

Patient Navigators for CKD and Kidney Failure: A Systematic Review



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Rationale & Objective: To what degree and how patient navigators improve clinical outcomes for patients with chronic kidney disease (CKD) and kidney failure is uncertain. We performed a systematic review to summarize patient navigator program design, evidence, and implementation in kidney disease.

Study Design: A search strategy was developed for randomized controlled trials and observational studies that evaluated the impact of navigators on outcomes in the setting of CKD and kidney failure. Articles were identified from various databases. Two reviewers independently screened the articles and identified those meeting the inclusion criteria.

Setting & Participants: Patients with CKD or kidney failure (in-center hemodialysis, peritoneal dialysis, home hemodialysis, or kidney transplantation).

Selection Criteria for Studies: Studies that compared patient navigators with a control, without limits on size, duration, setting, or language. Studies focusing solely on patient education were excluded.

Data Extraction: Data were abstracted from full texts and risk of bias was assessed.

Analytical Approach: No meta-analysis was performed.

Results: Of 3,371 citations, 17 articles met the inclusion criteria including 14 original studies. Navigators came from various healthcare backgrounds including nursing (n=6), social worker (n=2), medical interpreter (n=1), research (n=1), and also included kidney transplant recipients (n=2) and non-medical individuals (n=2). Navigators focused mostly on education (n=9) and support (n = 6). Navigators were used for patients with CKD (n=5), peritoneal dialysis (n=2), in-center hemodialysis (n=4), kidney transplantation (n=2), but not home hemodialysis. Navigators improved transplant workup and listing, peritoneal dialysis utilization, and patient knowledge.

Limitations: Many studies did not show benefits across other outcomes, were at a high risk of bias, and none reported cost-effectiveness or patient-reported experience measures.

Conclusions: Navigators improve some health outcomes for CKD but there was heterogeneity in their structure and function. High-quality randomized controlled trials are needed to evaluate navigator program efficacy and cost-effectiveness.

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Patients with chronic kidney disease (CKD) or kidney failure requiring treatment with dialysis or a kidney transplant interact with the health care system frequently and experience various transitions throughout their care journey.¹ These transitions may include the process of initiating dialysis, transitioning between kidney replacement therapy modalities, engaging with multiple health care providers including primary care teams and subspecialists as well as emergency room visits and hospitalizations for acute illnesses. As people with CKD navigate complex and often siloed health systems, they may face barriers to accessing timely and quality care; these barriers may include limited health literacy, limited self-management skills, poor access to transportation, and living in rural and remote settings.²⁻⁶ A patient navigator may serve as a bridge between patients and the health care system, assisting patients with accessing services, navigating services, and addressing barriers in their care.⁷ They are used in a variety of chronic diseases such as cancer care, diabetes, and HIV/AIDS.⁷

The role of patient navigators in improving clinical outcomes, patient-reported outcome measures, and patient-reported experience measures in the setting of CKD

and kidney failure is unclear. A previous systematic review of patient navigators in chronic diseases was not specific to kidney disease, did not capture many recent studies, nor did it explore the intervention and its delivery in detail.⁷

We performed a systematic review of patient navigators in patients with CKD and kidney failure including dialysis and kidney transplantation in order to characterize the scope of activities performed by navigators and to identify the settings in which they improve patient care.

METHODS

Data Sources and Searches

We developed and followed a protocol that included the PICO (population, intervention, comparison, outcomes) criteria for search strategy. We followed the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines for reporting of systematic reviews and meta-analyses. The study was prospectively registered at PROSPERO.⁸

We included studies evaluating the impact of a patient navigator on clinical outcomes and patient-reported outcome/experience measures in patients with CKD

PLAIN-LANGUAGE SUMMARY

Patient navigators are individuals who help patients access and address barriers to care. They have been used in chronic diseases like cancer and HIV/AIDS. We performed a systematic review to characterize the design of navigator programs and examine their impact on outcomes in patients with chronic kidney disease and kidney failure. This is the first systematic review specific to kidney disease and navigators and provides a summary of their use across kidney programs globally. We demonstrate that navigators improve certain outcomes, but there is heterogeneity in training, focus, and interactions with patients/caregivers. This study highlights the need for further high-quality research evaluating navigator efficacy across the spectrum of kidney disease, including cost-effectiveness and impact on patient-reported experience measures.

(general nephrology, pediatrics, glomerulonephritis, genetic kidney disease) or kidney failure (in-center hemodialysis [ICHHD], peritoneal dialysis [PD], home hemodialysis [HHD], or kidney transplantation). Clinical outcomes of interest were specific to each patient population and included: estimated glomerular filtration rate, kidney failure, crash starts, home modality use, pre-emptive transplant for CKD patients; health care utilization, mortality for ICHHD patients; technique failure for home modality patients; and rejection, transplant work up for kidney transplant patients. Although there is no standard definition of a patient navigator, we defined it as “an individual with or without a health care-related background that engages with patients on an individual basis to determine barriers to accessing care” but does not provide direct clinical care. We included randomized controlled trials and prospective or observational cohort studies that compared patient navigators with a control such as usual care, without any limits on sample size, duration, setting, or language. Studies that focused solely on patient education were excluded.⁷

In collaboration with a medical librarian, original research articles were identified from the following databases: Medline, Embase, the Cochrane Library Cumulative Index to Nursing and Allied Health Literature, and [ClinicalTrials.gov](https://www.clinicaltrials.gov). Our search of these databases ranged from the date of their establishment until January 15, 2021. The search strategy was tailored to each database and used a combination of key terms, including “continuity of patient care,” “patient navigation,” “patient-centered care,” “case management,” “coach,” “service,” “system,” “coordinator,” “facilitator,” “navigator,” “case manager,” “community health worker,” “peer,” and “kidney disease,” “dialysis,” and “transplant” (Tables S1-S5). MeSH terms were applied in the search strategy (see Item S1 for

full search strategy). We downloaded all the received citations into Covidence.

Two reviewers (AT and YI) independently reviewed each article by title and abstract, and articles were selected for full-text review. The 2 reviewers (AT and YI) then screened the full text of the articles and finalized them for inclusion after consultation with third and fourth reviewers (DC and JH). If a full text was not available through our multiple institutional libraries, we emailed authors directly. We also screened the references of all the included studies for additional studies that would meet inclusion criteria. All disagreements were resolved by consensus.

Data Extraction and Quality Assessment

We created a data extraction form to capture relevant information from the included studies. Two reviewers (AT and YI) independently extracted data from the studies, which included study characteristics (first author, year of publication), number of participants, participant characteristics (age, sex, gender, race, estimated glomerular filtration rate, kidney failure, kidney replacement therapy modality, comorbid conditions), intervention details (patient navigator roles, training, processes, intensity, frequency), and outcomes. Inconsistencies were corrected and resolved by consensus and consultation with third and fourth reviewers (DC and JH).

Two reviewers assessed the studies for risk of bias using the revised Cochrane risk of bias tool for randomized trials and Risk Of Bias In Non-Randomized Studies of Interventions (ROBINS-I) for observational studies.⁹ Conflicts were resolved by a third reviewer (DC).

Data Synthesis and Analysis

The components of patient navigator programs, including navigator type (nurse, social worker, patient, other), role (education, navigation, care coordination, support, and counseling), frequency of patient contact, and patient population (CKD, ICHHD, PD, HHD, kidney transplantation) were extracted and summarized. The outcome data of the included studies was also extracted including all primary and secondary outcomes including clinical outcomes, patient-reported outcome measures, and patient-reported experience measures. If any data was not available in the primary manuscript or supplement, corresponding authors were emailed with a request for additional information. Outcomes were categorized as those with statistically significant ($P < 0.05$), and non-statistically significant results ($P > 0.05$). For studies with positive primary outcomes, unadjusted effect sizes were presented for randomized control trials and adjusted effect sizes were presented for non-randomized trials. Because of the heterogeneity of the study populations and outcomes, meta-analysis and meta-regression to identify key components of patient navigator programs could not be performed.

RESULTS

The search was conducted from database inception to January 15, 2021, resulting in 3,371 citations (Fig 1). After screening and full-text review, 17 studies met inclusion criteria. Of these studies, 14 were unique cohorts without duplicate data and were included in this review. Of these 14 studies, 10 were randomized controlled trials, and 4 were observational studies. These studies included patients across 5 countries (United States n=9, China n=2, Australia n=1, United Kingdom n=1, India n=1).

All of the studies focused on adults, and included patients with CKD (n=5), PD (n=2), ICHD (n=4), kidney transplant (n=2), and kidney failure agnostic of kidney replacement therapy modality (n=1). There were no studies dedicated to pediatrics, glomerulonephritis, genetic kidney disease, or HHD. Characteristics of patient navigator programs are summarized in Tables 1 and 2.¹⁰⁻²³

The participant numbers in the included studies were variable, from as few as 36 patients to 5,571 patients in the largest study. Comparator groups received usual care. The duration of follow-up ranged from 2 weeks to as long as 60 months. Ten of the 14 included studies were at a high risk of bias (Figs 2 and 3) mostly because of a lack of blinding and unclear allocation concealment.

Patient Navigators

Patient navigators were mostly nurses (n=6), whereas 2 studies used social workers. Two studies focusing on improved rates of kidney transplantation in patients with kidney failure utilized kidney transplant recipients as patient navigators. Other backgrounds of patient navigators included nursing assistant (n=1), medical interpreter (n=1), researcher (n=1) and general non-medical individual (n=2).

Patient Navigator Role

All of the studies included navigation as a role, which we defined as assisting patients in accessing health care services and addressing barriers to care. Of the 14 studies, the

majority (n=9) included education as a navigator role.^{10,12,13,17,18,20-23} For example, in one of the studies in kidney transplant patients, patient navigators provided individualized education according to the patient's needs, helped guide patients through the process of evaluation and transplantation, provided coaching for advocating for a living donor, and carried out phone call reminders for appointments.²¹ In a study evaluating patient navigators in a CKD population, navigation included assessing patient compliance, addressing insurance needs, helping with transportation issues, and providing information related to CKD.¹¹ With regards to other roles, 6 studies included providing support,^{10-13,22,23} 5 included care coordination, which referred to specifically making appointments and discharge planning,^{10,17,13,20,22} and 1 included counseling.^{18,19} The providing of support often presented itself in different ways as the needs of patients varied through one another. One of the studies focused on providing support when it came to self-management of CKD. A home-care nurse would provide instructional material on dietary education, medications, and patient-centered education to both the key caregivers and the patient. The nurse would provide them with options that best suited their lifestyle and proceeded to guide and support them with decision making for various treatment options throughout the duration of the trial.¹⁰ Alternative to nurse support, in another study, "expert patients" were used as the main support system of the patients. This method was utilized in hopes of relieving the stress of the health-related decision-making process by having an individual who had already gone through a similar experience speak openly and honestly about their options and the decisions they made to provide clarity and support for the patient.¹⁶ Additionally, one study focused on ensuring patients were provided social support in the form of motivation and assurance when it came to dealing with CKD and the decision-making process. This social support system was implemented to raise awareness and provide knowledge of local resources to the patients and their caregivers.²³ As previously mentioned, in 2 of the studies, counseling was provided to the patients to help them evaluate and make informed decisions with regard to their own health. The studies that utilized counseling as a form of patient navigation provided the patient with an individual who could appropriately assess their current health and lifestyle status, advise them accordingly, and provide them the tools necessary to arrange appropriate action to reach their goals.¹⁸

Frequency of Contact with Patient Navigators

The most common frequency of contact between patient navigators and patients was every 2-4 weeks (n = 5).^{10,11,14-16} Three studies had a frequency of contact of every 1-2 weeks,^{19,22,23} 3 studies had a frequency of contact of every week or more,^{12,17,18} and one study had a frequency of contact greater than every 4 weeks.¹³ Two of the included studies did not specify the frequency of contact with patients.^{20,21}

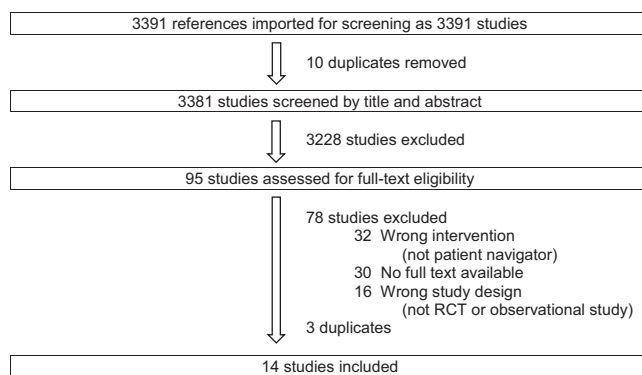


Figure 1. PRISMA flow diagram of screening and inclusion of studies. PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses; RCT, randomized controlled trial.

Table 1. Description of Patient Navigator, Training, Role, Frequency of Patient Contact, and Co-interventions for Randomized Studies

Study	Navigator	Navigator Training	Navigator Role					Frequency of Contact	Co-intervention(s)
			Navigation	Education	Support	Care coordination	Counseling		
Fishbane ¹⁰ (2017)	Nurse	1-wk training course with various sessions	✓	✓	✓	✓		Monthly	Informatics system, plan of care for patients developed by nephrologist and navigator, weight monitoring
Navaneethan ¹¹ (2017)	Non-medical individual	General PN training, CKD education, and electronic health record training	✓					Every 2-4 wk	Enhanced personal health record with online CKD education materials
Jadhav ¹² (2018)	Nurse	Unclear	✓	✓	✓			3 sessions 30-45 min each on 3 consecutive days	None
Basu ¹³ (2018)	Social worker	Master's degree in social work	✓	✓	✓	✓		Average of 8 times over course of study	None
Sullivan ¹⁴ (2018)	Kidney transplant recipient	3-d session: motivational interviewing, transplant education, medical record review	✓					Monthly	None
Sullivan ¹⁵ (2012)	Kidney transplant recipient	Instruction on transplant process, human subjects protection, motivational interviewing	✓					Monthly	None
O'Halloran ¹⁶ (2020)	Nurse	Half-day advanced care planning and communication skills training session	✓		✓			0, 2, and 12 wk	None
Chow ¹⁷ (2010)	Nurse	24 h training: theoretical input, case training and review, simulation	✓	✓		✓		Weekly phone call for 6 wk	Comprehensive discharge education program
Wong ¹⁸ (2010)	Nurse	12-24 h including theoretical input, case training and review	✓	✓			✓	Weekly	Pre-discharge assessment
Low ¹⁹ (2019)	Researcher	Unclear	✓				✓	Every 2 wk	18 min educational video on medications

CKD, chronic kidney disease; PN, practical nurse.

Table 2. Description of Patient Navigator, Training, Role, Frequency of Patient Contact, and Co-interventions for Non-randomized Studies

Study	Navigator	Navigator Role				Co-intervention(s)
		Navigator Training	Navigation	Education	Support	
Maddux ²⁰ (2016)	Nurse	Unclear	✓	✓	✓	None
Marlow ²¹ (2016)	Social worker	Instructional training on organ donation and ESRD cultural sensitivity	✓	✓	✓	Personalization of education materials based on patient needs and knowledge levels
Cervantes ²² (2019)	Nursing assistant, medical interpreter	Trained through Colorado Patient Navigator Program	✓	✓	✓	None
Locke ²³ (2020)	Non-medical individual	2-mo advocacy training based on John Hopkins Living Donor Champion Program	✓	✓	✓	None

ESRD, end stage renal disease.

Outcomes

The studies included a wide range of outcome measures, including laboratory values, health care utilization, kidney failure, transplant referral, quality of life, coping, diet adherence, vascular access, and mortality. No study reported a patient-reported experience measure. Study outcomes are summarized in [Tables 3](#) and [4](#). Eight of the 14 studies showed statistically significant improvements with patient navigators as compared with controls in various outcomes including: increased living kidney donor screening and living kidney donor approval, increased listing for transplant, improved sleep, reduced hospitalizations, increase in PD utilization, improved transplant processes, and improvement in coping skills.^{10,12,13,15,18,20,21,23} Many navigators programs consisted of other co-interventions beyond navigation including: personalization of patient electronic health record, weight monitoring, informatics system, and online patient education and videos ([Tables 3](#) and [4](#)).

DISCUSSION

In this systematic review of patient navigators for CKD and kidney failure, the impact of patient navigators on clinical outcomes was mixed, but benefits included decreasing all cause hospitalizations, increasing PD utilization, and improving the completion of steps required for kidney transplantation work up and listing. The review included 10 randomized controlled trials and 4 observational studies with 12,218 patients mostly from the United States, and there was heterogeneity in patient navigator identity, role, and frequency of contact with patients. In most studies, nurses and social workers were used, and patients were exclusively used in the setting of kidney transplantation. Patient navigators have been evaluated in the setting of CKD, ICHD, PD, and kidney transplant patients, but not HHD, pediatrics, glomerulonephritis, or genetic kidney diseases. Navigator roles were mostly dedicated to navigation and education but also support in health and lifestyle related decision-making, counseling to assess health status, motivate and provide action to reach health-related goals, and care coordination. Patient-reported experience measures and cost-effectiveness were not described in any of the included studies.

To our knowledge, this is the first systematic review to examine the efficacy of patient navigators for patients with CKD and kidney failure. Our results are consistent with the use of patient navigator programs in other settings. In an overview of systematic reviews of patient navigator programs, they were found to be most commonly used in cancer care, disease screening, transitional care, chronic disease, and multimorbidity, usually tailored to ethnic minorities or vulnerable populations. The most commonly performed tasks across populations and diseases in ambulatory care are education and counseling, translations, home visits, outreach, and scheduling.²⁴ In a systematic review of 67 studies of patient navigator programs

Study	Random sequence generation	Allocation concealment	Blinding of participants & personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Overall risk of bias
O'Halloran et al 2020	+	+	+	-	-	+	-
Low et al 2019	+	+	+	-	-	-	-
Basu et al 2018	+	?	-	?	+	+	-
Jadhav et al 2018	+	?	-	+	+	+	-
Sullivan et al 2018	+	+	+	?	+	+	?
Fishbane et al 2017	+	+	-	?	+	+	-
Navaneethan et al 2017	+	+	-	+	+	+	-
Sullivan et al 2012	+	?	+	?	?	+	?
Chow et al 2010	+	+	-	+	+	+	-
Wong et al 2010	+	+	?	?	+	+	?

Figure 2. Risk of bias assessment for randomized trials using the revised Cochrane risk of bias tool. Green: low risk; yellow: unclear risk; red: high risk.

for chronic diseases (44cancer, 8 diabetes, 7 HIV/AIDS, 4 cardiovascular disease, 2 CKD, 1 dementia, 1 multi-morbidity), program design and implementation also varied considerably. This heterogeneity is presumably related to their definition of a patient navigator, which we also used, but which is not standardized clinically, in research or administratively. Half of the included studies had statistically significant primary outcomes, but they were most commonly process measures, and few studies assessed patient-reported experience measures, clinical outcomes and costs.⁷ A content analysis of these patient navigator programs identified 17 unique patient navigation activities including education, facilitating referral, providing social and emotional support, and supporting self-management targeting knowledge barriers and those to physical opportunity (eg, insurance claims, scheduling, transportation).²⁵ There was also heterogeneity in patient navigator identity and training across settings and chronic diseases.²⁶ In the setting of cancer, patient navigators are used mostly for screening and diagnosis and are most commonly employed for breast and colorectal cancer. They increase the uptake of screening, timely diagnosis and follow-up, adherence, and completion of treatment

and have been shown to be cost effective.²⁷ In the setting of HIV/AIDS, patient navigators were associated with improved linkage to care, retention, and viral suppression but similar to our results, study quality was poor.²⁸ Lastly, although the evidence for patient navigator programs in kidney disease may not be as well established compared with cancer and other chronic diseases, it is further along compared with other diseases such as stroke and dementia.²⁹

There are many health system interventions that improve important patient outcomes across the spectrum of kidney disease that compete for health system and kidney program resources. For example, multidisciplinary CKD clinics are associated with improved outcomes compared with standard nephrology clinics.^{30,31} Educational programs improve self-management and knowledge, which translates into improved clinical outcomes.³² Transitional care units decrease morbidity and mortality and increase home modality utilization.³³⁻³⁵ How and to what degree patient navigator programs integrate with these complex interventions is unknown and deserves further study. A qualitative study of 19 patients and 5 caregivers identified 5 themes for patient navigator

Study	Confounding	Selection of participants	Classification of interventions	Deviations from intended interventions	Missing data	Measurement of outcomes	Selection of the reported outcomes	Overall risk of bias
Locke et al 2020								
Cervantes et al 2019								
Maddux et al 2016								
Marlow et al 2016								

Figure 3. Risk of bias assessment for non-randomized trials using the ROBINS-I tool. Green: low risk; yellow: moderate risk; red: serious risk.

Table 3. Summary of Randomized Patient Navigator Studies and Outcomes

Study	Population	N	Age, y	Intervention Group Characteristics ^a	Country	Duration of Intervention	Duration of Trial	Primary Outcomes ^b	Secondary Outcomes
Fishbane ¹⁰ (2017)	CKD	130	Mean 64.5-66.2	16% Black, 8% Hispanic, 52% White, 15% Asian, 16% other; 61% male	United States	18 mo	24 mo	Hospitalizations (+): 0.61 vs 0.92 per year; incidence rate ratio, 0.66; 95% CI, 0.43-0.99; <i>P</i> = 0.04	Catheter in place (+) PD or pre-emptive transplant (+)
Navaneethan ¹¹ (2017)	CKD	209	Median 68	74% White, 20% Black; 2% less than high school education; 33% annual income <30K; 57% male	United States	24 mo	24 mo	eGFR	
Jadhav ¹² (2018)	CKD	100	20-60 (mean 45.3-50.1)	68% male; 54% no medical insurance	India	3 d	2 wk	Adaptive coping (+): effect size <i>t</i> =2.509, <i>p</i> =0.01	
Basu ¹³ (2018)	KF	401	Median 54	81% Black, 9% Hispanic; 45% male; 33% less than high school education	United States	40 mo	40 mo	Waitlist for transplant (+): 75% vs 25% after 500 d; HR, 3.31; 95% CI, 1.20-9.12; <i>P</i> = 0.01	
Sullivan ¹⁴ (2018)	ICHD	1,899	Mean 62-63	36% Black, 61% White, 2% Hispanic; 58% male	United States	3 y	36 mo	Deceased donor transplant	Living donor transplant
Sullivan ¹⁵ (2012)	ICHD	167	18-70	71% Black, 18% White; 51% male	United States	24 mo	24 mo	Transplant process (+): 3.5 vs 1.6 steps completed; difference 1.9 steps; 95% CI, 1.3-2.5 steps; <i>P</i> < 0.001	
O'Halloran ¹⁶ (2020)	ICHD	36	65+	82% male	United Kingdom	12 wk	15 mo	Quality of life	Cost
Chow ¹⁷ (2010)	PD	85	23-78 (median 57)	93% "barely sufficient" financial status; 65% male	China	6 wk	3 mo	Symptom score	
Wong ¹⁸ (2010)	PD	120	Mean 62.4	30% "insufficient" financial status; 20% no formal education; 53% male	China	6 wk	1.5 mo	Diet non-adherence	Sleep (+): effect size <i>F</i> = 12.19, <i>P</i> < 0.001
Low ¹⁹ (2019)	KT	71	23-74 (mean 51)	63% male	Australia	3 mo	3 mo	Medication adherence	

CI, confidence interval; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; HR, hazard ratio; ICHD, in-center hemodialysis; KF, kidney failure; KT, kidney transplant; PD, peritoneal dialysis; (+), positive outcome.

^aSex/gender, race, socioeconomic status, education, insurance status if reported

^bUnadjusted effect sizes for primary outcomes for randomized control trials with positive outcomes

Table 4. Summary of Non-randomized Patient Navigator Studies and Outcomes

Study	Population	N	Age, y	Intervention Group Characteristics ^a	Country	Duration of Intervention	Duration of Trial	Primary Outcomes ^b			Secondary Outcomes	
Maddux et al [20]	CKD	1,386	Mean 63-64	66% White, 8% Hispanic; 57% male	United States	Until HD start	42 mo	PD as first modality (+): 24.1% vs 15.2%, <i>P</i> < 0.001	Central venous catheter (+): 42.4% vs 64.5%, <i>P</i> < 0.001		Hospitalization (+)	Mortality
Marlow et al [21]	CKD	5,571	Mean 54-56	58% Black; 56% male	United States	Unclear	60 mo	Potential living donor inquiry (+): OR, 1.21; 95% CI, 1.01-1.44; <i>P</i> = 0.03	Potential living donor screening (+): OR, 1.27; 95% CI, 1.05-1.54; <i>P</i> = 0.01	Potential living donor evaluation		
Cervantes et al [22]	ICHD	39	Mean 56	100% Hispanic; 50% male; 63% did not complete high school; 83% annual income <15K	United States	90 d	24 mo	Mental health	Care coordination	Diet		
Locke et al [23]	KT	2,004	46.7-61.9 (median 56.7)	80% African American; 46% male	United States	2 mo	26 mo	Donor screening (+): 9-fold increased likelihood, aHR, 9.27; 95% CI, 5.97-14.41; <i>P</i> < 0.001	Donor approval (+): 7-fold increased likelihood: aHR, 7.74; 95% CI, 3.54-16.93; <i>P</i> < 0.001			

aHR, adjusted hazard ratio; CI, confidence interval; CKD, chronic kidney disease; HD, hemodialysis; ICHD, in-center hemodialysis; KF, kidney failure; KT, kidney transplant; OR = odds ratio; PD, peritoneal dialysis; (+) = positive outcome.

^aSex/gender, race, socioeconomic status, education, insurance status if reported

^bAdjusted effect sizes (if available) for primary outcomes for non-randomized trials with positive outcomes

programs in the setting of CKD/kidney failure including trust and credibility, respecting patient choices, readiness to accept the program, accessibility, offering multiple ways to engage/communication, and confidentiality and privacy. The top 5 important features were education, psychosocial support, lifestyle modification, communication/decision-making support and facilitating care.³⁶ Nonetheless, this review provides evidence that navigators, when employed for the specific outcomes that improved here, have benefits and given the high costs of CKD and dialysis and focus on value based care, should be considered across health systems to improve quality measures, improve outcomes, and reduce costs.³⁷⁻³⁹ Of note, the most abundant evidence for navigators is in the setting of kidney transplant, with minimal co-interventions. These studies were associated with improved outcomes, including assessment, work up and listing, which support their use across renal programs.^{13,15,21,23} Furthermore, it is important to acknowledge the inequities and disparities faced by historically and socially marginalized groups with regards to kidney disease. This includes individuals who are Black, Indigenous, Hispanic, undocumented immigrants, those living with low income, and those living in rural and remote settings, who are at risk of worse kidney related outcomes.^{5,6,40-43} Patient navigators may be of particular benefit in these groups, and thus, future trials could select for eligibility criteria to enrich baseline risk based on these factors.

Strengths of our study include its broad search strategy and focus on patient navigator program structure and function and effects on clinical outcomes. Our review addresses a gap in the literature as the only systematic review dedicated to patient navigators in the setting of CKD and kidney failure. Limitations include the lack of a universally standardized definition of a patient navigator, but we accounted for this by using a broad initial search strategy to capture as many studies as possible related to patient navigation with the exclusion of purely educational interventions. In addition, many of the included studies were at a high risk of bias, including the domains of blinding and incomplete reporting of outcomes. It is not feasible to blind patients or clinicians to the intervention, but outcome ascertainment should be blinded to minimize risk of bias in all future studies evaluating the efficacy of patient navigator programs in the setting of CKD and kidney failure. Lastly, the heterogeneity in the study populations and outcomes prevented meta-analysis and meta-regression of patient navigator program characteristics associated with statistically significant outcomes.

In summary, patient navigators in CKD and kidney failure have been associated with improved outcomes in certain settings and patient populations. However, there is heterogeneity in their design and implementation and the majority of studies in this systematic review were at high risk of bias so the strength of evidence is limited. Future directions include how to optimally and efficiently design patient navigator programs across diverse populations and

health systems and whether or not they should be implemented in settings where co-interventions are abundant and resources are limited. Their role in the setting of HHD, pediatrics, and other settings needs to be evaluated in addition to their cost-effectiveness and impact on patient-reported experience measures in high-quality randomized controlled trials.

SUPPLEMENTARY MATERIAL

Supplementary File (PDF)

Item S1: Search Strategy.

Table S1: Medline Search Strategy and Results.

Table S2: Embase Search Strategy and Results.

Table S3: Cochrane Library Search Strategy and Results.

Table S4: CINAHL Search Strategy and Results.

Table S5: [ClinicalTrials.gov](https://www.clinicaltrials.gov) Search Strategy and Results.

ARTICLE INFORMATION

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