Renal Replacement Therapy

REVIEW

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Effectiveness of educational programs for patients with diabetic kidney disease: a systematic review and meta-analysis

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Abstract

Background To prevent the progression of diabetic nephropathy, educational programs to improve self-management are important. However, the effectiveness of educational programs to prevent worsening of diabetic kidney disease on renal function and quality of life is under characterised.

Objectives The purpose of this study was to conduct a systematic review and meta-analysis to identify effective educational programs for diabetic kidney disease and the impact of educational programs on improving renal function and quality of life in patients with diabetic kidney disease.

Design The study design is a systematic review and meta-analysis.

Method We systematically collected research papers, and two authors independently selected papers and evaluated them according to the inclusion criteria. The extracted data were entered into Review Manager 5.4, and the standardised mean difference of the delta estimated glomerular filtration rate (ml/min/1.73m^2/year) was calculated using a random effect size model for the renal function evaluation.

Results Overall, 207 articles were retrieved from five electronic databases and three studies were shortlisted. Data from the two studies on delta estimated glomerular filtration rate (ml/min/1.73 m^2/year) were combined, but the results were not significant. The effect on quality of life was observed in only one of the three studies, so they could not be pooled.

Conclusions Effective educational programs for self-management of diabetic kidney disease could not be identified because of the small number of studies included. Educational programs reviewed also lacked a significant effect on kidney function, likely related to their short durations. The effect of the education programs on quality of life is unknown because studies could not be pooled.

Keywords Diabetic kidney disease, Educational programs, Estimated glomerular filtration rate, Quality of life, Meta-analysis

Background

Approximately 40% of patients with diabetes develop diabetic kidney disease (DKD), the leading cause of chronic kidney disease (CKD) worldwide [1]. At least half of all patients with type 2 diabetes mellitus and one-third of those with type 1 diabetes develop kidney disease due to their disease or other comorbidities, including hypertension, dyslipidaemia, obesity, intrarenal vascular disease,

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glomerular atherosclerosis, renal ischaemia and ageing-related nephron loss [2]. To prevent the progression of diabetic nephropathy, educational programs to improve self-management are important.

Literature review

Several meta-analyses have reported that education programs for people with diabetes improve glycated haemoglobin levels [3–8]. Furthermore, studies have reported that individuals with diabetes improve their quality of life (QoL) by participating in diabetes education programs [9]. Previous studies have reported that educational programs for people with DKD improve their knowledge about diabetes and are effective in improving self-efficacy, treatment effectiveness and patients' beliefs about personal control, leading to behavioural changes. However, owing to heterogeneity and quality issues, no meta-analysis has been conducted [10].

A systematic review and meta-analysis was conducted on the multidisciplinary management of people with DKD in 2016. The control group had a significant decrease in estimated glomerular filtration rate (eGFR) than that in the intervention group. However, the report indicates that the inclusion of studies with small sample sizes and regular follow-up of patients in the control group with the same standard of care as the intervention group led to a bias in the results [11]. Thus, there is insufficient evidence on the effects of educational programs to prevent the worsening of DKD on renal function and QoL. Furthermore, a meta-analysis evaluating the effects of educational programs for people with DKD on renal function and QoL will enable the development and implementation of optimal evidence-based educational programs. Therefore, this study aimed to identify effective DKD education programs and conduct a systematic review and meta-analysis to identify the impact of education programs on improving renal function or QoL in people with DKD.

Methods

Search strategy and selection criteria

Five electronic databases, including the Cochrane Library (CENTRAL) (2010 to 31 December 2021), MEDLINE (EBSCOHOST) (2010 to 31 December 2021), EMBASE (2010 to 31 October 2020), CINAHL (EBSCOHOST) (2010 to 31 December 2021) and PsycINFO (2010 to 31 December 2021), were used in the study. Terms related to patient education, self-care, health behaviours, diabetes and kidney disease were included in the search (Supporting Information: Appendix A). The MeSH term was used as a keyword, and referring to previous research and the use of extended words was chosen as necessary. Because the controlled vocabulary used differed depending on the search database, some search keywords were modified on the basis of the database. The database was limited to randomised controlled trials (RCTs) and a web-based search was conducted.

Inclusion criteria for the studies were (1) participants aged ≥ 18 years, (2) participants with type 1 or type 2 diabetes and CKD, (3) a series of deliberate and planned educational activities by healthcare workers to slow DKD progression and (4) comparison of the educational programs with the usual care.

The exclusion criteria were (1) studies without primary outcomes, (2) conference abstracts or protocols and (3) only non-educational interventions. The primary outcomes were renal function data (delta eGFR) and QoL measures (SF-36, HDQOL), with no secondary outcomes. The study designs included RCTs, quasi-RCTs and randomised crossover trials. Grey literature was not searched, and only studies written in English were included.

The protocol was registered with PROSPERO (CRD42022383144) for review. It was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 statement, an updated guideline for reporting systematic reviews [12].

Study selection and screening

Search results were shared among reviewers using Endnote X9, literature management software. After the search results were collated and duplicates were removed, the titles and abstracts were reviewed independently by two reviewers; all studies were reviewed by T.K., and the studies were reviewed independently by other reviewers (A.I., N.S., R.T.). The full texts of potentially relevant studies were then obtained, and the studies were peer-reviewed for compliance with the inclusion criteria. All studies were reviewed by T.K, as were titles and abstracts, and the studies were independently reviewed by other reviewers (A.I., N.S., R.T.). Discordance between reviewers was resolved through discussion. To assess the quality of the literature, we conducted a risk assessment of bias using the Cochrane Risk of Bias Tool 2 (ROB2) [13].

Data analysis

The mean and standard deviation of delta eGFR (ml/min/1.73 m^2/year) in the intervention and control groups and the number of data points were extracted. The data were then entered into Revman5.4, and a meta-analysis of the standardised mean difference in delta eGFR (ml/min/1.73 m^2/year) was performed using a random-effect size model for the evaluation of renal function.

Results

A total of 207 studies were retrieved from five electronic databases. Of these 21 duplicate studies were excluded. On the basis of previous studies [10], studies published from January 2010 were included in the study. Hence, of the remaining 107 studies, 72 were excluded by two reviewers. Moreover, 20 studies not involving patients with DKD were excluded, 7 studies were not eligible based on interventions, 2 studies were not RCTs and 1 study did not compare the information with usual care. Additionally, one retracted paper, one protocol paper and one conference abstract were excluded. Finally, three studies were included in the study; two assessed delta eGFR (ml/min/1.73 m^2/year) as an outcome and one also assessed QoL measures (Fig. 1).

Risk of bias assessment

The risk of bias in the three studies was assessed for eGFR by using ROB2 (Fig. 2). There was some concern about the risk of bias due to domain 1, that is, bias arising from the randomisation process in the Fogelfeld et al. study [14] with allocation concealed and assignment order unknown. There was some concern about the risk of bias due to deviation from domain 2, that is, bias due to deviations from the intended interventions in all studies with the interventions not blinded. There was a high risk of bias due to missing domain 3, that is, bias due to missing outcome data in the Helou et al. study [15], with eight of the 32 patients dropping out. There was a low risk of bias in the measurement of domain 4, that is, bias in the measurement of the outcome because all studies were objective measures of blood sampling and were

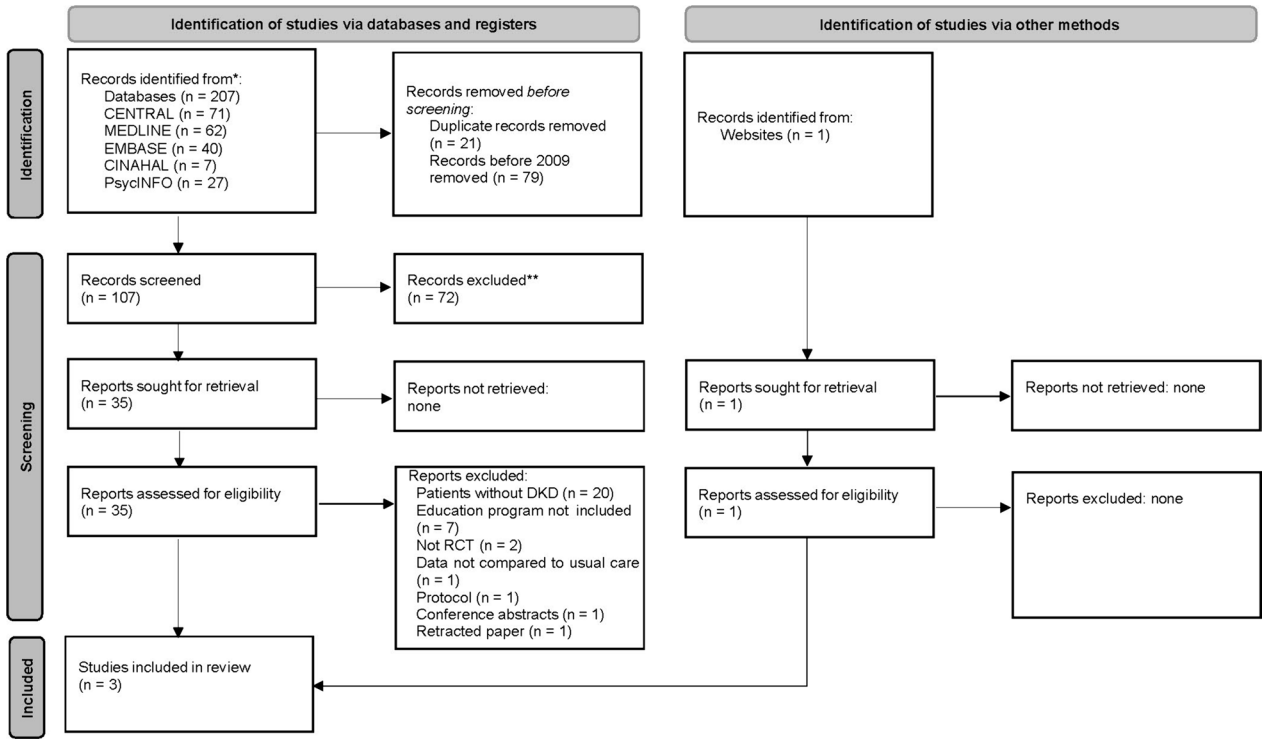

Fig. 1 Study selection flow diagram

Fig. 2 Risk of bias assessment (delta eGFR). D1 – randomisation process, D2 – deviations from the intended interventions, D3 – missing outcome data, D4 – measurement of the outcome, D5 – selection of the reported result

appropriately measured. There was some concern about the risk of bias in the selection of domain 5, that is, bias in the selection of the reported result in all studies with lack of information. Thus, in terms of bias, all three studies were of low quality because the risk of overall bias was of some concern in the Fogelfeld et al. and Kobe et al. studies [14, 16], and was high in the Helou et al. study [15].

Characteristics of included studies

Participants

Fogelfeld and Hart [14] conducted a single-centre proof-of-concept study in patients with type 2 diabetes and CKD stages 3–4. They screened 1365 patients, of which 1245 were excluded and 120 patients who met the inclusion criteria were enrolled and randomised. The dropout rate was 17.5%, with 23% in the intervention group and 12% in the control group. These patients were included in the analysis using their last observation. The mean ages of participants in the intervention and non-intervention groups were 56.27 ± 7.46 and 58.69 ± 7.46 years, respectively, and the percentage of men included was 60% and 56.7%, respectively. The duration of diabetes at baseline was 15 years in both groups, and the baseline eGFR was 37.95 ± 10.74 ml/min/1.73 m^2 and 37.18 ± 13.00 ml/min/1.73 m^2 in the intervention and non-intervention group, respectively. Overall, 31.7%, 38.7% and 30% of the participants had stage 3A, 3B and 4 CKD, respectively, in the intervention group, while 31.7%, 33% and 35% of the participants had stage 3A, 3B and 4 CKD, respectively, in the non-intervention group, not including patients with end-stage renal disease (ESRD). All baseline characteristics were similar between the two groups.

In the Kobe and Diamantidis [16], study, 18–75 year olds with type 2 diabetes and diabetic nephropathy visited primary care providers at least twice in the previous 3 years. The target sample size was 300 (150 per group), for a total of 281 participants (125 non-African Americans and 156 African Americans); 138 were randomised to the intervention group and 143 to the control group. At baseline, participants had a mean age of 61.9 years and 56% were African American. Most participants had graduated from high school and had a household income of less than $60,000. Participants 18 years or older with a clinical diagnosis of DKD, no cognitive deficit, no terminal illness and not on dialysis were included; 84 individuals were found to be eligible for recruitment. A total of 32 (mean age 67.8 ± 10.8 years; 90.6% men) agreed to participate. On average, the participants had 3.5 comorbidities. The eGFR (mL/min/1.73 m^2) ranged from 15–108 mL/min/1.73 m^2 with a mean of 41.3 ± 21.5 mL/min/1.73 m^2 and a median of 35 mL/min/1.73 m^2.

In the Helou and Talhouedec [15] study, five participants withdrew. These withdrawals occurred in two sequences which did not start with the intervention directly at enrolment. One participant with stage 4 DKD was excluded from the study because his renal function declined, and he started haemodialysis. Two participants died during the study period.

Intervention

In the Fogelfeld and Hart [14] study, the intervention was led by a team of endocrinologists, nephrologists, nurse practitioners, registered dietitians and integrated intensive diabetes–renal care with behavioural/dietary and pharmacological interventions. The patients were randomised into eGFR strata on the basis of the baseline estimated eGFRs. The three strata were CKD 3A (eGFR 46–59 ml/min/1.73 m^2), CKD 3B (eGFR 30–45 ml/min/1.73 m^2) and CKD 4 (eGFR 15–29 ml/min/1.73 m^2). A total of 20 consenting patients each were randomised into the following multifactorial–multidisciplinary intervention and control groups: CKD 3A, CKD 3B and CKD 4, resulting in a total of 60 participants in the intervention group and 60 in the control group. The intervention began with group diet instruction based on the guidelines for managing diabetes, dyslipidaemia and renal disease, followed by individual visits with the entire study staff (the endocrinologist, nephrologist, nurse practitioners, certified diabetes educator/dietitian and research coordinator). In addition to the study visits, case management and additional follow-ups were scheduled on the basis of need to promote target achievement.

In the Kobe et al. [16] study, participants underwent monthly telephone medication evaluations for 36 months and discussed major risk factors for DKD progression, including side effects, communication skills, health behaviours, health knowledge and diabetes self-management.

In the Helou and Talhouedec [15] study, the intervention group alternated nursing and dietary care with usual nephrology and diabetology consultations to ensure direct or telephone contact every 2 weeks with a healthcare professional. In each intervention period, the participants received two dietary consultations, three nursing consultations at their home or at the ambulatory clinic, and two nursing telephone follow-ups. Each nursing and dietary consultation lasted 1 h, except for the first nursing consultation of each intervention group, which lasted 1.5 h. The advanced practice nurse was responsible for ensuring evidence-based nursing, managing the intervention and coordinating care between healthcare professionals. The nursing intervention was structured on the basis of the self-care deficit nursing theory (SCDNT). It was built using specific nursing assessments, follow-up

documentation and educational materials adapted for the purpose of the study. The diabetes-specialised nurse conducted a comprehensive initial clinical and psychosocial assessment of the participant and an evaluation of medication safety; assisted the participant in setting a priority treatment goal and signing a self-management contract to achieve this goal; developed a collaborative care plan and delivered nursing interventions to help the participants meet the set goals; guided participants in symptom monitoring and problem-solving techniques; helped the participants develop their self-care abilities, identify and use their resources, engage in discussions about medication, and follow an exercise regimen (walking at least 90 min per week) and dietary recommendations; monitored the participants' progress towards the set goals; and provided psychosocial support and education for diabetes and kidney protection. The dietician adopted a self-management approach and established an individualised dietary plan.

Study results

In the Fogelfeld and Hart [14] study, the primary efficacy endpoint was the development of ESRD defined as eGFR < 15 ml/min/1.73 m^2 that persisted in subsequent tests. Rates of developing ESRD were lower in the intervention group (13%) but higher in the control group (28%). In both groups, ESRD occurred most frequently in patients with baseline CKD ≥ 4 in the control group (33% versus 57%). Moreover, 25 patients with ESRD as compared with the 95 ESRD-free patients had lower baseline eGFR (28.2 ± 10.8 versus 40.0 ± 10.9 ml/min/1.73 m^2, $p < 0.05$) and greater annual median eGFR decline (13.0 versus 3.0 ml/min/year, $p < 0.05$); 5.78 (0.1–11.36) 5.2 (1.19–10.17).

In a study by Kobe and Diamantidis [16], African Americans had a higher eGFR than non-African Americans. African Americans receiving the intervention had a slower mean rate of annual decline in eGFR than that of the control participants [−2.5 mL/min/1.73 m^2, 95% confidence interval (CI) −3.5, −1.4 versus −4.0 mL/min/1.73 m^2, 95% CI −5.1, −2.9], while non-African Americans receiving the intervention had a faster decline than the control participants (−3.4 mL/min/1.73 m^2, 95% CI −4.6, −2.3 versus −1.8 mL/min/1.73 m^2, 95% CI −2.9, −0.6). There was evidence of a differential intervention effect over time between racial subgroups ($p = 0.005$).

Helou and Talhouedec [15] assessed QoL, the primary outcome of the study, using the Audit of Diabetes-Dependent Quality of Life (ADDQoL). The intervention group had an improved general QoL of individuals with DKD as compared with the control group, with the highest significant mean rank (52.49 versus 41.01; $p = 0.026$, 95% CI), considering a 20% improvement as a clinically significant absolute difference. There were no significant differences in the clinical indicators related to renal function between the intervention and control groups.

The included studies had different intervention durations, and data were pooled using delta eGFR (ml/min/1.73 m^2/year) to assess its impact on renal failure progression.

In one study, delta eGFR (ml/min/1.73 m^2/year) could not be extracted and could not be obtained from the authors; therefore, data from two studies where delta eGFR (ml/min/1.73 m^2/year) could be extracted (201 in the active arm and 200 in the inactive arm, making a total of 401 patients) were statistically pooled (Fig. 3).

The two studies were combined to create a forest plot (Fig. 3). When combined, I^2 was 75%, with high heterogeneity in the individual studies in terms of delta eGFR (ml/min/1.73 m^2/year). The effect size was 0.06, with a confidence interval of −0.34 to 0.45, which was not significant.

Discussion

Renal function data

In this study, three educational programs for patients with DKD were identified. A meta-analysis of two studies with delta eGFR (ml/min/1.73 m^2/year) as an outcome showed no significant improvement with educational interventions.

Effect of intervention period

In a study by Fogelfeld and Hart [14], the 2-year intervention was evaluated every 6 months, and fewer patients in the intervention group (13%) developed ESRD than that in the non-intervention group (28%). However, no statistical differences were observed in eGFR at the end or in the rate of decline in eGFR per year between the

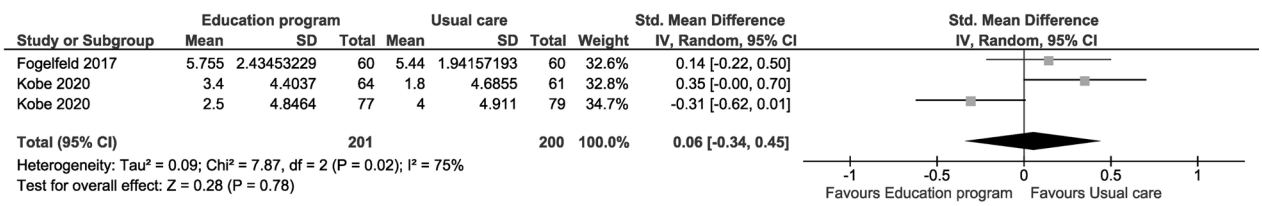

Fig. 3 Delta eGFR forest plot for education programs intervention and control groups

intervention and control groups. One of the factors that may have contributed to the lack of effectiveness of the intervention was the duration of the intervention; the three studies had durations from 3 months to 36 months, and no significant differences in eGFR were observed in the studies with a duration of up to 24 months. However, in a study by Kobe et al. [16], the intervention for African Americans showed a significant difference between eGFR values at baseline and at 36 months, even when no significant difference was observed between the groups at 12 months and 24 months. A previous study [11] also combined the results of two other studies [17, 18] on eGFR, but both had 12- and 24-month intervention periods, and none had more than 36 months of intervention. Educational programs for people with DKD often lead to behavioural changes in patients with DKD, which may result in changes in indicators, such as eGFR. However, it has been suggested that differences in eGFR may take time to develop, and that reductions in renal function decline accumulate over time [16], suggesting that long-term interventions may be required before the effects of educational programs result in changes in eGFR. Therefore, studies with at least 36 months of long-term intervention may be needed for significant differences to be observed in eGFR change after intervention. Moreover, only three studies on eGFR were eligible, and subgroup analyses by intervention type and duration were not possible; thus, more results are needed to conduct a more detailed analysis.

QoL

Only one of the three studies were eligible for examination of the impact of educational programs for patients with DKD on QoL. Hence, the study data could not pooled. Helou and Talhouedec [15], reported that interventions based on SCDNT improved general QoL. Patients with DKD have been reported to be mainly engaged in QoL and daily self-management. Moreover, implementation of educational programs to support coping with uncertainty improves physical and emotional living conditions [15]. The effect of an educational program for type 2 diabetes also showed a change in QoL only on the diabetes-specific scale (ADDQoL) and not on the general scale (SF-36), which indicates that in a study of self-management interventions, a general scale such as SF-36 may not be sensitive enough. Furthermore, educational programs have been reported to not improve QoL in the treatment group but prevent the deterioration in the non-treatment group [19]. Therefore, educational program interventions for patients with DKD may lead to improved QoL, but using ADDQoL as a QoL measure rather than a general scale, such as SF-36, may measure the effect of the interventions. The Kidney Disease Quality of Life-36 Questionnaire (KDQOL-36) is also used as a QoL measure for kidney disease. The KDQOL-36 is used as a QoL measure for dialysis and peritoneal dialysis patients but was not included in this study. Some studies [20] recommend the use of KDQOL-36 for patients with CKD before dialysis because of its internal consistency and validity, and it may be beneficial to use KDQOL-36 as a QoL measure for patients with DKD. There are few RCTs using QoL as an outcome in patients with DKD, and further studies and meta-analyses are needed to show that educational programs lead to improved QoL.

Contents to be considered in the development of educational programs

Frequency of intervention

In three studies [14–16], the frequency of interventions varied from once every 2 weeks to once every month. Therefore, no effective intervention frequency was identified. In a study by Dong and Li [21], albumin creatinine ratio continued to improve with biweekly interventions, but worsened with monthly interventions, suggesting that more frequent interventions may be more effective.

Intervenor

In two studies [14, 15], multi-professional interventions were performed; in one study [16], interventions were performed only by pharmacists. Although we were unable to identify the effect of interventions by different intervenors, multi-professional and team interventions may be effective.

Content of intervention (effect of remote intervention)

Two of the three studies involved remote interventions via telephone. Kobe et al. [16] found that monthly telephone educational interventions resulted in an improvement in the eGFR in African Americans at 36 months. In the Fogelfeld et al. study [14], frequent telephone contact and case management by researchers resulted in less ESRD in the intervention group (13%) than that in the non-intervention group (28%) among patients who required intensive follow-up. Prior research on remote interventions included an RCT comparing a self-management education program for patients with diabetic nephropathy in a face-to-face interview group and a remote tablet-based interview group. The self-management behaviour score at 12 months after enrolment was higher than that at the time of enrolment. Furthermore, the effect of the intervention on behaviour modification was observed before and after the intervention in each group, and differences were observed on the basis of interview methods [22]. El-Gayar, Ofori and Nawar [23] reported that the meta-analysis using a mobile health

app with patients with diabetes identified 21 studies, wherein interventions using mobile health apps were more likely to lead to improvements in participants' HbA1c levels as compared with those with standard care. Joboshi and Oka [24] conducted a RCT on the effectiveness of the EASE program in patients with CKD. In addition to monthly interviews, patients received support by phone or e-mail once a week to once every 2 weeks. If the interval between outpatient visits was longer than 1 month, the patients were evaluated by phone or e-mail. The results showed improvements in self-efficacy awareness and self-management behaviours. Without continuous supervision and management, it is difficult to change unhealthy lifestyles, and effective supervision is important to maintain changes in patients' lifestyles [21]. Therefore, it is useful to establish a comprehensive program that provides information, guidance and continuous support. In addition to face-to-face interviews, the combination of remote interventions, such as phone calls, videophones and mobile health apps, provides ongoing support with less burden on both patients and healthcare professionals, promotes patients behaviour change and may lead to improvements in eGFR and QoL.

Strengths and limitations

The strength of this study is that it addresses the content of the educational programs, including the duration and frequency of interventions, utility of remote intervention and QoL measures, for the development of an effective educational program for people with DKD.

Limitations of the study include that grey literature was not searched and the possibility that unpublished literature was not included. The small number of included studies did not allow for evaluation of publication bias by funnel plots, data extraction and bias evaluation were performed by one person and may have resulted in bias, and the small number of references identified in this study did not allow for subgroup analysis. In addition, it is difficult to derive consistent results owing to the diversity of intervention methods in the literature identified in this study. In the future, as the number of studies increases and subgroup analyses become available, it may be possible to analyse the effects of different interventions.

Conclusions

The systematic review and meta-analysis was conducted according to the PRISMA 2020 statement using Revman5.4 and sensitivity analysis. Two RCTs and one randomised crossover trial were eligible; of these, two studies with delta eGFR (ml/min/1.73 m^2/year) as an outcome were pooled using a meta-analysis, which showed high statistical heterogeneity, but sensitivity analysis using a random-effects model showed no significant effect with a pooled effect size of 0.06 (−0.34 to 0.45; 95% CIs). The effect on QoL was observed in only one of the three studies; hence, they could not pooled. The lack of significant results in terms of eGFR may have been due to the short duration of the intervention, suggesting that an intervention of at least 36 months is required to improve eGFR with an educational program. For QoL outcomes, using the ADDQoL and KDQOL-36 as disease-specific measures may provide sufficient sensitivity. In the future, as the number of studies increases, we may be able to evaluate effective educational programs through subgroup analyses such as the duration and frequency of the interventions.

Abbreviations

ADDQoL	Audit of diabetes-dependent quality of life
CI	Confidence interval
CKD	Chronic kidney disease
DKD	Diabetic kidney disease
eGFR	Estimated glomerular filtration rate
ESRD	End-stage renal disease
KDQOL-36	Kidney disease quality of life-36 questionnaire
RCTs	Randomised controlled trials
ROB2	Cochrane risk of bias tool 2
SCDNT	Self-care deficit nursing theory
QoL	Quality of life

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s41100-024-00554-y.

Additional file1

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Author contributions

T.K.: study conception and design, data collection, data analysis and draft manuscript. M.O.: provided general advice on study design, data collection, data analysis and revised it critically for important intellectual content. A.I.: study selection, data collection and data analysis. N.S.: study selection, data collection and data analysis. R.T.: study selection, data collection and data analysis. All authors read and approved the final manuscript.

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Availability of data and materials

The datasets generated and/or analysed during the current study are available in the repository, [https://www.sciencedirect.com/science/article/abs/pii/S1056872716309783?via%3Dihub], [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7408890/], [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7572637/].

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing interests
The authors declare that they have no competing interests.

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