engagement, self-efficacy, and long-term adherence [27,39,40,41,42,43]. The observed improvements are plausibly attributed to the integrative, multifaceted design of the ICST program, which incorporated multiple evidence-based components, including cognitive training, skill-building exercises, problem-solving strategies, and reinforcement. By enhancing cognitive function and self-regulatory capacity, the program may have facilitated patients' ability to comprehend complex treatment instructions, monitor symptoms, and make informed health-related decisions. This is broadly consistent with Curtin's conceptualization of self-management in patients with CKD and ESRD [17,43], which posits that individuals with adequate cognitive resources and self-efficacy are more likely to engage in effective self-management behaviors.

The findings may carry implications for clinical practice. Self-management is a cornerstone of ESKD care, yet many patients struggle with the complex treatment regimens and lifestyle adjustments required during hemodialysis [27,39,40,41,42,43]. The present pilot study suggests that structured, nurse-led programs such as ICST may help empower patients to take a more active role in their care, potentially reducing complications and improving overall health outcomes; this remains to be confirmed in a larger trial with clinical outcome endpoints.

In addition, these results indicated the feasibility of the ICST program for patients with ESKD undergoing HD. A 100% enrollment and retention rate was achieved from baseline through the 8-week post-intervention assessment. Qualitative feedback further supported these quantitative results: participants described the exercises as 'clear, practical, and easy to complete, and many requested take-home exercises to continue practicing at home, suggesting engagement with and satisfaction with the program. These acceptability data, however, were derived from a brief, informal feedback process rather than a rigorously designed qualitative study and should be interpreted as illustrative rather than as robust qualitative evidence.

Conversely, several self-management intervention trials in HD and peritoneal dialysis populations have reported only modest or non-significant effects on adherence-related outcomes, particularly when interventions were brief, lacked individualized coaching, or relied solely on educational materials without behavioral reinforcement [35,38]. The relatively large improvement observed in the present study may reflect the individualized, one-on-one delivery format and the

direct integration of cognitive skill-building with practical self-management tasks, features not present in many of these less effective interventions, though this interpretation remains hypothesis-generating given the pilot design and small sample.

Strengths and Limitations

This pilot study has several notable strengths. First, the randomized controlled design with concealed allocation and a blinded outcome assessor reduced the risk of selection and detection bias, which is uncommon among pilot nursing intervention studies in this population. Second, the ICST program was grounded in established theoretical frameworks (Transition Theory, Cognitive Training Principles, and Self-Management Frameworks) [17,20,21] and delivered using standardized, psychometrically validated outcome measures (MoCA-B, SMBQ) [16,19] with high reliability in this sample. Third, the program achieved 100% retention and attendance with no adverse events, providing valuable feasibility evidence to inform a future definitive trial.

Nonetheless, several limitations should be considered. First, serum creatinine was significantly higher in the experimental group at baseline, which may have influenced the magnitude of the observed effect and cannot be fully excluded as a confounding factor. Second, the very small sample size (n=10 per group) limits statistical power and precision; results should be interpreted as preliminary rather than confirmatory. Third, the study was conducted at a single hemodialysis center, limiting generalizability. Fourth, neither participants nor the intervention nurse could be blinded, which may have introduced performance bias, particularly for the self-reported SMBQ outcome. Fifth, the 8-week intervention period and single post-intervention assessment provide only a short-term evaluation; durability of gains is unknown. Sixth, voluntary participation raises the possibility of self-selection bias toward more motivated individuals. Finally, qualitative acceptability data were derived from an informal feedback process rather than a rigorously designed qualitative study. These limitations should be addressed in a larger, adequately powered, multi-center randomized controlled trial with longer follow-up.

Conclusion

This pilot randomized controlled trial demonstrates that the ICST program is feasible, highly acceptable, and safe for delivery to patients with ESKD undergoing HD, as reflected by 100% recruitment, retention, and attendance rates with no adverse events. The program also showed promising preliminary effects, with the experimental group demonstrating significantly greater improvements in cognitive function and self-management behaviors than the control group at 8 weeks. However, given the small sample size,

single-center setting, and short follow-up period inherent to a pilot design, these findings should be regarded as preliminary rather than confirmatory of efficacy.

From a public health perspective, cognitive impairment and poor self-management remain under-recognized yet consequential problems among the rapidly growing population of patients undergoing maintenance hemodialysis, contributing to poorer treatment adherence, increased complications, and reduced quality of life. Embedding a structured, nurse-led cognitive and self-management program within routine pre-dialysis waiting time, an otherwise unused period, represents a low-cost, scalable strategy that could be integrated into existing hemodialysis center workflows without requiring additional patient visits or major resource investment, if efficacy is confirmed.

Future research should prioritize (1) a fully powered, multi-center randomized controlled trial with an adequate sample size calculated from this pilot's effect size estimates, (2) longer-term follow-up (e.g., 3–6 months post-intervention) to determine the durability of cognitive and behavioral gains, (3) inclusion of clinical and economic outcomes (e.g., hospitalization rates, dialysis adequacy, cost-effectiveness) to establish real-world clinical impact, and (4) exploration of implementation strategies, such as training protocols for hemodialysis nursing staff, to support scale-up and sustainability in routine clinical practice.

Ethical Approval Statement

The study was approved by the Institutional Review Board for the Protection of Human Subjects in Research, Burapha University (IRB: G-HS145/2567). The study was registered as a randomized controlled trial in the Thai Clinical Trial Registry (project code TCTR20250226004). The participants took part in the research voluntarily, and informed consent forms were signed after receiving a clear explanation of the research objectives. The participants were informed of their right to withdraw from the study at any time without any negative consequences. The results were presented in an aggregated form to ensure confidentiality.

Author Contributions

BL, PH and CW conceived the study, developed the research protocol, and oversaw the implementation of the intervention. BL conducted data collection, coordinated recruitment, and managed participant follow-up. BL, PH, and CW performed data analysis, interpreted the findings, and drafted the manuscript. All authors reviewed, revised, and approved the final version of the manuscript prior to submission.

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Conflicts of Interest

The authors declared no potential conflicts of interest concerning the research, authorship, and publication of this article.

References

1. Chan FH, Newman S, Khan BA, Griva K. The role of subjective cognitive complaints in self-management among haemodialysis patients: a cross-sectional study. BMC Nephrol. 2022; 23(1): 363. DOI:10.1186/s12882-022-02994-2
2. Chan FH, Newman S, Khan BA, Griva K. Prevalence and trajectories of subjective cognitive complaints and implications for patient outcomes: a prospective study of haemodialysis patients. Br J Health Psychol. 2023; 28(3): 651-71. DOI:10.1111/bjhp.12645
3. Bolignano D, Simeoni M, Hafez G, Pepin M, Gallo A, Altieri M, et al. Cognitive impairment in CKD patients: a guidance document by the CONNECT network. Clin Kidney J. 2025; 18(2): sfae294. DOI:10.1093/ckj/sfae294
4. Chu NM, McAdams-DeMarco MA. Exercise and cognitive function in patients with end-stage kidney disease. Semin Dial. 2019; 32(4): 283–90. DOI:10.1111/sdi.12804
5. Liu J, He Y, Chen K. Cognitive impairment in hemodialysis needs sufficient attention. Cell Signal. 2025; 3(1): 19-22. DOI:10.46439/signaling.3.050
6. Mobushar JA, Shahzad A, Mumtaz B, Naeem I, Zafar AA, Jamil MI, et al. Prevalence and pattern of cognitive impairment in patients on maintenance hemodialysis. Cureus. 2025; 7(5): e84649. DOI:10.7759/cureus.84649
7. Thati A, Honnutagi RM, Patil S. Impact of haemodialysis on cognition. J Contemp Clin Pract. 2025; 11(6): 177-81. DOI:10.61336/jccp/25-06-27

8. Jayanti A, Foden P, Brenchley P, Wearden A, Mitra S. The burden of cognitive impairment in patients with end-stage renal disease and impact on dialysis modality choice. Kidney Int Rep. 2016; 1(4): 240-9. DOI:10.1016/j.ekir.2016.07.010
9. Pal S, Panduragan SL, Said FM, Poddar S. Effect of self-management intervention on improvement of quality of life in chronic kidney disease patients: a scoping review. Open Nurs J. 2024; 18(1): e18744346323309. DOI: 10.2174/0118744346323309241009074442
10. Rafiee-Vardanjani L, Arsalani N, Mohammadi-Shahbolaghi F, Tabrizi KN. Self-management in hemodialysis patients: a concept analysis. J Nurs Midwifery Sci. 2025; 2(12): e158696. DOI:10.5812/jnms-158696
11. Park Y, Jung S. Predictors of self-management behaviors among patients undergoing hemodialysis. Sci Rep. 2025; 15(1): 13823. DOI:10.1038/s41598-025-97414-4
12. Farragher J, Khan UK, Yau K, Stewart KE, Harrison TG, Engel L, et al. Interventions to improve cognitive performance in chronic kidney disease: a scoping review. PLoS One. 2025; 20(8): e0329815. DOI:10.1371/journal.pone.0329815
13. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, Lancaster GA; PAFS consensus group. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016 Oct 24; 355: i5239. DOI:10.1136/bmj.i5239
14. Montgomery R. Sample size justification in feasibility studies: moving beyond published guidance. Pilot Feasibility Stud. 2025; 11(1):88. DOI:10.1186/s40814-025-01675-9
15. Nasreddine ZS, Phillips NA, Bédirian V, Charbonneau S, Whitehead V, Collin I, et al. The Montreal cognitive assessment, MoCA: a brief screening tool for mild cognitive impairment. J Am Geriatr Soc. 2005; 53(4): 695-9. DOI:10.1111/j.1532-5415.2005.53221.x
16. Julayanont P, Tangwongchai S, Hemrungrojn S, Tunvirachaisakul C, Phanthumchinda K, Hongsawat J, et al. The Montreal cognitive assessment-basic: a screening tool for mild cognitive impairment in illiterate and low-educated elderly adults. J Am Geriatr Soc. 2015; 63(12): 2550-4. DOI:10.1111/jgs.13820
17. Curtin RB, Walters BA, Schatell D, Pennell P, Wise M, Klicko K. Self-efficacy and self-management behaviors in patients with chronic kidney disease. Adv Chronic Kidney Dis. 2008; 15(2): 191-205. DOI:10.1053/j.ackd.2008.01.006

18. Curtin RB, Mapes DL. Health care management strategies of long-term dialysis survivors. Nephrol Nurs J. 2001; 28(4): 385-92. PMID: 12143460. Available from: https://pubmed.ncbi.nlm.nih.gov/12143460/
19. Sritarapipat P, Pothiban L, Panuthai S, Lumlertgul D, Nanasilp P. Causal model of elderly Thais' self-management behaviors of pre-dialysis chronic kidney disease. Pac Rim Int J Nurs Res. 2012; 16(4): 277-93. (In Thai)
20. Meleis AI, Sawyer LM, Im EO, Hilfinger Messias DK, Schumacher K. Experiencing transitions: an emerging middle-range theory. ANS Adv Nurs Sci. 2000; 23(1): 12-28. DOI:10.1097/00012272-200009000-00006
21. Phanasathit M, Nimnuan C, Lohsoonthorn V. The effects of cognitive training in healthy community residing Thai elderly: a randomized controlled trial. Psychol Res Behav Manag. 2022; 15: 3709-20. DOI:10.2147/PRBM.S383526
22. Bogataj Š, Mesarič KK, Pajek M, Petrušič T, Pajek J. Physical exercise and cognitive training interventions to improve cognition in hemodialysis patients: a systematic review. Front Public Health. 2022; 10: 1032076. DOI:10.3389/fpubh.2022.1032076
23. Chan FH, Goh ZZ, Zhu X, Tudor Car L, Newman S, Khan BA, et al. Subjective cognitive complaints in end-stage renal disease: a systematic review and meta-analysis. Health Psychol Rev. 2023; 7(4): 614-40. DOI:10.1080/17437199.2022.2132980
24. Marin A-E. Redolat R, Gil-Gómez J-A, Mesa-Gresa P. Addressing cognitive function and psychological well-being in chronic kidney disease: a systematic review on the use of technology-based interventions. Int J Environ Res Public Health. 2023; 20(4): 3342. DOI:10.3390/ijerph20043342
25. Cortés-Álvarez NY, Vuelvas-Olmos CR, Marmolejo-Murillo LG, Sánchez-Duarte E, Lara-Morales A. Cognitive stimulation and its effects on well-being, executive functions, and brain-derived neurotrophic factor in older adults from a Mexican geriatric center: a quasi-experimental study. Nurs Rep. 2025; 15(5): 151. DOI:10.3390/nursrep15050151
26. Tao Y, Liu T, Hua Y, Lv A, Ni C. Effects of a temporal self-regulation theory-based intervention on self-management in hemodialysis patients: a randomized controlled trial. Patient Educ Couns. 2024; 119: 108059. DOI:10.1016/j.pec.2023.108059

27. Ali H, Soliman K, Mohamed MM, Daoud A, Shafiq T, FüIöp T, et al. The effects of dialysis modality choice on cognitive functions in patients with end-stage renal failure: a systematic review and meta-analysis. Int Urol Nephrol. 2021; 53(1): 155-63. DOI:10.1007/s11255-020-02603-x
28. Pépin M, Klimkowicz-Mrowiec A, Godefroy O, Delgado P, Carriazo S, Ferreira AC., et al. Cognitive disorders in patients with chronic kidney disease: approaches to prevention and treatment. Eur J Neurol. 2023; 30(9): 2899-911. DOI:10.1111/ene.15928
29. Farris O, Orbell S, Lamarche VM, Smith R. Promoting self-management in chronic disease: a systematic review and meta-analysis of behaviour change interventions for patients on dialysis. Health Psychol Rev. 2025; 19(2): 368-408. DOI:10.1080/17437199.2025.2471775
30. Kelly DM, Rothwell PM. Disentangling the relationship between chronic kidney disease and cognitive disorders. Front Neurol. 2022; 13: 830064. DOI:10.3389/fneur.2022.830064
31. Griva K, Nandakumar M, Jo-an HN, Lam KF, McBain H, Newman SP. Hemodialysis self-management intervention randomized trial (HED-SMART): a practical low-intensity intervention to improve adherence and clinical markers in patients receiving hemodialysis. Am J Kidney Dis. 2018; 71(3): 371-81. DOI:10.1053/j.ajkd.2017.09.014
32. Huang Y, Li S, Lu X, Chen W, Zhang Y. The effect of self-management on patients with chronic diseases: a systematic review and meta-analysis. Healthcare (Basel). 2024; 12(21): 2151. DOI:10.3390/healthcare12212151
33. Rossing P, Caramori ML, Chan JC, Heerspink HJ, Hurst C, Khunti K, et al. KDIGO 2022 clinical practice guideline for diabetes management in chronic kidney disease. Kidney Int. 2022; 102(5 Suppl): S1-127. DOI:10.1016/j.kint.2022.06.008
34. Bağrıaçik E, Dikmen BT. Self-management training in patients with chronic kidney disease undergoing hemodialysis: a systematic review. Semin Dial. 2024; 37(2): 91-100. DOI:10.1111/sdi.13164
35. Billany RE, Thopte A, Adenwalla SF, March DS, Burton JO, Graham-Brown MP. Associations of health literacy with self-management behaviours and health outcomes in chronic kidney disease: a systematic review. J Nephrol. 2023; 36(5): 1267-81. DOI:10.1007/s40620-022-01537-0
36. Lunardi LE, Hill K, Xu Q, Le Leu R, Bennett PN. The effectiveness of patient activation interventions in adults with chronic kidney disease: a systematic review and meta-analysis. Worldviews Evid Based Nurs. 2023; 20(3): 238-58. DOI:10.1111/wvn.12634

37. Moreels T, Van de Velde D, Goethals J, Vanden Wyngaert K, De Baets S, Nagler E, et al. Self-management interventions for facilitating life participation for persons with kidney failure: a systematic review. Clin J Am Soc Nephrol. 2024; 19(2): 189-201. DOI:10.2215/CJN.0000000000000347
38. Cao F, Hong F, Ruan Y, Lin M. Effect of patient-empowerment interaction model on self-management ability of peritoneal dialysis patients: a randomized controlled trial. Patient Prefer Adherence. 2023; 17: 873-81. DOI:10.2147/PPA.S402698
39. Chae YJ, Kim HS. Effects of a mobile application on improving self-management of adult patients receiving peritoneal dialysis: a randomized controlled trial. Jpn J Nurs Sci. 2024; 21(1): e12555. DOI:10.1111/jjns.12555
40. Lee MC, Wu SFV, Lu KC, Liu CY, Liang SY, Chuang YH. Effectiveness of a self-management program in enhancing quality of life, self-care, and self-efficacy in patients with hemodialysis: a quasi-experimental design. Semin Dial. 2021; 34(4): 292-9. DOI:10.1111/sdi.12957
41. Pack S, Lee J. Randomised controlled trial of a smartphone application-based dietary self-management program on haemodialysis patients. J Clin Nurs. 2021; 30(5-6): 840-8. DOI:10.1111/jocn.15627
42. YangÖz ŞT, Özer Z, Boz I. Comparison of the effect of educational and self-management interventions on adherence to treatment in hemodialysis patients: a systematic review and meta-analysis of randomized controlled trials. Int J Clin Pract. 2021; 75(5): e13842. DOI:10.1111/ijcp.13842
43. Curtin RB, Mapes D, Schatell D, Burrows-Hudson S. Self-management in patients with end stage renal disease: exploring domains and dimensions. Nephrol Nurs J. 2005; 32(4): 389-95. PMID: 16118938. Available from: https://pubmed.ncbi.nlm.nih.gov/16118938/