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CLINICAL RESEARCH

Frailty Impact on Kidney Transplantation in Older People

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Introduction: Kidney transplantation (KT) is increasing in older people. This cohort are vulnerable to frailty, which affects KT outcomes. This study investigated the impact of frailty on quality of life (QoL) and clinical outcomes in older KT candidates and recipients, improving understanding in this population specifically.

Methods: KT in Older People (KTOP): Impact of Frailty on Outcomes was a prospective, single-center, longitudinal, observational study. Older people (aged ≥ 60 years) listed for KT were recruited. Frailty was assessed using the Edmonton Frail Scale (EFS). Patient-reported outcomes (PROs) were evaluated using validated questionnaires. Waitlist and KT clinical outcomes were recorded. Descriptive, comparative, and mixed-effect analyses were used to determine PRO and clinical outcome variation by frailty.

Results: Two hundred ten participants were recruited, of which 120 were transplanted. At recruitment, 17.2% were frail and 19.4% were vulnerable. Frailty was associated with poorer PROs after KT across all questionnaires. Vulnerable/frail recipients experienced worsening symptom burden, mental QoL, and depression. Nonfrail recipients experienced early physical and mental QoL declines. Both groups reported improved treatment satisfaction and illness intrusiveness. Delayed graft function, 12-month graft function, and KT length-of-stay (LoS) were poorer in vulnerable/frail recipients. On the waitlist, nonfrail participants reported stable PROs, whereas vulnerable/frail participants experienced fluctuations, more infection events, and longer suspensions.

Conclusion: The KTOP study provides a detailed, holistic, and longitudinal description of frailty's influence throughout the KT journey in older people. These findings are crucial to enabling more accurate discussions, better shared decision-making, and targeted interventions and clearer goals of KT to be determined.

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KT demand in older people is growing as the number developing kidney failure increases with population aging.[1,2] Although KT may benefit many older people, many experience difficulties related to aging-related syndromes, particularly frailty, which is common in kidney failure populations.[3,4] Frailty, "a state of increased vulnerability to physical stressors," is distinct from comorbidity and disability, and results from the accumulation of deficits across multiple systems.[3-6] Individuals on dialysis living with frailty can gain survival benefits from transplantation; however, they also experience increased short-term complications (delayed graft function and hospitalization) and poorer posttransplantation survival.[3,7-12]

QoL is often more important for older people than survival.[13] Frailty is associated with poorer QoL in people with kidney failure.[14,15] Evidence of QoL in older transplant recipients is mixed, with some studies

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describing improved physical function and disease-specific scores but worse mental function scores following KT.[16] Others have reported early declines in physical function, followed by medium- to long-term improvement, and unchanged mental QoL.[16,17] Qualitative descriptions reveal similar conflicting themes; "regained vitality and strength" and "extended life" are met with limitations through "unabating and worsening forgetfulness" and "disillusion with side effects and complications.[18]"

Despite frailty being higher in older people undergoing KT, few studies have specifically examined frailty in older transplant candidates or described variations in QoL and clinical outcomes in older people with differing degrees of frailty. Existing QoL descriptions are often snapshots, with no mention of frailty, or where frailty is considered, this is not specific to older people.[15,16,19-21] A longitudinal, detailed assessment of QoL and patient experience in older adults is lacking. This longitudinal study has been designed to assess how frailty impacts patient experience, QoL, and clinical outcomes from being on the waitlist to after transplantation in older patients. This study aimed to provide a description of older people's experiences throughout the KT journey, using information and data available at the time of initial KT assessment and listing.

METHODS

The KTOP study protocol has been previously published.[22] This study was conducted between October 2019 and June 2023. Local institutional review and approval was obtained from the Imperial College London Joint Research Office and ethical approval from the Yorkshire and Humber Leeds West Research Ethics Committee (REC reference 19/YH/0287). The clinical and research activities are consistent with the Principles of the Declaration of Istanbul as outlined in the Declaration of Istanbul on Organ Trafficking and Transplant Tourism. The KTOP investigator group included transplant patients who were involved in the design, delivery, and reporting, ensuring that patient perspectives were considered.

Patients aged $\geq$ 60 years, who were "active" on the national kidney transplant deceased donor (DD) waitlist or worked-up for living kidney donation at Imperial College Renal and Transplant Centre, were eligible. To maximize inclusion from a multicultural population, patients were only excluded if they understood insufficient English to complete study questionnaires after enabling help with translation through staff, families, or caregivers. The recruitment target was 200 to 250 participants. The primary outcome was PRO changes following KT and their variation according to frailty status. The secondary outcomes were as follows: (i) describe PRO changes over time on the waitlist and their variation by frailty status, (ii) describe trajectories in PRO on the waitlist and following KT and their variation by frailty status, and (iii) report differences in waitlist and KT clinical outcomes by frailty status.

Written informed consent was obtained from all participants. All study visits were conducted when participants attended scheduled health care encounters. Study visits were completed at recruitment, at 12 and 24 months on the waitlist, and/or at 3 and 12 months after transplantation. At each visit, the participants completed the Montreal Cognitive Assessment, EFS, Subjective Global Assessment of Nutrition, and Nottingham Extended Activities of Daily Living scale. A broad range of PROs were assessed: Short Form-12 (SF-12) (physical and mental QoL), Patient Health Questionnaire-9 (depressive symptoms), Palliative Care Outcome Scale-Symptoms Renal, Renal Treatment Satisfaction Questionnaire (RTSQ), and the Illness Intrusiveness Ratings Scale (IIRS).[23-31] Demographic, medical history, and clinical event data were collected. Clinical event data were collected throughout even if participants chose not to complete the questionnaires. The following EFS score criteria were used to define each participant's frailty status: not-frail for scores of 0 to 5, vulnerable for scores of 6 and 7, and frail for scores of 8 to 17. Similarly, Montreal Cognitive Assessment scores $<$ 26 were used as suggesting a participant had a degree of cognitive impairment present. These score criteria are in keeping with those specified by the EFS and Montreal Cognitive Assessment tools.

Because of the unpredictability of DD transplantation, some participants were recruited after transplantation, contributing to posttransplant assessments only. The final waitlist cohort included all participants who did not undergo transplantation during the study. Participants who underwent transplantation and lost their grafts remained in the final transplant cohort. During the COVID-19 epidemic, all transplantation was suspended at the unit from March to July 2020 and January to March 2021. Postal questionnaires were provided to enable remote follow-up of recruited participants.

Statistical Analysis

Demographics and event frequencies were analyzed using descriptive statistics. Frailty group comparisons used appropriate tests (*t* test, analysis of variance, Chi-square, Fisher exact [if £ 5 observations were in any group], Mann-Whitney U tests). Unadjusted Kaplan-

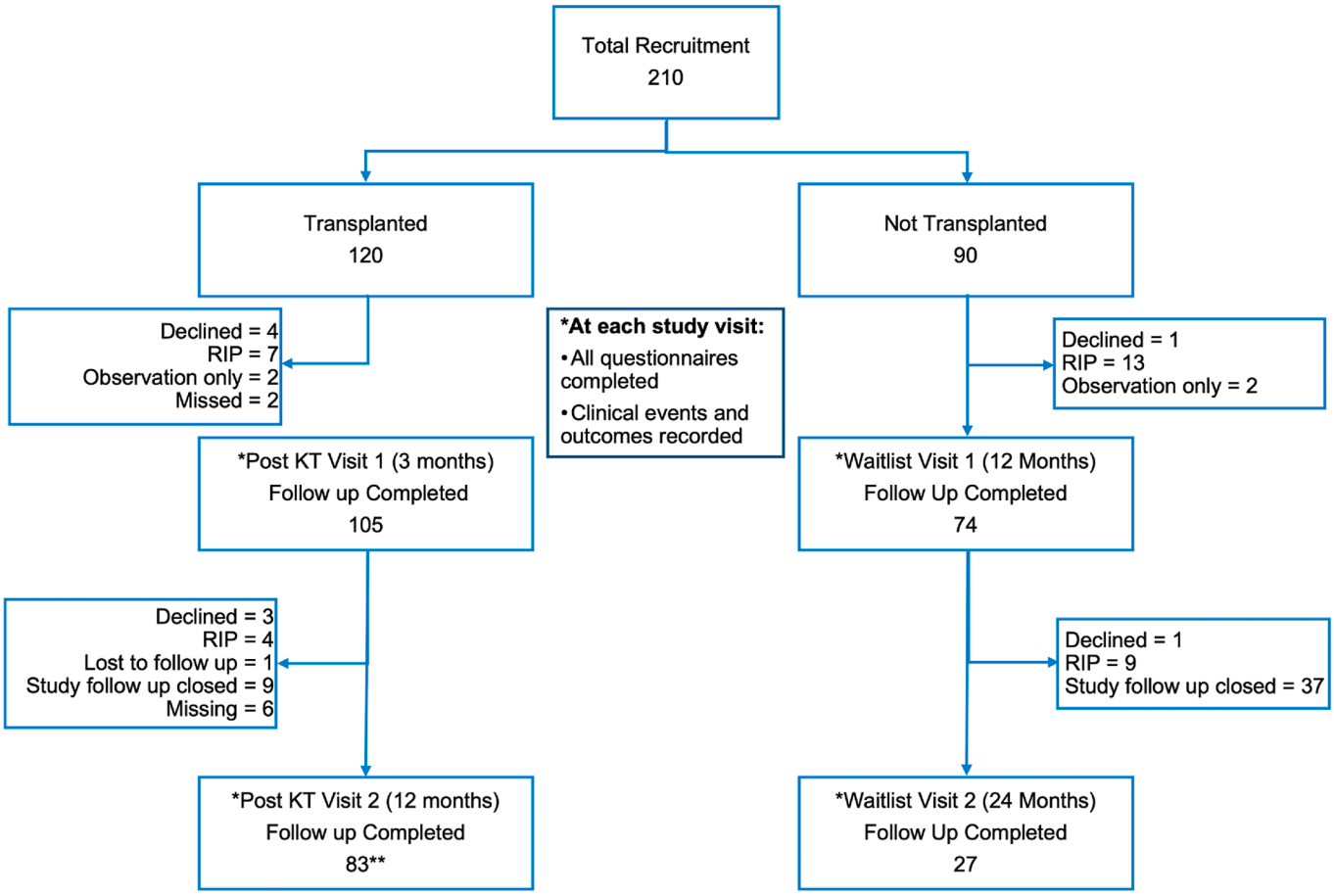

Figure 1. Overview of KTOP study recruitment and follow-up visits. *Tasks completed at each study visit, **1 patient returned to the study at 12-months posttransplant after declining to complete the 3-month posttransplant visit. Missing - study visits that were either not completed by the participant or where questionnaires were only partially completed and could not be included, study follow-up closed – study visits that did not occur because the study had closed to follow-up. KT – kidney transplantation; KTOP, KT in Older People; RIP, rest in peace.

Meier survival analyses were used for clinical events. Mixed-effect models were used to assess longitudinal SF-12 mental component scores (MCS) and physical component scores (PCS) accounting for repeated observations and allowing trajectories to be predicted. For clinical outcome and longitudinal questionnaire analyses, the following 2 frailty categories were used: nonfrail and vulnerable/frail. The vulnerable and frail participants were combined for the analysis because this group represents participants where frailty deficits are already present and those at risk of developing deficits. In combining this group, it was possible to assess how the presence of frailty deficits to a degree that is considered at risk and/or already established, was impacting on clinical and PRO outcomes. The 2-sided level of significance was set at $P < 0.05$. Specific strategies to replace missing data were not used. Analyses were completed using Stata/BE version 17.0 (StataCorp LLC, TX), with advisory support from the University of Hertfordshire.

A Strengthening the Reporting of Observational studies in Epidemiology analysis of this cohort study and manuscript was completed (checklist provided) in line with the recommended guidance.

RESULTS

Study Cohort

Altogether, 210 participants were recruited, of whom 120 were transplanted (20 recruited posttransplant). In the transplant cohort, 11 recipients were preemptively transplanted. The types of KT performed included 10 living donor (LD) and 110 DD transplants (69 donations after brainstem death and 41 donations after circulatory death). In Figure 1, we illustrate the completion of KTOP visits. The number of visits decreased over time because of participant death, declining to continue, being lost to follow-up, or not reaching the full 2-year waitlist or 12-month posttransplant follow-up during the study period.

In Table 1, we present the cohort characteristics; 73.3% of participants were non-White British, predominantly South Asian (46.2%). Diabetes was the cause of kidney failure in 44.8% of patients. The

Table 1. Baseline characteristics of the entire cohort, waitlist, and transplant groups

Characteristic	Entire cohort ($N = 210$)	Waitlist group ($n = 90$)	Transplant group ($n = 120$)
Recruitment age, median (range) (yrs)	65 (60–78)	66 (60–78)	65 (60–76)
Gender			
Male	138 (65.7)	59 (65.6)	79 (65.8)
Female	72 (34.3)	31 (34.4)	41 (34.2)
Ethnicity			
South Asian	97 (46.2)	41 (45.5)	56 (46.7)
Caucasian	56 (26.7)	22 (24.4)	34 (28.3)
Afro-Caribbean	33 (15.7)	15 (16.7)	18 (15)
Middle Eastern	14 (6.7)	6 (6.7)	8 (6.7)
East Asian	10 (4.7)	6 (6.7)	4 (3.3)
Cause of ESKD			
Diabetes	94 (44.8)	44 (48.9)	50 (41.7)
Unknown	29 (13.8)	8 (8.9)	21 (17.5)
Glomerulonephritis	24 (11.4)	9 (10)	15 (12.5)
Hypertension	7 (3.3)	3 (3.3)	4 (3.3)
Other[a]	56 (26.7)	26 (28.9)	30 (25)
Modality			
Hemodialysis	171 (81.4)	78 (86.7)	93 (77.5)
Peritoneal dialysis	26 (12.4)	11 (12.2)	15 (12.5)
AKCC	13 (6.2)	1 (1.1)	12 (10)
Mean KRT vintage (d) (SD)	1004.4 (± 1137)	1038 (± 1179)	979 (± 1109)
Previously transplanted	39 (18.6)	19 (21.1)	20 (16.7)
Charlson comorbidity index score (mean, LQ-UQ)	6 (5–7)	6.1 (5–7)	5.8 (5–7)
Diabetes	114 (54.3)	49 (54.4)	65 (54.2)
Hypertension	184 (87.6)	73 (81.1)	111 (92.5)
Ischemic heart disease	101 (48.1)	45 (50)	56 (46.7)
Cerebrovascular accidents	28 (13.3)	11 (12.2)	17 (14.2)
Peripheral vascular disease	7 (3.3)	3 (3.3)	4 (3.3)
Recruitment frailty status[b]			
Nonfrail	118 (63.4)	55 (62.5)	63 (64.3)
Vulnerable	36 (19.4)	16 (18.2)	20 (20.4)
Frail	32 (17.2)	17 (19.3)	15 (15.3)
Cognitive impairment[c]	65 (37.4)	53 (38.8)	32 (36)

AKCC, advanced kidney care clinic; ESKD, end-stage kidney disease; KRT, kidney replacement therapy; LQ, lower quartile; UQ, upper quartile.
[a]Other group includes urological, renovascular, polycystic kidney disease, and focal segmental glomerulosclerosis. Waitlist group includes any participant who remained untransplanted during the study, transplant group includes participants who lost their grafts following transplantation during the study.
[b]Frailty status determined by Edmonton Frail Status scores of 0–5 defining nonfrail, 6–7 defining vulnerable, and 8–17 defining frail.
[c]Cognitive impairment determined by Montreal Cognitive Assessment score < 26.
Data presented as *n* (%) unless otherwise stated.

majority were on hemodialysis (81.4%), 12.4% on peritoneal dialysis, 6.2% were in the advanced kidney care clinic, and 18.6% had been previously transplanted. Recruitment EFS assessments were available for 186 participants; the prevalence of frailty was 17.2% (32), 19.4% were vulnerable to frailty, and 63.4% (118) were nonfrail. Using recruitment Montreal Cognitive Assessment scores, 37.4% (65) had scores suggestive of cognitive impairment. Subsequent analyses were based on the nonfrail and combined frail/vulnerable groups (Table 2). The vulnerable/frail group had greater

Table 2. Baseline characteristics of the cohort by frailty status

Characteristic	Nonfrail ($n = 118$)	Vulnerable/frail ($n = 68$)	*P*-value
Recruitment age, median (range) (yrs)	65.5 (60–77)	64 (60–78)	0.12
Gender			
Male	78 (66.1)	43 (63.2)	0.69
Female	40 (33.9)	25 (36.8)	
Ethnicity			
South Asian	57 (48.3)	29 (42.7)	< 0.05
Caucasian	38 (32.3)	10 (14.7)	
Afro-Caribbean	16 (13.5)	15 (22)	
Middle Eastern	2 (1.7)	10 (14.7)	
East Asian	5 (4.2)	4 (5.9)	
Cause of ESKD			
Diabetes	49 (41.5)	35 (51.5)	0.32
Unknown	13 (11)	10 (14.7)	
Glomerulonephritis	15 (12.7)	8 (11.8)	
Hypertension	5 (4.2)	1 (1.5)	
Other[a]	36 (30.6)	14 (20.5)	
Modality			
Hemodialysis	92 (78)	62 (91.2)	0.08
Peritoneal dialysis	19 (16.1)	5 (7.3)	
AKCC	7 (5.9)	1 (1.5)	
Mean KRT vintage (d) (SD)	918.4 (± 1200)	1116.2 (± 1081)	0.26
Previously transplanted	21 (17.8)	15 (22.1)	0.5
Charlson comorbidity index score (mean, LQ-UQ)	5.8 (4-7)	6.3 (5-7)	0.02
Diabetes	55 (44.6)	46 (67.7)	< 0.05
Hypertension	100 (84.8)	61 (89.7)	0.34
Ischemic heart disease	53 (44.9)	37 (54.4)	0.21
Cerebrovascular accidents	15 (12.7)	11 (16.2)	0.51
Peripheral vascular disease	1 (0.9)	5 (7.3)	0.03
Cognitive impairment[b]	33 (29.5)	32 (51.6)	< 0.05

AKCC, advanced kidney care clinic; ESKD, end-stage kidney disease; KRT, kidney replacement therapy; LQ, lower quartile; UQ, upper quartile.
[a]Other group includes urological, renovascular, polycystic kidney disease, and focal segmental glomerulosclerosis. Frailty group determined by Edmonton Frail Scale score at recruitment into the study.
[b]Cognitive impairment determined by Montreal Cognitive Assessment score < 26.
Data presented as *n* (%) unless otherwise stated.

ethnic diversity (non-White participants 85.3% vs. 67.7%), higher mean Charlson comorbidity scores (6.3 vs. 5.8), more diabetes (67.7% vs. 44.6%), peripheral vascular disease (7.3% vs. 0.9%), and more were receiving hemodialysis (91.2% vs. 78%). The mean time between the final waitlist visit and the first post-KT visit between the nonfrail (6.8 months) and the frail/vulnerable (8.3 months) transplant recipients was not statistically significant different ($P = 0.07$).

Primary Outcome: PRO at 12 Months Posttransplant

Frailty was the strongest predictor of worse post-transplant outcomes (Figure 2). Across all questionnaires and at each post-KT visit, the scores were poorer in the vulnerable/frail group (Table 3). They had significantly worse symptom scores, depression scores, as well as PCS and MCS on the SF12 compared with the nonfrail group. Although by 12 months post-KT the

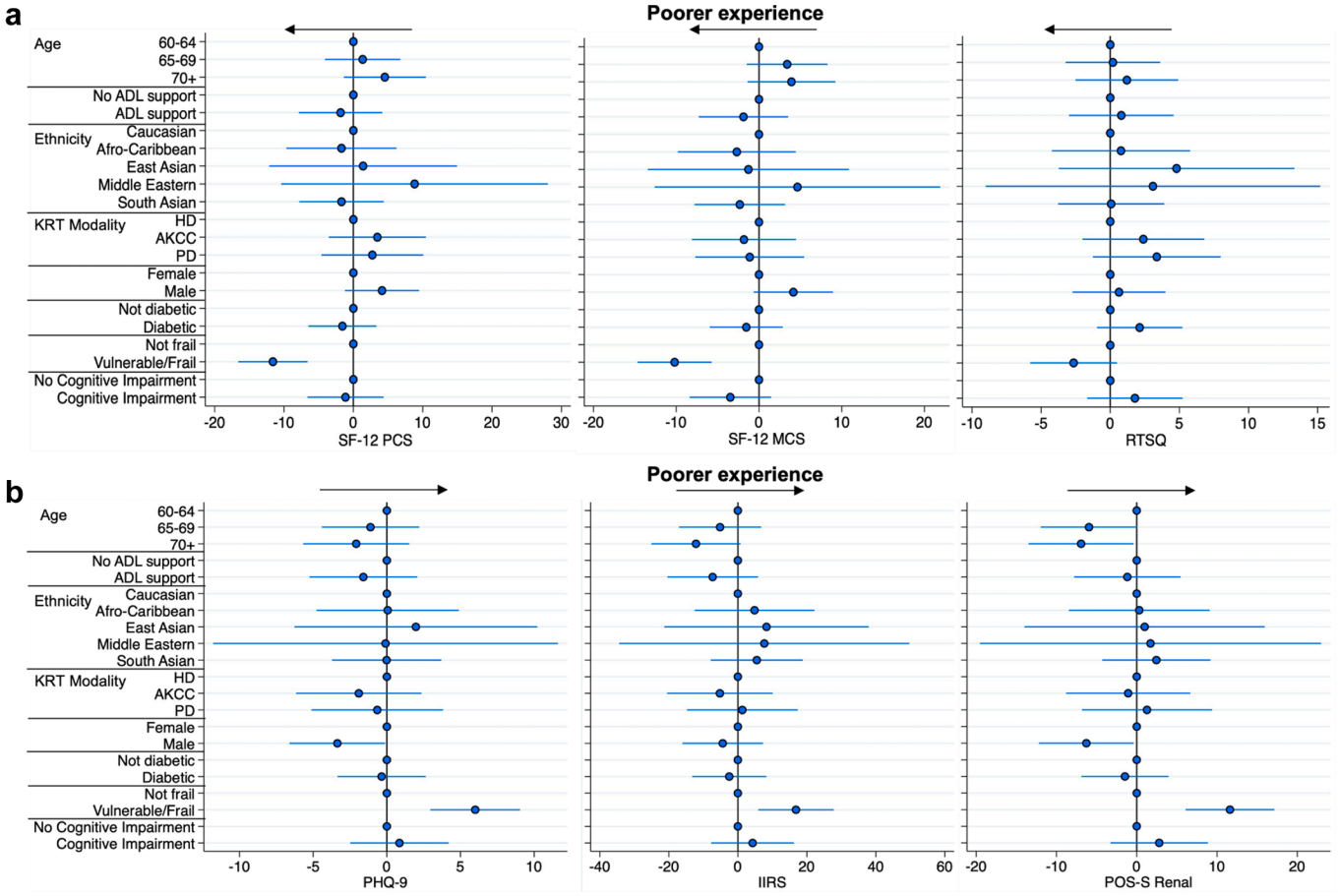

Figure 2. Association of clinical characteristics on questionnaire scores 1 year after kidney transplantation. Adjusted association of participant characteristics with the patient experience and quality of life scores. Coefficients adjusted for each characteristic listed in the figures. Panel (a) decreasing scores represent a worsening experience, panel (b) increasing scores represent a worsening experience. ADL, activities of daily life; AKCC, advanced kidney care clinic; HD, hemodialysis; IIRS, illness intrusiveness ratings scale; MCS, mental component scores; PCS, physical component score; PD, peritoneal dialysis; PHQ, patient health questionnaire; POS-S, palliative care outcome scale- symptoms; RTSQ, renal treatment satisfaction questionnaire; SF, short form.

majority of both nonfrail and vulnerable/frail recipients reported improved RTSQ and IIRS scores compared with pre-KT, the actual scores remained poorer in the vulnerable and frail groups (Figures 2 and 3b, Table 3, and Supplementary Table S1).

Clinical Outcomes Posttransplant

One year patient survival was 91.7%, with no significant difference in survival between the nonfrail and frail/vulnerable groups (Figure 4). Infection events (any episode requiring treatment, hospital admission, or alteration to maintenance immunosuppression, including COVID-19), was the most common cause of death, contributing to 8 of the 10 deaths, with no significant difference in overall infection-free survival according to frailty status (Figure 4). The 1-year death-censored graft survival in the full cohort was 95.8%, with no difference between the nonfrail and frail/vulnerable groups (Figure 4). However, frail/vulnerable patients were more likely to experience delayed graft function, with 38.9% frail/vulnerable patients requiring dialysis in the first week posttransplant compared with 19.1% nonfrail patients ($P = 0.03$) (Table 4). The median LoS during admission for the KT procedure (index admission) was 15 versus 11 days in the frail/vulnerable and no-frail patients, respectively ($P = 0.01$) (Table 4). There were no differences in readmissions or the median LoS for all readmissions during the first year after KT (Table 4). There was also no difference in median LoS for readmissions between the 4 nonfrail (93.5 days, range: 2–111) and 3 vulnerable/frail patients (50 days, range: 4–70) who died during the first year ($P = 0.29$). Allograft function at 12 months (Table 4) was associated with frailty; mean glomerular filtration rate was 39.1 ($\pm$ 17) ml/min per 1.73 m^2 in vulnerable/frail patients compared with 49.9 ($\pm$ 18.8) ml/min per 1.73 m^2 in nonfrail patients ($P = 0.01$) across all transplants performed. Only 1 of the 9 patients who received LD kidneys was classified as vulnerable or frail.

Table 3. Mean patient experience and quality of life questionnaire scores at final waitlist and post-kidney transplantation visits

				SF-12 (V2)		
	PHQ-9	POS-S Renal	IIRS	PCS	MCS	RTSQ
Scale	0–27	0–84 Higher scores reflect poorer experience	7–91	0–100 Lower scores reflect poorer experience		0–66
Final WL visit	$n = 98$	$n = 95$	$n = 95$	$n = 97$	$n = 97$	$n = 95$
Nonfrail	2.6 (1.86–3.33)	7 (5.39–8.61)	26.4 (22.78–30.2)	47.7 (45.48–50.01)	52.8 (51.03–54.56)	54.9 (52.67–57.06)
Vulnerable	5.8[a] (3.12–8.40)	12[a] (7.84–16.160	35.8[a] (26.28–45.38)	38.9[a] (34.85–42.94)	46.6[b] (41.81–51.29)	49.9 (44.48–55.33)
Frail	9.8[a] (6.82–12.78)	19.4[a] (14.47–24.33)	44.7[a] (33.12–56.35)	30.7[b] (25.67–35.66)	35.8[a] (29.48–42.03)	38.5[a] (29.49–47.44)
Post-KT visit 1	$n = 100$	$n = 100$	$n = 99$	$n = 100$	$n = 100$	$n = 99$
Nonfrail	3.7 (2.61–4.81)	8.1 (6.16–9.99)	29 (24.97–32.97)	44.2 (41.56–46.74)	49.1 (46.65–51.54)	58.4 (55.53–61.36)
Vulnerable	5 (3.14–6.86)	9.6 (7.39–11.74)	28.56 (21.53–35.59)	38.9[b] (35.72–42.03)	47.2 (44.06–50.34)	58.8 (54.34–63.25)
Frail	10[a] (7.01–12.89)	19.1[a] (12.65–25.59)	37.3[a] (28.45–46.22)	32.5[a] (28.82–36.23)	36.9[a] (31.75–42.01)	51.4[b] (45.89–56.40)
Post-KT visit 2	$n = 76$	$n = 74$	$n = 74$	$n = 74$	$n = 74$	$n = 74$
Nonfrail	2.9 (1.73–4.14)	6.6 (4.63–8.62)	22.4 (17.89–26.87)	47.6 (44.88–50.3)	51.4 (49.17–53.53)	62.3 (60.77–63.90)
Vulnerable	5.39 (2.89–7.89)	13.4[b] (8.31–18.46)	28.8 (19.01–38.65)	36.8[a] (32.33–41.41)	42.7[a] (38.42–46.98)	59.7 (56.59–62.75)
Frail	11.5[a] (7.41–15.59)	22.3[a] (12.94–31.6)	46.5[a] (31.74–61.17)	32.1[a] (27.64–36.51)	35.8[a] (29.9–41.7)	58.8 (53.93–63.71)

IIRS, illness intrusiveness ratings scale; KT, kidney transplantation; MCS, mental component score; PCS, physical component score; PHQ-9-patient health questionnaire 9; POS-S Renal, palliative care outcome scale- symptoms renal; RTSQ, renal treatment satisfaction questionnaire; SF-12 (V2), short form-12 version 2; WL, waitlist.
[a]*P*-value ≤ 0.005.
[b]*P*-value ≤ 0.05.
Results presented as mean score (95% confidence interval).

PRO Trajectories After Transplantation

Nonfrail KT recipients experienced initial declines in their physical and mental QoL at 3 months (Supplementary Table S1 and Figure 5). By 12 months post-KT the majority of nonfrail recipients reported worse mental QoL, but similar physical QoL scores compared with pre-KT (Supplementary Table S1, Figure 5). The results of the mixed-effect regression analysis (Supplementary Tables S2 and S3) suggested that in nonfrail recipients, the initial decline in PCS and MCS post-KT was followed by a slight improvement over time. However, PCS and MCS scores did not recover to pre-KT levels by 1-year post-KT (Figure 5a and b). The majority reported worse MCS at 12 months

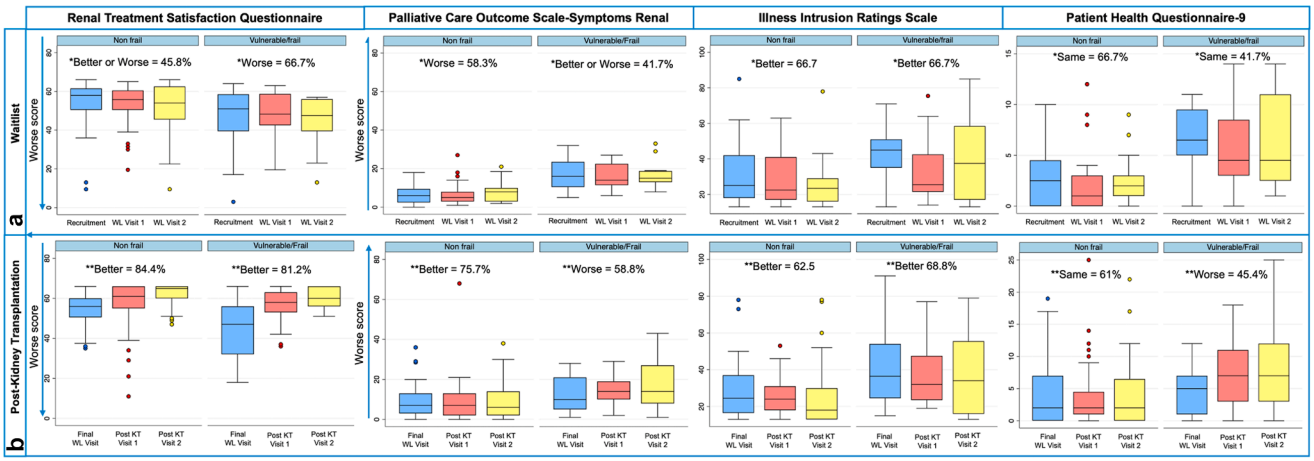

Figure 3. Distribution of questionnaire scores at each visit by frailty status on (a) the waitlist, (b) postkidney transplantation. The timing of visits was as follows; WL visit 1 at 12 months following recruitment, WL visit 2 at 24 months following recruitment, post-KT visit 1 at 3 months post-KT, post-KT visit 2 at 12 months post-KT. The final WL visit timing varied by each patient as the timing of KT was variable. *Describes the score trajectory (worse, better or the same) reported by the majority of participants in each group from recruitment to WL visit 2, or **from the final WL visit to post-KT visit 2. Where 2 trajectories are reported that means an equal proportion of participants experienced the changes described. KT, kidney transplantation; WL, waitlist.

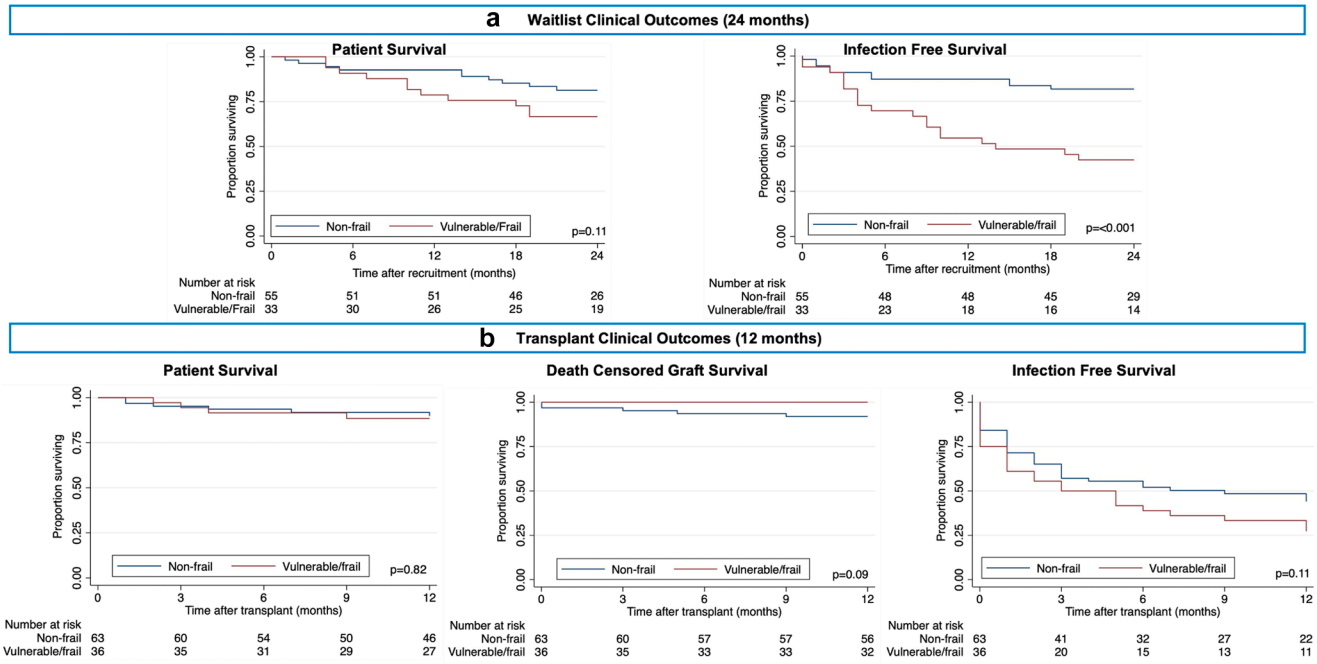

Figure 4. Survival analyses of clinical event outcomes on (a) waitlist, (b) following transplantation. Unadjusted Kaplan-Meier survival analyses during waitlist 24-month follow-up, and post-transplant 12-month follow-up.

post-KT, and most maintained the same level of depression as pre-KT (Supplementary Table S1, Figure 5b, and Figure 3).

Vulnerable/frail recipients experienced stabilization of their physical QoL post-KT, which was an improvement from their pre-KT trajectories (Figure 5a). However, mental QoL scores showed a worsening trajectory post-KT (Figure 5b), and the majority reported worsening degrees of depression at 12 months post-KT compared with pre-KT (Supplementary Table S1 and Figure 3b). Symptom burden worsened in the majority of vulnerable/frail recipients at every timepoint post-KT (Supplementary Table S1 and Figure 3b). In vulnerable/frail recipients, the mixed-effect regression analysis suggested that PCS stabilized post-KT (Supplementary Table S2 and Figure 5a), supported by an equal proportion reporting similar or improved PCS at 12 months post-KT (Supplementary

Table 4. Transplant outcomes by frailty status

Transplant outcomes (12 mo)	Nonfrail ($n = 63$)		Vulnerable/Frail ($n = 36$)		*P*-value
Delayed graft function	12 (19.1)		14 (38.9)		0.03
Primary nonfunction	2 (3.2)		0		0.53
Biopsy proven rejection	8 (13.1)		4 (11.4)		1.0
Graft function	*n*	Mean (± SD)	*n*	Mean (± SD)	
3-month graft function (ml/min per 1.73m^2)					
All transplants	60	48.1 (± 23)	34	43 (± 19.3)	0.28
Live donor transplants	8	56.5 (25.2)	1	59	[a]
Deceased donor transplants	52	46.8 (22.6)	33	42.5 (19.4)	0.37
12-month graft function (ml/min per 1.73m^2)					
All transplants	51	49.9 (± 18.8)	30	39.1 (± 17)	0.01
Live donor transplants	8	52.9 (20.9)	1	52	[a]
Deceased donor transplants	43	49.3 (18.6)	29	38.7 (17.1)	0.02
	($n = 63$)		($n = 36$)		
Median LoS for index admission (d) (range)	11 (5-92)		15 (5-65)		0.01
	($n = 63$)		($n = 35$)		
Readmitted in first 12 mo	38 (60.3)		23 (65.7)		0.60
	($n = 38$)		($n = 23$)		
Median LoS for readmissions in first 12 mo (d) (range)[b]	16.5 (1–111)		19 (1–79)		0.96

LoS, length-of-stay.
[a] *P*-value could not be calculated.
[b] LoS during the first 12 months represents LoS for any hospital readmissions beyond the index admission for the transplant itself.
Results presented as *n* (%) unless otherwise stated. Frailty status based on the recruitment EFS assessment.

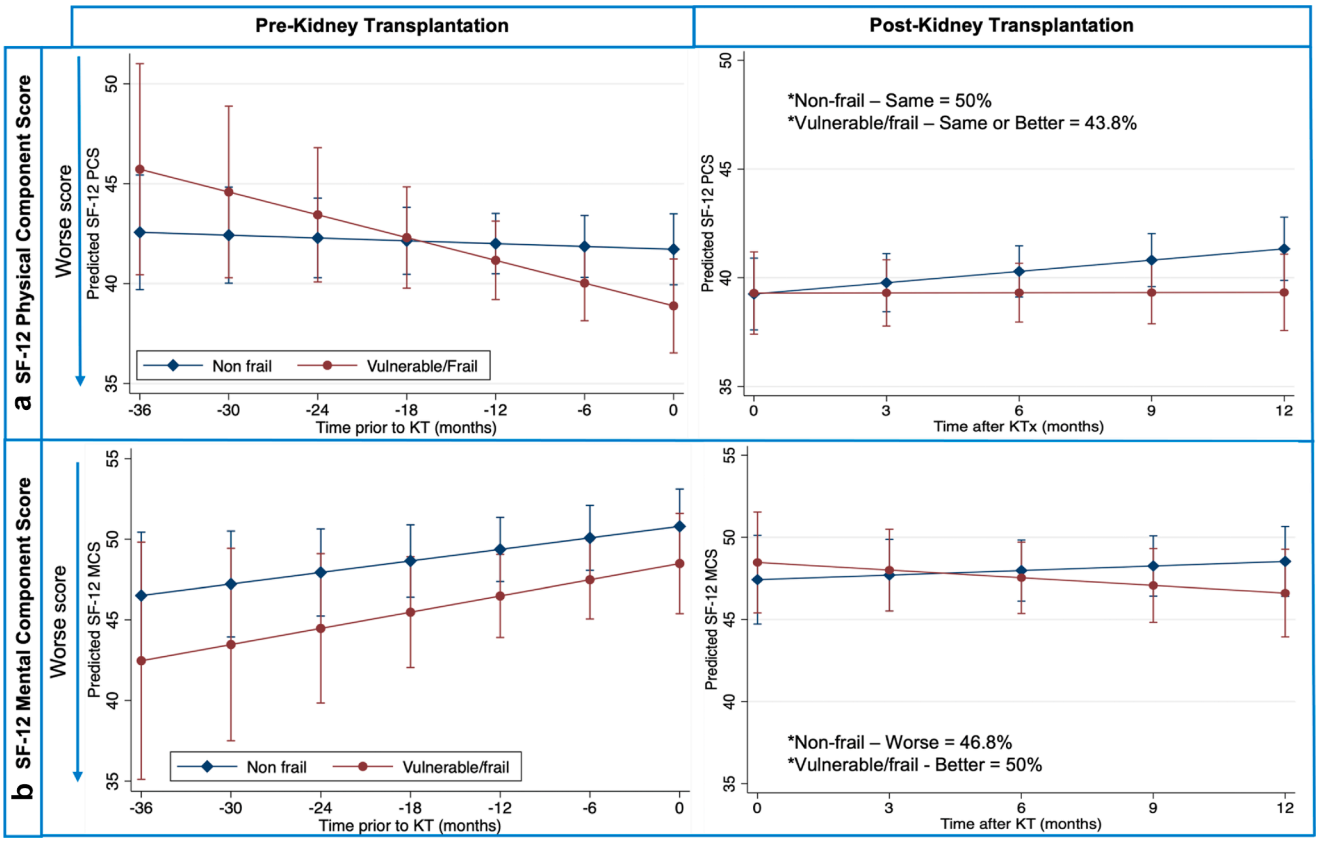

Figure 5. Predicted Short Form-12 score change over time in kidney transplant recipients pre- and post-kidney transplantation (a) Physical Component Score, (b) Mental Component Score. *Describes the score trajectory (worse, better or the same) reported by the majority of participants in each group from the final WL visit to post-KT visit 2. KT, kidney transplantation; MCS, mental component score; PCS-physical component score; SF-12-Short form-12.

Table S1 and Figure 5a). The mixed-effect regression analysis suggested that MCS declined post-KT in vulnerable/frail recipients (Supplementary Table S3 and Figure 5b); however, intrapatient analyses showed that the majority reported improved MCS at 12 months post-KT compared with pre-KT (Supplementary Table S1).

Fourteen KT recipients, including 11 who died posttransplant, did not complete the study, of whom 6 completed at least 2 visits suitable for paired analyses. In these 6 recipients, the majority showed worsening QoL and patient experience scores across all questionnaires, excluding the IIRS and RTSQ, before leaving the study (worsening SF-12 PCS, Palliative Care Outcome Scale-Symptoms Renal, PHQ-9 scores in 4/6 recipients, and SF-12 MCS in 5/6). The IIRS and RTSQ scores showed that half experienced improving scores and half experienced worsening scores, differing from the wider group where the majority experienced improvement.

PROs and Clinical Outcomes on the Waitlist

The mean questionnaire scores at each waitlist visit and their variations by frailty status are presented in Supplementary Table S4. Poorer patient experience and QoL scores across were observed in the vulnerable and frail individuals on the waitlist across a range of measures.[32]

Nonfrail participants reported improving IIRS scores (Supplementary Table S1 and Figure 3a) in the majority. RTSQ scores were more variable with only half reporting improvement (Supplementary Table S1 and Figure 3a). The majority of the nonfrail participants reported stable depression levels, physical QoL, and mental QoL scores on the waitlist (Supplementary Table S1 and Figure 3a). This was supported by the trajectories from the mixed-effect regression analysis (Supplementary Tables S5 and S6 and Figure S1A and B). However, the symptom burden worsened in the majority (Supplementary Table S1 and Figure 3a).

Vulnerable or frail participants reported poorer scores at all waitlist visits and across all questionnaires (Supplementary Table S4). These differences were statistically significant between all frailty categories at 12 months following recruitment and between only the nonfrail and frail participants at 24 months, excluding the RTSQ. IIRS scores improved in the majority whereas

Table 5. Waitlist outcomes by frailty status

WL Clinical Outcome (24 months)	Non frail ($n = 117$)	Vulnerable/Frail ($n = 69$)	*P*-value
WL not suspended	55 (47)	33 (47.8)	0.91
WL suspended	62 (53)	36 (52.2)	
WL single suspension episode[a]	38 (61.3)	30 (83.3)	0.03
WL multiple suspension episodes[a]	24 (38.7)	6 (16.7)	
WL total time suspended[a] (d) (mean, ± SD)	307 (244)	434 (295)	0.03
Transplanted	62 (53)	36 (52.2)	0.91
	($n = 55$)	($n = 33$)	
WL removal	16 (29.1)	13 (39.4)	0.32

EFS, Edmonton Frail Scales; WL, waitlist.
[a]Analysis period may be longer than 24 months because of variations in each individual's date of activation onto the waitlist.
Results presented as *n* (%) unless otherwise stated. Frailty status based on the recruitment EFS assessment.

RTSQ scores worsened (Supplementary Table S1 and Figure 3a). Physical QoL was stable in the majority (Supplementary Table S1); however, mixed-effect regression analysis suggested a declining (worsening) trajectory (Supplementary Table S5 and S1A). Mental QoL improved in most patients (Supplementary Table S1), which was supported by the mixed-effect regression trajectory (Supplementary Table S6 and Figure S1B). Similarly, depression levels remained stable in the majority (Supplementary Table S1 and Figure 3a). An equal proportion experienced improvement or worsening of their symptom burden on the waitlist (Supplementary Table S1 and Figure 3a). Overall experiences on the waitlist appeared to fluctuate more among vulnerable/frail participants.

On the waitlist, 22 participants died, and 9 had data for paired analysis. Among these 9 participants, the questionnaire score trajectories suggested that the majority had improved SF-12 MCS (6/9, 66.7%), IIRS (6/9, 66.7%), and RTSQ (8/9, 88.9%) scores before dropping out of the study. Palliative Care Outcome Scale-Symptoms Renal score trajectories were mixed (44.4% improvement, 33.3% worse), PHQ-9 depression levels were mostly stable (6/9, 66.7%), and the SF-12 PCS showed a slightly higher proportion with worsening scores (55.6%) before leaving the study. No clear trend emerged in this subgroup separating it from the wider cohort.

Clinical Outcomes

In the waitlist cohort, 21 deaths (23.3%) occurred over 2 years, with infection (9) (including COVID-19) being the leading cause. Vulnerable/frail waitlist participants were more likely to have experienced a major infection event (Figure 5a), have a single episode of suspension from the waitlist, and were suspended for longer (Table 5). A trend toward higher mortality (Figure 4a) and an increased likelihood of waitlist removal (Table 5) were observed in the vulnerable/frail waitlist participants, which was not statistically significant. No differences were observed in the likelihood of transplantation.

DISCUSSION

The KTOP study commenced after a change in the UK DD organ offering scheme was introduced in 2019, whereby older candidates were more likely to receive organs from older donors because "graft life expectancy was more effectively matched with patient life expectancy."[33] We have demonstrated that frailty and vulnerability to frailty affect QoL, patient experience, and clinical outcomes in older people awaiting and undergoing KT across a broad range of PRO measures. Use of the EFS provided a multidimensional measure of frailty, which is more objective than the commonly used Clinical Frailty Scale.[34] At 1 year post-KT, frailty status was the only characteristic significantly associated with poorer PRO scores across all questionnaires. Although treatment satisfaction and illness intrusiveness improved in both the vulnerable and frail groups, actual scores remained lower than for the nonfrail group. Both nonfrail and vulnerable/frail older adults reported worse mental QoL following KT. Vulnerable/frail recipients experienced greater symptom burden and worsening depression post-KT, increased delayed graft function, longer LoS for transplant admission, and poorer 12-month graft function. Nonfrail recipients experienced early declines in physical and mental QoL after transplantation, and despite subsequent slow improvement, they did not recover to pre-KT physical or mental QoL scores by 1 year post-KT. Approximately 5% of the cohort lost their graft and returned to dialysis within 1 year of KT. On the waitlist, nonfrail participants reported stability in PROs, whereas vulnerable/frail participants reported fluctuations over time. Vulnerable/frail older adults on the waitlist were more likely to experience major infection events and have longer waitlist suspensions. In the UK, no formal criteria exist to define when patients should be suspended. This is based on individual circumstances and the development of any new or acute medical events that would preclude transplantation. It is left to the judgement of the supervising nephrologist and transplant unit. KTOP has added value in providing a detailed, holistic, longitudinal description of experiences on the waitlist and following KT in older people with and without frailty.

The prospective longitudinal design is the principal strength of this study, enabling description of trajectories in older people considering transplantation. The poorer clinical outcomes in the vulnerable/frail group

have been reported previously.[3,9,35,36] Some of the QoL and patient experience trends described are also similar to other studies (poorer physical QoL and renal treatment satisfaction on the waitlist, initial physical QoL declines after KT, improved disease specific measures and poorer mental QoL in all after KT).[17,19,35,37,38] However, in using a variety of questionnaires, numerous aspects of QoL and patient experience have been studied, complex analyses completed, and a higher-level understanding of older people's experiences has been achieved. The large size of the center and ethnic diversity of the population studied has produced findings highly relevant to the increasingly complex and multimorbid older patients entering transplant waitlists. Collectively, this has enabled a holistic understanding of older people's experiences in the presence of frailty, and a key gap in existing knowledge, to be addressed.

Limitations include the impact of COVID-19, which caused some initial disruption to transplant activity (36 participants transplanted pre-COVID, 74 participants post-COVID suspensions) and may have affected the experiences captured. Although not powered for clinical outcomes, of the 90% of transplanted patients who were alive with a functioning graft at 1 year, vulnerable/frail recipients had a mean glomerular filtration rate of approximately 10 ml/min lower than the nonfrail group. This clinically significant difference at 1 year is a strong predictor of poorer allograft survival in vulnerable/frail patients in the long term.[39] The occurrence of rejection episodes and poorer allograft function may reflect increased use of extended criteria donors in this cohort, and will likely result in increased health care use. Combined with the reduced reserve to respond to all such events, in older people living with frailty or a vulnerability to frailty, these events will likely impact on their experiences of KT. The volume and granularity of data required to determine this relationship is not available within this study. The experiences of those who did not complete the study (33 participants) are less well-represented, highlighting the difficulties in conducting prospective, longitudinal studies in older people. The reduced data available at later time points limited the strength of the trends and predictions reported at these timepoints. The study was not statistically powered to detect clinical outcome differences, only unadjusted and univariate analyses of the clinical outcomes were possible. One year of follow-up was short, and recovery from surgery could mask QoL changes.[17] However, for older people with a shorter life expectancy than younger people, the whole year is relatively more important. Finally, the study does not include any data on older people who were not waitlisted because this is beyond the scope of the current study, which was focused on capturing experiences in older people waiting for and undergoing KT only to describe this particular aspect of advanced kidney care in older people.

Because deceased donations accounted for 91.7% of KT in this study, the outcomes reported will reflect those for older people who are listed for DD KT in the future in the UK and more widely.[40] Although LD transplantation may provide superior outcomes and offer particular benefits in older candidates' (e.g., planned timing of surgery, and preemptive KT) access to and uptake of LD KT in older people remains suboptimal.[41,42] Strategies to improve LD transplantation in older people should therefore be considered alongside the novel understanding gained from this study to improve older people's care.

This study highlights the need for and importance of incorporating frailty assessments in managing older people with advanced kidney disease. By doing so, a holistic assessment is achieved, frailty and geriatric impairments are identified, and targeted interventions can be considered.[43–45] The KTOP findings enable more realistic and patient-centered counselling of older people to take place. Poor QoL on dialysis may drive older people toward KT; however, this work demonstrated limited improvements in QoL and patient experience in the first year for both robust and vulnerable/frail older people. In older people, comorbidities may develop and progress over time, inevitably impacting on their prognosis. Developing an understanding of their evolving prognosis, the association with PROs, and the ongoing suitability for transplantation may be of value and will be the part of future work by this group. Ultimately, to arrive at the correct KT decision for older people with varying degrees of frailty, collective exploration of older peoples' expectations of KT and shared decision making is necessary to determine whether KT will achieve the desired benefits.

DISCLOSURE

EB is the immediate past-president of International Society for Peritoneal Dialysis and received speaker fees from Vantive Healthcare and Fresenius Medical Care, and consulting fees from Fresenius Medical Care. All the other authors declared no competing interests.

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DATA AVAILABILITY STATEMENT

The datasets presented in this article are not readily available; however, the data reported are available from the corresponding author on reasonable request. Requests to access the datasets should be directed to e.a.brown@imperial.ac.uk.

SUPPLEMENTARY MATERIAL

Supplementary File (PDF)

Study Questionnaires. Edmonton Frail Scale, Montreal Cognitive Assessment, Short-Form 12 (version 2), Patient Health Questionnaire, Illness Intrusiveness Ratings Scale, The Renal Treatment Satisfaction Questionnaire, and Palliative Care Outcome Scale - Symptoms Renal.

Figure S1. Predicted Short Form-12 score change over time in study participants on the waitlist (A) Physical Component Score and (B) SF-12 Mental Component Score.

Table S1. Change in questionnaire scores between waitlist and transplant study visits.

Table S2. Mixed-effect model regression output for changes in SF-12 PCS over time (random effect) pre-KT and post-KT.

Table S3. Mixed-effect model regression output for changes in SF-12 MCS over time (random effect) pre-KT and post-KT.

Table S4. Mean patient experience and quality of life questionnaire scores on the waitlist.

Table S5. Mixed-effect model regression output for change in SF-12 PCS score over time (random effect) on the waitlist.

Table S6. Mixed-effect model regression output for change in SF-12 MCS score over time (random effect) on the waitlist.

STROBE Checklist.

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